Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015

# U.S. Department of Health & Human Services

**Food and Drug Administration**

## SAVE REQUEST

| | |
|---|---|
| **USER:** | (smw) |
| **FOLDER:** | K062967 - 1269 pages |
| **COMPANY:** | ACCURAY, INC. (ACCURAY) |
| **PRODUCT:** | SYSTEM,PLANNING,RADIATION THERAPY TREATMENT (MUJ) |
| **SUMMARY:** | Product: CYBERKNIFE ROBOTIC RADIOSURGERY SYSTEM |
| **DATE REQUESTED:** | Oct 21, 2015 |
| **DATE PRINTED:** | Oct 21, 2015 |
| **Note:** | Printed |

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015

K062967

# APPENDIX F. 510(k) SUMMARY

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

**Name, Address, Phone and Fax number of the Applicant**

Accuray Incorporated
1310 Chesapeake Terrace
Sunnyvale, California 94089
Ph: (408) 716-4600
Fax: (408) 716-4601

OCT 30 2006

**Contact Person**

Anne Schlagenhaft

**Date Prepared**

September 15, 2006

**Device Name**

Trade Name: CyberKnife® Robotic Radiosurgery System

Classification Name: Medical charged particle radiotherapy device

**Device Description**

The CyberKnife Robotic Radiosurgery System is a computer controlled medical system for planning and performing minimally invasive stereotactic radiosurgery and precision radiotherapy using a treatment radiation generator, linear accelerator, manipulator (robot), and a target locating subsystem to accurately deliver radiation to the treatment target. The CyberKnife System uses skull tracking, fiducial tracking, Xsight™ spine tracking, Synchrony™ Respiratory Tracking and Lung Tumor Tracking for dynamic positioning and pointing of the linear accelerator.

**Intended Use**

The CyberKnife Robotic Radiosurgery System is intended to provide treatment planning and image-guided stereotactic radiosurgery and precision radiotherapy for tumors, lesions and conditions anywhere in the body when radiation treatment is indicated.

**Substantial Equivalence**

The CyberKnife Robotic Radiosurgery System with the Lung Tumor Tracking algorithm is substantially equivalent to the predicate device. The intended use, principles of operation, technological characteristics and labeling are the same or equivalent.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

OCT 3 0 2006

Ms. Anne Schlagenhaft
Sr. Regulatory Affairs Associate
Accuray, Inc.
1310 Chesapeake Terrace
SUNNYVALE CA 94089

Re: K062967
Trade/Device Name: CyberKnife® Robotic Radiosurgery System
Regulation Number: 21 CFR §892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: MUJ and IYE
Dated: September 28, 2006
Received: September 29, 2006

Dear Ms. Schlagenhaft:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

| | | |
|---|---|---|
| 21 CFR 876.xxx | (Gastroenterology/Renal/Urology | 240-276-0115 |
| 21 CFR 884.xxx | (Obstetrics/Gynecology) | 240-276-0115 |
| 21 CFR 894.xxx | (Radiology) | 240-276-0120 |
| Other | | 240-276-0100 |

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150
or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015

510(k) Number (if known): K 062967

Device Name: CyberKnife® Robotic Radiosurgery System

Indications For Use:

The CyberKnife® Robotic Radiosurgery System is indicated for treatment planning and image guided stereotactic radiosurgery and precision radiotherapy for lesions, tumors and conditions anywhere in the body when radiation treatment is indicated.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use ____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

Nancy C Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K062967

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

16 662 667 14

Form Approved: OMB No. 0910-511 Expiration Date: August 31, 2005 See Instructions for OMB Statement.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION
**MEDICAL DEVICE USER FEE COVER SHEET**

PAYMENT IDENTIFICATION NUMBER: **MD6027694-956733**
Write the Payment Identification number on your check.

A completed Cover Sheet must accompany each original application or supplement subject to fees. The following actions must be taken to properly submit your application and fee payment:

1. Electronically submits the completed Cover Sheet to the Food and Drug Administration (FDA) before payment is sent.
2. Include printed copy of this completed Cover Sheet with a check made payable to the Food and Drug Administration. Remember that the Payment Identification Number must be written on the check.
3. Mail Check and Cover Sheet to the US Bank Lock Box, FDA Account, P.O. Box 956733, St. Louis, MO 63195-6733. (*Note: In no case should payment be submitted with the application.*)
4. If you prefer to send a check by a courier, the courier may deliver the check and Cover Sheet to: US Bank, Attn: Government Lockbox 956733, 1005 Convention Plaza, St. Louis, MO 63101. (Note: This address is for courier delivery only. Contact the US Bank at 314-418-4821 if you have any questions concerning courier delivery.)
5. For Wire Transfer Payment Procedures, please refer to the MDUFMA Fee Payment Instructions at the following URL: http://www.fda.gov/cdrh/mdufma/faqs.html#3a. You are responsible for paying all fees associated with wire transfer.
6. Include a copy of the complete Cover Sheet in volume one of the application when submitting to the FDA at either the CBER or CDRH Document Mail Center.

1. COMPANY NAME AND ADDRESS (include name, street address, city state, country, and post office code)

ACCURAY INC
1310 Chesapeake Terrace
Sunnyvale CA 94089
US

1.1 EMPLOYER IDENTIFICATION NUMBER (EIN)
770268932

2. CONTACT NAME
Anne Schlagenhaft

2.1 E-MAIL ADDRESS
aschlagenhaft@accuray.com

2.2 TELEPHONE NUMBER (include Area code)
408-716-4628

2.3 FACSIMILE (FAX) NUMBER (Include Area code)
408-716-4601

3. TYPE OF PREMARKET APPLICATION (Select one of the following in each column; if you are unsure, please refer to the application descriptions at the following web site: http://www.fda.gov/dc/mdufma

Select an application type:
[X] Premarket notification(510(k)); except for third party
[ ] Biologics License Application (BLA)
[ ] Premarket Approval Application (PMA)
[ ] Modular PMA
[ ] Product Development Protocol (PDP)
[ ] Premarket Report (PMR)

3.1 Select one of the types below
[X] Original Application
Supplement Types:
[ ] Efficacy (BLA)
[ ] Panel Track (PMA, PMR, PDP)
[ ] Real-Time (PMA, PMR, PDP)
[ ] 180-day (PMA, PMR, PDP)

4. ARE YOU A SMALL BUSINESS? (See the instructions for more information on determining this status)
[ ] YES, I meet the small business criteria and have submitted the required qualifying documents to FDA
[X] NO, I am not a small business
4.1 If Yes, please enter your Small Business Decision Number:

5. IS THIS PREMARKET APPLICATION COVERED BY ANY OF THE FOLLOWING USER FEE EXCEPTIONS? IF SO, CHECK THE APPLICABLE EXCEPTION.
[ ] This application is the first PMA submitted by a qualified small business, including any affiliates, parents, and partner firms
[ ] This biologics application is submitted under secion 351 of the Public Health Service Act for a product licensed for further manufacturing use only
[ ] The sole purpose of the application is to support conditions of use for a pediatric population
[ ] The application is submitted by a state or federal government entity for a device that is not to be distributed commercially

6. IS THIS A SUPPLEMENT TO A PREMARKET APPLICATION FOR WHICH FEES WERE WAIVED DUE TO SOLE USE IN A PEDIATRIC POPULATION THAT NOW PROPOSES CONDITION OF USE FOR ANY ADULT POPULATION? (If so, the application is subject to the fee that applies for an original premarket approval application (PMA).)

[ ] YES [X] NO

7. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION (FOR FISCAL YEAR 2005)
$3,833.00

25-Sep-2006

Form FDA 3601 (08/2003)

Close Window

Print Cover sheet

K20

16

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015

ACCURAY

Accuray Incorporated
1310 Chesapeake Terrace
Sunnyvale, CA 94089

T: 408.716.4600
F: 408.716.4601
www.accuray.com

September 29, 2006

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, Maryland 20850

**RE: SPECIAL 510(k)**
**Payment Identification Number: MD6027694-956733**

Dear Sir or Madam:

Yesterday, September 28, 2006, Accuray Incorporated sent FDA a Special 510(k) for Lung Tumor Tracking, a modification of the CyberKnife Robotic Radiosurgery System. We inadvertently failed to attach the new Instructions for Use for the Lung Tumor Tracking modification. The predicate device Instructions for Use were sent yesterday with the full submission.

Enclosed please find the new Instructions for Use for the CyberKnife Robotic Radiosurgery System, Lung Tumor Tracking. The revised manuals are identical to the predicate manuals, but includes the enclosed module for Lung Tumor Tracking in the *Treatment Delivery User Guide*. The "QA Motion Phantom for Lung Tumor Tracking" is a new section in the *Physics Essentials Guide*.

If there are any questions, please feel free to contact me by phone at (408) 716-4628, by fax at (408) 716-4601 or by e-mail at aschlagenhaft@accuray.com.

Sincerely,

Anne Schlagenhaft
Sr. Regulatory Affairs Associate



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015

# APPENDIX H. MODIFIED DEVICE LABELING

**NOTE**: The **product labels** for the predicate and subject CyberKnife System are identical.

**Only the sections of the instructions for use that were changed** are provided here. Sections of the instructions for use that did **NOT** change are identical to the predicate manual and are not included in this section.

The "Lung Tumor Tracking System" is a new section in the CyberKnife System *Treatment Delivery User Guide*. The "QA Motion Phantom for Lung Tumor Tracking" is a new section in the *Physics Essentials Guide*.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015

**Lung Tumor Tracking System**

This is a new module in the CyberKnife System *Treatment Delivery User Guide*.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118 

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



# Lung Tumor Tracking™ System (option)
## Table of Contents


**Introduction** ..... 1

**Overview of Lung Tumor Tracking** ..... 2

- **Treatment Planning** ..... 2
- **Treatment Delivery** ..... 2
- **Visual QA Requirements** ..... 3

**Treatment Planning for Lung Tumor Tracking** ..... 4

- **Template Selection** ..... 4
  - Setup Lung Tumor Tracking Template ..... 4
  - Apply Lung Tumor Tracking Template ..... 6
- **Tumor and Spine Segmentation** ..... 7
  - Tumor Segmentation ..... 7
  - Spine Segmentation ..... 7
    - Spine VOI Selection ..... 8
    - The Spine Model ..... 9
    - Modifying a Spine Disk ..... 10
    - Adding a Spine Disk ..... 10
    - Removing a Spine Disk ..... 10
- **Tracking Mode Selection** ..... 11
- **Alignment Center Selection** ..... 12
- **DRR Review** ..... 13
  - Default Mode ..... 13
  - Display Tumor Contour ..... 14
  - Invert DRR Images ..... 16
  - Invert DRR Images with Tumor Contour ..... 17




DRAFT

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118 20

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



Quality Status Decision ..... 18
Pending ..... 18
Confirm ..... 20
Reject ..... 21

**Treatment Delivery Using Lung Tumor Tracking ..... 23**

**Patient Alignment ..... 23**

Alignment Using the Xsight System ..... 24
Imaging Parameters ..... 24
Xsight X-ray Parameters ..... 27
Xsight Patient Alignment ..... 27
Xsight Error Handling ..... 30
Transition to Lung Tracking ..... 32
Lung Tumor Tracking Alignment ..... 33
Lung Tumor Tracking Imaging Parameters ..... 34
Lung Tumor Tracking Patient Alignment ..... 35
Switching from Lung Tracking to Xsight Alignment ..... 37
Lung Tumor Tracking Error Handling ..... 37

**Treatment Delivery ..... 39**

**Patient Re-alignment ..... 39**



DRAFT

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

21

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



# LUNG TUMOR TRACKING™ SYSTEM (OPTION)

## INTRODUCTION

The CyberKnife® System with the Lung Tumor Tracking™ System enables accurate patient positioning and radiation beam delivery without the need for implanting fiducials.

Lung Tumor Tracking is used in combination with the Xsight™ Spine Tracking System to perform patient alignment. During treatment delivery, Lung Tumor Tracking is used with the Synchrony™ Respiratory Tracking System to track movement of the tumor and patient breathing patterns.

This module includes the following sections:

- "Overview of Lung Tumor Tracking," *on page 2*: This section describes the Lung Tumor Tracking algorithm and its intended use in the CyberKnife System.
- "Treatment Planning for Lung Tumor Tracking," *on page 4*: This section describes how to use the MultiPlan™ treatment planning system to create a Lung Tumor Tracking plan.
- "Treatment Delivery Using Lung Tumor Tracking," *on page 23*: This section describes how to use Lung Tumor Tracking for treatment delivery.

For more information about the Synchrony System, see the module, "*Synchrony™ Respiratory Tracking System*," in this manual.

For more information about the Xsight System, see the module, "*Xsight™ Spine Tracking System (Option)*," in this manual.



DRAFT

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



# Overview of Lung Tumor Tracking

Lung Tumor Tracking can accurately and automatically track lung tumors which meet the following conditions:

- Tumor diameter larger than 15 mm in all directions.
- Tumor location in the peripheral region of the lung.
- Tumor location not completely obstructed by skeletal structures in the projection images in the X-ray imaging geometry.

**NOTE:** Lung Tumor Tracking is not intended to track lung tumors smaller than 15 mm in any direction or lung tumors located in the central region of the lung.

## Treatment Planning

Treatment using Lung Tumor Tracking includes a treatment planning phase and a treatment delivery phase. In the treatment planning phase, the location of the tumor to be treated is identified and Digitally Reconstructed Radiographs (DRRs) are generated. Rectangular regions circumscribing the known tumor location in the DRRs provide reference information during treatment delivery for detecting the tumor location within a region of interest (ROI) in the live images.

## Treatment Delivery

The Lung Tumor Tracking algorithm computes three translational components of patient displacement. Because the algorithm provides information only about translation offsets, a Lung Tumor Tracking treatment begins with an alignment procedure. During the alignment procedure, the Xsight™ Spine Tracking System is used to determine rotational alignment corrections.

**NOTE:** The Xsight Spine Tracking System is required for Lung Tumor Tracking.

The alignment center used for tracking by the Xsight System is typically different from the treatment center used by Lung Tumor Tracking. After alignment using the Xsight System, the couch is moved to the treatment center for tracking using Lung Tumor Tracking.

Lung Tumor Tracking is then used in combination with the Synchrony™ Respiratory Tracking System to establish a correlation model to track patient breathing patterns. Treatment commences using both Lung Tumor Tracking and the Synchrony System to track movement of the target tumor.

During treatment delivery, Lung Tumor Tracking provides corrections for residual translation offsets. A constant rotational correction is provided by the results obtained by the Xsight System during initial alignment. The treatment robot continuously adjusts the position of the linear accelerator (Linac) to correct for translational offsets of the target and applies the constant rotational correction. For cases in which there is no significant motion of the tumor during patient respiration, Synchrony System tracking can be turned off.



**DRAFT**

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



# Visual QA Requirements

Visual quality assurance (QA) that the lung tumor is tracked correctly by the Lung Tumor Tracking algorithm is essential to safe treatment delivery. During treatment planning, sample DRRs should be generated and inspected to determine if the case is suitable for Lung Tumor Tracking. See the section, "Treatment Planning for Lung Tumor Tracking," *on page 4* for information on generating sample DRRs.

The CyberKnife System user interface provides tools for verifying that Lung Tumor Tracking and the Xsight System are able to register skeletal structures and lung tumors in the live images with those in the DRRs. For more information, see the section, "Treatment Delivery Using Lung Tumor Tracking," *on page 23*.

**WARNING: Visual QA assures that the Lung Tumor Tracking algorithm is producing results that are correct at a coarse level. However, Visual QA is not adequate for verifying sub-millimeter accuracy.**



DRAFT

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118 24

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



# TREATMENT PLANNING FOR LUNG TUMOR TRACKING

This section describes how to use the MultiPlan™ treatment planning system to create a Lung Tumor Tracking plan.

The first step in creating a treatment plan is to load patient data and the required medical images, including at least one CT series. This step is described in the module, "*MultiPlan™ Treatment Planning System,*" and does not change for Lung Tumor Tracking.

## Template Selection

After using the Startup Wizard to load patient data and images, you can optionally select a plan template to use to create a new plan. The MultiPlan system includes a template for Lung Tumor Tracking plans. Before this template can be used to create a plan, the template must be set up with actual tracking parameters and dose constraints.

### Setup Lung Tumor Tracking Template

To setup the Lung Tumor Tracking template, follow these steps:

**Step 1.** Launch MultiPlan™ and select the Advanced Load task.

**Step 2.** On the **Settings** tab, select the `Plan Template` step. The screen shown in Figure 1, "Plan Template," *on page 5* is displayed.



**DRAFT**

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015

**Figure 1 Plan Template**

**Step 3.** In the **Plan Templates** dropdown list, select the template named `Sample 7 - Lung Tumor tracking`.

**Step 4.** Initialize the template as follows:

1. In the **Name** textbox, change the name of the template. For example, enter `Lung Tumor Tracking`.
2. In the **Planning Parameters** group, specify values for each parameter.
3. In the **Isocurve Settings** group, customize the isocurve settings.
4. In the **VOI Setting** group, set dose constraints for each Volume of Interest (VOI).
5. Optionally, enter a name in the **Author** textbox.
6. Optionally, enable password protection by selecting the **Password protection** checkbox.

After completing the above steps, you can exit the MultiPlan system. The Lung Tumor Tracking template is saved locally on the computer for future use.



**DRAFT**

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



# Apply Lung Tumor Tracking Template

After the Lung Tumor Tracking template is initialized, you can use it to create a new Lung Tumor Tracking plan. To do this, go to the last step of the MultiPlan Start-Up Wizard.

Figure 2, "Select template," *on page 6* shows the Select Optional Plan Template screen of the Start-Up Wizard.

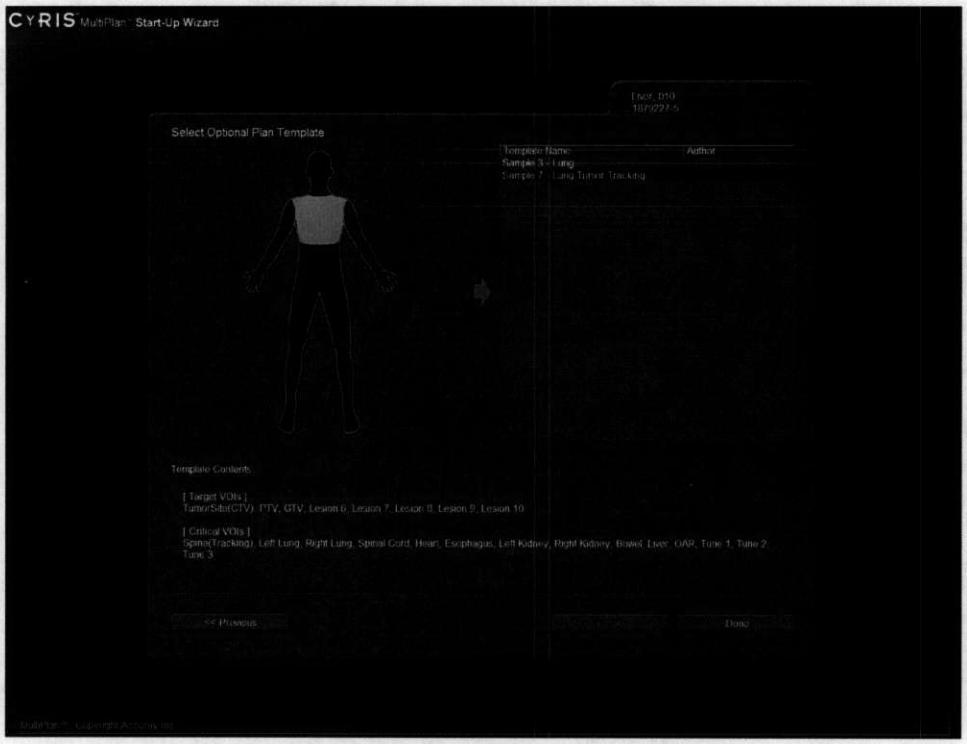



**Figure 2 Select template**

This screen displays a human model with an active region of the body highlighted. A list of plan templates on the right of the screen displays all the templates that apply to that region of the body.

To select the Lung Tumor Tracking template, follow these steps:

**Step 1.** Click the chest region on the human model to highlight it.

**Step 2.** Select the Lung Tumor Tracking template from the list on the right.

**Step 3.** Then click the **Done** button.

A new plan that uses the Lung Tumor Tracking template is created.



**DRAFT**

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118 27

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



# Tumor and Spine Segmentation

Two special VOIs are required in order to use Lung Tumor Tracking. The first VOI includes the tumor itself. The second VOI is required to coarsely delineate the spine region. You use MultiPlan segmentation tools to segment the tumor and spine VOIs.

## Tumor Segmentation

To segment the tumor VOI, you use standard MultiPlan segmentation tools. Follow these steps:

**Step 1.** On the **Contour** tab, select the **Delineate** step.

**Step 2.** In the **Select VOI** dropdown list, select the Tumor VOI.

**Step 3.** Then segment the Tumor VOI using the standard MultiPlan segmentation tools.

The standard MultiPlan segmentation tools for delineating a tumor VOI are described in the module, "*MultiPlan™ Treatment Planning System,*" and do not change for Lung Tumor Tracking.

## Spine Segmentation

To segment the rough spine, you can use either the standard MultiPlan segmentation tools in the **Delineate** step, or the special model-based spine segmentation tool in the **Spine Model** step. This section describes how to use the model-based spine segmentation tool to create the rough spine VOI.

Figure 3, "Model-based spine segmentation," *on page 8* shows the Spine Model screen.



DRAFT

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118 28

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



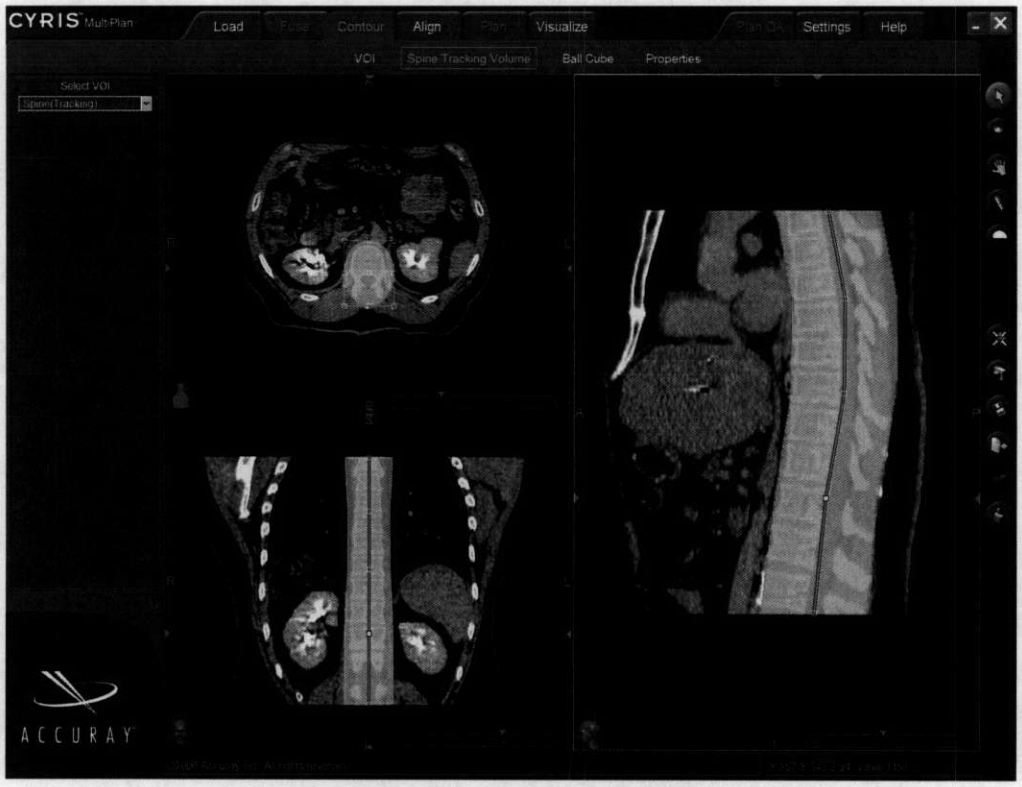



**Figure 3 Model-based spine segmentation**

## Spine VOI Selection

On the Spine Model screen, the Select VOI dropdown list displays the current spine VOI. You can select a different spine VOI from the list. When you change VOIs, the previous spine VOI is reset to a standard VOI. Any existing contour set is removed, and the VOI type is automatically set to be a critical structure.



**DRAFT**

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118 

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



## The Spine Model

The spine model defines a VOI that includes the spine structure and the area surrounding it. The area surrounding the spine structure of a patient contains useful information that helps to generate higher quality DRR images.

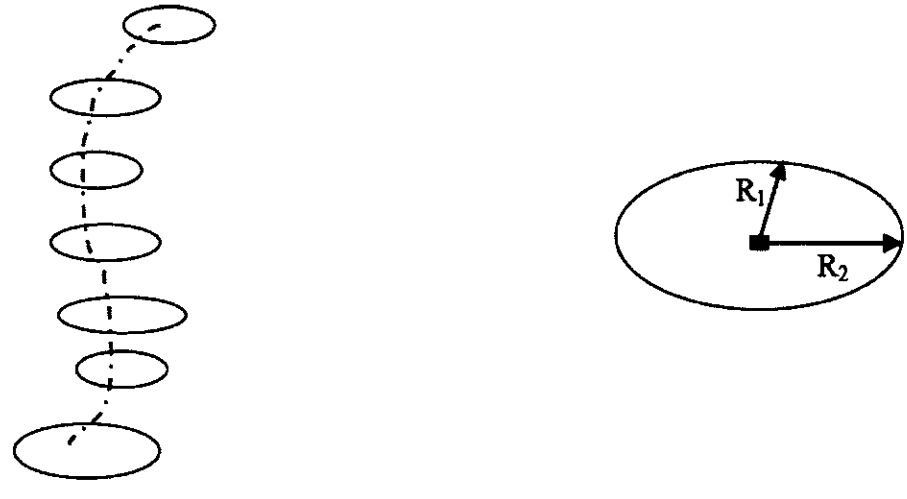
**NOTE:** The spine VOI must not contain just the segmented spine structure. The spine VOI should also contain the area surrounding the spine structure.

**WARNING: The spine VOI should not include any part of the tumor VOI. The treatment plan cannot be saved if any part of the tumor VOI is included in the spine VOI.**

Figure 4, "Spine Model," *on page 9* illustrates the spine model. The spine model defines a stack of spine disks. Each spine disk is defined as an elliptical contour on one of the axial image slices. The position and the size of each elliptical contour are determined by a center point and two radius vectors.

A spine model contains two or more spine disks. A spine model includes the following adjustable parameters:

- the number of spine disks
- the center point and radius of each disk




**(a) Spine disk stack** **(b) Spine disk**

**Figure 4 Spine Model**



**DRAFT**

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



## Modifying a Spine Disk

You can move and resize a spine disk.

To move a spine disk, do the following:

**Step 1.** In any of the 2D views, click on the center of the spine disk.

**Step 2.** Drag the spine disk to the new position.

To resize a spine disk, do the following:

**Step 1.** Browse through the axial view to the image slice that includes the spine disk.

**Step 2.** Resize the box that encloses the spine disk.

## Adding a Spine Disk

You can add a spine disk. Follow these steps:

**Step 1.** In either the sagittal view or the coronal view, click on the spine axis line to define the center position of the new spine disk.

The radius of the new spine disk is interpolated automatically from the radii of the neighboring spine disks.

## Removing a Spine Disk

To remove an existing spine disk, do the following:

**Step 1.** In either the sagittal view or the coronal view, click on the center point of the disk you want to remove.

**Step 2.** Drag the center point of the spine disk over the neighboring spine disks and release the mouse.

Alternatively, drag the center point outside the image view and release the mouse.-



**DRAFT**



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



# Tracking Mode Selection

To enable Lung Tumor Tracking, you select the Lung Tumor Tracking mode as follows:

**Step 1.** On the **Align** tab, select the **Treatment Parameters** step.

**Step 2.** In the **Tracking Method** dropdown list, select the `Lung` tracking method.

Figure 5, "Select tracking method," *on page 11* shows the Treatment Parameters screen.

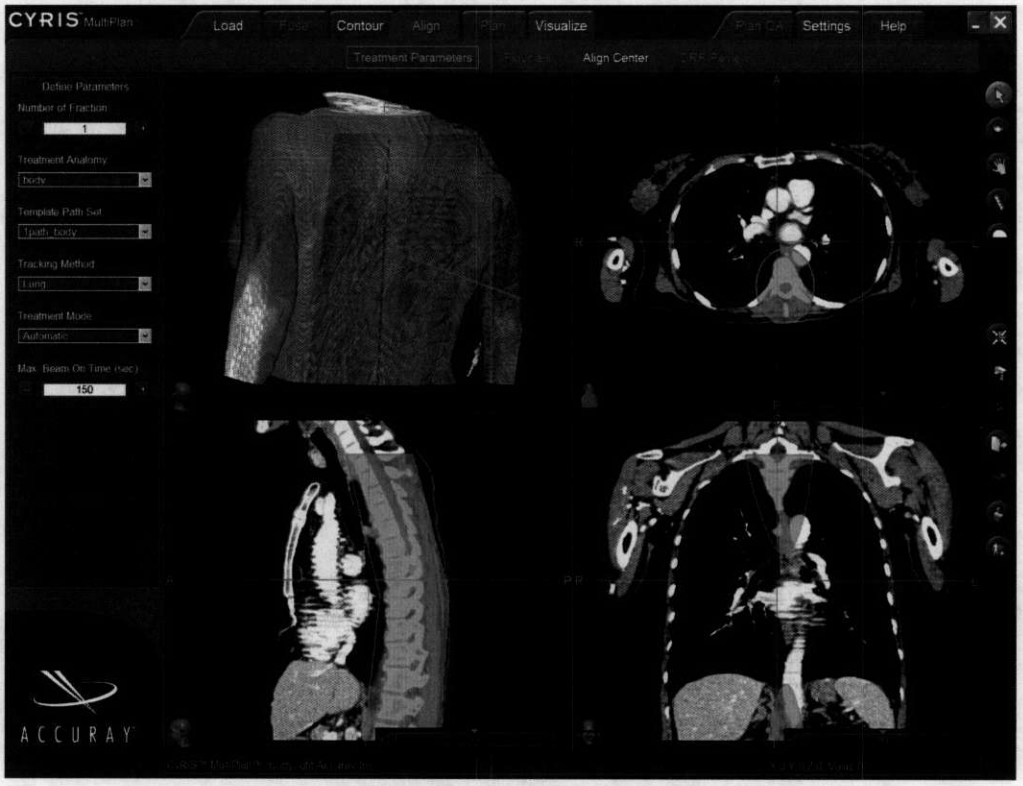



**Figure 5 Select tracking method**



DRAFT

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



# Alignment Center Selection

For Lung Tumor Tracking, the alignment center is selected based on the requirements of the Xsight System. The alignment center is used to align the patient at the machine center and allow the image tracking system to track the patient in 6D using Xsight.

**NOTE:** It is recommended that you position the alignment center on the same axial slice as the tumor and centered on the spinal cord.

If the alignment center is on the same axial slice as the tumor, the tumor will be visible in the axial view. When you select the alignment center, you should be able to see the spine model in all three cardinal views.

Figure 6, "Alignment Center," *on page 12* shows the tumor in the axial view. The spine model is visible in all three cardinal views.

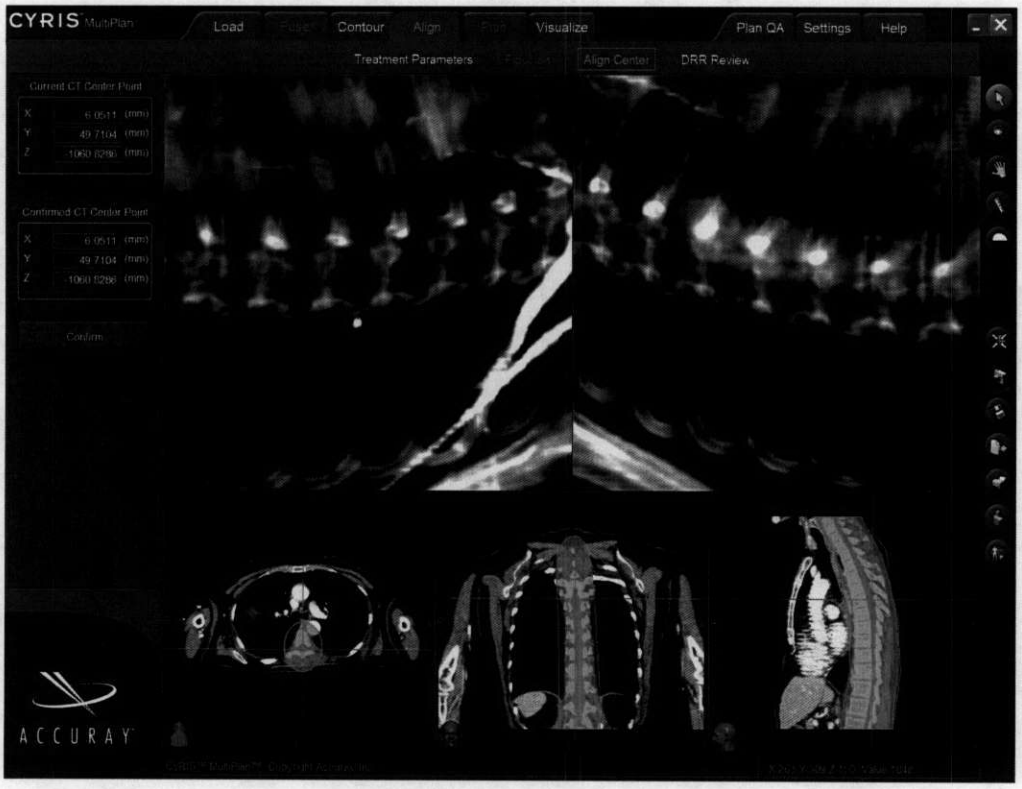



**Figure 6 Alignment Center**



**DRAFT**

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



# DRR Review

The DRR Review step allows you to decide whether the lung tumor can be visually identified in the DRR images. You perform the DRR Review step during the Align task. This section describes screen controls used for Lung Tumor Tracking on the DRR Review screen.

## Default Mode

If only one tumor is defined as a target in the Contour task, that tumor is automatically selected as the tracking tumor in the **DRR Review** step on the **Align** tab.

Figure 7, "Default mode," *on page 14* shows the DRR Review screen. The name of the tumor VOI and the centroid position point in CT space is displayed on the left of the screen.

If multiple targets are defined in the Contour task, the DRR views will be blank when you switch to the Align task. You must select one tumor as the target before DRR images can be generated. Follow these steps:

**Step 1.** From the **Choose Tracking Tumor** dropdown list, select one tumor as the target.

**Step 1.** Click the **Update DRR** button to generate DRR images.

The DRR images are generated based on the centroid of the tumor VOI. As a result, the tumor will always be shown at the center of the DRR images.

**NOTE:** To identify the target tumor in the DRR images, you should look in the region at the center of the DRR images.

Because the tumor overlays the spine, the tumor in one DRR image most likely will look better than in the other.



DRAFT



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015

**Figure 7 Default mode**

## Display Tumor Contour

On the DRR Review screen, you can display the tumor contour overlaid on the DRR images as follows:

**Step 1.** Select the **Display Tumor Contour** checkbox to overlay the tumor contour on the DRR images.

**Step 1.** Deselect the **Display Tumor Contour** checkbox to hide the tumor countour in the DRR images.

The tumor contour is displayed in the same color specified in the Delineate step. Tumor contour projections in the DRR images are generated based on the tumor VOI. The tumor centroid is also indicated in the DRR images by a plus sign (+). The tumor centroid should always be located at the center of of the DRR images.

Figure 8, "Tumor Contour Overlay.," *on page 15* shows the tumor contour overlaid on the DRR images. The tumor centroid is indicated at the center of the DRR images.



DRAFT

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8116

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



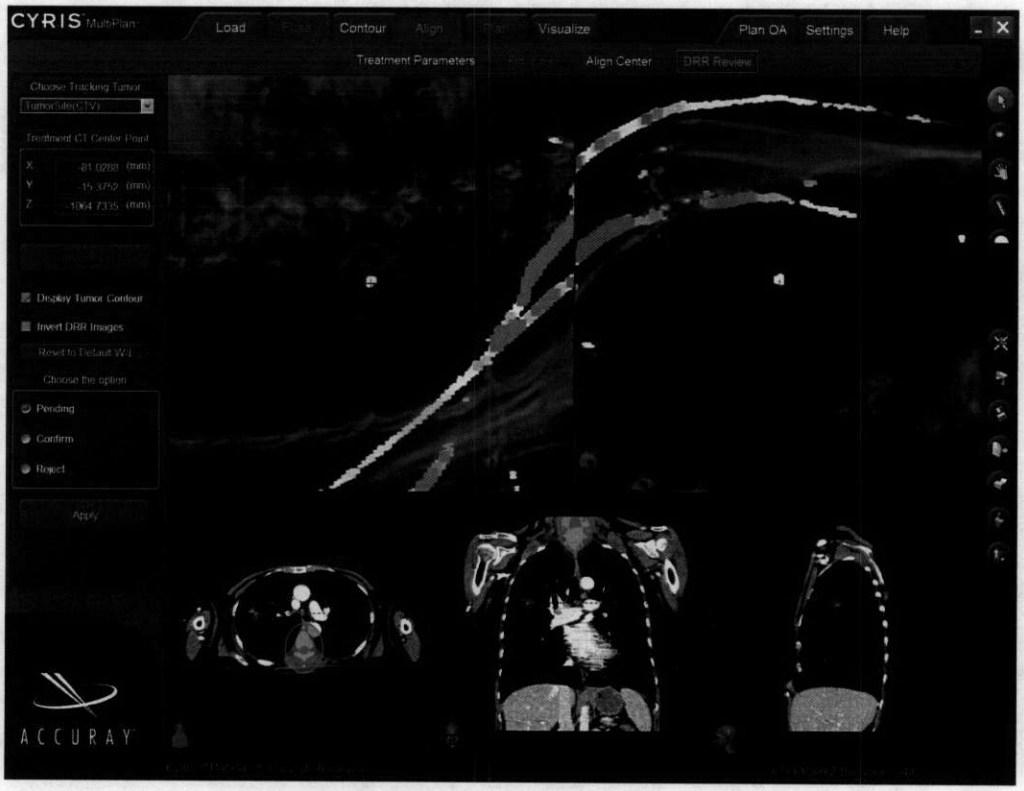



**Figure 8 Tumor Contour Overlay.**



DRAFT

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



# Invert DRR Images

You can invert the DRR images to reverse the contrast to help visually identify the tumor. In some cases the tumor may be more visible in inverted DRR images. The inverted DRR images are generated by mapping black to white, and white to black, in the images. Invert the DRR images as follows:

**Step 1.** Select the **Invert DRR Images** checkbox to invert the DRR images.

**Step 2.** Deselect the **Invert DRR Images** checkbox to return to the default contrast in the DRR images.

Figure 9, "Invert DRR images.," *on page 16* shows the DRR Review screen with inverted DRR images.

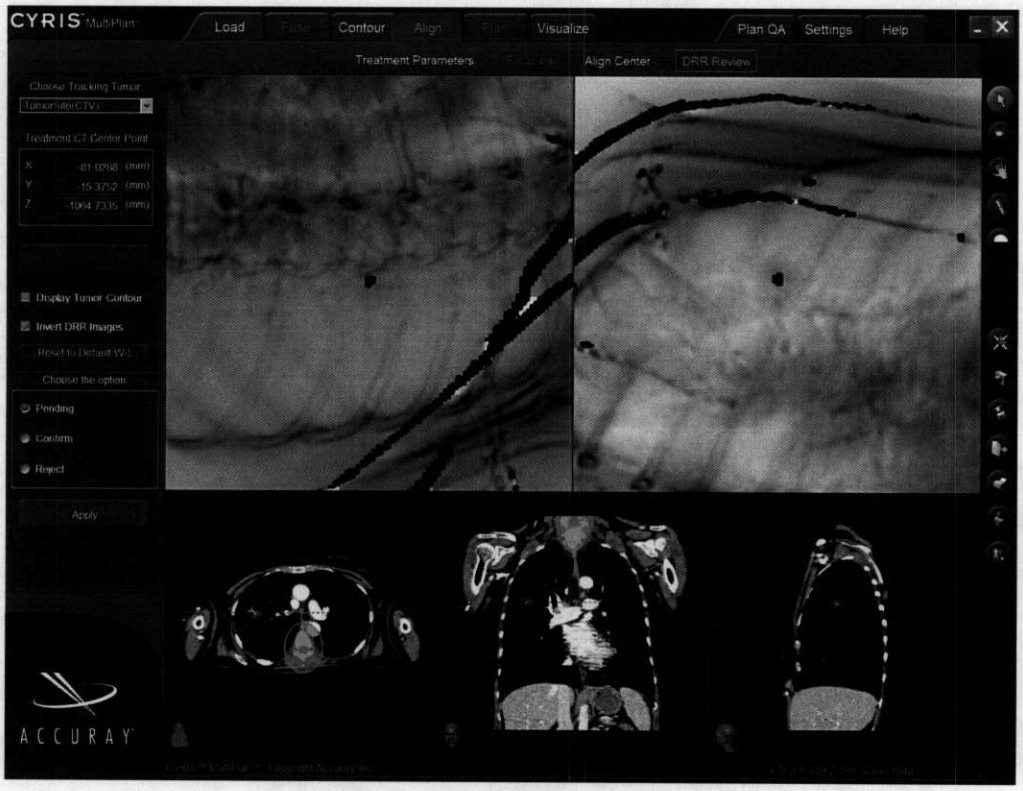



**Figure 9 Invert DRR images.**



**DRAFT**

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-3118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



# Invert DRR Images with Tumor Contour

You can simultaneously display the tumor contour and invert image contrast in the DRR images as follows:

**Step 1.** Select both the **Display Tumor Contour** checkbox and the **Invert DRR Images** checkbox.

**Step 2.** Deselect the checkboxes to return to the default view.

Figure 10, "Inverted DRR images with tumor contour.," *on page 17* shows the DRR Review screen with the tumor contour overlaid on inverted DRR images.

**Figure 10 Inverted DRR images with tumor contour.**



DRAFT

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



# Quality Status Decision

In the DRR Review step, you must indicate whether the lung tumor can be visually identified in the DRR images.

The following three options are available:

- **Pending**: Select this option when you are not able to make a decision at this time or need to consult with others. This option allows you to defer the decision to a later time.
- **Confirm**: Select this option when you can see the the lung tumor clearly in the DRR images, and when the size and location of the lung tumor meet the requirement for using Lung Tumor Tracking method described in the section, "Overview of Lung Tumor Tracking," *on page 2*.
- **Reject**: Select this option when you cannot see the lung tumor in both DRR images.

To select one of the above options, do the follwing:

**Step 1.** On the DRR Review screen, click a radio button in the **Choose the option** section.

**Step 1.** Then click the **Apply** button.

## Pending

When you select the **Pending** option, you are prompted to save the current plan to the central database for future review. Plans in the Pending state are always nondeliverable. You can reload the plan later and perform the necessary steps to review the quality of the DRR images. At that time you can make a final decision on whether the lung tumor is visible or not.

Figure 11, "DRR Review - Pending.," *on page 19* shows the **Save Plan** dialog box for entering the name of a plan in the Pending state.



**DRAFT**



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



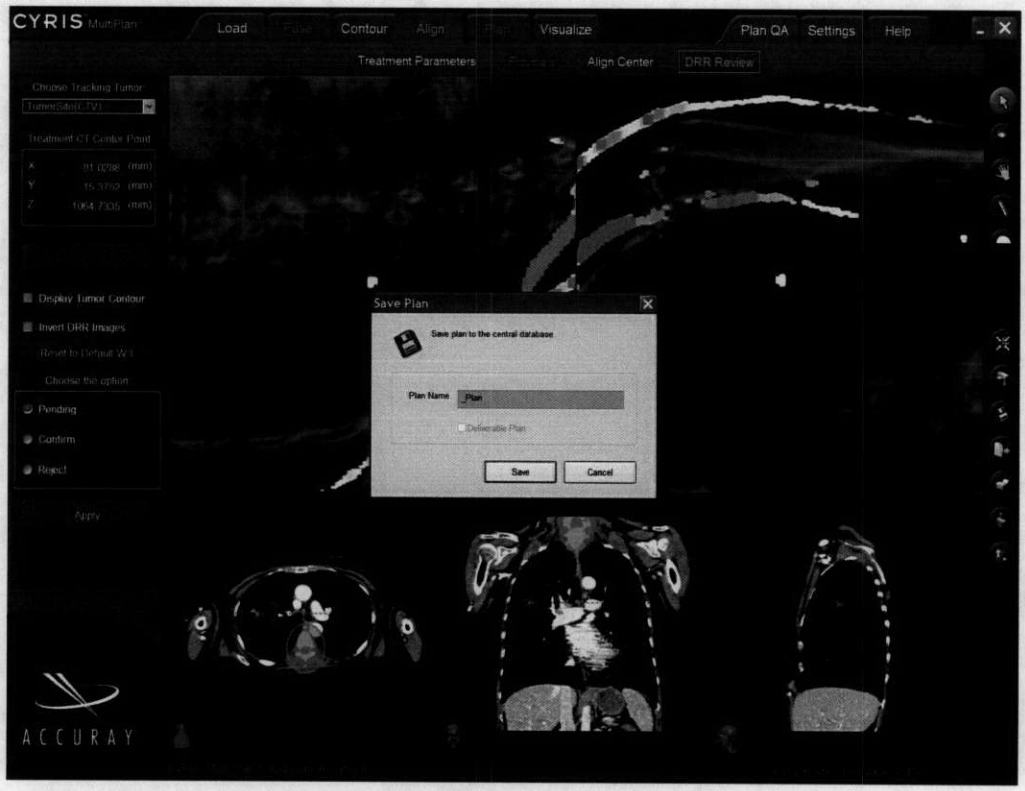



**Figure 11 DRR Review - Pending.**



**DRAFT**

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



## Confirm

When you select the **Confirm** option to indicate that the lung tumor is clearly visible in the DRR images, the Plan task becomes available.

**WARNING: Users are advised to be cautious before deciding to select the Confirm option. If the lung tumor is not clear enough in the DRR images, Lung Tumor Tracking may produce inaccurate results during treatment, resulting in targeting errors.**

Figure 12, "DRR Review - Confirm.," *on page 20* shows the Plan task active after the Confirm option has been selected.

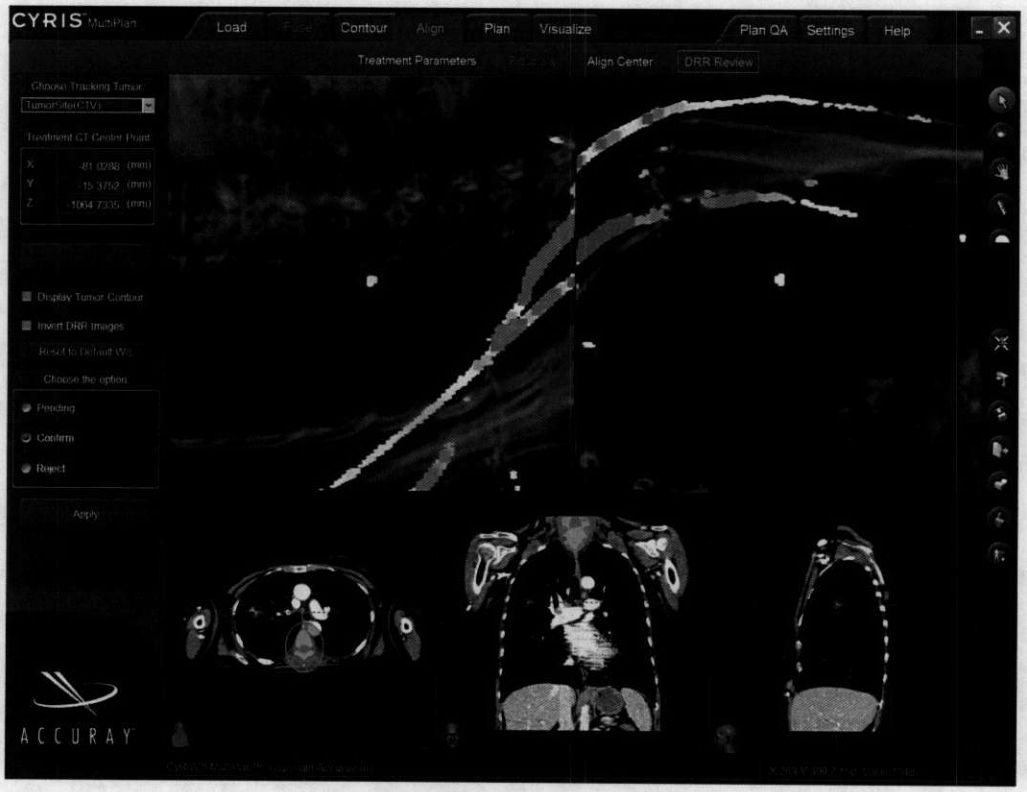



**Figure 12 DRR Review - Confirm.**



**DRAFT**

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



## Reject

If you cannot visually identify the lung tumor in the DRR images, you should select the **Reject** option. When you select this option and click the **Apply** button, a warning message is displayed to notify you that this patient cannot be treated using Lung Tumor Tracking. After you click **OK** to close the dialog box, you will not be able to do any further planning for this patient. The **Save Plan** dialog box is displayed, allowing you to save the plan as nondeliverable for future review or record.

Figure 13, "DRR Review - Reject Warning.," *on page 21* shows the Warning message that is displayed after you select the **Reject** option.

Figure 14, "DRR Review - Reject Saving Plan.," *on page 22* shows the Save Plan dialog box that allows you to save the plan as nondeliverable.

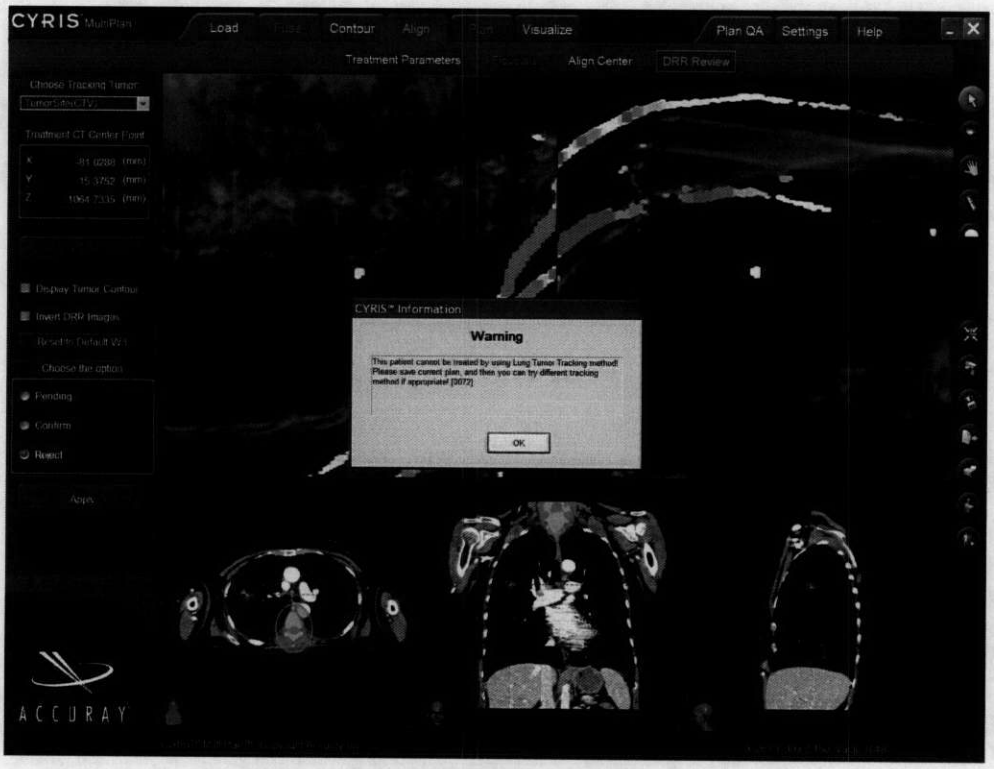



**Figure 13 DRR Review - Reject Warning.**



DRAFT

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



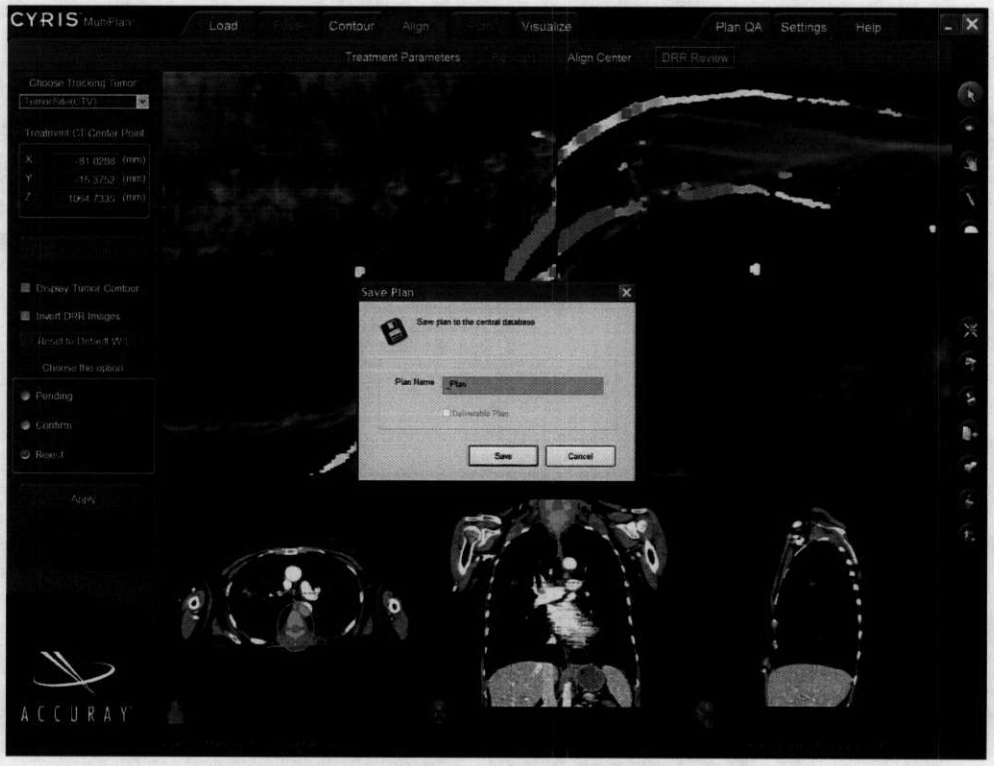



**Figure 14 DRR Review - Reject Saving Plan.**



**DRAFT**

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



# TREATMENT DELIVERY USING LUNG TUMOR TRACKING

This section describes how to use Lung Tumor Tracking for treatment delivery.

## Patient Alignment

Patient alignment begins with path downloading. During path downloading, DRR images from Lung Tumor Tracking and the Xsight System are transmitted from the User Control Console to the Target Locating Computer (TLS) computer for use by the tracking algorithms.

Reference DRR images are loaded from the User Control Console for display for the user, and the Lung Tumor Tracking and Xsight System algorithms are initialized.

For more information on path downloading, please refer to the Treatment Delivery User's Manual.

When path downloading is complete, the Patient Alignment window is displayed. Figure 15, "Patient Alignment window: Xsight Tracking," *on page 24* shows the Patient Alignment window with segmented spine DRR images.

Patient alignment comprises two phases. Initially, the Patient Alignment window is configured for alignment using the Xsight System. After alignment has been achieved, alignment using Lung Tumor Tracking is performed, and the Synchrony System is used to establish a correlation model, prior to commencing treatment delivery.



DRAFT



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



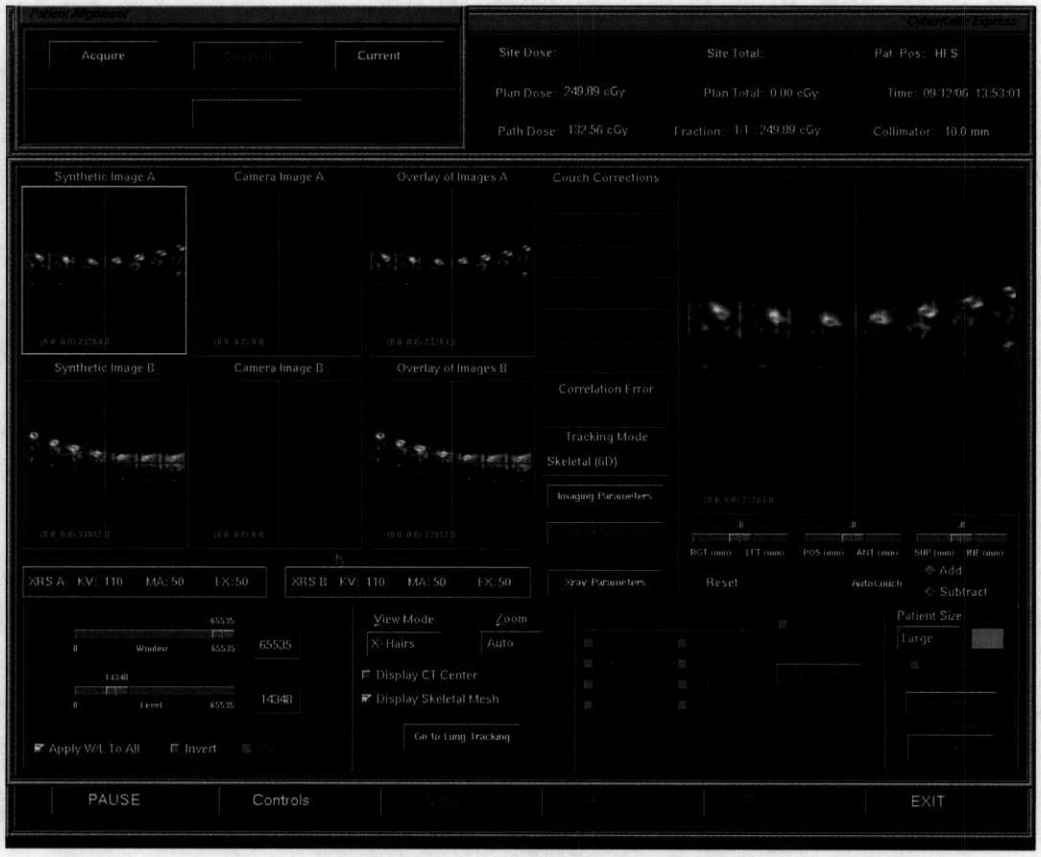



**Figure 15 Patient Alignment window: Xsight Tracking**

# Alignment Using the Xsight System

The appearance and operation of the Patient Alignment window is similar to the Patient Alignment window for standard Xsight alignment as described in the Treatment Delivery User's Manual.

The main difference is the **Go to Lung Tracking** button in the View mode section of the screen. After patient alignment using Xsight has been accomplished, you click this button to transition into Lung Tumor Tracking alignment, discussed later in the section , "Lung Tumor Tracking Alignment," *on page 33.*

## Imaging Parameters

When you click the **Imaging Parameters** button in the Patient Alignment window, the Imaging Parameters window is displayed as shown in Figure 16, "Imaging Parameters window for Xsight alignment," *on page 25.* These imaging parameters are described in the Treatment Delivery User's Manual.



**DRAFT**

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



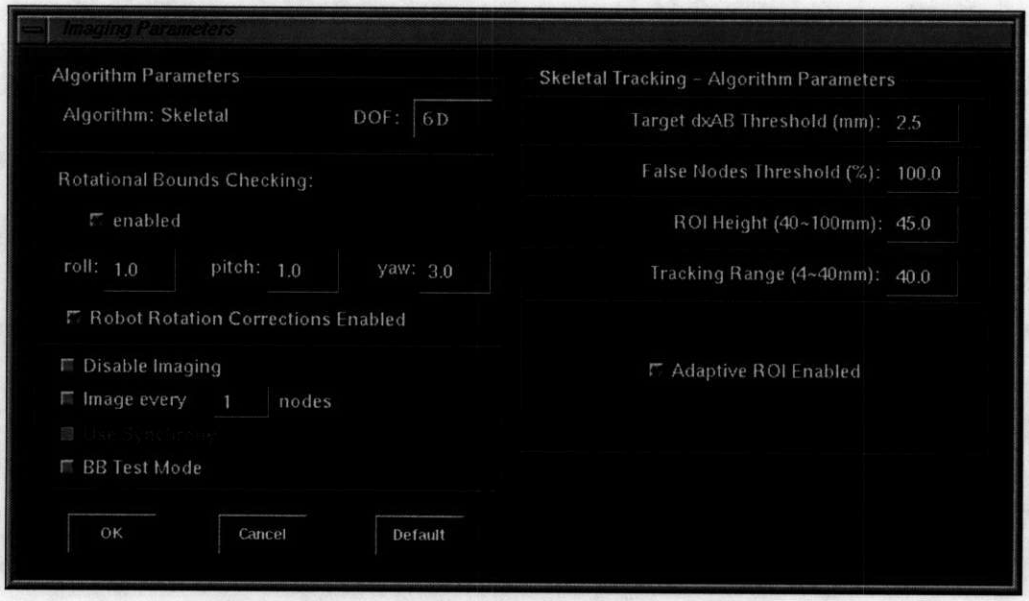



**Figure 16 Imaging Parameters window for Xsight alignment**

The **Skeletal Tracking - Algorithm Parameters** section of the Imaging Parameters window displays parameters which are configurable within specified ranges. The default settings are adequate for most cases and are recommended for use. When the Xsight tracking algorithm fails, tuning some of these parameters may allow successful tracking.

The first two parameters, **Target dxAB Threshold** and **False Nodes Threshold**, prevent the Xsight tracking algorithm from producing incorrect results. When the number of mesh nodes with false estimation exceeds the preconfigured threshold, mismatching between the DRR images and the live images usually occurs. In this case, the Xsignt tracking algorithm produces no output. Instead, an error message describing corrective actions is displayed.

The Target dxAB Threshold parameter is the absolute difference between the Superior/Inferior translations for Camera A and Camera B. When the algorithm works correctly, this value should be small. However, in the presence of large rotations, dxAB could be somewhat larger, for instance, exceeding 2 mm.



DRAFT

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118 

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



The default value of the False Nodes Threshold is 50%. For most cases, the actual percentage of false nodes is considerably less. However, in some lumbar cases or in some cases of lower parts of thoracic spines, the value of this parameter may need to be increased. When you change the value of this parameter and then click **OK**, the dialog box displayed in Figure 17, "Confirmation of change to False Nodes Threshold parameter," *on page 26* to confirm the change and warn that visual inspection of tracking results is required.

**WARNING: When larger values are used for the Target dxAB Threshold parameter or the False Nodes Threshold parameter, it is very important to perform visual inspection after the tracking results are displayed. Increasing the value of these parameters may cause the Xsight algorithm to produce incorrect estimates of the patient position, which in turn can lead to misdirected radiation beams. Use caution before increasing these parameter values.**

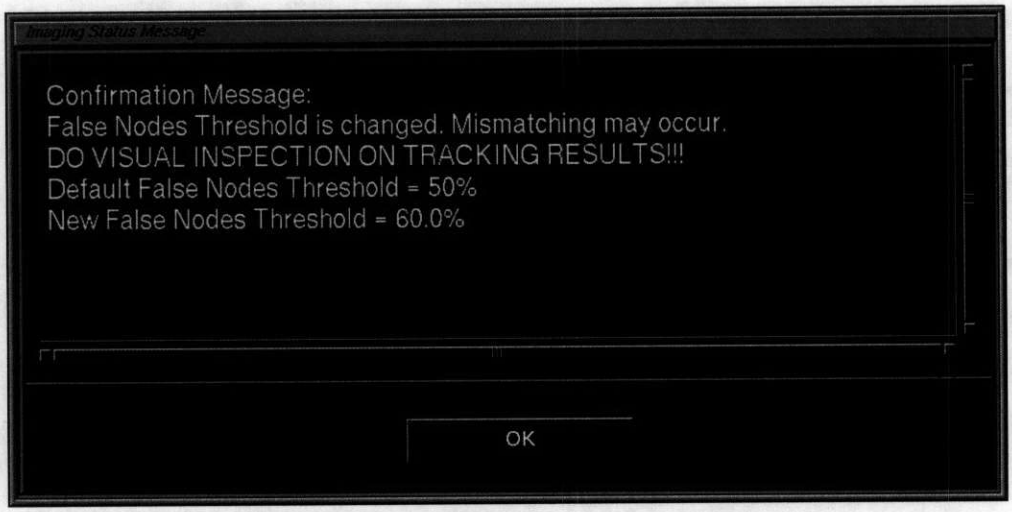



**Figure 17 Confirmation of change to False Nodes Threshold parameter**

**ROI Height** defines the height of the ROI for image registration. The ROI width is proportional to the ROI height by the ratio 4/3. The default ROI size is good for all C-spine [What?] and the upper part of T-spine [What?]. The ROI size could increase to contain more skeletal structures for lower part of T-spine and L-spine.

**Tracking Range** specifies the largest displacements of patients that the tracking algorithm is able to track. From the tracking algorithm's perspective, the larger the search range, the more likely a mismatch occurs. When the tracking algorithm fails, decreasing the tracking range may be helpful.

**Adaptive ROI Enabled** optimizes the location of the ROI so that the ROI contains most of the skeletal structures for the best registration. By default, this checkbox is enabled and it works well for most cases. In C1-C3 regions, if it is found that the ROI lies over a part of the jaws, this checkbox should be deselected.



**DRAFT**



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



## Xsight X-ray Parameters

The general recommendations for setting the X-ray parameters is lower X-ray energy for C-spine and the upper part of T-spine, and higher X-ray energy for the lower part of T-spine and L-spine.

For the normal cases of T-spine, the X-ray parameters 125KV, 100MA, 100EX are recommended. For some difficult cases, for example, patients with a large body, larger values of MA and EX may be needed for more X-ray penetration of soft tissues.

## Xsight Patient Alignment

Using the default settings in the Imaging Parameters window, click the **Acquire** button in the Patient Alignment window, shown in Figure 18, "Patient Alignment window," *on page 27*. X-Ray images are acquired and image registration is performed.

Within a few seconds, the tracking results are displayed, as shown in Figure 19, "Using Skeletal Mesh to display tracking results," *on page 28*. There are two ways to display the results: skeletal mesh and CT-Center. In the View mode section of the Patient Alignment window, there are two buttons for options to display results. **Display Skeletal Mesh** is the default option. The meshes in the DRR images and the live images appear immediately after image correction is done. When you click the **Align** button, the meshes in the DRR images and the live images in both projections A and B are aligned, as shown in Figure 20, "Using Skeletal Mesh to display aligned tracking results," *on page 29*. Clicking the **Display Skeletal Markers** button results in the visualization of the tracking results using markers as indicated Figure 21, "Using Skeletal Markers to display aligned tracking results," *on page 30*. Similar to fiducial tracking, the tracking results can be visually inspected from the alignment of markers in the DRR images and the live images.

The **Align** button uses only translations to perform alignment. When large rotations exist, the rotations of the mesh in the live images can be clearly seen. In the Overlay images, the accuracy of tracking can be visually inspected from the alignment of the mesh nodes in the area close to the image center.

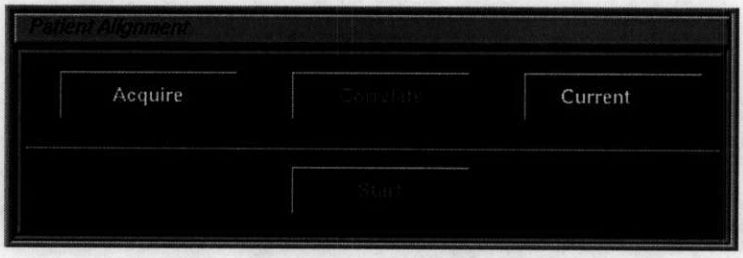



**Figure 18 Patient Alignment window**

The meshes in the DRR images and the live images are displayed in different colors. Also, in the live images, the false nodes (nodes for which the estimated translation in 2D do not agree with the surrounding nodes) are displayed in a different color from the rest of the mesh. The smaller the number of false nodes, the more reliable the estimates from the Xsight tracking algorithm.

The Xsight System relies on skeletal structures in the ROI for accurate tracking. Users should inspect the ROIs for both camera images to verify that the ROI includes sufficient skeletal structures.



DRAFT

48

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



**WARNING: Lack of skeletal features in the ROI may result in incorrect estimates of the patient position, which in turn can lead to misdirected radiation beams. Inspect the ROIs for both camera images to verify that the ROI includes sufficient skeletal structures.**

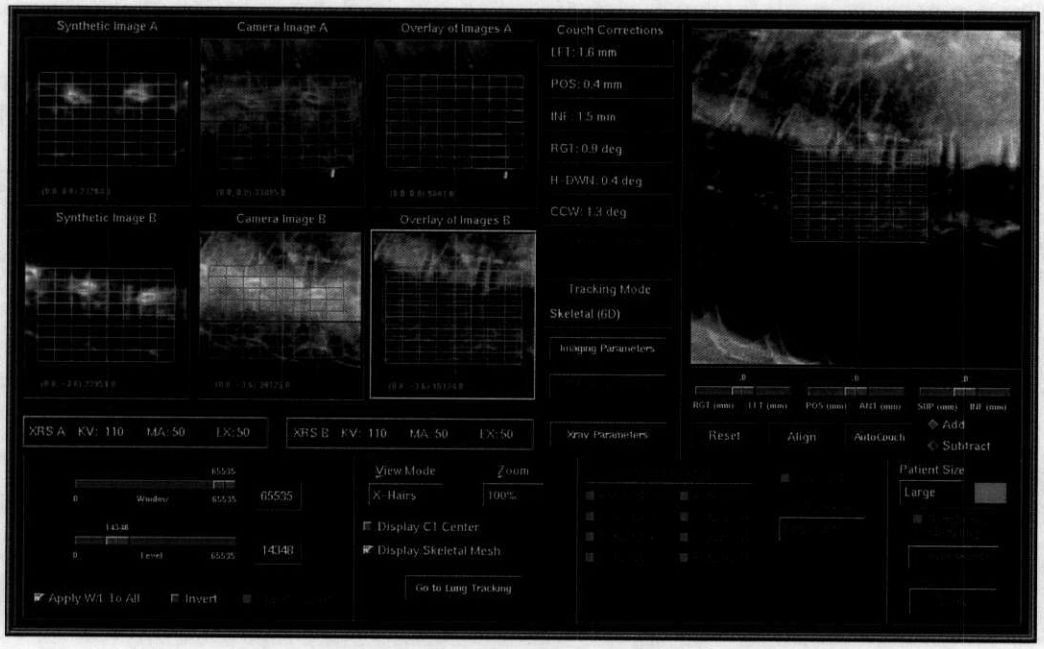



**Figure 19 Using Skeletal Mesh to display tracking results**



**DRAFT**

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



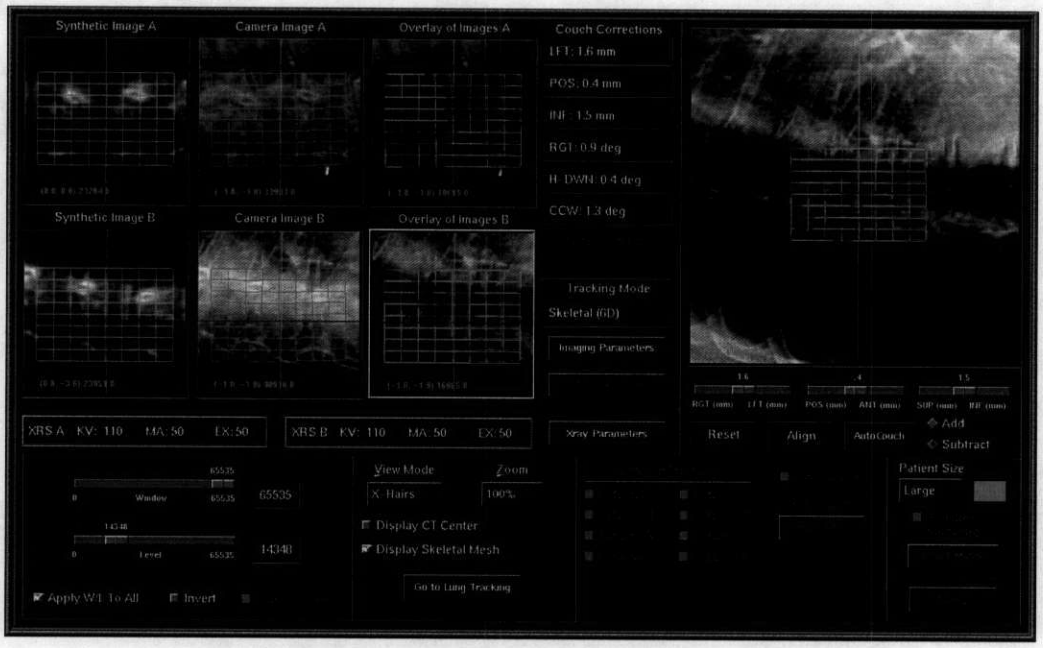



**Figure 20 Using Skeletal Mesh to display aligned tracking results**



DRAFT

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



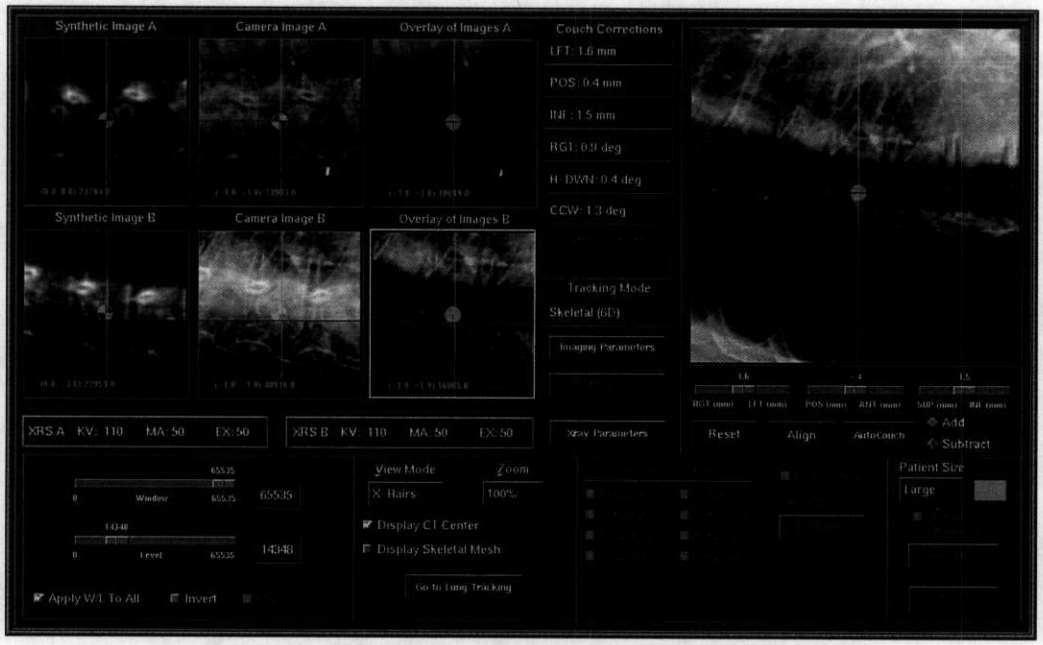



**Figure 21 Using Skeletal Markers to display aligned tracking results**

Xsight relies on the nodes in the center columns of the ROI for estimation of the patient roll rotations (rotation about the inferior-superior axis). Users should inspect the ROI's in both camera images to ensure that the nodes in the center columns of the ROI include skeletal structures.

**WARNING: Lack of features in the center columns of the ROI may cause the Xsight algorithm to produce incorrect estimates of the patient roll rotation, which in turn can lead to misdirected radiation beams. Inspect the both camera images to ensure that the nodes in the center columns of the ROI include sufficient features in them.**

## Xsight Error Handling

The tracking algorithm may fail for one of two reasons:

- a false nodes error
- a target dxAB error

The Xsight algorithm parameters in the Imaging Parameters window, shown in Figure 16, "Imaging Parameters window for Xsight alignment," *on page 25*, should be tuned to make the algorithm work. The false nodes error most commonly occurs if the live images are mismatched with the DRR images. In this case, the error dialog box, shown in Figure 22, "Imaging Status dialog box for False Nodes Error," *on page 31*, provides suggestions to help the Xsight algorithm find the right corrections. Overly large dxAB might be caused by large rotations. To address this error, increase the dxAB threshold as suggested by the error dialog shown in Figure 23, "Imaging Status dialog box for Target DxAB Error," *on page 31*.



DRAFT

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



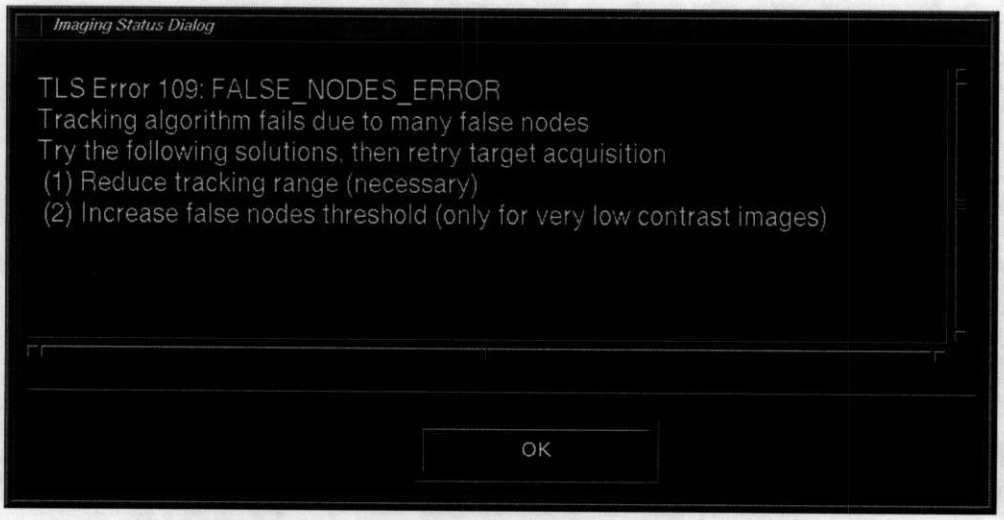



**Figure 22 Imaging Status dialog box for False Nodes Error**

**Figure 23 Imaging Status dialog box for Target DxAB Error**

**WARNING: Increasing the value of the Target dxAB Threshold parameter or the False Nodes Threshold parameter may cause the Xsight algorithm to produce incorrect estimates of the patient position, which in turn can lead to misdirected radiation beams. Use caution before increasing these parameter values.**



DRAFT

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118 

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



## Transition to Lung Tracking

Once Xsight alignment has been accomplished, pushing the **Go to Lung Tracking** button effects a transition to Lung Tumor Tracking alignment. This transition causes the DRR images and the live images to update as appropriate for Lung Tumor Tracking. Also, some controls on the Patient Alignment window and Imaging Parameters window are changed, as appropriate for Lung Tumor Tracking. These changes are discussed in the following sections.

During the transition from Xsight alignment to Lung Tumor Tracking alignment, the user is prompted to confirm whether the couch should be moved from the Xsight alignment position to the Lung Tumor Tracking alignment position, as shown in Figure 24, "Couch motion prompt: Transition from Xsight Tracking to Lung Tumor Tracking," *on page 32*. Under normal circumstances, the **Yes** button should be clicked. This will cause the couch to automatically reposition as needed for Lung Tumor Tracking. If the user clicks the **No** button, the system will still successfully transition to Lung Tumor Tracking mode, but the couch will remain in its current position.

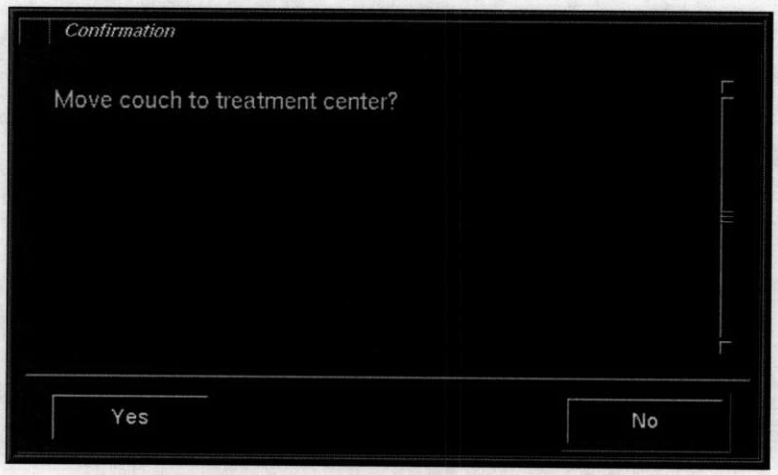



**Figure 24 Couch motion prompt: Transition from Xsight Tracking to Lung Tumor Tracking**



**DRAFT**

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118 

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



# Lung Tumor Tracking Alignment

Figure 25, "Intial Lung Tumor Tracking Alignment window," *on page 33* shows the Patient Alignment window as it initially appears for Lung Tumor Tracking. The Xsight controls at the bottom center of the screen are replaced with the following Lung Tumor Tracking controls:

The **Marker On** checkbox determines whether or not a graphic overlay of the tumor outline appears on the DRR images and live images.

The **Enable Offset** checkbox determines whether or not translational offsets determined from user manipulation of a graphic overlay on the live image should be used as input to the Lung Tumor Tracking algorithm.

**Go to Xsight Align** causes a transition from the Lung Tumor Tracking state back to the Xsight alignment state. When this transition occurs, the DRR images, live images, and displayed Couch Corrections are replaced with the most recent Xsight results, and the user is explicitly prompted to permit the couch motion.

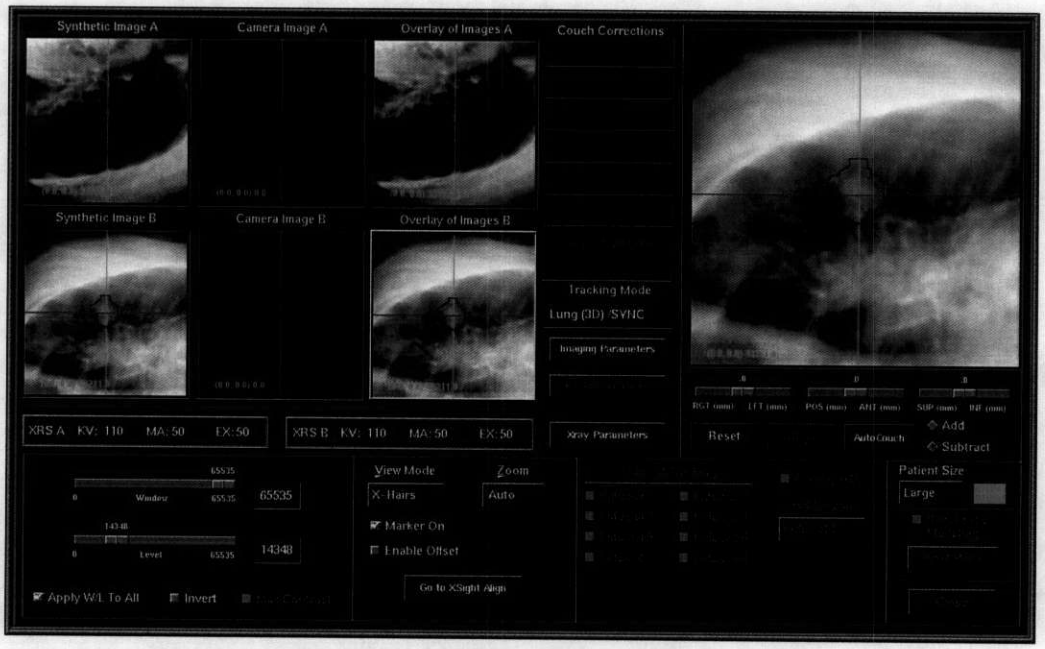



**Figure 25 Intial Lung Tumor Tracking Alignment window**



DRAFT

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118 54

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



## Lung Tumor Tracking Imaging Parameters

The Imaging Parameters window for Lung Tumor Tracking is shown in Figure 26, "Imaging Parameters window for Lung Tumor Tracking," *on page 34*. The parameters in the **Algorithm Parameters** section are the standard imaging parameters which are discussed in the Treatment Delivery User's Manual.

In the **Lung Tumor Tracking - Algorithm Parameters** ,section, all the parameters are configurable within specified ranges. The default settings are adequate for most cases, and are recommended for use. When the tracking algorithm fails, tuning some of these parameters may make tracking successful.

The first parameter, **Target dxAB Threshold** , prevents the tracking algorithm from giving incorrect output. The Target dxAB Threshold parameter is the absolute differenece between the superior-inferior translations for Camera A and Camera B. When the algorithm works correctly, this value should be small. However, in the presence of large rotations, dxAB could be somewhat larger, for instance exceeding 2 mm.

**Live Contrast Factor** is the image contrast between the lung and the image background.

**Tracking Range X** and **Tracking Range Y** specify the size of the rectangle in the live image against which the tumor in the DRR image will be correlated to determine the position of the tumor in the live image.

**Confidence Threshold** is a number between 0 and 1 specifying a minimum detection confidence level. Tracking algorithm results are rejected if the confidence estimate produced by the algorithm is less than the threshold.

You can elect not to use the Synchrony System by deselecting the **Use Synchrony** checkbox.

**Figure 26 Imaging Parameters window for Lung Tumor Tracking**



**DRAFT**

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



## Lung Tumor Tracking Patient Alignment

Lung Tumor Tracking patient alignment and establishment of a Synchrony correlation model is performed as described in the Treatment Delivery User's Manual, except that the tracking algorithm used by the TLS is Lung Tumor Tracking rather than Fiducial tracking.

Clicking the **Acquire** button in the Patient Alignment window causes X-ray images to be acquired and the tracking algorithm to be executed. Within a few seconds, the tracking results are displayed, as shown in Figure 27, "Using Tumor Outline to display tracking results," *on page 36*. If the tumor was successfully detected in the live image and the **Marker On** checkbox is selected, then a graphic outline appears over the detected location of the tumor in the image. If the patient was correctly aligned, the graphic overlay in the DRR images and live images would be matched in the overlay image.

Pressing the **Align** button on the user interface adjusts the live images according to the measured translational offsets, as shown in Figure 28, "Using Tumor Outline to display aligned tracking results," *on page 36*.

The Lung Tumor Tracking algorithm does not estimate rotational couch corrections. The rotational corrections obtained from Xsight alignment are used to perform rotational adjustments of the Linac during treatment delivery. To indicate that the rotational corrections used do not originate from the Lung Tumor Tracking algorithm, they are displayed in grey, as shown in Figure 27 and Figure 28.

In some difficult cases, it is possible that the tracking algorithm does not correctly determine the tumor location. When this occurs, the displayed tumor outline on the live image will not be aligned with the actual tumor. A Patient Out of Bounds message may also be displayed. In this situation, the user can provide guidance to the algorithm by selecting **Offset** from the **View Mode** pulldown menu. A green tumor outline is then displayed on the live image. The user can then use the mouse to drag the green outline so that it lies over the position of the tumor in each of the live images. Then when the **Correlate** button is clicked, the translational offset information provided by the user's graphic manipulations are incorporated into the tracking algorithm so that it can better lock on to the correct target in the live image. The use of user-provided offsets in this manner is completely analogous to the fiducial tracking offset functionality described in the Treatment Delivery User's Manual.



DRAFT



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



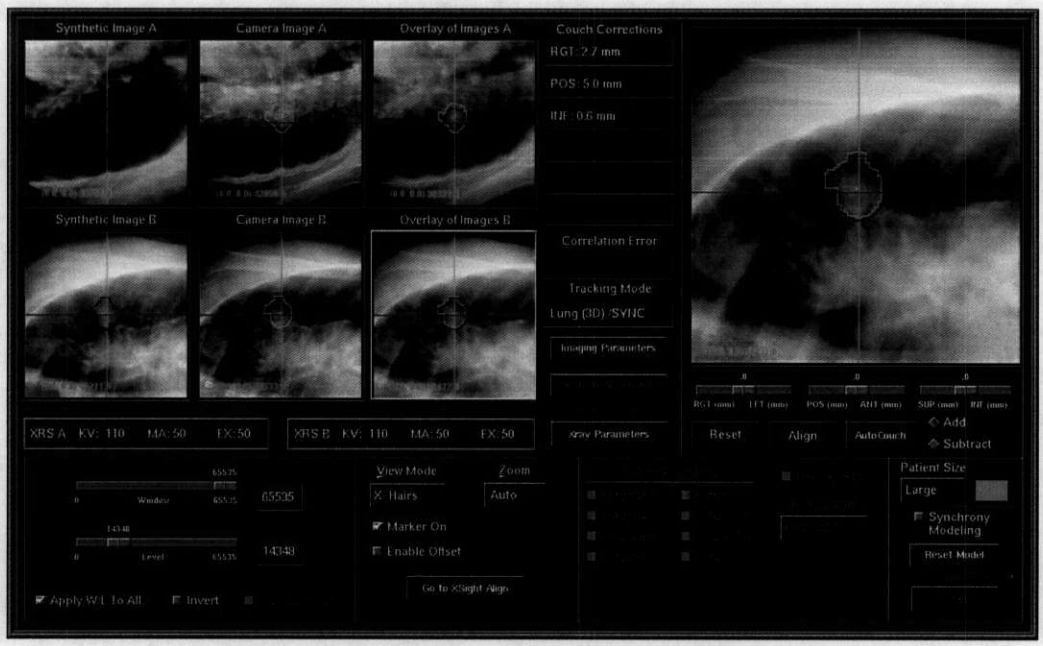



**Figure 27 Using Tumor Outline to display tracking results**

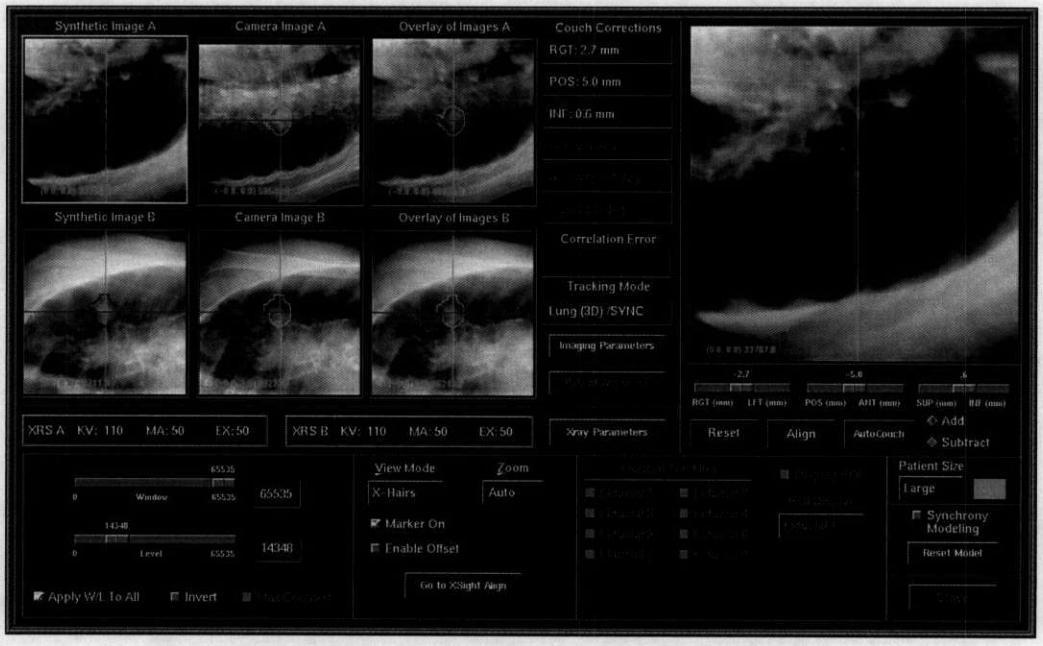



**Figure 28 Using Tumor Outline to display aligned tracking results**



**DRAFT**

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118 57

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



## Switching from Lung Tracking to Xsight Alignment

The user may choose at any time to return to Xsight alignment by clicking the **Go to Xsight Align** button. However, it is important to be aware that any motion of the couch will invalidate the Synchrony correlation model and require that a new model be established prior to treatment delivery.

If you desire to review the Xsight alignment user interface without invalidating the Synchrony correlation model, then click the **No** button when presented with the couch motion prompt dialog box, shown in Figure 29.

**Figure 29 Couch motion prompt: Transition from Lung Tumor Tracking to Xsight Tracking**

## Lung Tumor Tracking Error Handling

### Tracking Algorithm Errors

The tracking algorithm may fail for the following reasons:

- the computed confidence fails to meet the confidence threshold
- a target dxAB error

The algorithm parameters in the Imaging Parameters window (Figure 16) should be tuned to make the algorithm work.

Overly large dxAB might be caused by large rotations. To address this error, increase the dxAB threshold as suggested by the error dialog shown earlier in Figure 23.

### Interrupted couch motion

Using the Automatic Patient Positioning window, shown in Figure 30, "Automatic Patient Positioning dialog box," *on page 38* and accessed by clicking the **AutoCouch** button in the Patient Alignment window, it is always possible to command the couch to move to either the Alignment Position (for Xsight alignment) or the Treatment Position (for Lung Tumor Tracking). This is most useful in the case where couch motion was interrupted during the transition between the two tracking modes, for example if the user pushed an E-Stop button.



DRAFT

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118 

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



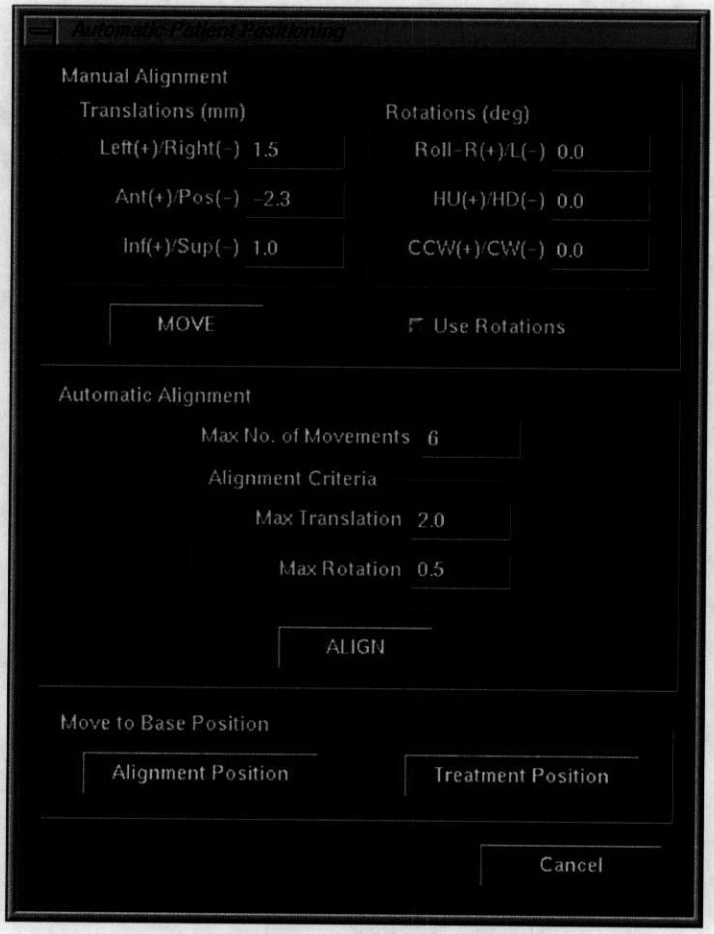



**Figure 30 Automatic Patient Positioning dialog box**



DRAFT

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118 

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



# Treatment Delivery

There are no changes in functionalities in Treatment Delivery -- refer to the Treatment Delivery User's Manual for details regarding treatment delivery.

# Patient Re-alignment

All alignment functionality provided with Patient Alignment is also provided during Patient Re-Alignment. However, as for Patient Alignment, Patient Realignment consists of two alignment tracking modes, Lung Tumor Tracking alignment and Xsight alignment.

If Treatment Delivery is interrupted, either by an E-Stop or because the user presses the **Pause** button, then the Lung Tumor Tracking Realignment state is entered. If the Synchrony correlation model is still valid, then the user can press the **Resume** button to resume treatment. Alternatively, the user could choose to re-enter Xsight alignment by pressing the **Go to Xsight Align** button. However, if the user chooses to move the couch to the Xsight alignment position, the resulting couch motion will cause the Synchrony correlation model to be reset, and a new model will have to be established in Lung alignment mode prior to the resumption of Treatment Delivery.



DRAFT

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118 60

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015





**DRAFT**

61

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015

**QA Motion Phantom for Lung Tumor Tracking**

This is a new module in the *Physics Essentials Guide*.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



# MODULE 9:

# QA MOTION PHANTOM FOR LUNG TUMOR TRACKING

*© 2006 Accuray Incorporated. All rights reserved. The Accuray stylized logo, Accuray, CyberKnife, Xsight, CyRIS, InView, MultiPlan, and Synchrony are trademarks and/or registered trademarks of Accuray Incorporated in the United States and other countries.*

**DRAFT**

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



# Table of Contents

Overview ..... 2
Quality Assurance (QA) Motion Phantom ..... 2
Lung Tumor Tracking ..... 3
End-to-End (E2E) Test ..... 4
Introduction ..... 4
Materials Required for Lung Tumor Tracking E2E Test ..... 4
Quality Assurance (QA) Motion Phantom ..... 6
Receiving Inspection Checklist ..... 6
Setup Procedure ..... 6
Basic Setup ..... 6
Setup for Lung Tumor Tracking QA ..... 9
Basic Operation ..... 10
Operation for Lung Tumor Tracking QA ..... 10
Maintenance ..... 11
Fuse Replacement ..... 11
Lung Tumor Tracking Quality Assurance ..... 12
Treatment Plan ..... 12
Treatment Delivery ..... 13
E2E Analysis ..... 16
Appendix A ..... 18



DRAFT

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118 64

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



# Module Objectives:

General introduction to the QA Phantom Motion for Lung Tumor Tracking and Quality Assurance procedures.

# Module Objectives:

To learn the Methodology and Quality Assurance procedures for the QA Motion Phantom for Lung Tumor Tracking



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



# QA Motion Phantom for Lung Tumor Tracking

## OVERVIEW

## QUALITY ASSURANCE (QA) MOTION PHANTOM

The Quality Assurance (QA) motion phantom is a QA tool for testing the Lung Tumor Tracking (Lung Tumor Tracking) option in the CyberKnife® system. This phantom simulates respiratory motion of a human torso and provides radiochromic film-based test capability at locations inside the phantom corresponding to a typical lung tumor and a critical structure in a human body. Figure 1 shows the QA motion phantom. The phantom shares some similar components with a standard torso motion phantom from CIRS Inc. but is specifically designed for use with CyberKnife Lung Tumor Tracking.

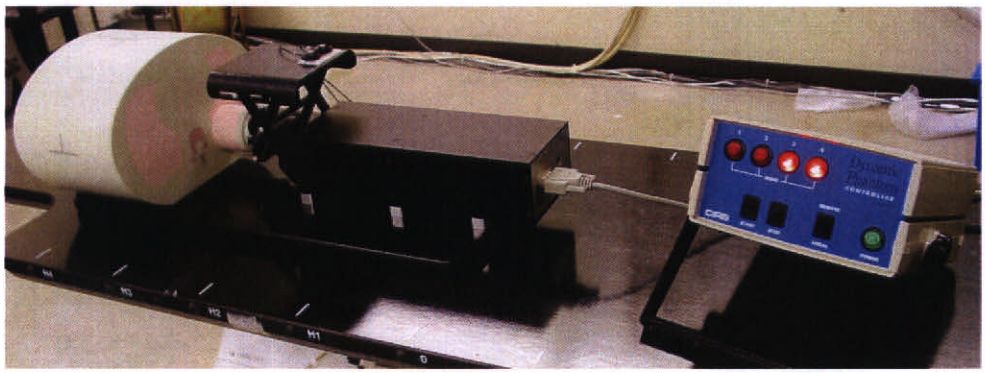


**Figure 2-1 QA motion phantom**

Major components of the QA motion phantom are a motion controller box, a motion actuator, an LED platform, thorax body, and moving rods containing film cubes for dosimetry. The motion controller box provides the option of choosing 16 motion profiles and drives the motion actuator to provide such motion. Figure 2 shows how LEDs are attached to the platform which moves up-down (simulating Anterior-Posterior chest motion) in order to work in conjunction with the Synchrony® Respiratory Tracking System. Figure 3 shows the Lung Tumor Tracking thorax body and film cube insert for performing targeting accuracy tests (see section on End-to-End tests).

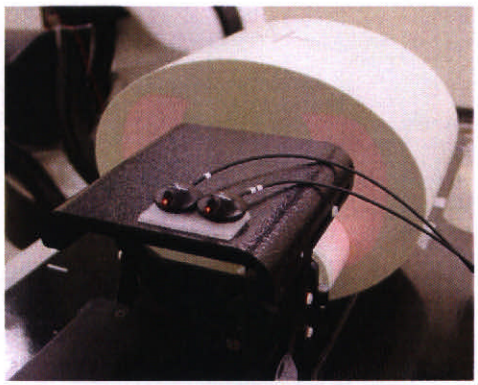


**Figure 2-2 Tracking device**



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118 66

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



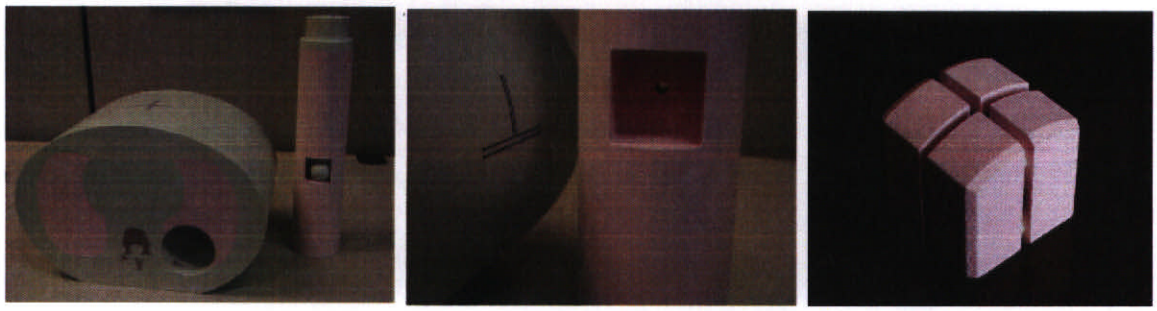
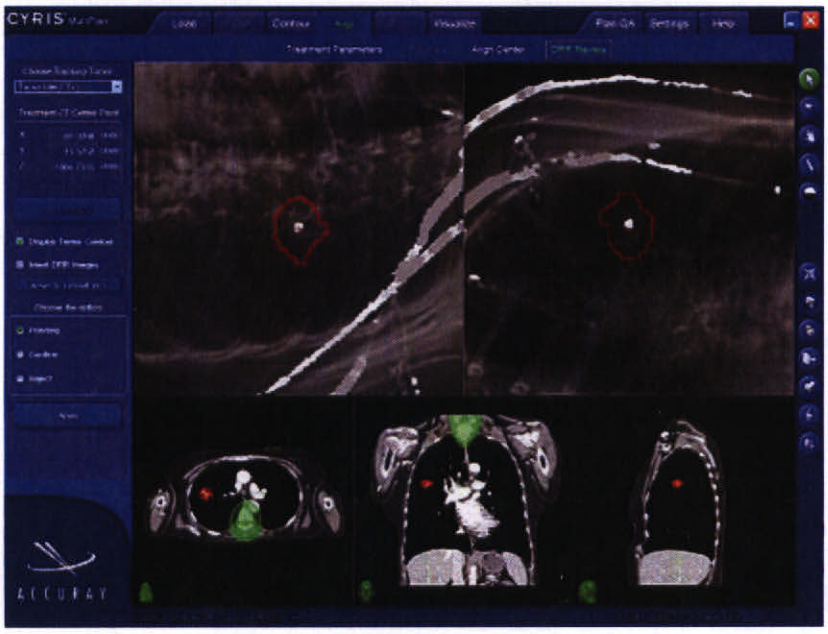


**Figure 2-3 Lung Tumor Tracking thorax body, moving rod, and film cube**

The moving rod can translate in-out (simulating Superior-Anterior motion) and can simultaneously rotate about the central axis of the rod (simulating lateral motion). Dosimetry and beam targeting accuracy measurements are possible using the film cubes while the motion is activated so that a user can perform QA of Lung Tumor Tracking and/or 4DP options in their CyberKnife System.

## LUNG TUMOR TRACKING

The CyberKnife Lung Tumor Tracking option provides the capability of precision targeting of radiosurgery beams and accurate patient positioning without the need for implanting fiducials. During the treatment planning phase, locations of the tumor to be treated are identified. During treatment delivery, anatomical features proximal to the known tumor location in the digitally reconstructed radiographs (DRRs) provide reference information for detecting the tumor location in the real-time x-ray images, within a region of interest. Figure 4 shows how Lung Tumor Tracking is used with the CyberKnife System. For detailed description of Lung Tumor Tracking, please refer to the Treatment Delivery User's Manual.






Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



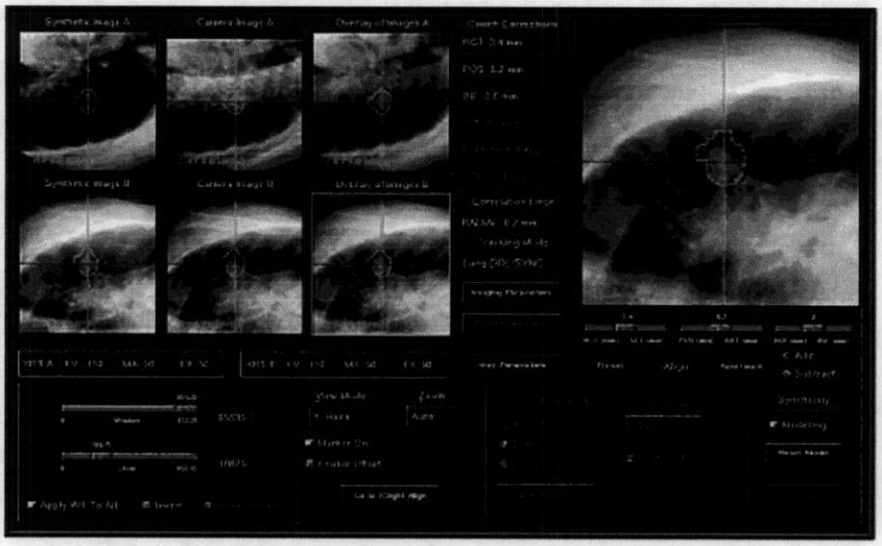


**Figure 2-4 Screen image of Lung Tumor Tracking option in Multi-Plan™ treatment planning software (top) and CyberKnife System user interface (bottom)**

# END-TO-END (E2E) TEST

## Introduction

The End-to-End test (E2E) is designed to demonstrate the CyberKnife Robotic Radiosurgery System's geometric targeting accuracy. The dose distributions recorded on films inserted within a ball cube are analyzed to quantify the targeting accuracy based on radiation delivered to the phantom. The test integrates CT (Computerized Tomography) scanning of the phantom, treatment planning, robot positioning, image processing, LINAC functions, and safety components of the CyberKnife System. The E2E test incorporates the entire treatment process by including all steps of a patient treatment.

The treatment process includes a CT scan, importing the CT into the CyberKnife System, delineation of relevant treatment volumes including lesions and critical structures, designing a treatment plan, generating DRRs, and delivering the plan. After the plan is delivered to film inside the phantom, the centroid of the delivered dose distribution on the exposed film is compared with the planned dose distribution. E2E testing is used to determine total positional error for each treatment delivery/tumor tracking modality that is installed on any given CyberKnife System. For details on standard E2E procedures, please refer to Module 3 and Module 4 of this Physics Essential Guide.

## Materials Required for Lung Tumor Tracking E2E Test

- QA Motion Phantom with the Lung Tumor Tracking thorax body: The QA Motion Phantom is included with CyberKnife Systems that include the Lung Tumor Tracking option.
- Radiochromic film: Accuray recommends either Gafchromic MD-22 precut film, Gafchromic MD-22 pre-notched or Gafchromic MD-55, which comes in 5 inch square sheets. The larger MD-55 films must be cut down. Unless the pre-notched film is used, slots must be cut along the center line of the film as shown in Figure 11.
- Optical transparency scanner: This is required to digitally analyze the film. Accuray recommends using a 16-bit (or 48-bit color) scanner with reproducibly accurate optical density and position measurements such as the Epson



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



Expression 1680 Professional flatbed scanner. Regular calibration of scanners is essential to assure accurate measurements.

- End-to-End Test Tool software: This is provided by Accuray.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118 

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



# QUALITY ASSURANCE (QA) MOTION PHANTOM

## RECEIVING INSPECTION CHECKLIST

Following table describes the components included in the Lung Tumor Tracking QA Motion Phantom delivery package.

| Quantity | Component Description |
|---|---|
| 1 | Tissue equivalent thorax |
| 1 | Moving rod with cavities for film cubes |
| 1 | Low density cube (4 pieces) with spherical ball inside |
| 1 | Base plate with actuator platform |
| 1 | Motion actuator box |
| 1 | Motion controller |
| 1 | LED platform |
| 6 | 8-32 x 1/2" black flat socket head screws for gating platform |
| 1 | 3/32 hex key wrench |
| 1 | Four-in-one screwdriver |
| 1 | Power cord |
| 1 | DB 15 male to female cable |
| 1 | Mini-Din to 9 pin D female RS-232 serial computer cable |
| 1 | USB to serial cable (6 ft.) |
| 1 | 1 bag of miscellaneous replacement fasteners |
| 2 | 2 Amp F fast acting fuses |
| 1 | TRIO Motion Software CD-Rom |
| 1 | CIRS Motion Profiles Data CD-Rom |
| 1 | User's manual (this document) |
| 1 | Carrying case |

## SETUP PROCEDURE

### Basic Setup

1. Open Case.
2. Remove any foam blocks which act as spacers (Figure 5). Your exact configuration may vary.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118 

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



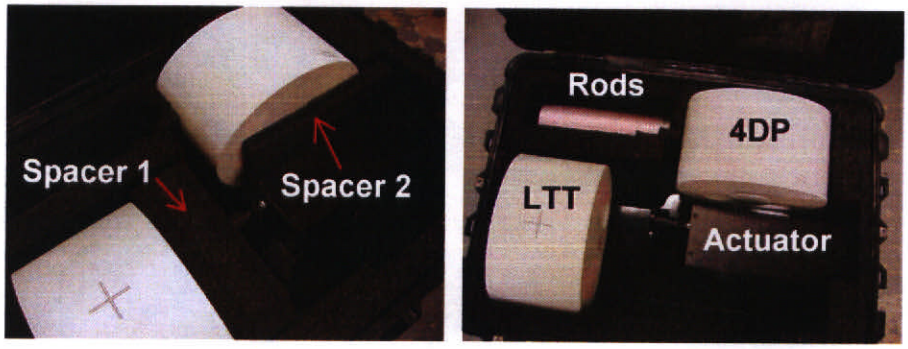



**Figure 2-5 QA Motion Phantom in the carrying case**

3. Grasp center handle and back of stand (Figure 6).

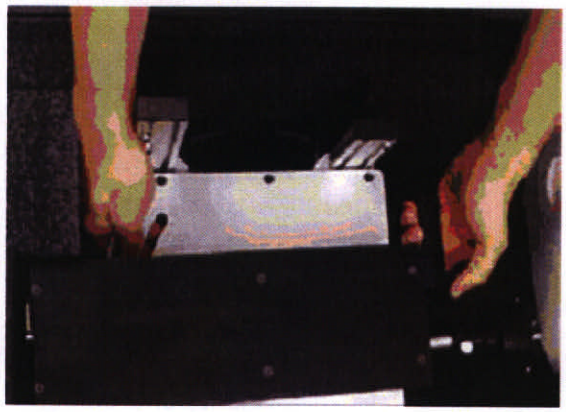


**Figure 2-6 Unloading the actuator box**

4. Lift phantom from case and place on a flat level surface.
5. Remove lower tray from case.
6. Remove control box, tracking platform and motion controller.
7. Loosen retaining ring screw and move towards actuator box (Figure 7).

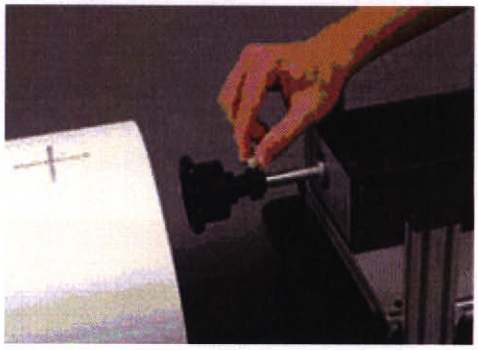


**Figure 2-7 Actuator Setup**



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118 71

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



8. Set Tracking platform in place.
9. Secure front plate with retaining as shown in Figure 8.

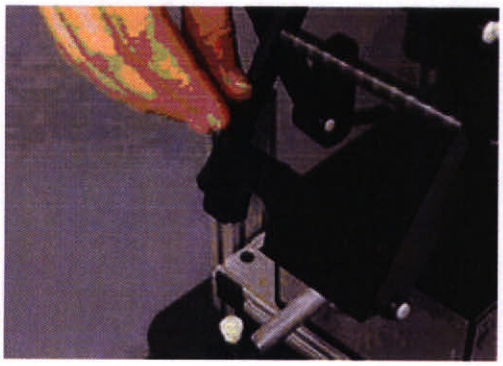


**Figure 2-8 Attaching tracking device**

10. Set front plate between flange and retaining ring.
11. Align right and left side brackets with holes in the actuator box and secure with screws provided (Figure 9).

**Figure 2-9 Securing the actuator**

12. Attach cables but do not plug power cord into power supply (Figure 10).

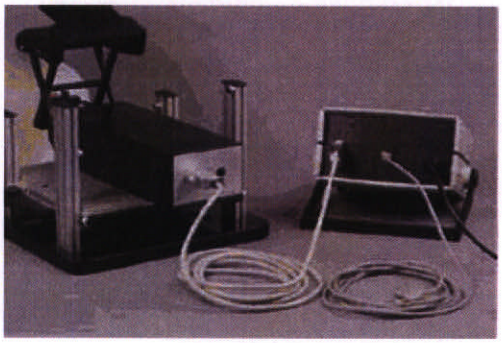


**Figure 2-10 Cables**



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118 

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



## Setup for Lung Tumor Tracking QA

1. Load two films to the low-density ball cube (Figure 11).

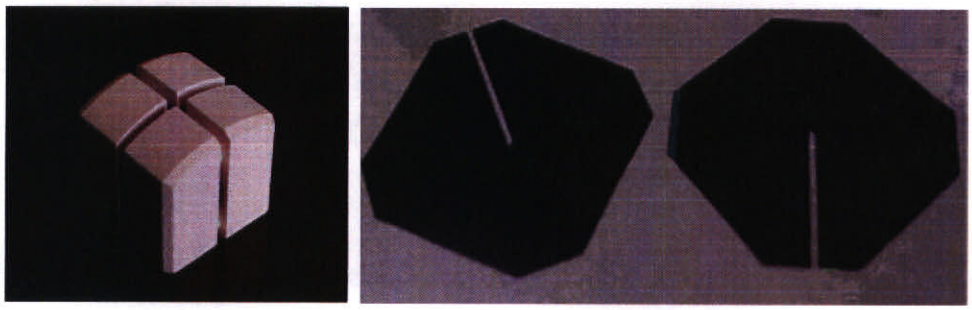


**Figure 2-11 Low-density ball "cube" (left) and radiochromic film (right)**

**NOTE:** It is important to properly align the films in the cube. The films are aligned precisely with the straight edges of the film cube. One way to align the films with the edge of the cube is to first install the films in the cube without tightening the cube. Next, carefully press the film cube against a hard flat surface so the film edges are flush with the cube faces. Sometimes the film gets stuck and it is necessary to push the film from the opposite side using a piece of paper or a business card. To determine if the films are aligned with the edges of the assembled film cube, look at the reference edges from about a 45 degree angle with respect to the surface. The edge of the unexposed film should appear as a black line. If the film is below the surface the line will not appear. If it is sticking out too far you can see it sticking out and you can also feel it with your fingers.

2. Insert the cube into the cavity in the moving rod (Figure 12). Make sure that the cube is properly oriented within the phantom.

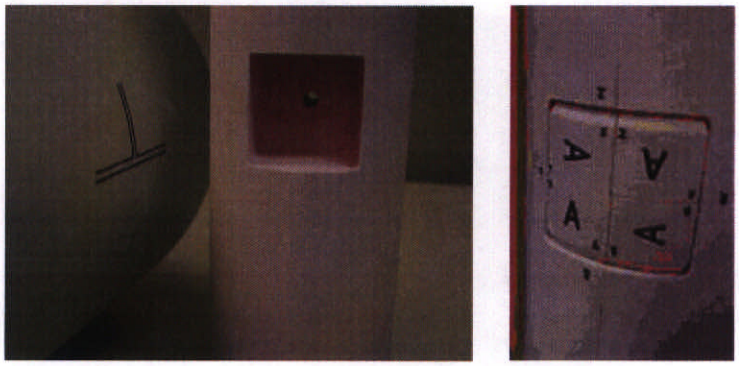


**Figure 2-12 Lung Tumor Tracking moving rod without and with the cube inserted**

3. Attach the Lung Tumor Tracking thorax body and the moving rod to the actuator (Figure 13).



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118 

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



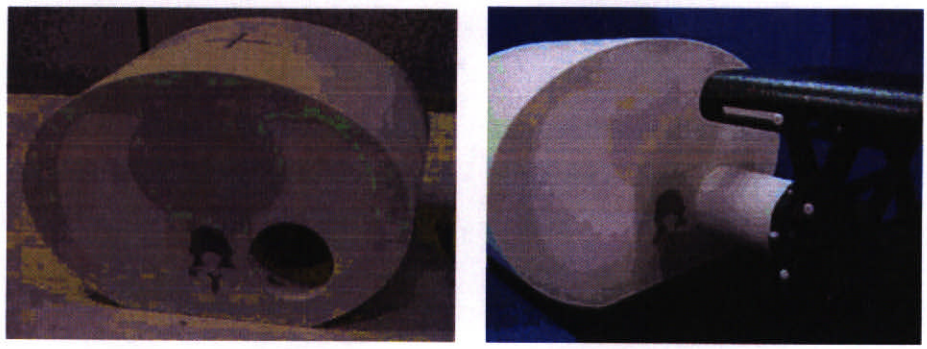


**Figure 2-13 Lung Tumor Tracking body separated (left) and attached (right)**

4. Set up the Lung Tumor Tracking phantom on the treatment couch as you would for an actual patient by using the XSight™ spine alignment feature of the Lung Tumor Tracking user interface of the CyberKnife System (see section on Treatment Delivery).
5. Attach the LED markers to the platform (Figure 14).
6. Connect the motion control box to the motion actuator using the DB15 cable provided (Figure 14).

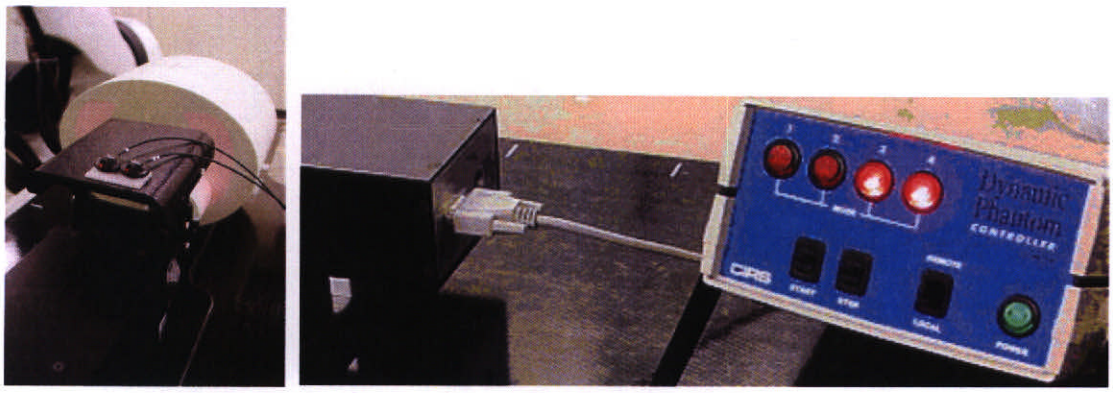



**Figure 2-14 Phantom setup on a patient table showing LED markers (left) and the motion control box (right)**

# BASIC OPERATION

## Operation for Lung Tumor Tracking QA

The Lung Tumor Tracking phantom itself requires only minimal operator control.

1. There are 4 binary switches along the face of the motion controller (Figure 15). Each can be set in either an up or down position for a combination of 16 different settings. Each setting corresponds to a different motion profile. Select the desired motion profile and set the switches accordingly. Motion profiles are described in Appendix A.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015

**Figure 2-15 Motion controller**

2. Turn on the power switch. Leave the control switch in the "Local" setting.
3. Depress the "Start" switch once and the motion actuator will undergo a homing cycle.
4. Depress the "Start" switch once again and the actuator will move to its starting position.
5. Depress the "Start" switch a third time and the system will begin executing the selected preprogrammed motion. With the phantom loaded with film and undergoing its motion, it is ready for delivery of the treatment beam.

# MAINTENANCE

## Fuse Replacement

If the unit does not power up (green light on the switch will illuminate) check the power cord and source. If connections are good, check the fuses on the back of the control box. See Figure 16.

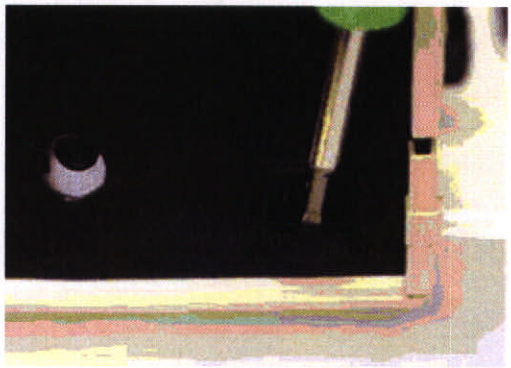


**Figure 2-16 Fuse Replacement**

1. Unplug unit.
2. Using a flat head screwdriver, pry open fuse tray.
3. Slide tray out and fold down fuse drawer.
4. Remove and replace fuses with 2 Amp, F fast acting fuses 5x20mm ONLY!
5. Close fuse tray and proceed.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



# LUNG TUMOR TRACKING QUALITY ASSURANCE

The QA motion phantom permits testing of the targeting accuracy of the Lung Tumor Tracking feature of the CyberKnife System.

## TREATMENT PLAN

In order to create a plan, the user will obtain a CT scan of the phantom (with motion off) containing the film cube loaded with film. To minimize measurement error due to localization, use 1.5 mm slice thickness or less, and use sequential axial slices. Helical CT scans may sometimes not be precise enough to function satisfactorily with the CyberKnife System which is capable of delivering beams with sub-millimeter precision.

**NOTE:** Follow the appropriate Accuray procedure for CT scanning.

Export the Ball-Cube CT AXIAL slices only to the CK system. If a multi-slice scanner is used, confirm that the kVP is 120, and that minimum pitch is set. After taking the CT images of the phantom, the user will upload the CT data into the MultiPlan™ treatment planning software. Figure 17 shows a screen image of the phantom CT images loaded into the MultiPlan treatment planning software.

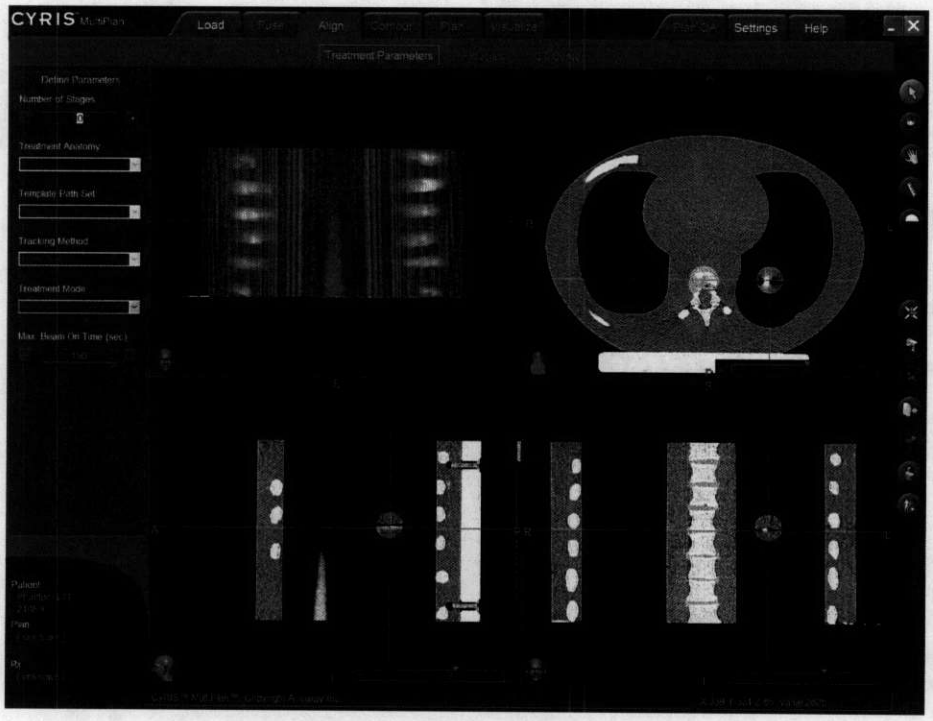



**Figure 2-17 MultiPlan screen image of the phantom with the Lung Tumor Tracking body**

For detailed information on how to create Lung Tumor Tracking treatment plan for End-to-End test using the QA motion phantom with the Lung Tumor Tracking body, please refer to the Treatment Planning User's Manual.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118 76

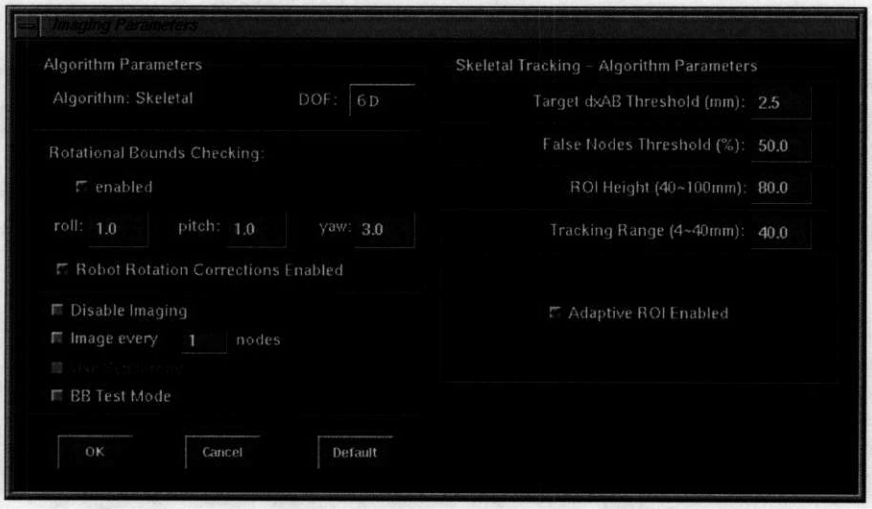
Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



**NOTE:** It is necessary to create a plan with the 15 mm collimator due to the small size of the film. The nomenclature for field size of a collimator for the CyberKnife system is based on a LINAC beam source-to-target distance of 800 mm. The distance for lung treatments is around 950 mm. Therefore the beam size at the distance to the Lung Tumor Tracking film cube will be larger than 15 mm. The ball diameter in the film cube is 1 inch and should be used for contouring of the phantom tumor volume, but the isodose contour that will be used for film analysis should be smaller than 1 inch to ensure that it is within the physical bounds of the film.

## TREATMENT DELIVERY

After setting up the Lung Tumor Tracking phantom on the treatment couch, you will first align the phantom using the XSight spine alignment feature. Next, you will use Lung Tumor Tracking option to align the tumor and use Synchrony Respiratory Tracking system to track the tumor during the treatment. Figure 18, Figure 19, and Figure 20 show screen images for these steps. For specific instructions on how to deliver the treatment plan, please refer to the Treatement Delivery User's Manual.

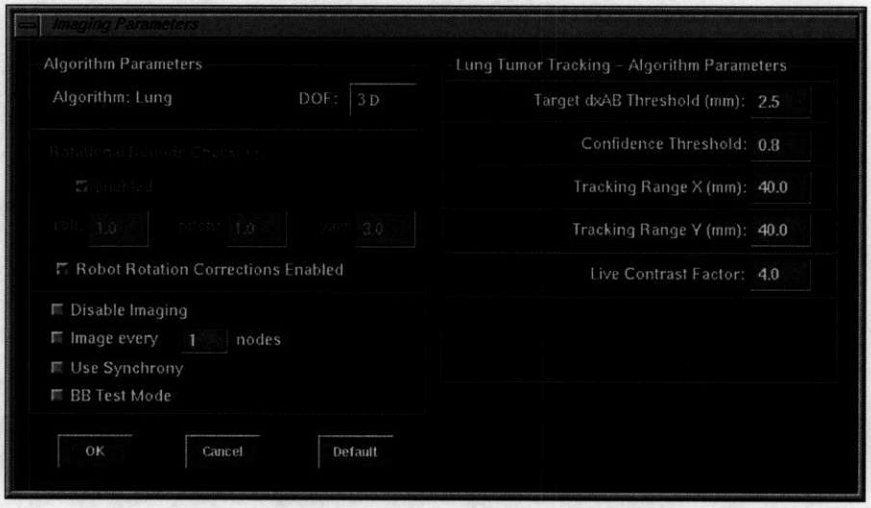





Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118 77

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015

**Figure 2-18 Using XSight spine alignment feature for initial phantom alignment**






Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118 78

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



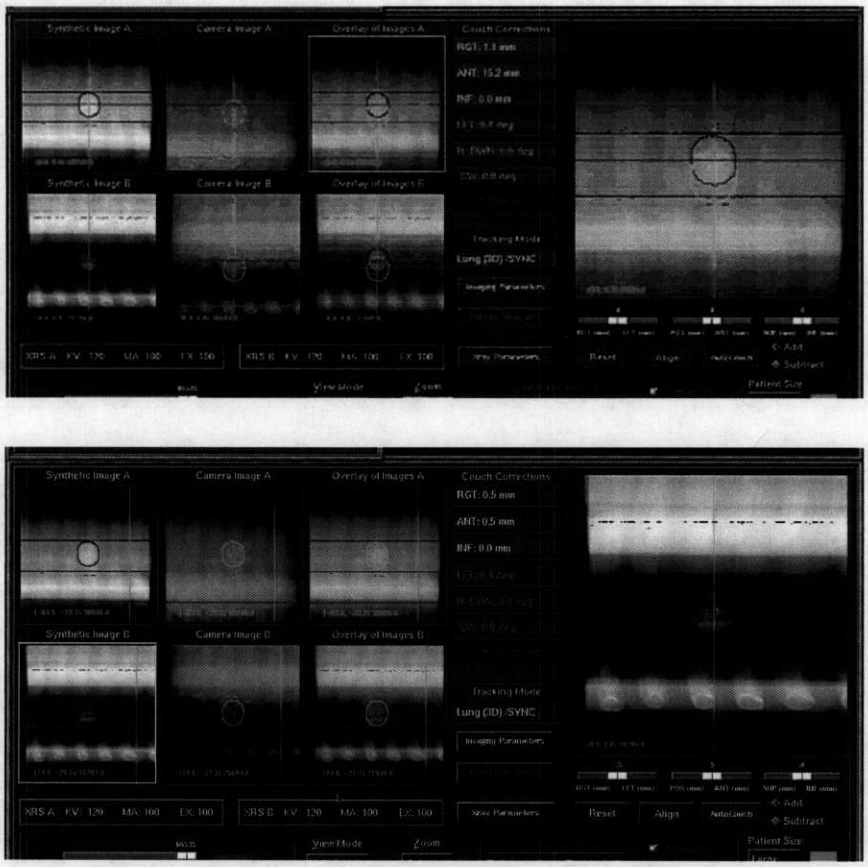



**Figure 2-19 Using the Lung Tumor Tracking feature to align the tumor in the phantom. The middle and the bottom images are before and after tracking the tumor using Lung Tumor Tracking, respectively.**



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



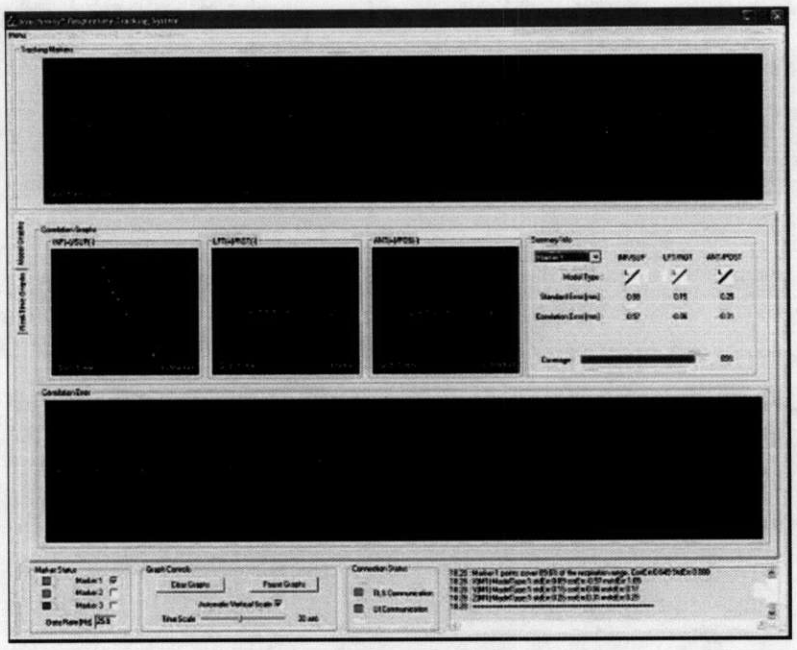


**Figure 2-20 Synchrony Respiratory Tracking system displaying the detected phantom motion**

## E2E ANALYSIS

1. After delivering the treatment, remove the film cube from the phantom body.
2. Right after removing the film from the cube, label the orientations of the film reference edges with a fine tip permanent marker. It is important that the labels on the films match the edges of the cube. The writing will be preserved in the scanned image for identification purposes.
3. Scan the film in a calibrated optical scanner. Please refer to Module 3 of this Physics Essential Guide for proper setup of the optical scanner.
4. Analyze the film using E2E software. Please refer to Module 3 of this Physics Essential Guide for how to use E2E software. Figure 21 shows a screen image of using E2E software to analyze the films from QA motion phantom with the Lung Tumor Tracking body.



80

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



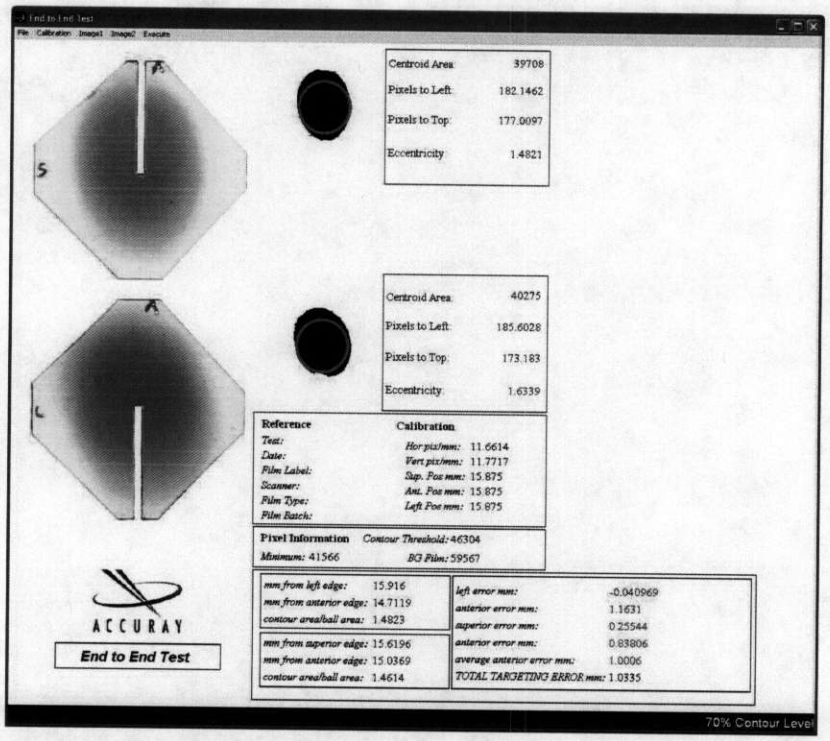



**Figure 2-21 E2E software analysis of the films used in the Lung Tumor Tracking phantom**



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



# APPENDIX A

| Motion Profile # | Mode Switches | | | | Target center displacement, mm | | | Cycle time, |
|---|---|---|---|---|---|---|---|---|
| | | | | | AP | LR | IS | sec |
| 1 | OFF | OFF | OFF | ON | 5 | 2 | 10 | 4.0 |
| 2 | OFF | OFF | ON | ON | 5 | 2 | 10 | 4.5 |
| 3 | OFF | ON | ON | ON | 5 | 2 | 10 | 5.0 |
| 4 | OFF | OFF | OFF | OFF | 5 | 2 | 10 | 5.5 |
| 5 | OFF | ON | OFF | ON | 5 | 2 | 10 | 6.0 |
| 6 | OFF | ON | OFF | OFF | 5 | 2 | 20 | 4.0 |
| 7 | OFF | ON | ON | OFF | 5 | 2 | 20 | 4.5 |
| 8 | OFF | OFF | ON | OFF | 5 | 2 | 20 | 5.0 |
| 9 | ON | OFF | OFF | OFF | 5 | 2 | 20 | 5.5 |
| 10 | ON | ON | OFF | OFF | 5 | 2 | 20 | 6.0 |
| 11 | ON | ON | ON | OFF | 5 | 2 | 30 | 4.0 |
| 12 | ON | OFF | OFF | ON | 5 | 2 | 30 | 4.5 |
| 13 | ON | OFF | ON | OFF | 5 | 2 | 30 | 5.0 |
| 14 | ON | ON | OFF | ON | 5 | 2 | 30 | 5.5 |
| 15 | ON | OFF | ON | ON | 5 | 2 | 30 | 6.0 |
| Computer directed manual motion set-up | | | | | | | | |
| 16 | ON | ON | ON | ON | Manual | | | |

**Figure 2-22 Mode switch settings**

The mode switch settings permit the selection of one of sixteen motion profiles shown in the table in Figure 22. The Lung Tumor Tracking phantom kit includes 2 CD ROMs and an RS-232 serial cable which were used to set up the motion profiles at the factory.

**NOTE:** Motion profile #16 can be reprogrammed but the others cannot. Accuray does not support user reprogramming of profile #16. Contact Accuray if you have a specific need for a custom motion profile.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8108

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

OCT 3 0 2006

Ms. Anne Schlagenhaft
Sr. Regulatory Affairs Associate
Accuray, Inc.
1310 Chesapeake Terrace
SUNNYVALE CA 94089

Re: K062967
Trade/Device Name: CyberKnife® Robotic Radiosurgery System
Regulation Number: 21 CFR §892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: MUJ and IYE
Dated: September 28, 2006
Received: September 29, 2006

Dear Ms. Schlagenhaft:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

| | | |
|---|---|---|
| 21 CFR 876.xxx | (Gastroenterology/Renal/Urology | 240-276-0115 |
| 21 CFR 884.xxx | (Obstetrics/Gynecology) | 240-276-0115 |
| 21 CFR 894.xxx | (Radiology) | 240-276-0120 |
| Other | | 240-276-0100 |

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150
or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015

510(k) Number (if known): K 062967

Device Name: CyberKnife® Robotic Radiosurgery System

Indications For Use:

The CyberKnife® Robotic Radiosurgery System is indicated for treatment planning and image guided stereotactic radiosurgery and precision radiotherapy for lesions, tumors and conditions anywhere in the body when radiation treatment is indicated.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR (Per 21 CFR 801.109) Over-The-Counter Use _____

(Optional Format 1-2-96)

Nancy C Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K062967

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8718

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, Maryland 20850

October 02, 2006

ACCURAY, INC.
1310 CHESAPEAKE TERRACE
SUNNYVALE, CA 94089
ATTN: ANNE SCHLAGENHAFT

510(k) Number: K062967
Received: 29-SEP-2006
Product: CYBERKNIFE ROBOTIC RADIOSURGERY SYSTEM

The Food and Drug Administration (FDA), Center for Devices and Radiological Health (CDRH), has received the Premarket Notification, (510(k)), you submitted in accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act(Act) for the above referenced product and for the above referenced 510(k) submitter. Please note, if the 510(k) submitter is incorrect, please notify the 510(k) Staff immediately. We have assigned your submission a unique 510(k) number that is cited above. Please refer prominently to this 510(k) number in all future correspondence that relates to this submission. We will notify you when the processing of your 510(k) has been completed or if any additional information is required. YOU MAY NOT PLACE THIS DEVICE INTO COMMERCIAL DISTRIBUTION UNTIL YOU RECEIVE A LETTER FROM FDA ALLOWING YOU TO DO SO.

Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (DMC)(HFZ-401) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official 510(k) submission.

Please note the following documents as they relate to 510(k) review: 1)Guidance for Industry and FDA Staff entitled, "FDA and Industry Actions on Premarket Notification (510(k))Submissions: Effect on FDA Review Clock and Performance Assessment". The purpose of this document is to assist agency staff and the device industry in understanding how various FDA and industry actions that may be taken on 510(k)s should affect the review clock for purposes of meeting the Medical Device User Fee and Modernization Act (MDUFMA). Please review this document at www.fda.gov/cdrh/mdufma/guidance/1219.html. 2)Guidance for Industry and FDA Staff entitled, "Format for Traditional and Abbreviated 510(k)s". This guidance can be found at www.fda.gov/cdrh/ode/guidance/1567.html. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k). 3)Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review". Please refer to this guidance for information on current fax and e-mail practices at www.fda.gov/cdrh/ode/a02-01.html.

In all future premarket submissions, we encourage you to provide an electronic copy of your submission. By doing so, you will save FDA resources and may help reviewers navigate through longer documents more easily. Under CDRHs e-Copy Program, you may replace one paper copy of an premarket submission (e.g., 510(k), IDE, PMA, HDE) with an electronic copy. For more information about the program, including the formatting requirements, please visit our web site at www.fda.gov/cdrh/elecsub.html.

83

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015

Lastly, you should be familiar with the regulatory requirements for medical devices available at Device Advice www.fda.gov/cdrh/devadvice/". If you have questions on the status of your submission, please contact DSMICA at (240) 276-3150 or the toll-free number (800) 638-2041, or at their Internet address http://www.fda.gov/cdrh/dsma/dsmastaf.html. If you have policy or procedural questions, please contact anyone on the 510(k) Staff at (301)594-1190.

Sincerely yours,

Marjorie Shulman
Supervisory Consumer Safety Officer
Office of Device Evaluation
Center for Devices and Radiological Health



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

K062967

Form Approved. OMB No. 0910-511 Expiration Date: August 31, 2005. See Instructions for OMB Statement.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION
**MEDICAL DEVICE USER FEE COVER SHEET**

PAYMENT IDENTIFICATION NUMBER: **MD6027694-956733**
Write the Payment Identification number on your check.

A completed Cover Sheet must accompany each original application or supplement subject to fees. The following actions must be taken to properly submit your application and fee payment:

1. Electronically submits the completed Cover Sheet to the Food and Drug Administration (FDA) before payment is sent.
2. Include printed copy of this completed Cover Sheet with a check made payable to the Food and Drug Administration. Remember that the Payment Identification Number must be written on the check.
3. Mail Check and Cover Sheet to the US Bank Lock Box, FDA Account, P.O. Box 956733, St. Louis, MO 63195-6733. (*Note: In no case should payment be submitted with the application.*)
4. If you prefer to send a check by a courier, the courier may deliver the check and Cover Sheet to: US Bank, Attn: Government Lockbox 956733, 1005 Convention Plaza, St. Louis, MO 63101. (Note: This address is for courier delivery only. Contact the US Bank at 314-418-4821 if you have any questions concerning courier delivery.)
5. For Wire Transfer Payment Procedures, please refer to the MDUFMA Fee Payment Instructions at the following URL: http://www.fda.gov/cdrh/mdufma/faqs.html#3a. You are responsible for paying all fees associated with wire transfer.
6. Include a copy of the complete Cover Sheet in volume one of the application when submitting to the FDA at either the CBER or CDRH Document Mail Center.

-->

1. COMPANY NAME AND ADDRESS (include name, street address, city state, country, and post office code)

ACCURAY INC
1310 Chesapeake Terrace
Sunnyvale CA 94089
US

1.1 EMPLOYER IDENTIFICATION NUMBER (EIN)
770268932

2. CONTACT NAME
Anne Schlagenhaft

2.1 E-MAIL ADDRESS
aschlagenhaft@accuray.com

2.2 TELEPHONE NUMBER (include Area code)
408-716-4628

2.3 FACSIMILE (FAX) NUMBER (Include Area code)
408-716-4601

3. TYPE OF PREMARKET APPLICATION (Select one of the following in each column; if you are unsure, please refer to the application descriptions at the following web site: http://www.fda.gov/dc/mdufma

Select an application type:
[X] Premarket notification(510(k)); except for third party
[ ] Biologics License Application (BLA)
[ ] Premarket Approval Application (PMA)
[ ] Modular PMA
[ ] Product Development Protocol (PDP)
[ ] Premarket Report (PMR)

3.1 Select one of the types below
[X] Original Application
Supplement Types:
[ ] Efficacy (BLA)
[ ] Panel Track (PMA, PMR, PDP)
[ ] Real-Time (PMA, PMR, PDP)
[ ] 180-day (PMA, PMR, PDP)

4. ARE YOU A SMALL BUSINESS? (See the instructions for more information on determining this status)
[ ] YES, I meet the small business criteria and have submitted the required qualifying documents to FDA
[X] NO, I am not a small business
4.1 If Yes, please enter your Small Business Decision Number:

5. IS THIS PREMARKET APPLICATION COVERED BY ANY OF THE FOLLOWING USER FEE EXCEPTIONS? IF SO, CHECK THE APPLICABLE EXCEPTION.
[ ] This application is the first PMA submitted by a qualified small business, including any affiliates, parents, and partner firms
[ ] The sole purpose of the application is to support conditions of use for a pediatric population
[ ] This biologics application is submitted under secion 351 of the Public Health Service Act for a product licensed for further manufacturing use only
[ ] The application is submitted by a state or federal government entity for a device that is not to be distributed commercially

6. IS THIS A SUPPLEMENT TO A PREMARKET APPLICATION FOR WHICH FEES WERE WAIVED DUE TO SOLE USE IN A PEDIATRIC POPULATION THAT NOW PROPOSES CONDITION OF USE FOR ANY ADULT POPULATION? (If so, the application is subject to the fee that applies for an original premarket approval application (PMA).)
[ ] YES [X] NO

RA II

7. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION (FOR FISCAL YEAR 2005)
$3,833.00

25-Sep-2006

Form FDA 3601 (08/2003)

Close Window

Print Cover sheet

85

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015

PAYMENT IDENTIFICATION NUMBER:
**MD6027694-956733**

This submission was shipped in **two** boxes.

This box contains the:

- [x] Original submission
- [ ] Additional copy of the submission
- [x] Predicate manuals (Treatment Planning, Treatment Delivery, Physics Essentials Guide)
- [ ] Additional copy of predicate manuals

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015

ACCURAY

Accuray Incorporated
1310 Chesapeake Terrace
Sunnyvale, CA 94089

T: 408.716.4600
F: 408.716.4601
www.accuray.com

September 28, 2006

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, Maryland 20850

**RE: SPECIAL 510(k): DEVICE MODIFICATION**
**K020294, CyberKnife® System for Stereotactic Radiosurgery/Radiotherapy, April 22, 2002,**
**K041315, CyberKnife® System for Stereotactic Radiosurgery/Radiotherapy, May 14, 2004, as amended in**
**K062514, CyberKnife® Robotic Radiosurgery System, September 28, 2006**

Dear Sir or Madam:

Accuray Incorporated hereby submits this **Special 510(k): Device Modification** to request clearance of a modification to the CyberKnife® System. The modification is addition of the Lung Tumor Tracking algorithm in the Target Locating Subsystem. We believe this modification is eligible for the Special 510(k) process since the fundamental scientific technology and intended use are the same as the predicate device.

We consider our intent to market this device as confidential commercial information and request that it be treated as such by FDA. We have taken precautions to protect the confidentiality of the intent to market this device. We understand that the submission to the government of false information is prohibited by 18 U.S.C. 1001 and 21 U.S.C. 331(q).

Thank you in advance for your consideration of our application. If there are any questions, please feel free to contact me by phone at (408) 716-4628, by fax at (408) 716-4601 or by e-mail at aschlagenhaft@accuray.com.

Sincerely,

Anne Schlagenhaft
Sr. Regulatory Affairs Associate



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

# CDRH PREMARKET REVIEW SUBMISSION COVER SHEET

Form Approved
OMB No. 9010-0120
Expiration Date: September 30, 2004.
See OMB Statement on page 5.

| Date of Submission | User Fee Payment ID Number | FDA Submission Document Number (if known) |
|---|---|---|
| 9/28/06 | MD6027694-956733 | |

## SECTION A — TYPE OF SUBMISSION

| PMA | PMA & HDE Supplement | PDP | 510(k) | Meeting |
|---|---|---|---|---|
| ☐ Original Submission | ☐ Regular (120 day) | ☐ Original PDP | ☒ Original Submission: | ☐ Pre-510(K) Meeting |
| ☐ Premarket Report | ☐ Special | ☐ Notice of Completion | ☐ Traditional | ☐ Pre-IDE Meeting |
| ☐ Modular Submission | ☐ Panel Track (PMA Only) | ☐ Amendment to PDP | ☒ Special | ☐ Pre-PMA Meeting |
| ☐ Amendment | ☐ 30-day Supplement | | ☐ Abbreviated (Complete section I, Page 5) | ☐ Pre-PDP Meeting |
| ☐ Report | ☐ 30-day Notice | | ☐ Additional Information | ☐ Day 100 Meeting |
| ☐ Report Amendment | ☐ 135-day Supplement | | ☐ Third Party | ☐ Agreement Meeting |
| ☐ Licensing Agreement | ☐ Real-time Review | | | ☐ Determination Meeting |
| | ☐ Amendment to PMA &HDE Supplement | | | ☐ Other *(specify):* |
| | ☐ Other | | | |

| IDE | Humanitarian Device Exemption (HDE) | Class II Exemption Petition | Evaluation of Automatic Class III Designation (De Novo) | Other Submission |
|---|---|---|---|---|
| ☐ Original Submission | ☐ Original Submission | ☐ Original Submission | ☐ Original Submission | ☐ 513(g) |
| ☐ Amendment | ☐ Amendment | ☐ Additional Information | ☐ Additional Information | ☐ Other *(describe submission):* |
| ☐ Supplement | ☐ Supplement | | | |
| | ☐ Report | | | |
| | ☐ Report Amendment | | | |

Have you used or cited Standards in your submission? ☐ Yes ☐ No *(If Yes, please complete Section I, Page 5)*

## SECTION B — SUBMITTER, APPLICANT OR SPONSOR

| | | | |
|---|---|---|---|
| Company / Institution Name: Accuray Incorporated | Establishment Registration Number *(if known)*: 2950679 | | |
| Division Name *(if applicable)*: NA | Phone Number *(including area code)*: ( 408 ) 716-4628 | | |
| Street Address: 1310 Chesapeake Terrace | FAX Number *(including area code)*: ( 408 ) 716-4601 | | |
| City: Sunnyvale | State / Province: CA | ZIP/Postal Code: 94089 | Country: USA |
| Contact Name: Anne Schlagenhaft | | | |
| Contact Title: Sr. Regulatory Affairs Associate | Contact E-mail Address: aschlagenhaft@accuray.com | | |

## SECTION C — APPLICATION CORRESPONDENT (e.g., consultant, if different from above)

| | | | |
|---|---|---|---|
| Company / Institution Name | | | |
| Division Name *(if applicable)* | Phone Number *(including area code)*: ( ) | | |
| Street Address | FAX Number *(including area code)*: ( ) | | |
| City | State / Province | ZIP/Postal Code | Country |
| Contact Name | | | |
| Contact Title | Contact E-mail Address | | |



PSC Media Arts (301) 443-2454 EF

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015

## SECTION D1 — REASON FOR APPLICATION - PMA, PDP, OR HDE

- [ ] Withdrawal
- [ ] Additional or Expanded Indications
- [ ] Request for Extension
- [ ] Post-approval Study Protocol
- [ ] Request for Applicant Hold
- [ ] Request for Removal of Applicant Hold
- [ ] Request to Remove or Add Manufacturing Site

- [ ] Change in design, component, or specification:
  - [ ] Software / Hardware
  - [ ] Color Additive
  - [ ] Material
  - [ ] Specifications
  - [ ] Other *(specify below)*

- [ ] Location change:
  - [ ] Manufacturer
  - [ ] Sterilizer
  - [ ] Packager

- [ ] Process change:
  - [ ] Manufacturing
  - [ ] Sterilization
  - [ ] Packaging
  - [ ] Other *(specify below)*

- [ ] Labeling change:
  - [ ] Indications
  - [ ] Instructions
  - [ ] Performance
  - [ ] Shelf Life
  - [ ] Trade Name
  - [ ] Other *(specify below)*

- [ ] Report Submission:
  - [ ] Annual or Periodic
  - [ ] Post-approval Study
  - [ ] Adverse Reaction
  - [ ] Device Defect
  - [ ] Amendment

- [ ] Response to FDA correspondence:

- [ ] Change in Ownership
- [ ] Change in Correspondent
- [ ] Change of Applicant Address

- [ ] Other Reason *(specify)*:

## SECTION D2 — REASON FOR APPLICATION - IDE

- [ ] New Device
- [ ] New Indication
- [ ] Addition of Institution
- [ ] Expansion / Extension of Study
- [ ] IRB Certification
- [ ] Termination of Study
- [ ] Withdrawal of Application
- [ ] Unanticipated Adverse Effect
- [ ] Notification of Emergency Use
- [ ] Compassionate Use Request
- [ ] Treatment IDE
- [ ] Continued Access

- [ ] Change in:
  - [ ] Correspondent / Applicant
  - [ ] Design / Device
  - [ ] Informed Consent
  - [ ] Manufacturer
  - [ ] Manufacturing Process
  - [ ] Protocol - Feasibility
  - [ ] Protocol - Other
  - [ ] Sponsor

- [ ] Report submission:
  - [ ] Current Investigator
  - [ ] Annual Progress Report
  - [ ] Site Waiver Report
  - [ ] Final

- [ ] Repose to FDA Letter Concerning:
  - [ ] Conditional Approval
  - [ ] Deemed Approved
  - [ ] Deficient Final Report
  - [ ] Deficient Progress Report
  - [ ] Deficient Investigator Report
  - [ ] Disapproval
  - [ ] Request Extension of Time to Respond to FDA
  - [ ] Request Meeting
  - [ ] Request Hearing

- [ ] Other Reason *(specify)*:

## SECTION D3 — REASON FOR SUBMISSION - 510(k)

- [ ] New Device
- [ ] Additional or Expanded Indications
- [ ] Change in Technology
- [x] Other Reason *(specify)*:
  modified software (algorithm)



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

89

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015

## SECTION E — ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS

Product codes of devices to which substantial equivalence is claimed

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| 1 | IYE | 2 | | 3 | | 4 | |
| 5 | | 6 | | 7 | | 8 | |

Summary of, or statement concerning, safety and effectiveness information

- ☐ 510 (k) summary attached
- ☐ 510 (k) statement

Information on devices to which substantial equivalence is claimed *(if known)*

| | *510(k) Number* | | *Trade or Proprietary or Model Name* | | *Manufacturer* |
|---|---|---|---|---|---|
| 1 | K020294 | 1 | CyberKnife System for Stereotactic Radiosurgery/Radiotherapy | 1 | Accuray Incorporated |
| 2 | K041315 | 2 | CyberKnife System for Stereotactic Radiosurgery/Radiotherapy | 2 | Accuray Incorporated |
| 3 | K062514 | 3 | CyberKnife Robotic Radiosurgery System | 3 | Accuray Incorporated |
| 4 | | 4 | | 4 | |
| 5 | | 5 | | 5 | |
| 6 | | 6 | | 6 | |

## SECTION F — PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS

Common or usual name or classification

Medical charged particle radiotherapy system

| | Trade or Proprietary or Model Name for This Device | | Model Number |
|---|---|---|---|
| 1 | CyberKnife Robotic Radiosurgery System | 1 | NA |
| 2 | | 2 | |
| 3 | | 3 | |
| 4 | | 4 | |
| 5 | | 5 | |

FDA document numbers of all prior related submissions *(regardless of outcome)*

| 1 | 2 | 3 | 4 | 5 | 6 |
|---|---|---|---|---|---|
| K984563 | K000478 | K011024 | K020294 | K032345 | K041315 |
| 7 | 8 | 9 | 10 | 11 | 12 |
| K051941 | K052325 | K062514 | | | |

Data Included in Submission

- ☒ Laboratory Testing
- ☐ Animal Trials
- ☐ Human Trials

## SECTION G — PRODUCT CLASSIFICATION - APPLICATION TO ALL APPLICATIONS

Product Code: IYE

C.F.R. Section *(if applicable)*: 21CFR 892.5050

Classification Panel: Division of Reproductive, Abdominal and Radiological Devices

Device Class

- ☐ Class I
- ☒ Class II
- ☐ Class III
- ☐ Unclassified

Indications *(from labeling)*

The CyberKnife Robotic Radiosurgery System is indicated for treatment planning and image guided stereotactic radiosurgery and precision radiotherapy for lesions, tumors and conditions anywhere in the body when radiation treatment is indicated.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015

*Note:* Submission of this information does not affect the need to submit a 2891 or 2891a Device Establishment Registration form.

FDA Document Number *(if known)*

## SECTION H MANUFACTURING / PACKAGING / STERILIZATION SITES RELATING TO A SUBMISSION

☒ Original ☐ Add ☐ Delete

FDA Establishment Registration Number: 2950679

☒ Manufacturer ☐ Contract Sterilizer ☐ Contract Manufacturer ☐ Repackager / Relabeler

| | |
|---|---|
| Company / Institution Name: Accuray Incorporated | Establishment Registration Number: 2950679 |
| Division Name *(if applicable)*: NA | Phone Number *(including area code)*: ( 408 ) 716-4600 |
| Street Address: 1310 Orleans Drive | FAX Number *(including area code)*: ( 408 ) 716-4601 |

| City | State / Province | ZIP Code | Country |
|---|---|---|---|
| Sunnyvale | CA | 94089 | USA |

| Contact Name | Contact Title | Contact E-mail Address |
|---|---|---|
| Garth Nobis | Vice President, RA/QA | gnobis@accuray.com |

☒ Original ☐ Add ☐ Delete

FDA Establishment Registration Number: 3005738050

☒ Manufacturer ☐ Contract Sterilizer ☐ Contract Manufacturer ☐ Repackager / Relabeler

| | |
|---|---|
| Company / Institution Name: Accuray Incorporated | Establishment Registration Number: 3005738050 |
| Division Name *(if applicable)*: NA | Phone Number *(including area code)*: ( 408 ) 716-4600 |
| Street Address: 1383 Shorebird Way | FAX Number *(including area code)*: ( 408 ) 716-4601 |

| City | State / Province | ZIP Code | Country |
|---|---|---|---|
| Mountain View | CA | 94043` | USA |

| Contact Name | Contact Title | Contact E-mail Address |
|---|---|---|
| Garth Nobis | Vice President, RA/QA | gnobis@accuray.com |

☐ Original ☐ Add ☐ Delete

FDA Establishment Registration Number:

☐ Manufacturer ☐ Contract Sterilizer ☐ Contract Manufacturer ☐ Repackager / Relabeler

| | |
|---|---|
| Company / Institution Name: | Establishment Registration Number: |
| Division Name *(if applicable)*: | Phone Number *(including area code)*: ( ) |
| Street Address: | FAX Number *(including area code)*: ( ) |

| City | State / Province | ZIP Code | Country |
|---|---|---|---|
| | | | |

| Contact Name | Contact Title | Contact E-mail Address |
|---|---|---|
| | | |



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

91

FOIA Request #2014-4000, Released by CDRH on 12-8-2015

## SECTION I — UTILIZATION OF STANDARDS

Note: Complete this section if your application or submission cites standards or includes a *"Declaration of Conformity to a Recognized Standard"* statement.

| | Standards No. | Standards Organization | Standards Title | Version | Date |
|---|---|---|---|---|---|
| 1 | | | | | |
| 2 | | | | | |
| 3 | | | | | |
| 4 | | | | | |
| 5 | | | | | |
| 6 | | | | | |
| 7 | | | | | |

**Please include any additional standards to be cited on a separate page.**

**Public reporting burden for this collection of information** is estimated to average 0.5 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Food and Drug Administration
CDRH (HFZ-342)
9200 Corporate Blvd.
Rockville, MD 20850

***n agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control***



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015

ACCURAY

# Special 510(k): Device Modification

# CyberKnife® Robotic Radiosurgery System

# Lung Tumor Tracking

**September 28, 2006**

1310 Chesapeake Terrace, Sunnyvale, California 94089
Phone: (408) 716-4600 – Fax: (408) 716-4601

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015

# TABLE OF CONTENTS

**SECTION 1. GENERAL INFORMATION ..... 1**
A. Device Name ..... 1
B. Address and Registration Number ..... 1
C. Device Class, Product Code and CFR Reference ..... 1
D. Definitions ..... 2
**SECTION 2. PREDICATE DEVICE INFORMATION ..... 3**
A. Predicate Device Name and 510(k) Number ..... 3
**SECTION 3. LABELING AND INTENDED USE ..... 4**
A. Product Label ..... 4
B. Instructions for Use ..... 4
C. Intended Use ..... 4
**SECTION 4. DEVICE DESCRIPTION ..... 5**
A. Device Description ..... 5
B. Device Modification ..... 5
C. Algorithm Description ..... 6
**SECTION 5. SUBSTANTIAL EQUIVALENCE ..... 12**
A. Predicate Device Comparison ..... 12
B. Device Comparison Table ..... 12
C. Technology Statement ..... 12
D. Summary ..... 12
**SECTION 6. SUMMARY OF DESIGN CONTROL ACTIVITIES ..... 14**
A. Risk Analysis ..... 14
B. Design Verification and Validation ..... 16
**APPENDIX A. INDICATIONS FOR USE STATEMENT ..... 20**
**APPENDIX B. DECLARATION OF CONFORMITY WITH DESIGN CONTROLS ..... 21**
**APPENDIX C. CERTIFICATION OF TRUTHFULNESS AND ACCURACY ..... 22**
**APPENDIX D. INTENDED USE STATEMENT ..... 23**
**APPENDIX E. TECHNOLOGY STATEMENT ..... 24**
**APPENDIX F. 510(k) SUMMARY ..... 25**
**APPENDIX G. PREDICATE DEVICE LABELING ..... 26**
**APPENDIX H. MODIFIED DEVICE LABELING ..... 27**



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015


# SECTION 1. GENERAL INFORMATION

## A. Device Name

| Device Trade Name | Common/Classification Name |
|---|---|
| CyberKnife® Robotic Radiosurgery System | Medical charged particle radiotherapy system |

## B. Address and Registration Number

Address and registration number of the manufacturer of both the modified and predicate devices:

| Manufacturer | Registration Number |
|---|---|
| Accuray Incorporated<br>1310 Orleans Drive<br>Sunnyvale, CA 94089 | 2950679 |
| 1383 Shorebird Way<br>Mountain View, CA 94043 | 3005738050 |

## C. Device Class, Product Code and CFR Reference

| Classification | Product Code | CFR Section |
|---|---|---|
| II | IYE | 892.5050 |

No performance standards have been established under Section 514 of the Food, Drug and Cosmetic Act for medical charged particle radiotherapy systems.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015


## D. Definitions

**CT scan**: Computed tomography scan.

**Delineate**: Identification of a Volume of Interest (e.g., target tumor or critical structure) by defining its outline in a medical image using CyberKnife treatment planning tools.

**DICOM**: Digital Imaging and Communications in Medicine standard for distributing and viewing any kind of medical image regardless of the origin. DICOM is a standard method for transferring images and associated data so that it can be interpreted by devices manufactured by various vendors.

**Displacement**: Motion/movement with respect to a reference image or a prior position.

**DRR**: Digitally reconstructed radiographs are synthetic X-ray images generated from CT, MR, or PET scans or other DICOM compatible images.

**Fiducials**: Radiographic markers such as stainless steel screws or gold seeds, implanted in or near the target location that show a noticeable contrast against background anatomy in CT scans and X-ray images.

**Lung Tumor Tracking**: An algorithm that allows the CyberKnife Target Locating Subsystem to track soft tissue peripheral lung tumors that are at least 15 mm in size in all directions.

**MR scan**: Magnetic resonance scan.

**PET scan**: Positron-emission tomography scan.

**Registration**: The alignment of one or more images to a reference image (CT and CT, CT and X-ray, etc.) in order to compare and delineate targets, critical structures, etc.

**ROI**: Region of Interest, for example, the area containing the radiation target.

**Rotation**: Movement about an axis.

**Six degrees of freedom (6D)**: A Cartesian coordinate system with 6 parameters: x, y, z, w (yaw), p (pitch), and r (roll). X, y, and z represent the three Cartesian axes, while w is the rotation about the z-axis, p is the rotation about the y-axis, and r is the rotation about the x-axis. This coordinate system is used to track the radiation target in real space.

**Translation**: Movement occurring in one plane along the x, y, or z axis (moving straight up or down, straight across to the left or right, or diagonally in one plane).

**VOI**: Volume of Interest, for example, the target tumor volume or critical structure volume, i.e., any volume you are targeting for radiation or avoiding irradiating.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-3118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015


# SECTION 2. PREDICATE DEVICE INFORMATION

## A. Predicate Device Name and 510(k) Number

| Predicate Device Trade Name | 510(k) Number | Clearance Date |
|---|---|---|
| CyberKnife Robotic Radiosurgery System or<br>CyberKnife System for Stereotactic Radiosurgery | K041315<br>K062514 | 8/10/01<br>9/15/06 |



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015


# SECTION 3. LABELING AND INTENDED USE

## A. Product Label

There was no change to the product label.

The product label is located in Appendix H.

## B. Instructions for Use

The Instructions for Use consist of two manuals and a physics guide:

- CyberKnife Robotic Radiosurgery System Treatment Planning User's Manual
- CyberKnife Robotic Radiosurgery System Treatment Delivery User's Manual
- Physics Essentials Guide

Some additions were required in both the Treatment Planning and Treatment Delivery User's Manuals to describe the Lung Tumor Tracking function, how to plan for it and how to use it.

The Treatment Planning and Delivery User's Manuals for the predicate device were sent separately with this submission. The modified manuals are in Appendix H.

## C. Intended Use

The intended use is not changed from that cleared for the predicate CyberKnife:

The CyberKnife Robotic Radiosurgery System is intended to provide treatment planning and image-guided stereotactic radiosurgery and precision radiotherapy for lesions, tumors and conditions anywhere in the body when radiation treatment is indicated.

An intended use statement is provided in Appendix D.

The Indications for Use statement is in Appendix A. A copy of the predicate indications for use statement is also provided for your convenience.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015


# SECTION 4. DEVICE DESCRIPTION

## A. Device Description

The CyberKnife Robotic Radiosurgery System is a computer controlled medical system for planning and performing minimally invasive stereotactic radiosurgery and precision radiotherapy using a linear accelerator mounted on a manipulator (robot) and a Target Locating Subsystem to accurately deliver high-energy radiation to the treatment target. The CyberKnife System uses skull tracking, Fiducial Tracking (tracking of implanted radiographic markers), Synchrony™ respiratory tracking and skeletal structure tracking for dynamic positioning and pointing of the linear accelerator.

The cleared CyberKnife Target Locating Subsystem (TLS) utilizes a dual diagnostic energy X-ray system to periodically obtain orthogonal X-ray images of patient anatomy and fiducials to accurately verify target position and to provide information for dynamically positioning and pointing the linear accelerator. The system then compares the diagnostic X-ray images with pre-treatment CT information to determine patient/lesion position and allow adjustment for patient/lesion movement, if any. In general, image capture, calculation and re-targeting, if necessary, are performed prior to delivery of each radiation beam from the CyberKnife System's linear accelerator.

The Patient Positioning Subsystem provides a radiolucent treatment table for supporting and positioning the patient during treatment. It may be a standard treatment table with the capability of moving in the anterior/posterior and superior/inferior planes, in addition to rolling left or right or a robotic treatment couch. The robotic treatment couch consists of a robot, like the treatment delivery robot, that holds a standard treatment table top (cleared in K042146 and K051941).

## B. Device Modification

This submission describes a new tracking algorithm, the Lung Tumor Tracking algorithm (LTT). The purpose of tracking is to locate a tumor or lesion for precise radiation targeting during patient alignment and throughout treatment delivery. In lung tumor tracking, this is accomplished by matching lung tumors in the digitally reconstructed radiographs (DRR's), generated from pre-treatment images, with real-time X-rays of the patient taken during treatment delivery. DRR's are synthetic X-ray images generated from CT, MR, or PET scans or other DICOM compatible images.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-3118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015


## C. Algorithm Description

Lung Tumor Tracking (LTT) was devised so that lung tumors can be treated without implanting fiducial markers in the lung. Based on observation and analysis of patient data acquired from previous CyberKnife lung tumor treatments, it was determined that a number of lung tumors are sufficiently visible for delineation and tracking in medical images.

Treatment Planning System

Changes in the Treatment Planning System were required to support treatment with Lung Tumor Tracking. These are:

- Additional user interface for creating a treatment plan for Lung Tumor Tracking
- Spine segmentation software and tool
  - Add spine Volume of Interest (VOI) model
  - Create new spine VOI segmentation step in which the spine is "masked" and is not visible to Lung Tumor Tracking. This
- Qualification tool for Lung Tumor Tracking
- Integrate existing DRR generation code, currently used by the CyberKnife Treatment Delivery System, into the MultiPlan™ Treatment Planning System code base

Lung Tumor Tracking begins in treatment planning, with the user defining the exact outline of the lung tumor in the CT study for use by the LTT tracking mode. Besides delineation of the tumor and any critical structures, the user specifies:

- An alignment center for optimal use of XSight™ skeletal structure tracking for rotational alignment of the patient prior to initiation of LTT tracking
- A treatment center for the patient treatment position, used for LTT translational tracking during treatment delivery
- The offset between the alignment center and treatment center

Once the treatment plan is completed, digitally reconstructed radiographs (DRR's) are generated for both Xsight and Lung Tumor Tracking for the treatment plan.

Patient Alignment with Xsight Tracking

A problem with tracking soft tissue tumors is that tumor rotations cannot be determined by tracking the tumor alone. Tumor translations can be determined via direct tumor registration, but not tumor rotations. This is because the 2D soft tissue image cannot render an accurate image in roll, pitch and yaw rotations.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015


An LTT treatment consists of two phases. In the first phase, the patient is aligned using an existing tracking algorithm, XSight™ Skeletal Structure Tracking, cleared in K041315. Patient rotations near the lung tumor region are well represented by rotations of the spinal skeletal structures near the tumor. Therefore, vertebrae near the lung tumor can be used to correct for patient set up errors in rotations and accurately position the patient for treatment. During patient alignment, XSight Skeletal Structure Tracking is used to track the vertebrae near the lung tumor in 6 degrees of freedom (3 translations and 3 rotations), with respect to the alignment center. Rotations from Xsight are used to correct for patient set up errors in rotations. Translations from Xsight are used to determine the amount of initial adjustment required to move the patient from the alignment center to the treatment center, to start the second phase of LTT described below.

LTT operation introduces the ability to switch from an alignment-only patient setup position (alignment center) to a treatment patient setup position (treatment center). Thus, after spine tracking is performed and the patient is aligned, the couch is translated by a known offset between the spine tracking/alignment center and the lung tracking/treatment center. The spine tracking and lung tracking centers are defined in the CT volume during treatment planning. Upon completion of this offset correction, the user switches to Lung Tumor Tracking.

Treatment Delivery System

LTT uses the principles of Synchrony™ Respiratory Tracking, cleared in K020294, to establish a breathing model. After the Synchrony model is established, Lung Tumor Tracking tracks the tumor itself as it moves with respiration and treatment begins.

Throughout treatment delivery, the Lung Tumor Tracking algorithm and the Synchrony model are used to compute translational corrections. The LTT algorithm provides three degrees of freedom of translational corrections ($x$, $y$, and $z$), but no correction for rotations. Corrections for rotations are provided by the spine tracking alignment that was performed prior to the beginning of treatment delivery, that is, the LTT algorithm refers back to the last known rotational correction determined by Xsight. If the patient rotates beyond a certain amount, the system triggers an error message that the patient is out of alignment. In this case, the user would re-align the patient using Xsight tracking to establish the correct rotation, then move back to treatment mode for LTT and continue tracking as usual.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015


Lung Tumor Tracking uses a similarity measure and multi-level block matching concepts used in the Xsight tracking algorithm (K041315) to search for the target in the real-time X-ray images of the patient during treatment. These concepts are used to reduce the number of potential tumor locations in the X-ray images.

Tumor region translation estimation is then performed on the remaining candidate tumor positions in the X-ray images by comparing them with the known tumor location defined in the DRR's. The Region of Interest (ROI) in the X-ray image is estimated based on how closely it matches the ROI in the DRR's. A quality measure is used to determine the likelihood that the ROI selection is accurate.

The quality measure is based on the following assumptions. The ROI is defined at the boundary of the 2D tumor contour in the CT. It contains information about both the tumor and the surrounding background. If the ROI shifts slightly in any direction, most of the tumor and background information will still be included in the ROI. Using the shifted ROI for matching should give the same or similar results based on the tumor and background image data. The following steps are performed by the algorithm to determine the accuracy of the tracking results:

- Use the first tracking result as the initial estimate
- Define a smaller search window using the initial estimate as the center of the search window
- Repeat tumor registration (matching ROI in DRR and X-ray image)
- Calculate the difference between the repeated registrations and the tracking results
- If the difference is less then a defined threshold, the tracking results are considered acceptable. If the difference is greater than the threshold, the tracking results are inaccurate. If the results are correct, the results of repeated registrations will be consistent.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015


## Lung Tumor Tracking Treatment Overview

Figure 2 on page 11 is a flowchart of a typical CyberKnife treatment using Lung Tumor Tracking. The figure also identifies the changes in the tracking process as a result of the device modifications described in this submission. A brief overview of these steps in a CyberKnife treatment follows:

1. When planning, the user contours the lung tumor for use by the LTT Tracking system. There is no change in this step in the modified device.
2. When creating the plan, the user specifies an alignment center for optimal use of XSight Tracking to align the patient rotationally prior to initiation of LTT tracking. A treatment center is also selected for the patient treatment position, used for LTT translational tracking during treatment delivery.
3. The user completes the planning process to create a deliverable plan.
4. The user generates Xsight and LTT DRR's for the plan. The ability to create different sets of DRR's is new with this modification.
5. The user loads the plan into the Treatment Delivery module. This step is the same except that two sets of DRR's (Xsight and LTT) are loaded as reference images.
6. The user introduces the patient into the treatment room and places them on the couch. There is no change in this step for the modified device.
7. The user utilizes the "Treat" positional button on the couch hand controller to move the patient to the Alignment position for initial XSight tracking. There is no change in this step in the modified device.
8. The user utilizes the standard XSight alignment processes to align the patient translationally and rotationally for tracking. There is no change in this step.
9. The user transitions from *Alignment Center* mode to *Treatment Center* mode based on the difference between the two CT offsets defined in the plan. This transition prompts the user for confirmation of an automatic couch motion to the Treatment Center which the user confirms after visual verification. Lung Tumor Tracking parameters are displayed in the User Interface after the couch movement is completed. This is a new step introduced with this modification.
10. Lung Tumor Tracking is used to translationally align the patient sufficiently for tracking. There is no change in this step in the modified device.
11. The user establishes a Synchrony breathing model. This step is the same in a Synchrony treatment, but is not required for static targets in the predicate device or with this modification.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-5118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015


12. The user initiates treatment delivery using Lung Tumor Tracking to locate the tumor position. Only the three translations are calculated and updated in each X-ray acquisition. The three rotations are transferred from the previous Xsight tracking and always displayed for reference. This step is slightly different in the modified device because Lung Tumor Tracking only tracks patient/tumor translations, not rotations. The rotations defined in the previous Xsight alignment step are used to determine rotations during treatment.

13. If the patient rotates beyond a certain amount, the system triggers an error message that the patient is out of alignment. The user would then go back to the alignment center and re-align the patient using Xsight tracking to establish the correct rotations. After correcting the rotations, the user would move back to treatment center for Lung Tumor Tracking and continue treatment as usual.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015

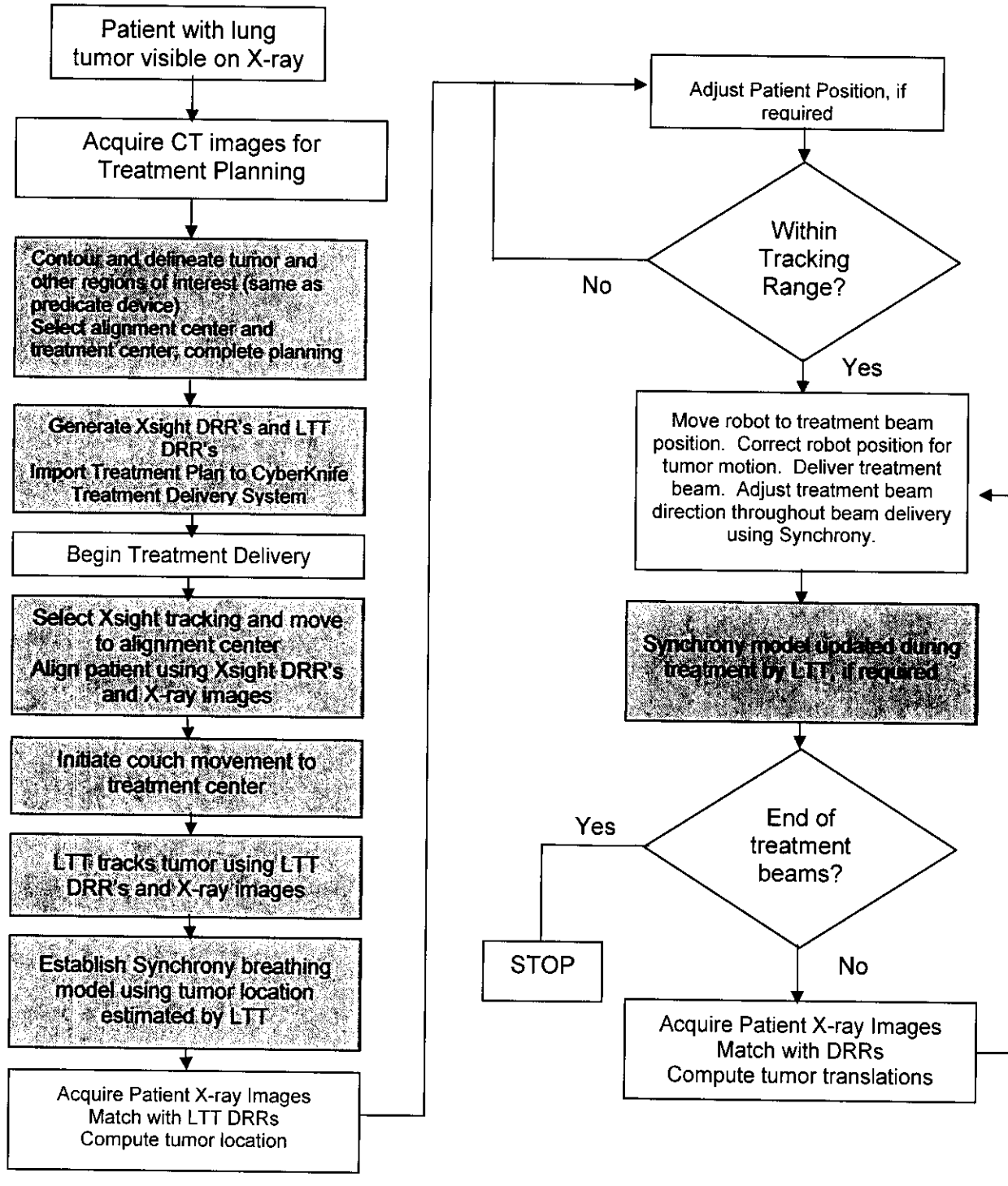




**Figure 2. Flow chart of a Typical CyberKnife Treatment Procedure**
The shaded boxes indicate steps that changed with the new algorithm.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015


# SECTION 5. SUBSTANTIAL EQUIVALENCE

## A. Predicate Device Comparison

The modified device has the following similarities to the predicate device cleared in K062514:

1. The indications and intended use are the same.
2. The fundamental scientific technology is the same.
3. All top level system specifications are the same.
4. All device hardware is the same or equivalent.

## B. Device Comparison Table

A table comparing the features of the current CyberKnife and the CyberKnife with Lung Tumor Tracking is provided on the following page.

## C. Technology Statement

The modification described in this submission has not altered the fundamental scientific technology of the predicate CyberKnife System cleared under K062514. A technology statement is provided in Appendix E.

## D. Summary

The CyberKnife System with Lung Tumor Tracking, described in this submission, is substantially equivalent to the predicate device.

The intended use, principles of operation, and technological characteristics are the same or substantially equivalent. The function and operation of the Lung Tumor Tracking algorithm are similar to the function and operation of the Xsight Skeletal Structure Tracking algorithm cleared in K041315, Synchrony Respiratory Tracking, cleared in K020294, and the CyberKnife Robotic Radiosurgery System, cleared in K062514.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-9118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015


## Table 1. Device Comparison Table

| Feature | Predicate CyberKnife System K020294, K041315, K062514 | Modified CyberKnife System (with Lung Tumor Tracking) |
|---|---|---|
| Intended Use | To provide treatment planning and image-guided stereotactic radiosurgery and precision radiotherapy for lesions, tumors and conditions anywhere in the body when radiation treatment is indicated | Same as predicate device |
| CyberKnife System Specifications | All top level system specifications for the CyberKnife System | Same as predicate device |
| Target Locating System Software | One tracking mode per patient treatment | Two tracking modes per patient treatment: "Alignment Center" tracking mode (Xsight) and "Treatment Center" tracking mode (LTT) |
| Treatment Planning System | Each plan has one set of DRRs for use in a specific tracking mode | Same as predicate device PLUS (for LTT only) can plan for two tracking modes: Xsight and LTT; ability to contour and delineate lung tumors; ability to generate two sets of DRRs for one plan<br>Add patient alignment user interface for LTT<br>Add tumor graphics to image display library for lung tumor delineation, etc. |
| Other Subsystem Hardware and Software Specifications | Software and Hardware Specifications for the other Subsystems (User Control Console, Manipulator, Imaging Subsystem, Distributed Safety Subsystems). | Same as predicate device |
| Features tracked | Skull, fiducials, skeletal structures | Same as predicate device PLUS lung tumors visible in medical images |
| ***Algorithm Feature*** | ***Current Tracking Modes*** | ***Lung Tumor Tracking*** |
| Tracking method | Registration of live images and Digitally Reconstructed Radiographs (DRR's). | Same as predicate device |
| Translation tracking accuracy | Range ± 10 mm for each axis<br>Radial RMS Error ≤ 0.5 mm | Same as predicate device |
| Rotation tracking accuracy | Range ± 5° for each axis<br>Radial RMS Error ≤ 0.5° | Same as predicate device for Xsight tracking, not LTT (LTT does not measure rotations) |
| Translation tracking stability | Standard deviation ≤ 0.3 mm | Same as predicate device |
| Rotation tracking stability | Standard deviation ≤ 0.3° | Same as predicate device for Xsight tracking, not LTT (LTT does not measure rotations) |
| DRR image generation | Treatment Planning System creates 1 set of DRR's for 1 tracking mode for 1 patient treatment | Same as predicate device PLUS Treatment Planning System creates multiple sets of DRR's for multiple tracking modes for 1 patient treatment (for LTT only) |
| DRR image enhancement | Enhanced using bilinear interpolation followed by 1-D polynomial interpolation and band-pass filtering, similarity measure, multi-level block matching | Same as predicate device |



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-3118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015


# SECTION 6. SUMMARY OF DESIGN CONTROL ACTIVITIES

## A. Risk Analysis

The risk analysis method used to assess the safety impact of the modification is **ISO 14971:2000**.

After mitigation, all risks were determined to be of severity and probability "as low as reasonably practical" or acceptable.

All mitigations were tested and passed.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-3118

| Hazard Description | Root Cause | Mitigations |
|---|---|---|
| Incorrect patient selection | LTT is not able to correctly treat lung tumors that are located in the central region of the lung and whose sizes are smaller than 15mm | • Error message generated if tumor is not trackable |
| Misjudge the DRR image quality in the LTT qualification tool | LTT is not able to correctly treat those lung tumors that are not visible in two DRR projections | • Quality measure in tracking algorithm<br>• Error message generated if tumor is not trackable |
| Wrong movement of couch from alignment CT center to treatment CT center | Wrong distance between two centers is given | • Couch movement confirmation and visual verification (not part of LTT) |
| Mistargeting tumor | LTT algorithm fails to track correctly because of poor X-ray image quality or large tracking range | • Visual inspection of tracking results<br>• Use manual offset to assist LTT to obtain the right results<br>• Quality measure in tracking algorithm |
| Mistreatment using alignment center as the reference for target location | User error | • Treatment will not start until LTT is selected and the Synchrony model is built |
| Partial treatment due to failure to track after the initial treatment session | Tumor shape may change between treatment sessions; Tumor obscured by skeletal structures | • Retreatment with a new CT scan |
| Alignment Center and Treatment Center inadvertently switched for Lung Tumor Tracking, leading to misdirection of the tumor dose | Software reports incorrect treatment CT center to delivery | • User inspection of images during alignment<br>• User inspection of images during treatment<br>• MultiPlan automatically defines treatment CT center from the center of mass of the Lung Tumor Volume<br>• Unit and integration testing to verify that the correct treatment center is assigned<br>• System tests, including end-to-end tests |
| Spine Segmentation –<br>Spine mask does not fully encompass vertebral column, yielding degradation of tracking accuracy | User delineates spine VOI that does not fully encompass the vertebral column | • Algorithm quality measure<br>• DX_AB check in skeletal spine tracking<br>• Visual inspection of DRR and live image during treatment<br>• User training, user manual |
| Spine Segmentation with Lung Tumor Tracking – Spine segment overlaps lung tumor volume, yielding degradation of tumor tracking | User generates intersecting volumes for Spine Segment and Lung Tumor | • Algorithm quality measure<br>• User training to correctly contour vertebral column and tumor volume<br>• MultiPlan prevents user from saving a deliverable LTT plan unless the two volumes exist and do not intersect |



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8148

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015


## B. Design Verification and Validation

The design verification tests performed to demonstrate mitigation of risks are listed in Table 2 below. Design verification and validation were carried out using a phantom and archived patient images from previous CyberKnife treatments. The test methods are similar to those used in the submission for the predicate device.

**Table 2. Design Verification Test**

| Test Parameter | Test Performed | Acceptance Criteria |
|---|---|---|
| Lung Tumor Tracking Accuracy | Simulated treatment using anthropomorphic phantom placed in a variety of positions and using different X-ray techniques | Radial RMS* ≤ 0.5 mm translation for static tumors and ≤ 1.5 mm translation for dynamic tumors (same as predicate) |
| Lung Tumor Tracking Stability | Simulated treatment using anthropomorphic phantom placed in a one position and using the same X-ray techniques | SD** ≤ 0.3 mm translation and (same as predicate) |
| End-to-End Targeting Accuracy+ | Simulated treatment using archived patient images from pervious CyberKnife fiducial treatments | Lung Tumor Tracking performance equivalent to current Fiducial Tracking for static tumors and current Synchrony tracking for dynamic tumors |

*RMS = root mean square
**SD = standard deviation
+End-to-end targeting accuracy includes the error in the treatment planning, DRR's, X-ray images and treatment delivery using LTT.

Lung Tumor Tracking Accuracy Test using a Body Phantom

Table 3 summarizes the test results for algorithm accuracy under typical treatment conditions in 6 test cases using a phantom specifically designed for Lung Tumor Tracking. The phantom was placed in predefined positions (approximately 37 different positions representing 3 degrees of translation) using a motion table. The motion table was designed to simulate human breathing motion. The phantom positions and X-ray parameters (kV, mA, ms) were varied to mimic actual treatment conditions, using the typical range of X-ray parameters that would be encountered during actual patient treatments. The tests were performed using a different set of phantom positions in different test cases. In each case, the Lung Tumor Tracking algorithm output was analyzed to determine its performance in simulated treatments, by measuring the radial Root Mean Square (RMS) translation errors.

Acceptance criteria for accuracy are radial RMS ≤ 0.5 mm translation.


Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015


**Table 3. Accuracy Test**
**Average *x, y, z* Error and Radial Root Mean Square for Translations Using a Phantom in Varying Positions with Varying X-Ray Parameters**

| Test Case | *x* error (mm) | *y* error (mm) | *z* error (mm) | Radial RMS Translation Error (mm) |
|---|---|---|---|---|
| 1 | 0.12 | 0.32 | 0.36 | **0.49** |
| 2 | 0.13 | 0.24 | 0.26 | **0.38** |
| 3 | 0.13 | 0.26 | 0.32 | **0.43** |
| 4 | 0.14 | 0.28 | 0.29 | **0.43** |
| 5 | 0.12 | 0.32 | 0.33 | **0.48** |
| 6 | 0.13 | 0.20 | 0.23 | **0.33** |

Test results using the phantom demonstrate that the radial RMS error for translations meets the specification of less than or equal to 0.5 mm which is the same specification for translations in the CyberKnife tracking modes for skull tracking, fiducial tracking and Xsight tracking.

Lung Tumor Tracking Stability Test using a Body Phantom

The tracking stability test was performed using a phantom positioned in a predetermined location. Table 4 summarizes the standard deviations for translations determined for 20 separate location determinations using the same X-ray parameters and the same phantom position. The results are the average of the standard deviations for the 20 translations.

Acceptance criteria for stability: SD ≤ 0.3 mm translation.

**Table 4. Standard Deviations for Translations Using Same X-Ray Parameters and Same Phantom Position***

| Translations | | |
|---|---|---|
| *x* | *y* | *z* |
| 0.12 | 0.11 | 0.09 |

***Values given are the average standard deviation for 20 location determinations**



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015


Lung Tumor Tracking Accuracy Test using Archived Data from Fiducial Tracking Treatments

Table 5 summarizes the results obtained using archived patient data and images from previous CyberKnife fiducial treatments. Ten pairs of X-ray images for each of 5 patients were randomly selected from the archived data for testing.

Radial Root Mean Square (RMS) was calculated to evaluate the algorithm. The translation targeting error is the difference between the locations determined by the Lung Tumor Tracking algorithm in a simulated treatment and the locations determined by the Fiducial Tracking algorithm (K011024) in the original patient treatment. The targeting error for each target translation in each patient was calculated for a total of 50 values. Table 5 shows the difference between the Fiducial Tracking calculation and the LTT calculation for the *x*, *y* and *z* translations and the radial RMS for the translation error.

**Table 5. Accuracy Test Using Archived Patient Data**

| Patient | Targeting Error in Translation (mm) | | | Radial RMS Translation Error (mm) |
|---|---|---|---|---|
| | *x* | *y* | *z* | |
| 1 | 0.50 | 0.77 | 0.87 | 1.27 |
| 2 | 0.57 | 0.88 | 0.43 | 1.14 |
| 3 | 0.61 | 0.25 | 0.21 | 0.69 |
| 4 | 0.46 | 0.36 | 0.72 | 0.93 |
| 5 | 0.15 | 0.65 | 0.67 | 0.95 |

This results demonstrate that the Lung Tumor Tracking algorithm is capable of performance equal to the Synchrony Respiratory Tracking algorithm in determining body target locations.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8218

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015


Total CyberKnife System targeting accuracy was determined for Lung Tumor Tracking. This test takes into account the error in the CT study, the treatment plan, DRR generation, and tracking. Accuracy was measured for both dynamic and static lung tumors, since some lung tumors do not move with respiration. For instance, tumors in the lung apex may remain static. When the tumor is moving, LTT works with Synchrony™ Respiratory Tracking (K020294) to track the tumor in real-time. Results are provided in Table 6.

**Table 6: Total Targeting Error from End-to-End Tests with CyberKnife Using Lung Tumor Tracking**

| Target | Targeting Error in Translation (mm) | | | Total Targeting Error (mm) |
|---|---|---|---|---|
| | Inf-Sup | Left-Right | Ant-Post | Radial RMS |
| Static Fiducial (reference) | 0.34 | 0.31 | -0.71 | 0.84 |
| Static Tumor | 0.33 | 0.40 | -0.68 | 0.86 |
| Dynamic Tumor | 0.62 | 0.29 | -0.82 | 1.07 |

The results demonstrate that the Lung Tumor Tracking algorithm is capable of performance equal to Fiducial Tracking in determining static body target locations and equal to Synchrony Respiratory Tracking in determining body targets that move with respiration.

Summary

For all tests, the results meet the requirements and specifications as defined in the Lung Tumor Tracking design documents.

A declaration of conformity with design controls is provided in Appendix B.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015


# APPENDIX A. INDICATIONS FOR USE STATEMENT



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015

510(k) Number (if known): K 062967

Device Name: CyberKnife® Robotic Radiosurgery System

Indications For Use:

The CyberKnife® Robotic Radiosurgery System is indicated for treatment planning and image guided stereotactic radiosurgery and precision radiotherapy for lesions, tumors and conditions anywhere in the body when radiation treatment is indicated.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use_____ OR (Per 21 CFR 801.109) Over-The-Counter Use_____

(Optional Format 1-2-96)



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015


# APPENDIX B. DECLARATION OF CONFORMITY WITH DESIGN CONTROLS

## Verification Activities

To the best of my knowledge, the verification activities, as required by the risk analysis, for the modification were performed by the designated individuals and the results demonstrated that the predetermined acceptance criteria were met.

9-28-06

Gopi Kuduvalli, Ph.D.
Director, Systems Architecture
Accuray Incorporated

Date

## Manufacturing Facility

The Accuray Incorporated manufacturing facility is in conformance with the design control requirements as specified in 21 CFR 820. 30 and the records are available for review.

9-28-06

Garth Nobis
Vice President
Quality Assurance and Regulatory Affairs
Accuray Incorporated

Date



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015


# APPENDIX C. CERTIFICATION OF TRUTHFULNESS AND ACCURACY

Pursuant to 21 CFR 807. 87(k), I, Garth Nobis, certify that to the best of my knowledge and belief and based upon the data and information submitted to me in the course of my responsibilities as Vice President of Quality Assurance and Regulatory Affairs of Accuray Incorporated and in reliance thereupon, the data and information submitted in this premarket notification are truthful and accurate and that no facts material for a review of the substantial equivalence of this device have been knowingly omitted from this submission.

Garth Nobis

Garth Nobis

9/28/06

Date



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015


# APPENDIX D. INTENDED USE STATEMENT

I certify that, in my capacity as Vice President of Quality Assurance and Regulatory Affairs of Accuray Incorporated, the intended use and indications for use of the modified device, as described in its labeling, have not changed from those of the predicate device.

Garth Nobis

Garth Nobis

9/28/06

Date



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8718

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015


# APPENDIX E. TECHNOLOGY STATEMENT

I certify that, in my capacity as Director of Systems Architecture at Accuray Incorporated, the fundamental scientific technology of the modified device has not changed from that of the predicate device.

Gopinath Kuduvalli, Ph.D.

9-28-06

Date


Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015

# APPENDIX F. 510(k) SUMMARY

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

**Name, Address, Phone and Fax number of the Applicant**

Accuray Incorporated
1310 Chesapeake Terrace
Sunnyvale, California 94089
Ph: (408) 716-4600
Fax: (408) 716-4601

**Contact Person**

Anne Schlagenhaft

**Date Prepared**

September 15, 2006

**Device Name**

Trade Name: CyberKnife® Robotic Radiosurgery System
Classification Name: Medical charged particle radiotherapy device

**Device Description**

The CyberKnife Robotic Radiosurgery System is a computer controlled medical system for planning and performing minimally invasive stereotactic radiosurgery and precision radiotherapy using a treatment radiation generator, linear accelerator, manipulator (robot), and a target locating subsystem to accurately deliver radiation to the treatment target. The CyberKnife System uses skull tracking, fiducial tracking, Xsight™ spine tracking, Synchrony™ Respiratory Tracking and Lung Tumor Tracking for dynamic positioning and pointing of the linear accelerator.

**Intended Use**

The CyberKnife Robotic Radiosurgery System is intended to provide treatment planning and image-guided stereotactic radiosurgery and precision radiotherapy for tumors, lesions and conditions anywhere in the body when radiation treatment is indicated.

**Substantial Equivalence**

The CyberKnife Robotic Radiosurgery System with the Lung Tumor Tracking algorithm is substantially equivalent to the predicate device. The intended use, principles of operation, technological characteristics and labeling are the same or equivalent.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8418

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015


# APPENDIX G. PREDICATE DEVICE LABELING

**NOTE**: The **product label** for the predicate and subject CyberKnife Systems is identical and is provided on the next page.

The predicate instructions for use are enclosed separately:

- Treatment Planning User Guide
- Treatment Delivery User Guide
- Physics Essentials Guide


Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015

ACCURAY

MODEL CYBERKNIFE® SN_____

REF ☐013500 ☐017800 ☐019200

| VOLTS 3~ | CURRENT | HZ |
|---|---|---|
| 200-240V | 24 A | 50/60 |

Manufacturer
Accuray, Inc.
Sunnyvale, CA USA
(408) 522-3740

Date of Manufacture

Voltage setting: ☐200 ☐210 ☐220 ☐230 ☐240

IPXO

81

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015


# APPENDIX H. MODIFIED DEVICE LABELING

**NOTE**: The **product labels** for the predicate and subject CyberKnife System are identical.

**Only the sections of the instructions for use that were changed** are provided here. Sections of the instructions for use that did **NOT** change are identical to the predicate manual and are not included in this section.


Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015


# Physics Technical Training Table of Contents

## Module 1: Medical Physics Technical Training Agenda

General Resources Contact Information ..... 1
Introduction to Physics Technical Training ..... 2
Section 1-1: Physics Training Agenda at Sunnyvale ..... 4
Section 1-2: Prerequisites for Customer Site Support ..... 6
Section 1-3: Customer Physics Commissioning Tasks ..... 8

## Module 2: System Overview

Subsystems Description ..... 3
Information Systems ..... 15
System Administration ..... 17
Power-Up Due to Power Interruption for CyberKnife Systems pre-Version 6.x. ..... 35

## Module 3: Commissioning Linac and Annual QA

CyberKnife® TPS Requirements ..... 3
Data Acquisition and Transfer ..... 3
Dose Calibration ..... 21
CyberKnife Absolute Dose Calibration ..... 21
CyberKnife System Targeting Accuracy ..... 33
End-to-End Targeting Test Description ..... 33
Film Scanner Setup ..... 41
Film Analysis with Automation Tool ..... 45
Running the E2E Program ..... 49
APPENDIX ..... 59
Recommended Equipment ..... 59
TPR Table Example ..... 60
Direct TPR Measurements ..... 61
Example - Processing OCR data in PTW MEPHYSTO MC2 ..... 62
5 mm OCR Plot ..... 66
5 mm OCR Data Example ..... 67
Output Factor Table ..... 70

*© 2006 Accuray Incorporated. All rights reserved. The Accuray stylized logo, Accuray, CyberKnife, Xsight, CyRIS, InView, MultiPlan, and Synchrony are trademarks and/or registered trademarks of Accuray Incorporated in the United States and other countries.*

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015


## Module 4: TPS Commissioning and Annual QA

**CyRIS™ MultiPlan™ (TPS)** ..... 3
TPS Data Verification ..... 3
Treatment Plan Generation for End to End (E2E) Ball-Cube Test ..... 7
Treatment Delivery Dose Verification ..... 13

**Dose Calculation Options** ..... 17
Dose Calculation ..... 17
CyberKnife Treatment Planning Data Fitting ..... 27

## Module 5: Quality Assurance Tests and Schedule

**Introduction** ..... 3
Quality Assurance Schedule ..... 3
Introduction ..... 5
Equipment QA Benefits ..... 6

**Quality Assurance Procedures** ..... 9
Daily ..... 9

**Film Analysis Software** ..... 21

**Monthly Quality Assurance** ..... 31
Monthly ..... 31

**Quarterly Quality Assurance** ..... 39
Quarterly ..... 39

**Annual Testing Requirements** ..... 47

**Appendix** ..... 49

## Module 6: QA Practicum

Robot Operation ..... 3
Beam Measurements ..... 9
Robot Targeting Visual Check (or Centering to Isopost) ..... 10
System Alignment ..... 11
TLS Tracking ..... 12
Training Checklist ..... 13

## Module 7: Basic Unix Review

**Basic UNIX and System Administration Practical** ..... 3
Basic UNIX Commands ..... 5
Helpful Shortcuts ..... 7
The Cyberknife File system: File Editing and Security ..... 9
Transferring Files using ftp ..... 11
ASCII Conversions ..... 13
Screen Dumps ..... 15
TAR and ZIP ..... 17

## Module 8: Synchrony

Quality Assurance ..... 2
Synchrony Motion Table Maintenance ..... 9



125

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015


# MODULE 1:

# MEDICAL PHYSICS TECHNICAL TRAINING AGENDA

*© 2006 Accuray Incorporated. All rights reserved. The Accuray stylized logo, Accuray, CyberKnife, Xsight, CyRIS, InView, MultiPlan, and Synchrony are trademarks and/or registered trademarks of Accuray Incorporated in the United States and other countries.*

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118 

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015


# Table of Contents

General Resources Contact Information ..... 1
Physics Training and Technical Support: ..... 1
FTP Institution Site Access: ..... 1
Physics Discussion Forum Access: www.accuray.com ..... 1
Physics Focus Group: 5 Areas ..... 1
Introduction to Physics Technical Training ..... 2
ACCURAY Training ..... 2
Customer Site PHYSICS SUPPORT ..... 3
Section 1-1: Physics Training Agenda at Sunnyvale ..... 4
Commissioning ..... 4
QA Program ..... 4
TPS ..... 4
Section 1-2: Prerequisites for Customer Site Support ..... 6
Section 1-3: Customer Physics Commissioning Tasks ..... 8



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

127

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015


# GENERAL RESOURCES CONTACT INFORMATION

## PHYSICS TRAINING AND TECHNICAL SUPPORT:

Physics Training and Technical Support can be reached through Customer Support:

Phone: 877 668 8667

(or)

E-mail: customersupport@accuray.com

## FTP INSTITUTION SITE ACCESS:

**ftp//:ftp.accuray.com**

This file transfer protocol allows large data file transfers like CTs, plans, and beam data, quickly and securely.

Site Name _____

Password _____

## PHYSICS DISCUSSION FORUM ACCESS: WWW.ACCURAY.COM

From www.accuray.com, select Physics Info. There is a Physics Focus Group forum and other helpful information such as typical beam data.

Your password will be E-mailed to you next week.

## PHYSICS FOCUS GROUP: 5 AREAS

Dose Calculation

Small Field Dosimetry

Motion Tracking

Tracking, Imaging

Protocols



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015


# INTRODUCTION TO PHYSICS TECHNICAL TRAINING

Three sessions are provided to physicists who will be using the Accuray™ CyberKnife® Robotic Radiosurgery System.

- Training course at Accuray in Sunnyvale
- A visit to a clinical site
- Optional on-site support during commissioning at the customer's clinic.

## ACCURAY TRAINING

The Accuray training course provides an introduction to the operation of the CyberKnife Radiosurgery treatment delivery and planning system. The CyberKnife System is a real time image-guided radiosurgery system where the treatment delivered corresponds within 1 mm to the CT image set used for planning the treatment.

The purpose of the Cyberknife training at Accuray is for medical physicists to gain the knowledge and skills necessary to commission the system correctly, and to use the treatment planning and delivery system with confidence.

The focus of the physics technical training is preparation for commissioning the system and includes:

**System Overview**

- Equipment description and LAN function
- Radiosurgery dosimetry equipment requirements

**LINAC Commissioning and Annual QA**

- Beam scanning and data validation procedures
- Beam data conversion and transfer to the CyberKnife (UNIX) system
- Absolute dose calibration
- End to End (E2E) system accuracy test including film scanner calibration

**TPS Commissioning and Validation**

- Data review and validation
- Plan generation for targeting accuracy tests
- Dose delivery verification
- Manual dose calculations
- Quick test to verify safety of plan delivery (BB test)

**Quality Assurance Procedures**

- Frequency of tests
- Description of test procedures

**UNIX Introduction and Practice**

**Synchrony™ Motion Tracking System QA**





Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015


## CLINICAL VISIT

Clinical visits provide the medical physicist the opportunity to observe clinical work flow and routine physics tasks.

## CUSTOMER SITE PHYSICS SUPPORT

Accuray Support Physicists are available to support the CyberKnife physicist as the commissioning tasks are performed.

The training agenda is presented for both the Sunnyvale location and the customer site in *Section 1-1: Physics Training Agenda at Sunnyvale, page 4*: Physics Training Agenda at Sunnyvale. In *Section 1-2: Prerequisites for Customer Site Support, page 6*: Prerequisites for On-site Support, the requirements to be met before the Customer Support Physicist visit to the clinic is presented which includes having the necessary equipment available, completion of the absolute dose calibration, and completion of beam scanning with an acceptable set of beam data tables in ASCII format. The raw scan data can be sent to a customer support physicist for review.

Tasks that need to be accomplished prior to patient treatment can be found in *Section 1-3: Customer Physics Commissioning Tasks, page 8.*



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015


# SECTION 1-1: PHYSICS TRAINING AGENDA AT SUNNYVALE

## COMMISSIONING

Measurement Equipment Requirements: Chambers, Diodes, Phantoms, Film Scanners, Film Analysis Software.

Data Collection: Tissue Phantom Ratio (TPR), Off Center Ratio (OCR), and Output Factors (DM).

Absolute Dose Calibration: TG51, IAEA 398.

Data Transfer: ASCII to UNIX with TPS printed verification of beam data accuracy.

TPS Data Validation and Expected Values.

RPC Independent Dose TLD measurement, RPC Radiosurgery Dose, and Geometric Accuracy Test Treatment Delivery Dose Validation; (or Similar international requirements).

## QA PROGRAM

End to End CyberKnife System Test using a "Ball-Cube" film cassette and radiochromic film.

Alignment Procedures: Robot, Table, Imager.

Daily Output Check, Calibration Factor Adjustment Tracking

Quality Assurance Log Book.

## TPS

Dose Calculation Algorithm.

TPS Optimization.

Manual Constraints.

CT Density corrections, Custom Model Entry.

Patient specific QA Overlay plans and hand calculations.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015

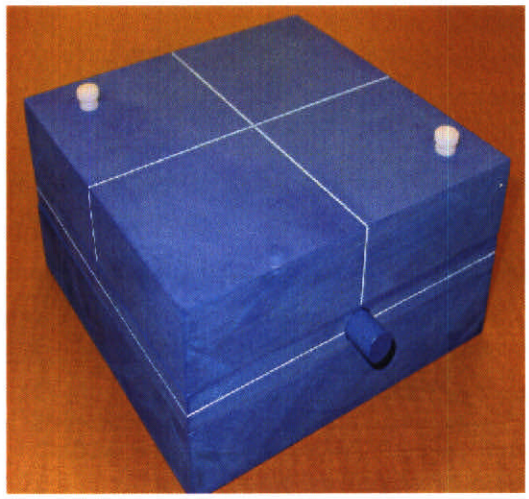



**Figure 1-1 Accuray Small Solid Water Phantom**

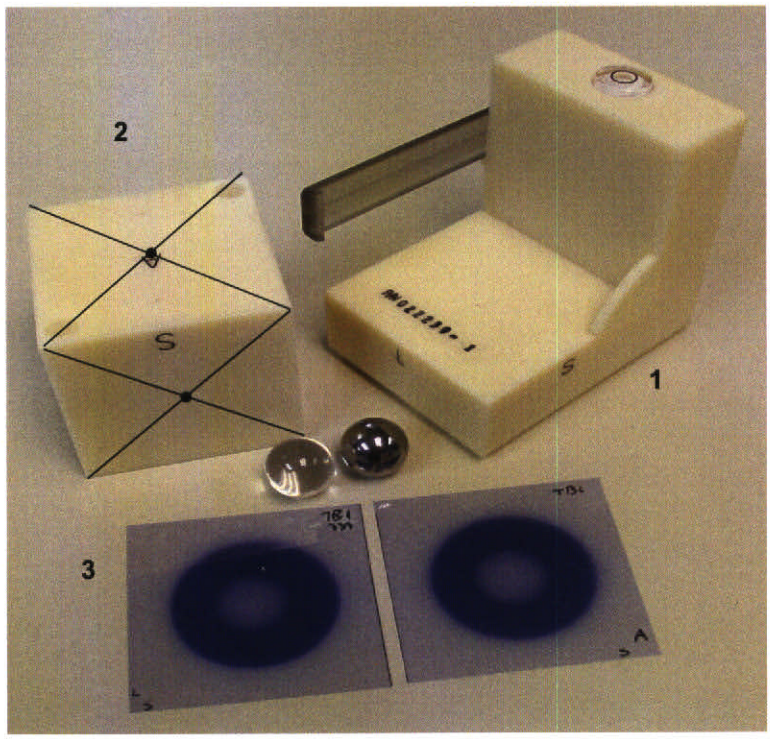



**Figure 1-2 AQA Hardware Components**



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015


# SECTION 1-2: PREREQUISITES FOR CUSTOMER SITE SUPPORT

1. PTW60008 diodes must be available on-site, or an equivalent.
2. Absolute dose calibration must be completed.
3. CT scans needed.
   - Three total CT scans of the Accuray anthropomorphic head phantom.

     The "Ball-Cube" film cassette must be loaded ***WITH*** FILM per Accuray protocol.

     At least one such scan is required for each CT scanner to be used for patient treatments.
   - CT scans of phantom for treatment dose delivery validation. CT scan of a solid water phantom with a Farmer Baldwin type calibrated chamber.

     If the Accuray solid water Phantom is not used (*Figure 1-1 Accuray Small Solid Water Phantom, page 5)*, place several BB's on the phantom with a L/R and AP spacing of 15 cm and 30 cm Sup/Inf. This CT study will be used to verify CT geometric accuracy and the dosimetric accuracy of a delivered plan. The generated plan can also be used for TPS quality assurance.
   - Automatic Quality Assurance (AQA) The AQA phantom will need to be scanned *Figure 1-2 AQA Hardware Components, page 5.* AQA Hardware Components).
   - Beam data must be collected and reviewed.




Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015

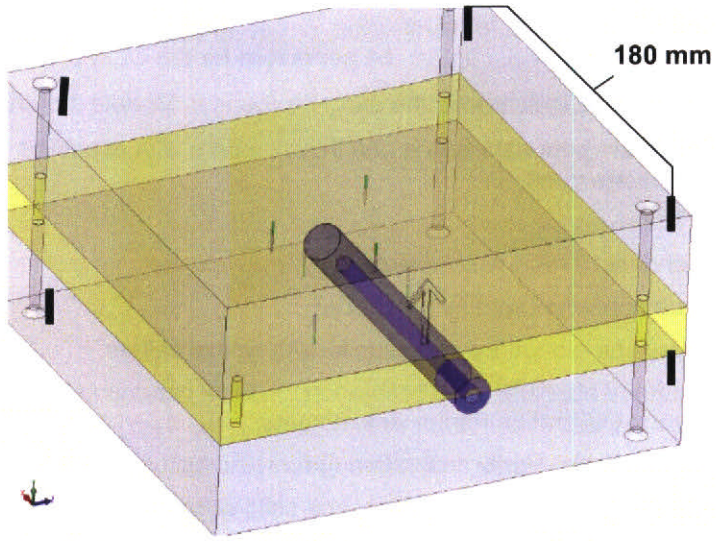




**Figure 1-3 Accuray Small Solid Water Phantom with Implanted Fiducials**



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015


# SECTION 1-3: CUSTOMER PHYSICS COMMISSIONING TASKS

1. Raw Data Review. Verify that the measurements are within 2% of the typical CyberKnife values before on-site support is confirmed. TPR, OCR, DM (output)

   May send data to CyberKnife physicists for verification, or use average data from Accuray Support Physicists for comparison. Plot comparisons can be generated for the OCR and DM tables.

   Tables must be in ASCII format as indicated in the samples found in Module 3 of this manual.

2. Export data to SGI. In MultiPlan, print data tables and intercompare with expected values. Plot values to confirm that all data points are good.
3. Validate treatment data.
   - **A.** Measure subset of direct TPR's in solid water.
   - **B.** OCR values can be confirmed with film if desired.
   - **C.** Output factors should be plotted for comparison with typical values.
4. Set up QA node for subsequent absolute dose calibrations. Check correction factors for daily output setup. Set up method to track Calibration Factor Adjustments.
5. Set up film scanner for film analysis. Verify calibration (geometric accuracy) with graph paper.
6. Import phantom CT studies; three ballcube phantom, one solid water phantom, and the AQA phantom.
   - Verify geometric accuracy of the CT images from the phantom studies in the TPS.
   - Custom CT Density model data is measured and entered in TPS if the density phantom has been scanned and imported.
7. Perform the End to End CyberKnife System Test
   - **A.** Review CT head ball cube test phantom studies in TPS.
   - **B.** Measure geometric image accuracy of CT scanners using the "ruler" tool.
   - **C.** Generate a treatment plan based on fiducials for each CT study. Refer to Module 4, Procedure 3 for directions to generate plans.
   - **D.** Perform the treatment for the Ball Cube tests.
   - **E.** Analyze the test films using Accuray analysis software.
   - **F.** Adjust Cyberknife targeting offset (deltaman) if needed.
   - **G.** Perform one spine and one fiducial plan to verify that the system has less than .95 mm total error.
8. Confirm treatment delivery dose accuracy
   - Develop a treatment plan for the solid water ion chamber phantom (*Figure 1-3 Accuray Small Solid Water Phantom with Implanted Fiducials, page 7*).
   - Deliver the treatment to the phantom and measure total dose.
   - Perform hand calculations for several of the beams to confirm MU calculations.
9. Review all elements of the QA program; Perform daily and monthly tests to establish baseline values. Set up AQA tool and test. Set up Synchrony QA tool and use for E2E test.
10. Be sure to **BACK UP** your data.
11. Perform RPC (Radiological Physics Center) TLD test for independent absolute dose accuracy verification. Review the adaptations required to perform the RPC radiosurgery phantom RTOG test; i.e. 20mm spherical dose plan and fiducial dots placement.
12. FTP (File Transfer Protocol) a file to Accuray.

Accuray Support Physicists are available to support the CyberKnife physicists as the commissioning tasks are performed.




Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015


# MODULE 2:

# SYSTEM OVERVIEW

*© 2006 Accuray Incorporated. All rights reserved. The Accuray stylized logo, Accuray, CyberKnife, Xsight, CyRIS, InView, MultiPlan, and Synchrony are trademarks and/or registered trademarks of Accuray Incorporated in the United States and other countries.*

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015


# Table of Contents

Subsystems Description ..... 3
Component Description ..... 3
(A) Treatment Room ..... 3
(B) Equipment Room ..... 7
(C) Control Area ..... 13
(D) Planning Area - Dosimetry or staff office ..... 13
Information Systems ..... 15
Network Environment ..... 15
System Administration ..... 17
Add New User ..... 17
Access Level ..... 17
Procedure 2-1: Add New User ..... 17
Delete User ..... 19
Procedure 2-2: Delete User ..... 19
Change User ACCESS ..... 21
Procedure 2-3: Change User Access ..... 21
User Preference, Changing Password ..... 21
Procedure 2-4: User Preference, Changing Password ..... 21
Database Backup ..... 23
Procedure 2-5: Database Backup ..... 23
Restore Database ..... 27
Procedure 2-6: Restore Database ..... 27
Obtaining Screen CaptureS ..... 29
Procedure 2-7: Screen Capture to Save Image ..... 31
Remote Diagnostics - Data Transfer Options ..... 31
Procedure 2-8: Transfer Option Procedure ..... 31
Cyberknife Computer Shutdown ..... 33
Procedure 2-9: Computer Shutdown ..... 33
Power-Up Due to Power Interruption for CyberKnife Systems pre-Version 6.x. ... 35
Procedure 2-10: Power-Up Due to Power Interruption ..... 35
Step 1. Establish "Normal" CKS Power-Off Status ..... 35
Step 2. E-Stop Circuit Check ..... 37
Step 3. Reset All Subsystems ..... 37



137

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015


# Module Description:

Learn subsystems and components that comprise the CyberKnife® Robotic Radiosurgery System.

# Module Objectives:

**Become familiar with:**

- Equipment and the location of the main components
- Local Area Network (LAN)
- Power Restore procedure

**Introduction to the System Administration functions**



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118 

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015


# ROOM LAYOUT

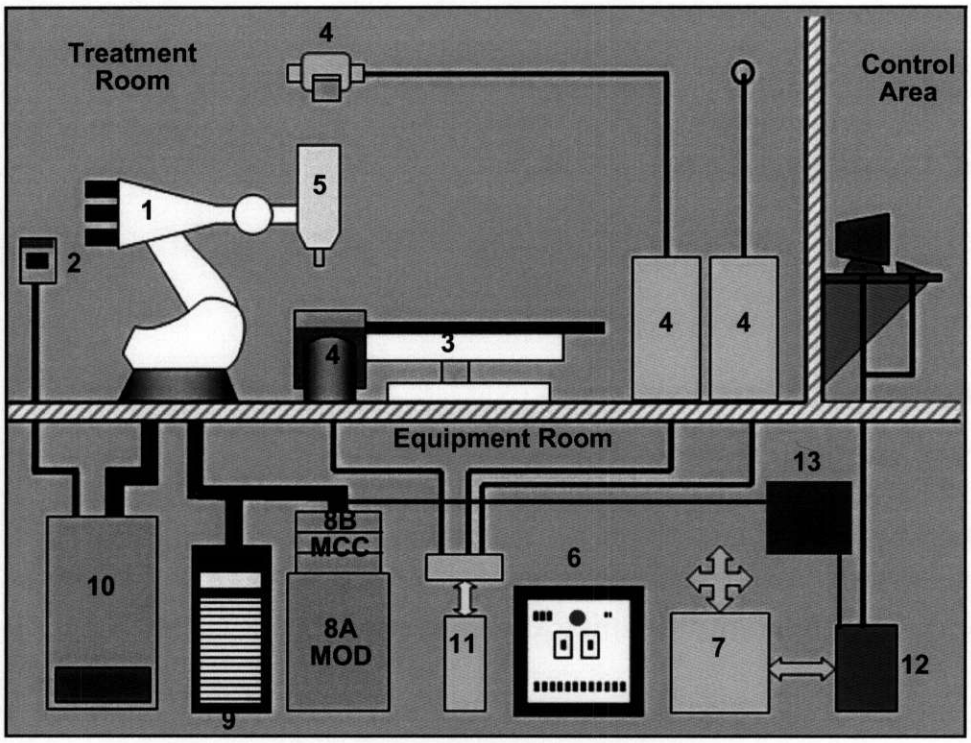



**Figure 2-1 CyberKnife System Equipment**

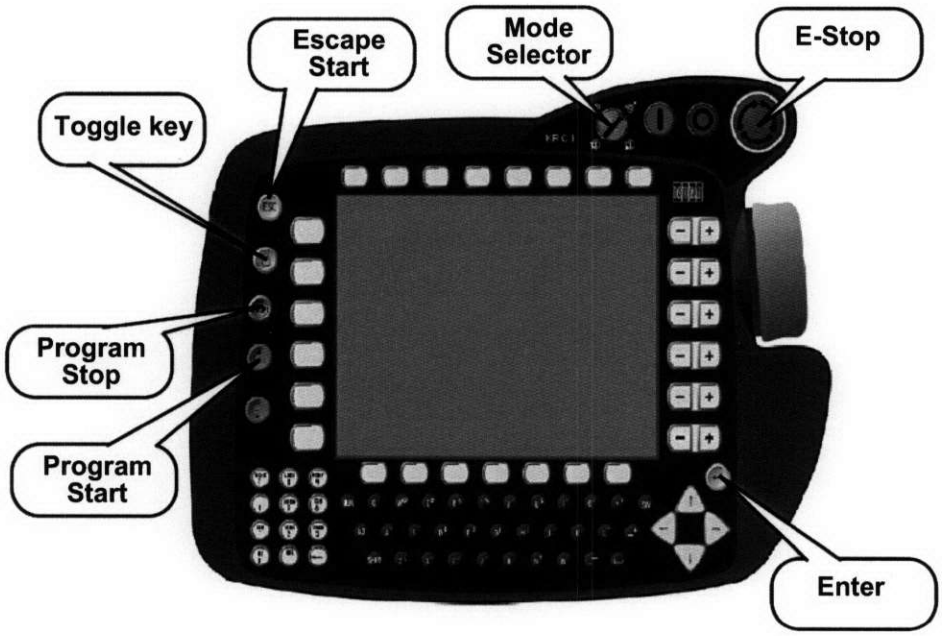



**Figure 2-2 Teach Pendant**



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

139

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015


# SUBSYSTEMS DESCRIPTION

### CyberKnife System Equipment

*(Figure 2-1, CyberKnife System Equipment, Page 2)*

### (A) Treatment Room:

1. Robot (Manipulator)
2. Teach Pendant
3. Patient Positioning System
4. Target Locating System (TLS)
   - Above Floor-Stands Amorphous Silicon Imager.
   - Floor-Mounted Flat Amorphous Silicon Imager.
5. Linear Accelerator (LINAC)

### (B) Equipment Room:

6. Power Distribution Unit (PDU)
7. ESCC
8. A: LINAC Modulator; B: Modulator Control Chassis (MCC)
9. Chiller
10. Robot Controller
11. TLS/Target Locating System Control Chassis (TLSCC)
12. SGI Octane Primary Computer
13. Interface Control Chassis (IFCC)

### (C) Control Area

- Control panel and monitor
- Emergency Power OFF control System
- Printer
- TV Monitors

# COMPONENT DESCRIPTION

## (A) Treatment Room

The treatment room contains the Robot, LINAC, Patient Positioning System, and the TLS.

**1. Robot (Manipulator)**

A six-axis manipulator used for positioning and pointing the LINAC for patient treatment.

- Provides a 65-100 cm (SAD) Source-to-Axis Distance with up to 1200 treatment positions.
- 0.2 mm repeatability.
- 13 foot by 16 foot operating envelope.

**2. Teach Pendant**

- The Teach Pendant, is a hand held computer used to manually operate the robot *(Figure 2-2, Teach Pendant, Page 2)*.

**3. Patient Treatment Couch (patient positioning system)**

The couch is used to position the patient for treatment.

- It utilizes automatic patient positioning technology.
- The maximum capacity of the couch is 350 pounds (159 kgs).
- It has motorized control, with five degrees of freedom: translations: inferior-superior, anterior- posterior, right-left. rotations: roll, pitch (trendelenberg) and yaw, which is adjusted manually.
- It includes a couch top, head base plate, hand control pad, and readout display.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015

**Figure 2-3 TLSCC**

**Figure 2-4 X-ray Sources**

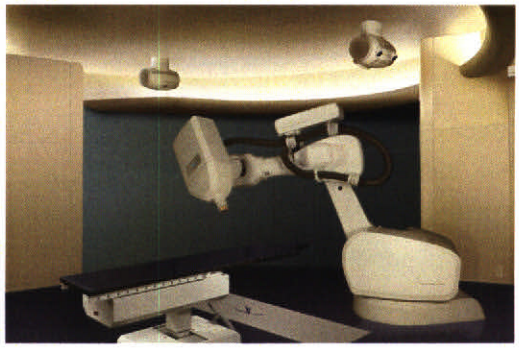


**Figure 2-5 Floor-Mounted Flat Imagers CyberKnife System Platform**

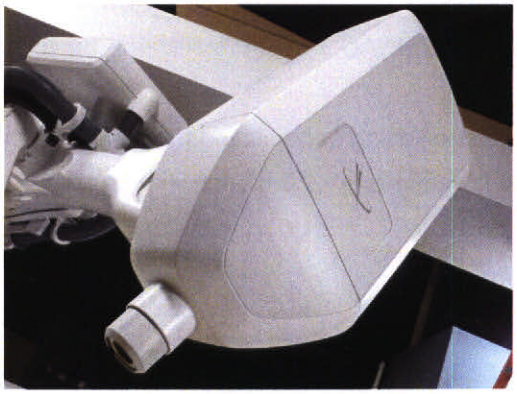


**Figure 2-6 Linear Accelerator (LINAC)**



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015


- Accuray provides up to 2 Med-Tec™ indexed (CT) Computer Tomography overlay kits (CT overlay + head base plate) to be used on the CT scanners that are used to prepare image data sets for the CyberKnife® treatment planning system. Additional overlay kits may be purchased as needed.

**4. Target Localizing System Stereotactic Imaging System**

**Control Panel** *(Figure 2-3, TLSCC, Page 4)*

**A. X-ray Sources:** *(Figure 2-4, X-ray Sources, Page 4)*

- The X-ray sources are used to track patient positioning.
- They are attached to the ceiling on each side of the table.
- They are fitted with > 2.5 mm aluminum equivalent filtration.

**B. X-ray generators:**

(also called High Frequency (HF) Generators), supply high-voltage power to the X-ray sources, may be located in either the treatment room or the equipment room.

- 37.5 kW X-ray generators; 40 – 125 kV, 25 – 300 mA, 1 – 500 ms

**C. Amorphous Silicon Detectors**

- Above floor stand imagers.
  - 512 x 512 pixels amorphous silicon digital X-ray imagers.
- Floor-mounted flat imagers are installed in the floor (*(Figure 2-5, Floor-Mounted Flat Imagers CyberKnife System Platform, Page 4)*).
  - 1024 x 1024 pixels amorphous silicon digital X-ray images.
- The detectors are used along with the X-ray sources to correctly position the patient for treatment.

**5. LINAC**

*(Figure 2-6, Linear Accelerator (LINAC), Page 4)*

- The LINAC is attached to the end of the robot and delivers the radiation treatment to the patient.
- Compact 6MV LINAC, dose rate 300/400/600 cGy/minute, 9.5 GHz X Band accelerator.
- 60 +/- 2% depth dose for field size of 40 mm diameter, at SSD of 800 mm and depth of 100 mm (Dmax = 15 +/- 2 mm).
- < 2% asymmetry.
- < 0.2% leakage at 800 mm SSD.
- Secondary Collimators are included in diameters of 5.0, 7.5, 10.0, 12.5, 15.0, 20.0, 25.0, 30.0, 35.0, 40.0, 50.0, and 60.0 mm.
- Contact Detection Sensor safety interlock surrounds collimators.

**6. Synchrony™ Motion Tracking System (MTS) (OPTION)**

The Synchrony MTS is used to monitor patient breathing and adjust the radiation treatment to match the patient movement.

Within the treatment room, there is a camera bar for tracking Synchrony LED's mounted to the ceiling near the foot of the table.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015

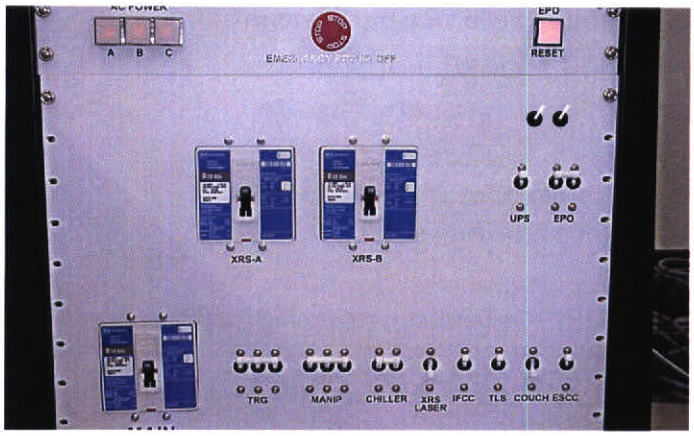




**Figure 2-7 PDU Power Distribution Unit**

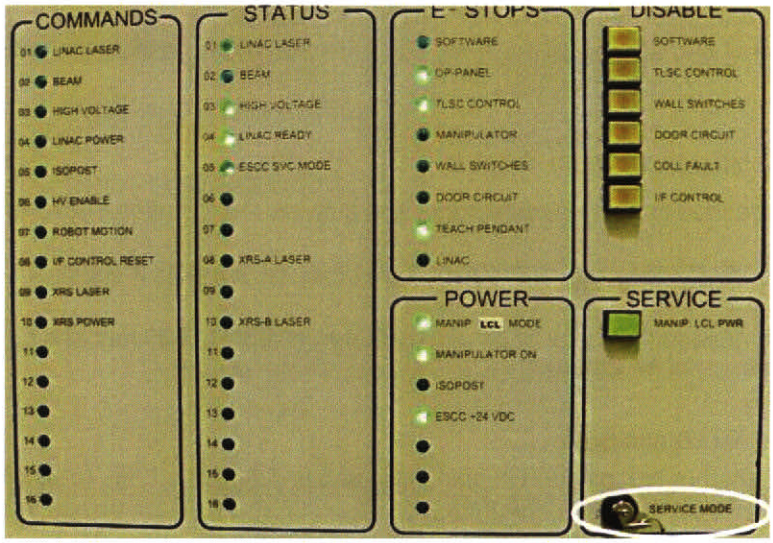



**Figure 2-8 E-Stop Control Chassis**



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015


**7. Miscellaneous Equipment and Information:**

- The treatment room also contains the patient positioning lasers. The phone, intercom and patient monitoring camera system need to be installed and functional prior to the installation of the CyberKnife System. The patient positioning lasers and medical gases are not needed for systeminstallation and can be installed later.
- A physics conduit port should exist between the treatment room and the control room for system QA testing equipment. It can also be used for routing cables used in patient monitoring (monitoring anesthetized patients).

## (B) Equipment Room

- The equipment room *(Figure 2-9, Modulator/Modulator Control Chassis and Dual Equipment Rack, Page 8)* is located adjacent to the shielded walls of the treatment room and is intended to hold the bulk of support equipment needed for planning and treatment. This equipment includes the facility power interface, E-stop assembly, primary and target locating computers, and robot controller. The room is cooled with a customer-supplied A/C unit. A telephone is required in the equipment room for the CyberKnife System.

**8. Power Distribution Unit (PDU)**

- The PDU *(Figure 2-7, PDU Power Distribution Unit, Page 6)* supplies power to all components of the CyberKnife System. The customer supplies the power input to the PDU (see power section).
- Input: 208VAC, 3 phase, 4 wire, 150amp, 55kVA.

**9. E-Stop Control Chassis (ESCC)**

- The ESCC *(Figure 2-8, E-Stop Control Chassis, Page 6)* performs a wide variety of hardware functions, and also functions as a central point for E-stop signals.
- Detects E-stop input (wall switches and other sources).
- Asserts hardware interlock for detected unsafe condition.
- Building circuit control.
- X-ray on/off warning light.
- Door interlock.
- The service mode is selected with a key switch.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015

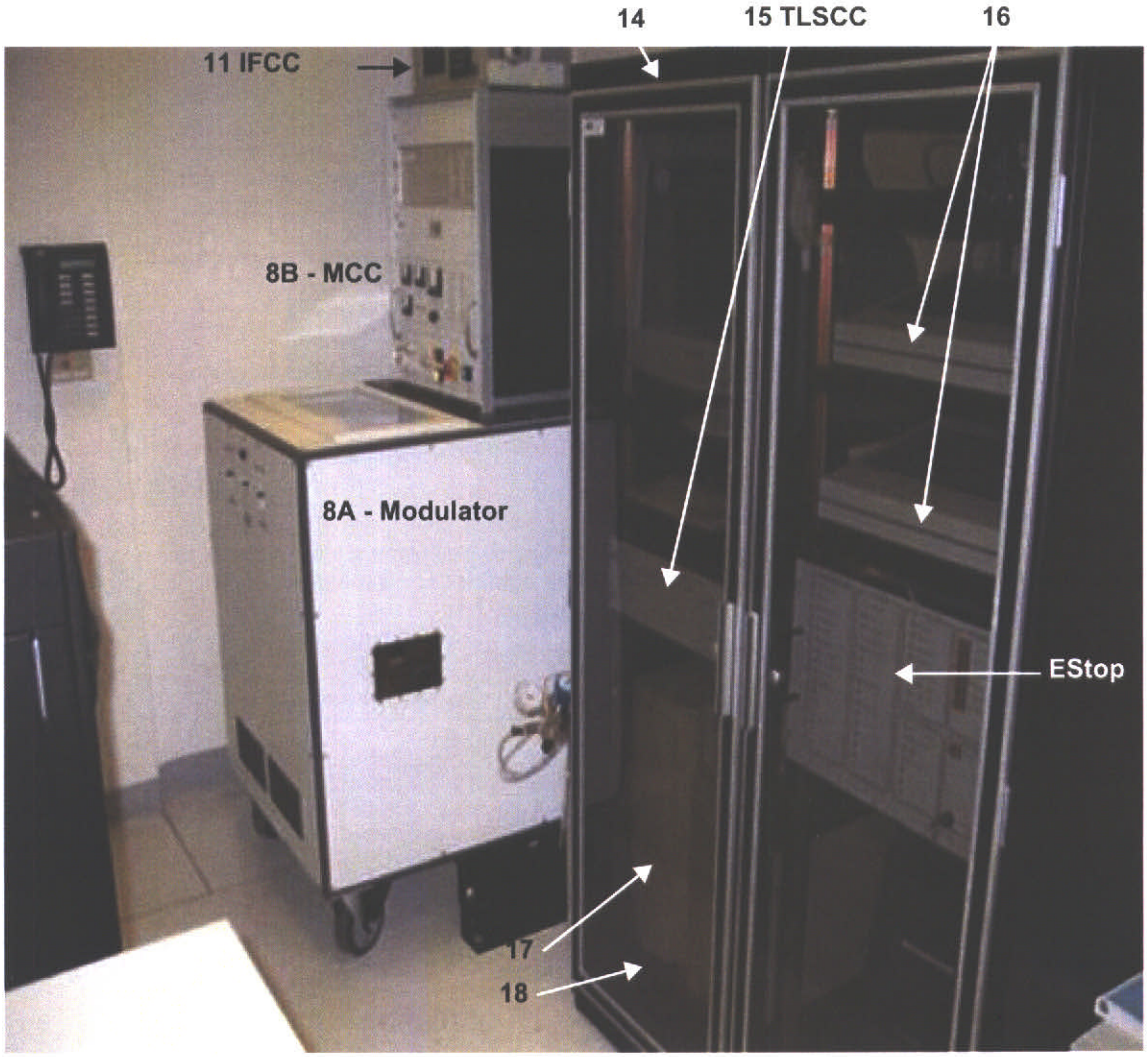




Figure 2-9 Modulator/Modulator Control Chassis and Dual Equipment Rack



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015


**10. Linac Modulator**

**A. The modulator provides a pulse to the magnetron so it can produce RF energy.**

- The Modulator Control Chassis (MCC) (*(Figure 2-9, Modulator/Modulator Control Chassis and Dual Equipment Rack, Page 8)*) contains the modulator and LINAC control circuits, as well as the fault circuitry and an interface card allowing control by the CyberKnife System.
- It contains a back-up dose counter.

**B. The MCC displays:**

(1) dose rate,

(2) beam-steering currents,

(3) magnetron tuner position, and

(4) miscellaneous faults.

**11. Chiller**

- The chiller *(Figure 2-10, NESCO Chiller, Page 10)* is a closed loop (distilled water) system that cools the LINAC on page 2-8. It is self-contained and does not need any outside water supply. All heat is dissipated into the Equipment room.

**12. Robot Controller**

- The robot controller directs the robot positioning.
- Reproducibility is +/- 0.2 mm.

**13. Interface Control Chassis (IFCC)**

- The IFCC includes a Motorola 68000 computer and functions as an interface between the CyberKnife SGI computer system and other components, including the LINAC and the robot.
- The IFCC also handles most digital processing of the dosimetry signals as well as generating a variety of fault signals.
- It also provides status and display information, such as monitoring the sense potentiometers for the collimator.

**14. CyberKnife SGI Main Computer and Specifications:**

- SGI Octane II Workstation (Primary)
- Dual R14000A 600 MHz/2MB Cache (or better)
- 1 GB Memory (or better)
- 18GB 10,000 RPM System Disk
- 73GB Hard Drive (additional storage)
- DAT20-INT Internal 4 mm SCSI Tape, 20GB (patient data archive / restore)
- 32x SCSI CD-Rom Drive
- IRIX Operating System

**15. Synchrony MTS (if option is purchased)**

- Serial Port Server.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015

Figure 2-10 NESCO Chiller

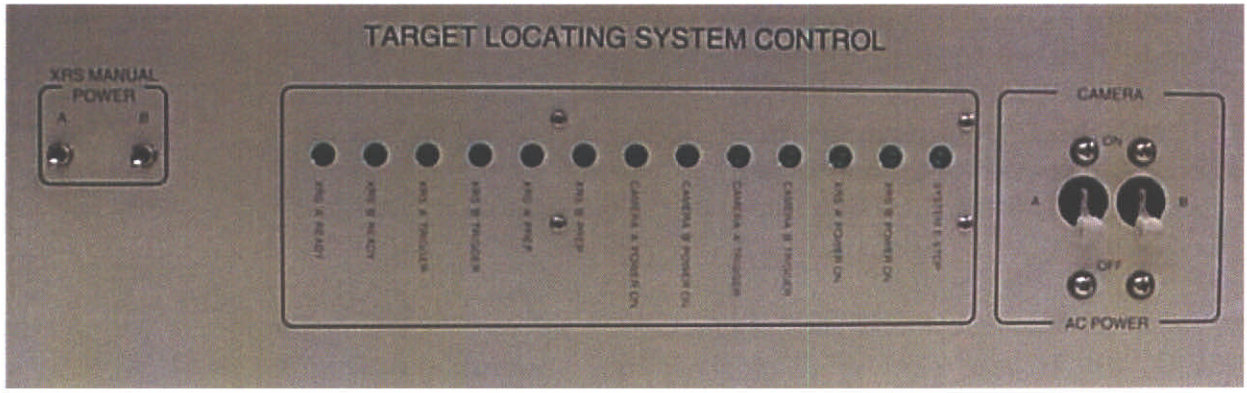



Figure 2-11 Target Locating System Control Chassis (TLSCC)



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

147

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015


**16. Dual 19-inch Rack Components**

**17. TLSCC**

*(Figure 2-11, Target Locating System Control Chassis (TLSCC), Page 10).* This is an interface between the TLS PC and the imaging system.

**18. Two X-ray generator control panels for each tube**

**19. SMART Uninterruptible Power Supply (UPS)**

Provides power to workstations for up to 30 minutes.

**20. TLS Computer**

Considered the Imaging System PC, it is primarily used to control the TLS and the interface between the TLS and the SGI.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015


**NOTE:** Page Left Intentionally Blank



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015


## (C) Control Area

- Synchrony Monitor (Synchrony is optional)
- SGI Octane Monitor and Keyboard
- Control Panel
- Emergency Pause and Power Off
- TV Monitors should have zoom and pan on each camera, and a large enough screen to easily view all four screens at once
- System Printer
- Intercom
- PC with hospital and internet access for billing, scheduling, and E-mail functions.
- Telephones must be operational before Physics On Site Support

## (D) Planning Area - Dosimetry or Staff Office

- MultiPlan™ Treatment Planning System

**WARNING: Keep planning and control areas separate. Distractions lead to errors.**



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118 

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015

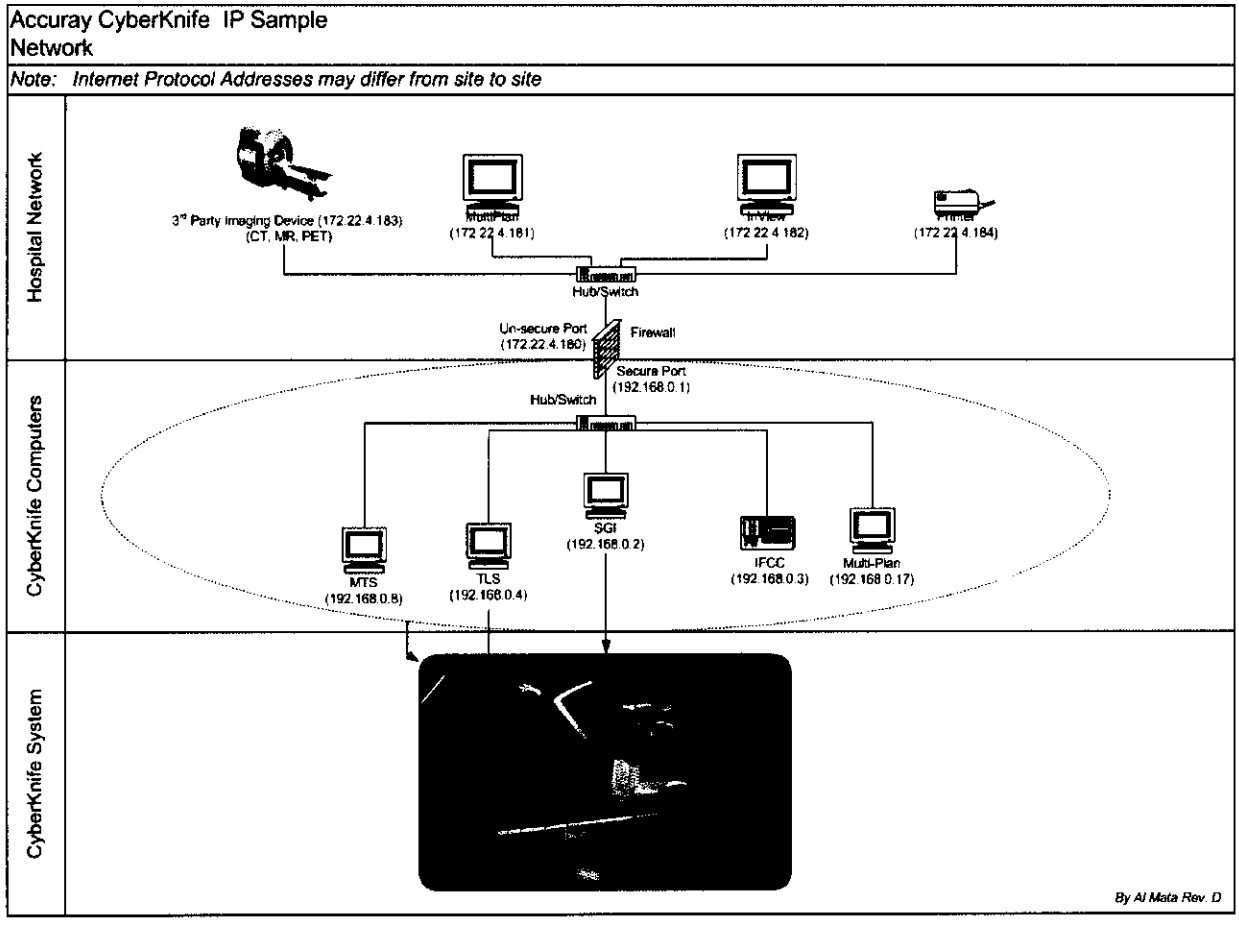




**Figure 2-12 Network Configuration**



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

151

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015


# INFORMATION SYSTEMS

## NETWORK ENVIRONMENT

A typical CyberKnife network environment is illustrated in *(Figure 2-12, Network Configuration, Page 14)*. The configuration has three essential sections: the firewall, computers outside the firewall, and computers behind the firewall.

### FIREWALL

The firewall prevents queries from computers not associated with CyberKnife treatments to CyberKnife computers during treatment delivery. The firewall has ports open to receive and send data. Port 104 is set to send DICOM medical image data from the CyberKnife to other systems outside the firewall. Systems that may receive data are the CyRIS™ InView™, MultiPlan workstations, and the Patient Archive and Restore System. Ports are also available for ftp transfers and telnet links to other computers.

### OUTSIDE FIREWALL

The computers that may be outside the firewall are the secondary workstations, CyRIS MultiPlan and CyRIS InView stations. The secondary workstations use a network file system (NFS) mount to access data (data files, patient database, and imported DICOM RTSS directory trees) from the primary workstation. The CyRIS InView stations pass data to and receive data from the primary CyberKnife workstation using the DICOM file transfer protocol. These transfers are made through Port 104.

### BEHIND THE FIREWALL

The CyberKnife system may have five computers behind the firewall. These system components require individual IP addresses. Those addresses are shown in *(Figure 2-12, Network Configuration, Page 14)* (Note: at some sites one or more MultiPlan or InView stations may also be located behind the firewall.)

**SGI Octane** The primary workstation is the central control computer for the CyberKnife System.

A PCI board on the SGI is a switch used to communicate between the primary workstation and the manipulator (robot).

The **IFCC** communicates between the primary SGI workstation and the LINAC.

The **TLS PC** controls the components of the target locating system. This system includes the cameras and the X-ray sources. Communications with the TLSCC use an ethernet connection.

The **Motion Tracking System PC (MTSPC)** communicates between the primary workstation, Synchrony™ camera, and robot. It also communicates directly with the manipulator controller. Communications with the MTSCC is via an ethernet connection.

**WARNING: Do not install unapproved third-party software applications behind the firewall.**



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015

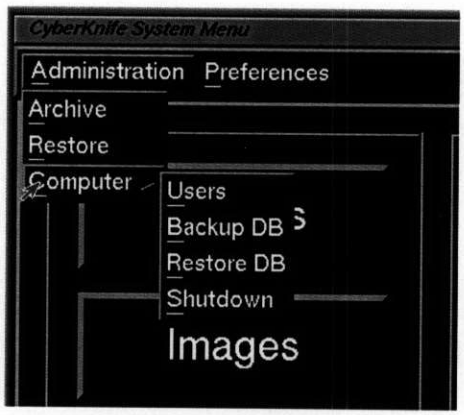




**Figure 2-13 CyberKnife System Menu with Computer Submenu Visible**

**Figure 2-14 New User Screen**



153
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015


# SYSTEM ADMINISTRATION

This section provides information for performing CyberKnife System computer administration tasks, such as adding or deleting a user, changing user status, database backup, restoring the database, print screen and computer shutdown. In addition, this section describes how users can change their passwords.

## ADD NEW USER

The designated CyberKnife computer administrator enters the names and access permissions for users of the CyberKnife System and assigns and changes the access level of the user. The access level limits the access to various console computer functions of the system. The levels of access are as follows:

### Access Level

**Level 1**

Limited to activating the PATIENTS AND EQUIPMENT POWER of the CyberKnife System menu, commonly referred to as the "9-button screen."

**Level 2 (e.g., Therapist)**

Access to Level 1 plus Images and Prescription on the CyberKnife System menu.

**Level 3 (e.g., Physicist)**

Full access to all functions of the CyberKnife System menu, including system calibration and managing users.

**Procedure 2-1: Add New User**

1. Navigate to:

   **CyberKnife System Menu -> CyberKnife Users -> New User -> Password and Access Level Verification -> Status Messages**

2. Click the **ADMINISTRATION** item in the menu bar on the CyberKnife System menu (the 9-button screen).
   *(Figure 2-13, CyberKnife System Menu with Computer Submenu Visible, Page 16)*
3. Click the **COMPUTER** item. Another submenu appears.
4. Click the **USERS** item. The CyberKnife System menu disappears and the CyberKnife Users window appears. A list of users is displayed in this window.
5. Click the **ADD USER** button and the New User window *(Figure 2-14, New User Screen, Page 16)* appears. Click **CANCEL** on the Add User window to return to the CyberKnife System menu. Click in the **NEW USER** text area to activate the text area. The 'I' shaped text cursor appears in the text area.
6. Type the name of the user. Do not use blanks or start a name with a numeric character. Press <Enter>.
7. Type in the password. Characters are not displayed in the Password box. This is a form of password protection. When done, press <Enter>. The pointer moves to the **ACCESS LEVEL** buttons. Select the desired access level.
8. Click **OK**. The Password and Access Level Verification window *(Figure 2-15, Password and Access Verification Screen, Page 18)* appears. Click **CANCEL** on the New User window to redisplay the CyberKnife System menu.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015

**Figure 2-15 Password and Access Verification Screen**

**Figure 2-16 New User Status Message**

**Figure 2-17 Delete User Confirmation Message**



155

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015


9. Move the cursor into **Verify Password** text area. Type in the password. Visually check the access level. If the information is not accurate, click **CANCEL** to return to the New User window.
10. Click **OK**. The Status Message *(Figure 2-16, New User Status Message, Page 18)* informs you that the new user data is being entered into the CyberKnife System database. Click **OK** on the Status Message to redisplay the CyberKnife Users window. The new user name and access level are displayed in the User list area.

Any errors will appear in the Error Message. Follow the instructions and click **CONTINUE** to return to the appropriate window for corrections.

## DELETE USER

Accounts for users who may no longer have access to the CyberKnife System should be deleted from the CyberKnife database. Only a user with Level 3 access can delete user accounts from the system.

**Procedure 2-2: Delete User**

1. Navigate to: CyberKnife System menu -> Administration -> Users
2. From the CyberKnife Users window, select the name of the user to be deleted.
3. Click the **DELETE USER** button and the Confirmation Message *(Figure 2-17, Delete User Confirmation Message, Page 18)* appears. The system prompts you to verify that the correct item will be deleted.
4. Click **YES** to delete the selected user and the Status Message appears with a message confirming the deletion of the user. Click **OK** to return to the CyberKnife Users window. If you click **NO** in the Verify Selection window, no action is taken and the CyberKnife Users window reappears.

If any errors are displayed in the Error Message window, follow the instructions and click **CONTINUE** to return to the appropriate window for corrections.

5. Perform System Backup



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015

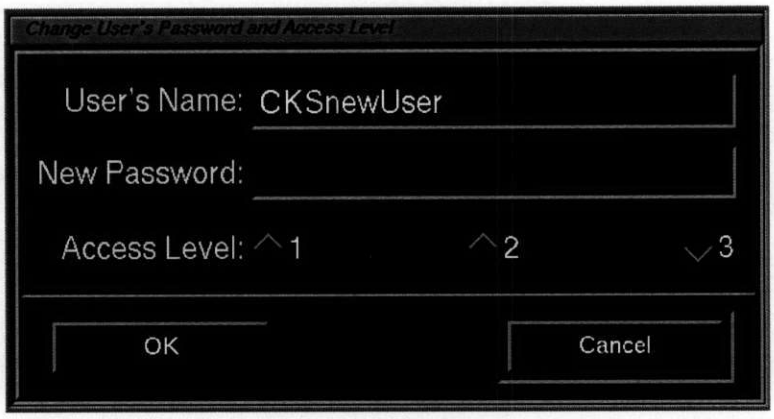




**Figure 2-18 Change User's Password and Access Level**

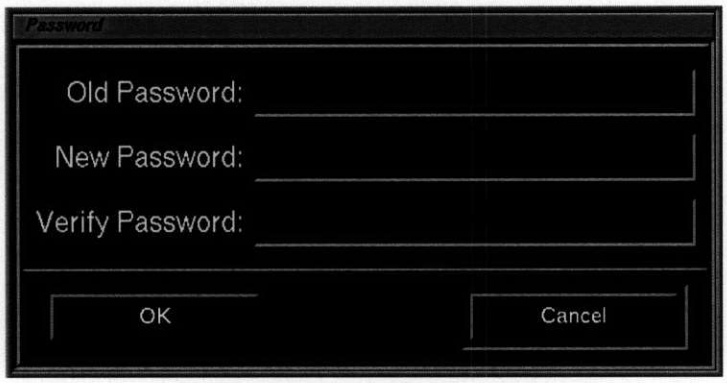



**Figure 2-19 Change Password Window**

**Figure 2-20 Password Changed Status Message**



157

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015


# CHANGE USER ACCESS

A user's password and access level can be changed as needed. Any user with Level 3 access can perform this activity.

**Procedure 2-3: Change User Access**

1. From the CyberKnife Users window, click the name of the user. This selects the item for changes to password or access level.
2. Click the **CHANGE** button. The CyberKnife Users window disappears and the Change User's Password and Access Level window *(Figure 2-18, Change User's Password and Access Level, Page 20)* appears. This window displays the user's name and access level.
3. Move the cursor into the New Password text area and type in the password. Click the desired access level button. This selects the new access level.
4. Click **OK** and the Password and Access Level Verification window appears. Type the new password in the Verify Password text area. Visually verify the access level. If the information is not correct, click **CANCEL** to return to the Change User's Password and Access Level window.
5. If the data is correct, click **OK** and the STATUS MESSAGE appears. This window informs you that the changes have been incorporated into the CyberKnife database. Click **OK** on the Status Message to redisplay the CyberKnife System Menu.

# USER PREFERENCE, CHANGING PASSWORD

This subsection allows any user to change their password.

**Procedure 2-4: User Preference, Changing Password**

**CyberKnife System Menu -> Password -> Status Message**

1. Click the **PREFERENCE** button in the menu bar on the CyberKnife System menu above the 9-button display. The **PASSWORD** button appears.
2. Click the **PASSWORD** button and the Password window *(Figure 2-19, Change Password Window, Page 20)* appears.
3. Type in the old password in the Old Password text area. Notice that no characters appear on the screen when the password is entered, but that the cursor moves. The characters are present but hidden for security. Use the <Delete> and <Backspace> keys to make corrections in the text.

   When the password is entered, press <Enter>. The 'I' shaped text cursor moves to the New Password text area. To return to the CyberKnife System menu at any time from the Password window, click **CANCEL**. No changes will be made to the CyberKnife System database.
4. Type in the new password. When finished, press <Enter>. The text cursor moves to the Verify Password text area.
5. Type in the new password. When finished, click **OK**. The Password window disappears and the Status Message *(Figure 2-20, Password Changed Status Message, Page 20)* appears with a message that the new password is accepted.
6. Click **OK** on the Status Message to redisplay the CyberKnife System menu.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015


**NOTE:** This page left intentionally blank.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015


# DATABASE BACKUP

This procedure allows you to backup the CyberKnife System database and all configuration data files to 12 GByte DAT tapes.

**WARNING: Backup your data periodically to protect against data loss.**

**Procedure 2-5: Database Backup**

1. Click the **ADMINISTRATION** menu in the menu bar of the CyberKnife System menu. The Administration submenu appears in *Figure 2-13 CyberKnife System Menu with Computer Submenu Visible, Page 16.*
2. Click **COMPUTER** menu to bring up the submenu.
3. Click **BACKUP DB**. The CyberKnife System Database Backup window appears.
4. Follow the instructions displayed in the CyberKnife System Database Backup window. The following message is shown where:

   Backup CyberKnife System database

   Calculating size of your database.

   You have xxx Megabytes of data. It will take about xx minutes and need x tapes (20 Gigabyte).

   Insert new tape into tape drive and Press <Enter> key to continue or type 'q' to quit this backup.
5. If a new tape is placed into the tape drive, the system begins to backup the database to tape.
6. If a used tape is placed into the tape drive, one of the following messages may be displayed:

   **6a.** Tape is write-protected. Set it to unsafe mode, move write protect tab to the unlocked position, and insert the tape back into the drive.

   **6b.** Tape drive has Patient Archive data tape. Do you want to overwrite this tape? [y=yes, n=no, q=quit]

   **6c.** Tape drive has Unknown data tape. Do you want to overwrite this tape? [y=yes, n=no, q =quit]

   **6d.** Tape drive has Database backup tape. Do you want to overwrite this tape? [y=yes, n=no, q=quit]

   **6e.** Backup completed successfully.

   **6f.** Remove the tape from the drive and make sure to label it with the appropriate patient file information.
7. Press <Enter> key to return to CyberKnife System menu.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118 160

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015


**NOTE:** This page intentionally left blank.



161
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015


8. When you see message 6a, remove the tape from the drive and move the write-protect tab to the unlocked position. When you see messages 6b, 6c, or 6d, make sure the data is not needed before you overwrite the tape. For the questions with the options of yes, no, or quit:
   - If you specify **Y**, the backup software overwrites the tape and continues to backup.
   - If you specify **N**, the backup process asks you to insert new tape into the tape drive and press <Enter>.
   - If you specify **Q**, the system returns to the main menu on the CyberKnife System Database Backup window.
9. When the backup has been successfully completed, locate the mouse over the back up display box text and Select <Enter>. If no text appears, select the ALT + F3 keys at the same time.
10. The CyberKnife System menu appears and the database backup disappears.

**NOTE:** If problems occur while transferring data to tape, clean the tape drive head with a standard cleaning tape. To avoid problems due to dirty tape drive heads, clean the tape drive once a month.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118 162

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015


Restore CyberKnife System database
==========

Insert the CyberKnife System Database Backup tape into tape drive and press the <Enter> key to continue or type in 'q' to abort this restore.

**Figure 2-21 CyberKnife System Database Restore Window**

***WARNING: You can not stop Restoring process from this point.
***WARNING: This process will erase all CyberKnife System Database

and

***WARNING: restore it from this tape.
***WARNING: Once this process starts, you can not stop this process.
***WARNING: After restoring is completed, CyberKnife System will be shutdown automatically.
Are you sure to continue? [y=yes, n=no]
Type in 'y' to continue with the tape in the drive, or 'n' to abort this process.

**Figure 2-22 Database Backup Check**

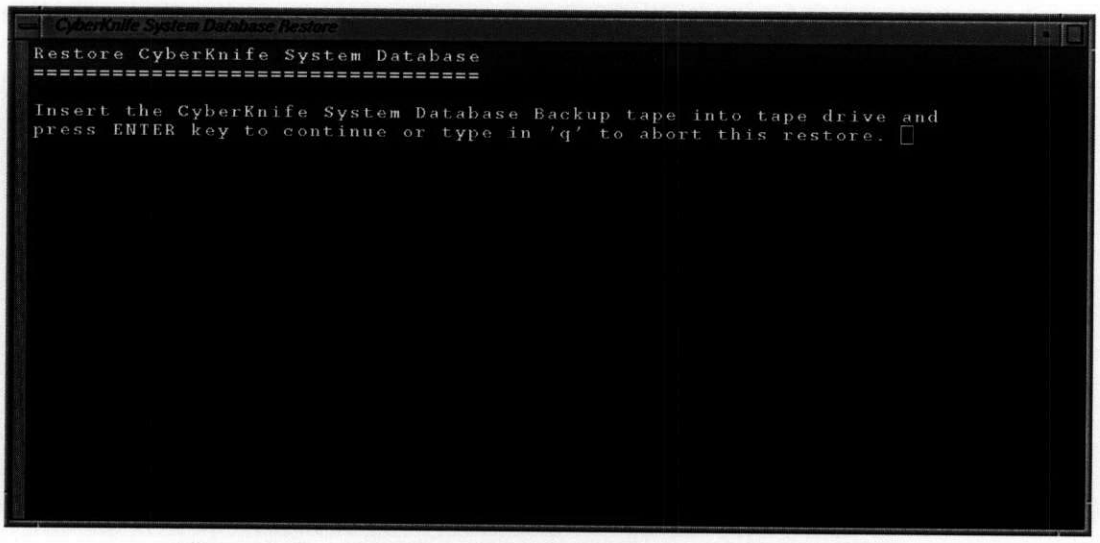



**Figure 2-23 CyberKnife Restore System Database Screen**



163

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015


# RESTORE DATABASE

This procedure allows you to restore the CyberKnife System database and the configuration data files from the backup tape. This procedure replaces your database and configuration data files with the backup you made previously.

**WARNING: Ensure that a current database backup is available, as performing a database restore will overwrite all data currently existing on the CyberKnife system, including patient data and system configuration information.**

**Procedure 2-6: Restore Database**

Click the **ADMINISTRATION** selection in the menu bar on the CyberKnife System menu to activate the submenu.

1. Click **COMPUTER** and another submenu appears.
2. Click **RESTORE DB**. The CyberKnife System Database Restore window *(Figure 2-23, CyberKnife Restore System Database Screen, Page 26)* appears.
3. Follow the instructions shown in the CyberKnife System Database Restore window. The message appears in *Figure 2-21 CyberKnife System Database Restore Window, Page 26*:

**NOTE:** To abort the restore process, type 'q' and press <Enter> to return to the CyberKnife System menu.

4. Insert the CyberKnife System Database Backup tape into tape drive and press the <Enter> key to continue or type in 'q' to abort this restore.
5. The restore process verifies the data on the tape. It displays the result of verification and one of the following messages are shown:
   - This tape contains no data.
   - Tape not found in the tape drive.
   - Tape drive has Patient Archive data.
   - Tape drive has Unknown data tape. Insert the CyberKnife System Database Backup tape into tape drive and press the <Enter> key to continue or type in 'q' to abort this restore.
   - Tape drive has Database backup tape. Do you want to restore this tape? [y=yes, n=no, q=quit]

When the restore process checks the database backup tape, the message in *Figure 2-22 Database Backup Check, Page 26* is displayed.

- Type in 'y' and press <Enter> to continue restoring the database.
- If you specify 'n' and press <Enter>, put in another tape.

If any other messages are displayed, correct the problem and insert the database backup tape into the tape drive and follow the instructions on the screen. Before restoring information from the tape, the following warning messages are displayed on the screen. *(Figure 2-24, Restoration Process, Page 28)* and *(Figure 2-25, Restoration Complete, Page 28)*.

Restore aborted.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015


:

Note:==========
When your CyberKnife System Database can not be contained on one tape, you will see the following messages on this screen when the first tape is fully read:
If you want to go on, type device/file name when ready:
When you see this message, insert the next tape into the tape drive, type in "/dev/tape" and press <Enter> key at the prompt.
==========
Restoring CyberKnife System Database...

**Figure 2-24 Restoration Process**

Restore completed successfully.
Press <Enter> key to return to CyberKnife System Menu.

**Figure 2-25 Restoration Complete**



165

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015


**6.** Press <Enter> key to return to CyberKnife System Menu.

**WARNING: You can not stop Restoring process from this point. This process will erase entire CyberKnife System Database and restore it from this tape. Once this process starts, you can not stop this process. After restoring is completed, the CyberKnife System will shutdown automatically.**

Are you sure to continue? [y=yes, n=no]

Type in 'y' to continue with the tape in the drive, or 'n' to abort this process.

Once the restoring process has begun, the following message in *Figure 2-24 Restoration Process, Page 28* is displayed:

**Reached end of medium on input**

When you are instructed to put in the next tape, remove the tape from the tape drive and put the next tape into the drive. Using the keyboard, type in /dev/tape and press <Enter>.

The following message appears at the end of a successful restoration (*Figure 2-25 Restoration Complete, Page 28*):

**Restore completed successfully.**

**Press <Enter> key to return to CyberKnife System Menu.**

When you press <Enter>, the CyberKnife System deactivates all buttons from the CyberKnife System menu except EXIT. Restart the system and reboot the SGI.

**7.** Log in again to view the restored database.

## OBTAINING SCREEN CAPTURES

There are two ways to print displays from screens:

- Clicking the PRINT SCREEN key, which prints the full screen and sends it to your default printer as a postscript file.

**CAUTION: Do not press the PRINT SCREEN key while treating a patient, otherwise the normal treatment process may be interrupted.**

- Taking a snapshot of a selected area of your screen and sending it to your default printer. Consult your System Administrator to setup your default printer.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015

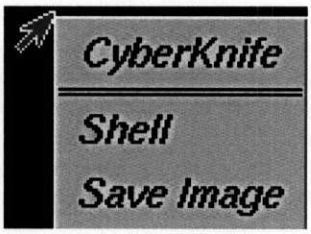




**Figure 2-26 CyberKnife Hidden Buttons**

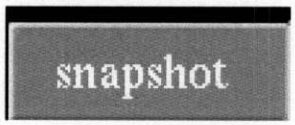



**Figure 2-27 Snapshot Button**

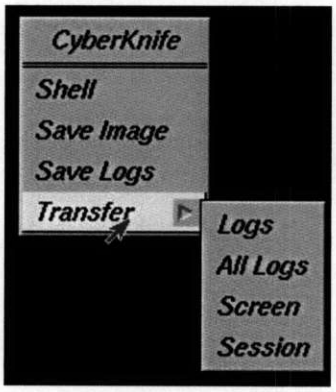



**Figure 2-28 CyberKnife System Transfer Options**



167

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015


**Procedure 2-7: Screen Capture to Save Image**

1. Right-click over the background screen to reveal a hidden menu. Select the SAVE IMAGE button. The SNAPSHOT button appears at the bottom left of the screen.
2. Position the pointer over the SNAPSHOT button and press the <Shift> key or middle mouse button. A special pointer appears in the shape of a camera.
3. While still holding the SHIFT key or middle mouse button, move the camera pointer over to the starting point of the area to be captured, generally a corner. Click and hold the left mouse button. The pointer changes to a corner shape. Once the left mouse button is held, the <Shift> key or middle mouse button can be released.
4. Left click, hold and drag a box around the area to be captured. When you've outlined the area, release the mouse.
5. Click **PRINT IMAGE** to print the snapshot of the selected area.
6. Click **EXIT** to exit the Snapshot.

## REMOTE DIAGNOSTICS - DATA TRANSFER OPTIONS

**CAUTION:** Do not select any of the transfer options while treating a patient. The data collection process may interrupt the normal treatment process.

Accuray provides four options to transfer system information using the Transfer Options menu. The purpose of collecting and transferring system information, is to help an Accuray Service Engineer to analyze a particular problem and provide a solution.

**Logs** used to transfer a subset of the CyberKnife System logs. The subset includes the log files that are most likely to reveal the system problem.

**All Logs** used to transfer all CyberKnife System logs.

**Screen** used to transfer the active visible interface. This gives an Accuray Service Engineer a view into a particular local problem.

**Session** used to transfer all information needed for an Accuray Service Engineer to reproduce the current imaging environment. Files that are transferred include the patient DRR's and the last pair of live images captured.

### Procedure 2-8: Transfer Option Procedure



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118 

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015

**Figure 2-29 Computer Shutdown Warning Message**



169

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015


# CYBERKNIFE COMPUTER SHUTDOWN

Use these steps to shut down the SGI primary workstation for computer maintenance. You must use an account with Access Level 2 or 3 to shut down the console computer.

## Procedure 2-9: Computer Shutdown

1. Click the **ADMINISTRATION** selection menu bar on the CyberKnife System menu. The Administration submenu appears.
2. Click the **COMPUTER** selection. Another submenu appears.
3. Click the **SHUTDOWN** selection. The Confirmation Message *(Figure 2-29, Computer Shutdown Warning Message, Page 32)* appears. Follow the instructions shown in this window.
4. To shut down the computer, click **YES**.
5. Wait until the Computer System Maintenance Menu appears.
6. When you see the Computer System Maintenance Menu, it is safe to turn the power off.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015


**NOTE:** This page intentionally left blank.



171

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015


# POWER-UP DUE TO POWER INTERRUPTION FOR CYBERKNIFE SYSTEMS PRE-VERSION 6.X.

**NOTE:** The Version 6x or higher CyberKnife Platform utilizes a computer controlled Power Restore.

This procedure describes taking the CyberKnife System from a shutdown state, typical of how the system would be left for the weekend, up to a Powered-On condition where it is ready to perform a treatment or be operated in physics mode.

**NOTE:** This procedure is most often used when a power interruption or some other disruptive event has occurred, usually when the system was unattended (during the night or over a weekend).

It insures all sub-systems and computers are in the proper condition for power-up and that communications between various sub-systems are working correctly.

## Procedure 2-10: Power-Up Due to Power Interruption

## Step 1. Establish "Normal" CKS Power-Off Status

This step ensures that the CyberKnife System is powered down properly and in the correct standby state, thereby establishing a dependable starting point.

**To achieve normal power-off status:**

1. The SGI (Primary workstation) should be at the UNIX log-on screen. This is the screen where the login is "cks."
2. The TLS PC should be at the Desktop. This can be seen on the monitor in the equipment room.
3. The robot should be in the perch position and powered off.
4. The PDU (Power Distribution Unit) and UPS (Uninterruptible Power Supply) should be set properly. To do this check the following:
   - Verify the three lights on the upper left-hand side of the PDU, labeled AC POWER, L1, L2 and L3 are illuminated. If the lights are not on, press to engage.
   - Press the EPO RESET button on the upper right–hand side to ensure the EPO circuit is latched on.
   - Verify all circuit breakers on the PDU except the XRS LASER (optional) are on. Reset if necessary by turning them off, then on again.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015


**NOTE:** This page intentionally left blank.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015


## Step 2. E-Stop Circuit Check

If any system E-Stop conditions exist, the CyberKnife System may not power up without generating a fault condition.

**To check out E-Stop issues:**

1. Turn the ESCC keyswitch to the SERVICE MODE (CW).
2. Power on the robot by depressing the MANIP. LCL PWR button on the ESCC.
   - Insure the robot is completely booted up before proceeding. This can be confirmed by monitoring the display on the robot pendant.

The robot can also be monitored in the equipment room by selecting it with the KVM switch. The KVM switch toggles the Keyboard, Video and Mouse controls between the TLS PC and the Robot PC.

> **NOTE:** Do not attempt to turn the robot on or off while it is going through a boot up or power down sequence! Robot mastering can be lost which takes many days to restore.

3. Depress the **SOFTWARE** button located in the disable section of the ESCC front panel and insure no other disable buttons are depressed.
4. Verify the System E-Stop LED on the right-hand side of the TLSCC is illuminated.
   - If the System E-Stop LED is not illuminated an E-Stop engaged. Troubleshoot by checking E-Stop buttons, Collimator, door, etc. or call Accuray Customer Service.
5. Power down the robot by releasing the MANIP. LCL PWR button on the ESCC.
   - Ensure robot is completely off before proceeding. This can be confirmed by observing the robot display or Teach Pendant and ensuring it is blank.
6. Turn the ESCC key switch out of the Service Mode (CCW).

## Step 3. Reset All Subsystems

There are several computers and microprocessors included in the CyberKnife System. Resetting, or rebooting them before powering up will usually eliminate them as a cause of operational problems.

**To reset/reboot all sub-systems:**

1. Turn SGI on.
2. Turn off the IFCC for 20 seconds and then turn it back on.
   - This will cause the IFCC computer to reboot and request initialization information from the SGI.
   - This step can be performed by using the rocker power switch on the rear of the 19 inch rack mounted chassis (in the MCC rack). The front of this chassis is plain with only a set of handles on each side. Do not confuse this with the display power switch on the rear of the display that rests on top of the MCC.
3. Reboot the MTSPC. Leave the MTSPC off for 20 seconds before turning back on.
   - The reason for a power-down reboot is that the two frame grabber PCB's use microprocessors. These microprocessors reboot only when power is removed.
4. Reboot the MTS PC.
5. Reboot the SGI computer.
6. Proceed with System Tasks.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118 

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015





Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015


# MODULE 3:

# COMMISSIONING LINAC AND ANNUAL QA

*© 2006 Accuray Incorporated. All rights reserved. The Accuray stylized logo, Accuray, CyberKnife, Xsight, CyRIS, InView, MultiPlan, and Synchrony are trademarks and/or registered trademarks of Accuray Incorporated in the United States and other countries.*

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015


# Table of Contents

**CyberKnife® TPS Requirements** ..... 3
Data Acquisition and Transfer ..... 3
Equipment Required ..... 3
Beam Measurements ..... 5
Procedure 3-1: Linac Laser/Radiation Field Alignment Check ..... 5
Procedure 3-2: Beam Scanning Water Tank Setup ..... 5
Tissue Phantom Ratio (TPR) ..... 7
Tissue Phantom Ratio ..... 9
Direct TPR Measurement ..... 9
Procedure 3-3: Direct TPR Measurement ..... 9
Off CENTER Ratio Measurements ..... 13
Off Center Ratio Scan Methods ..... 13
Measurement Requirements: ..... 13
Procedure 3-4: Off Center Ratio Beam Profile Scanning ..... 15
Output Factors ..... 17
Procedure 3-5: Output Factor Measurement Method ..... 17
Summary Of Beam Data Measurement Requirements ..... 19
**Dose Calibration** ..... 21
CyberKnife Absolute Dose Calibration ..... 21
General Formalism for TG51 ..... 21
Beam Quality Specification ..... 21
Procedure 3-6: CyberKnife $k_Q$ Beam Quality Measurement ..... 23
LINAC Calibration ..... 25
Calibrating the LINAC from Physics Linac ..... 25
Errors ..... 27
Viewing and Modifying Calibration Factors from The Parameters Screen ..... 27
To view calibration factors ..... 27
Procedure 3-7: Constancy Correction Factor ..... 31
**CyberKnife System Targeting Accuracy** ..... 33
End-to-End Targeting Test Description ..... 33
Materials Required for E2E Test ..... 35
Procedure 3-8: Ball-Cube Test Phantom Preparation ..... 37
Film Scanner Setup ..... 41
Film Analysis with Automation Tool ..... 45
Introduction ..... 45
Requirements ..... 45
Install Procedure ..... 45
Preparing Images for Analysis ..... 47
Film Selection ..... 47
Procedure 3-9: Film Scanning ..... 47



177
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015


Running the E2E Program ..... 49
Starting E2E ..... 49
Loading Images ..... 49
Single Images ..... 49
Three Films at Once ..... 49
Processing Steps ..... 49
Reorienting Images ..... 51
Modifying Information ..... 51
Reference Information ..... 51
Target Ball Information ..... 51
Performing Analysis ..... 53
Single Threshold ..... 53
Changing Threshold ..... 53
Multiple Threshold ..... 53
Printing ..... 55
Saving Results to a Text File ..... 55
Showing DeltaMan Values ..... 55
Exporting Images ..... 55
Exiting ..... 55
Solutions to Common Problems ..... 57
APPENDIX ..... 59
Recommended Equipment ..... 59
TPR Table Example ..... 60
Direct TPR Measurements ..... 61
Example - Processing OCR data in PTW MEPHYSTO MC2 ..... 62
5 mm OCR Plot ..... 66
5 mm OCR Data Example ..... 67
Output Factor Table ..... 70



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118 178

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015




179

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015


# Module Description:

Learn the methods to commission the linear accelerator, and perform initial QA tasks to establish baseline values for the system.

# Module Objectives:

- Beam Measurement Data acquisition procedures.
- Absolute Dose Calibration.
- Geometric targeting accuracy test using the Ball-Cube Phantom.

**WARNING: Do NOT use any of the sample or example data for the CyberKnife Radiosurgery System calibration or QA. Use only data measured or obtained from your system. Use of example data will compromise patient safety.**



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015


**NOTE:** Page Left Intentionally Blank




Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015


# CyberKnife® TPS Requirements

## DATA ACQUISITION AND TRANSFER

Radiation therapy system Quality Assurance (QA) is the legal responsibility of the hospital or equipment owner and is usually delegated to a qualified Medical Physicist.

***The Physics of Radiation Therapy*** by: Faiz M. Khan, 2nd ed. (March 1, 1997) Lippincott, Williams & Wilkins; ISBN: 0683045024 is a primary reference and contains relevant definitions and protocols for use with the CyberKnife System. The commissioning tasks described in Module 1 must be completed before patient treatment commences.

Three types of relative measurements are required:

1. Tissue Phantom Ratio (**TPR**) data must be measured for each collimator and prepared as a single ASCII-file-format data table.
2. Off Center Ratios (**OCR**) must be taken for each collimator at five depths. 15, 50, 100, 200, and 300 mm are typically acquired. Two orthogonal scans must be taken at each depth and the results averaged.

   Each half of the average scan is then averaged to produce a file containing the radial off-axis factors per collimator at 5 depths. This results in 12 ASCII file format data tables.
3. Output factors are measured per collimator and entered into one table, the DM table.

The ASCII data files must be generated in accordance with a very specific format. These files are then converted to UNIX. They are located on the SGI Octane computer at /usr/*accuray/datafiles/site_df/beam_data/*.

**WARNING: Extra spaces or line breaks will generate serious errors in the SGI UNIX data. Patient treatments will be compromised. Print all tables from the TPS and confirm that they match the initial measured values.**

After the data is converted to UNIX, the data tables must be printed out and thoroughly checked to verify the agreement of the loaded data with the original measured values.

## EQUIPMENT REQUIRED

A chart listing all the equipment required is included as Appendix 3-1 at the end of this module.

1. A water tank beam scanning system is required. The PTW MP3 Water Phantom or any equivalent system is recommended.

   **NOTE:** The water scanning system must be capable of **0.1 mm** measurement accuracy, **NOT** 1.0 mm accuracy.

2. All measurements must be made using a set of two (2) detectors approved for radiosurgery measurements. The smallest diode detectors produce measurements that most closely match the linear accelerator (LINAC) performance capabilities.

**WARNING: It is critical that either the PTW 60008 diode or an equivalent be used for all measurements. Otherwise, the data will not be sufficiently accurate for the small radiosurgery fields, and treatment plans and dose delivered can be compromised.**



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118 182

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015

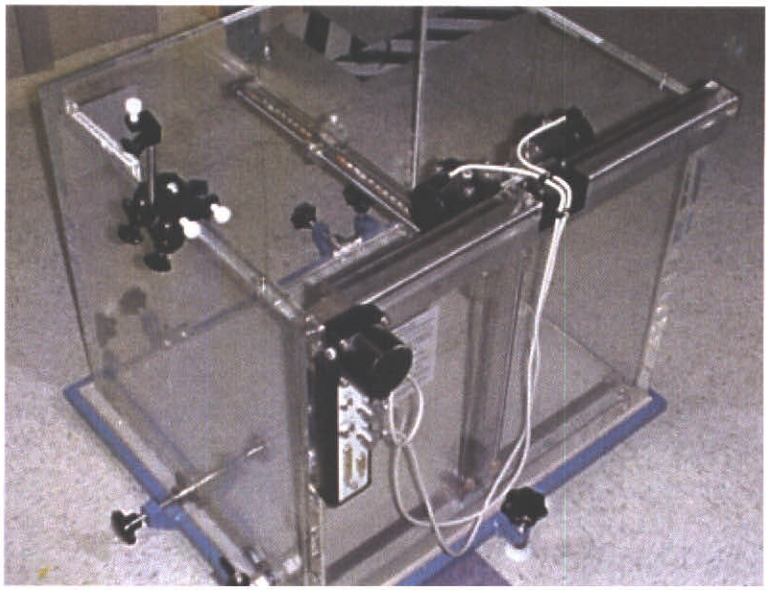



**Figure 3-1 Floor Setup**



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015


3. A calibrated Farmer-Baldwin type chamber *with a* 6 MV build up cap is required for daily output checks.

Also required is solid water phantom with BB or Beekley dot markers. Ball-Cube and AQA (Automatic Quality Assurance) geometric targeting phantoms are supplied with the system.

# BEAM MEASUREMENTS

After the LINAC laser/radiation field CAX (Central Axis) congruence has been determined to be within 1 mm at 800 mm SAD (Source Axis Distance), the rest of the data may be acquired.

**NOTE:** This test must be performed to prevent systemic error in the data sets.

The CyberKnife System uses a point laser that is coincident with the radiation field central axis as a QA tool. The laser is reflected off an adjustable mirror. The alignment must be checked periodically. Use the following procedure to check the mechanical alignment, and its congruence with the radiation central axis (CAX).

## PROCEDURE 3-1: LINAC LASER/RADIATION FIELD ALIGNMENT CHECK

1. Install the laser secondary collimator.
2. Move the robot so that the collimator is approximately 40 cm from a flat surface (floor or table). Place a piece of paper on the surface.
3. Allow the collimator to rotate by releasing the stop pin and hold.
4. Use an exposed film of optical density of 2.0 to filter the laser light and find the true center of the laser beam.
5. Rotate the collimator housing through its full range and mark the furthest extent of the laser as it walks across the paper.

   It should walk no more than 1 mm at 800 mm SAD. Although this is a subjective test, the next steps describe a more quantitative technique.
6. Place a sheet of Ready-Pack diagnostic film on a flat surface.
7. With a mirror, adjust the robot trajectory so it is perpendicular with the film by reflecting the laser back to the hole in the laser collimator.
8. Using the front pointer, adjust the SAD to 80 cm with the robot and table asa low as possible. Then, Step 14. can be done by simply moving the robot toward the ceiling using the z axis only.
9. Remove the front pointer and install the 60 mm collimator.
10. Expose the film with the appropriate number of monitor units so as to not saturate the film. For XV film, Use about 25 monitor units (without buildup).
11. Using a sharp pin, poke a hole in the film where the laser hits. This must be done very carefully so as to not shift the film inside the envelope. Immediately cover the pin prick with opaque tape to prevent adding light exposure.
12. Develop the film and measure the location of pin hole with respect to the radiation field. This can be done using the software tool ImageJ (Freeware from the NIH website).

This should not differ more than 1 mm from the center of the radiation field.

13. Repeat the above procedure at 160 cm SAD.

## PROCEDURE 3-2: BEAM SCANNING WATER TANK SETUP

1. Water tank should be placed on the floor (*Figure 3-1 Floor Setup, page 4*). If on a cart no more than 20 cm from the floor.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118 

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015

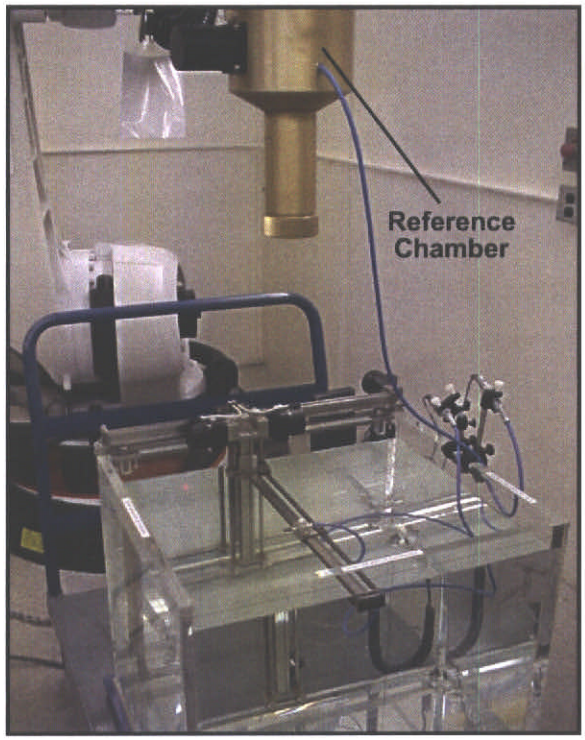




Figure 3-2 Beam Scanning Setup



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015


1. Look at diode from below the water surface. Use an alignment tool if available.
2. Scan the chamber across the surface of the water to confirm that the depths in the x and y axes are constant across the scan field.
3. Use a reference chamber mounted as in *Figure 3-2 Beam Scanning Setup, page 6*.
4. Confirm the central axis of the beam and the detector correspond in the x and y plane.
   - Reference the laser beam back to the laser alignment tool to confirm that the linac is perpendicular to the water surface.
   - Set the detector to 15 mm depth.
   - With the beam ON, scan in each direction to determine the radiation beam center, then set the 0,0,0 of the scanning system.
5. Verify that the chamber is on the beam vertical central axis.
   - Using the 5 mm secondary collimator, run the chamber up and down making sure the laser hits the same spot on the chamber at all depths.
   - Confirm that the LINAC radiation beam is truly perpendicular to the water surface. Repeat step 3. at another depth to confirm that the LINAC beam is truly perpendicular to the water surface. If necessary, adjust 0,0,0. Some scanning systems have a function to perform this exercise automatically. Some systems will only make the change at the most superficial depth, so be sure to make the correction so that the overall difference of radiation 0,0 is minimized.
6. Be sure that the electrometer is set so that the entire depth scan distance gives a good signal.
7. If the tank is not on the floor, be sure the wheels are locked on the cart.

## TISSUE PHANTOM RATIO (TPR)

The Tissue Phantom Ratio (TPR) is the ratio of absorbed dose at a given point to the dose at a fixed reference depth using constant SAD. The CyberKnife System's reference depth is 15 mm, and is fixed at 15 mm for all collimator sizes. Values can be measured directly at constant 80 cm SAD. After the data has been acquired, compare with the typical data which can be confirmed by sampling with direct TPR measurements for the large fields, and for all small fields.

This differs from a Tissue Maximum Ratio (TMR), in which data is normalized to the maximum reading obtained from the TPR curve. The depth for that maximum dose, $d_{max}$, will vary as a function of field size. However, the TPR with a fixed reference of 15 mm is used for all collimators.

The $d_{max}$ ranges from 13 mm for the 5 mm collimator to 17 mm for the 60 mm collimator.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118 186

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015

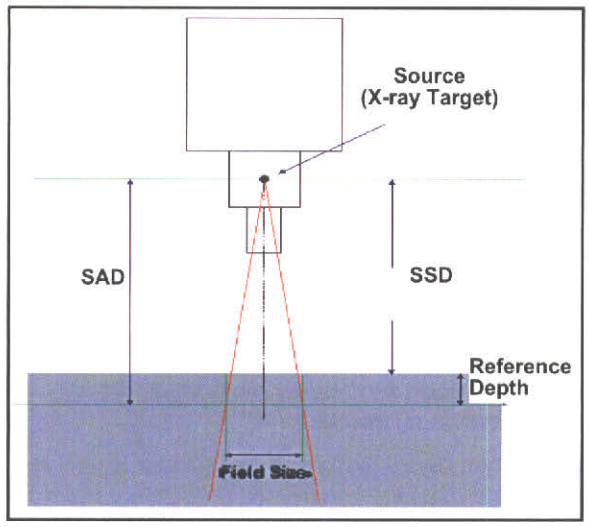




Figure 3-3 Measurement Method Diagram

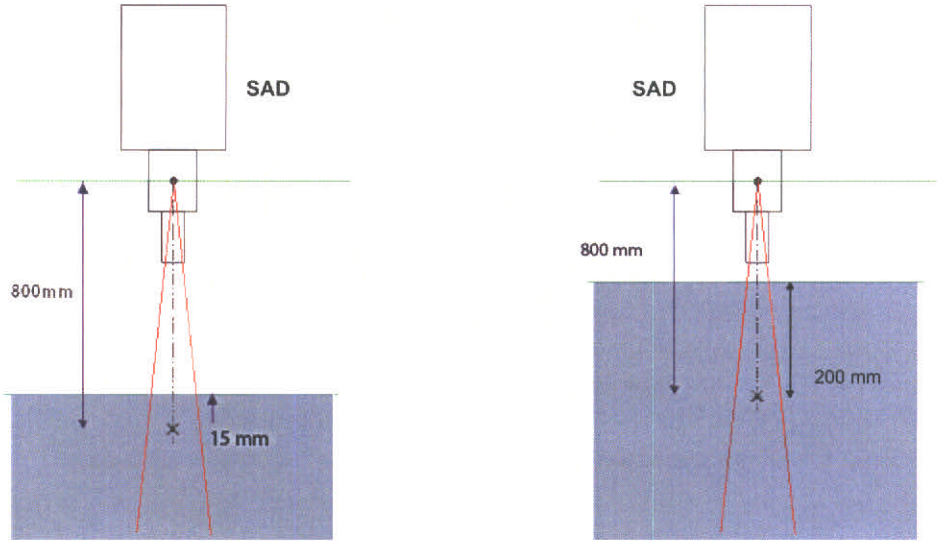



Figure 3-4 SAD TPR Measurement Setup

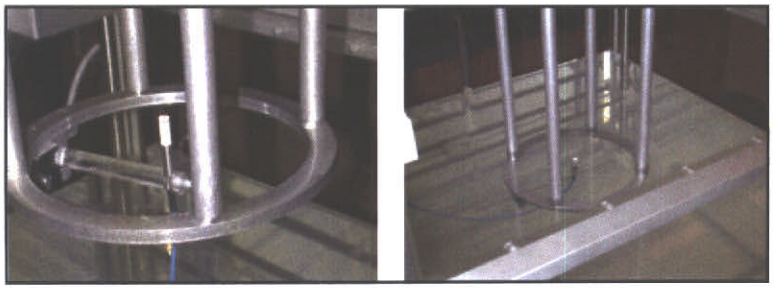


Figure 3-5 Diode Detector Holder Mounted in Bird Cage



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015


# TISSUE PHANTOM RATIO

## DIRECT TPR MEASUREMENT

Direct TPR measurement uses a constant SAD: the distance from the radiation source (X-ray target) to the axis of the detector is fixed at the distance of 80 cm from the target. As the chamber depth is changed, the target detector distance remains fixed (*Figure 3-3 Measurement Method Diagram, page 8*). The waterproof detector is mounted to the robot with an attached fixture called the Bird Cage for scanning. For changing depths of measurement, either the LINAC and chamber z positions must change, or the water level must be adjusted for each depth of measurement as in *Figure 3-4 SAD TPR Measurement Setup, page 8*. Accuray recommends that TPR be measured according to Procedure 3-3.

# PROCEDURE 3-3: DIRECT TPR MEASUREMENT

1. Water Tank Set-Up: Using the laser, position the LINAC so that the Central Axis (CAX) is perpendicular to the floor. Place a level across the secondary collimator holder to confirm.
2. Make sure that the laser is aligned. Insert the laser collimator. Rotate the collimator housing with the laser on to confirm that it does not walk.
3. Be sure the phantom is level before filling with water.
   - Confirm that the rails are truly perpendicular to the walls of the tank.
   - Use a level that is verified to be correct, compare levels etc.
   - Fill the tank to the height necessary to obtain a reading at a 300 mm depth.
4. Turn on the laser.
5. Using the Teach Pendant (TP), select **WORLD COORDINATES**, so you can operate the robot manually.
6. In joint mode, manipulate the axes such that the laser beam is reflected back at the pin hole to establish that the beam is perpendicular to the surface.
7. Remove the Farmer-Baldwin type chamber mounting holder.
8. Attach the TPR diode detector and install Bird Cage on the collimator housing. (*Figure 3-5 Diode Detector Holder Mounted in Bird Cage, page 8*).
9. Insert the diode and establish initial position using the LINAC laser.
10. Use the distance pointer to set the diode at 800 mm. Make note of the adjustable distance that can be achieved with the TPR diode detector holder.
11. Attach an electrometer.
12. Using the LINAC beam and the electrometer output, adjust the detector position so the diode is at the radiation center (maximum signal) of the X and Y axis.
13. Establish the surface position. Diode black line should be parallel with and at the water surface.
14. Record the surface position in (mm) and enter this into the yellow box in the spreadsheet shown in *Appendix 3-3: Direct TPR Measurements, page 61*. (On the TP, select MONITOR > ROBOT POSITION > CARTESIAN). Leave this screen open throughout the measurements.
15. Move the robot to -300 mm depth and verify proper tank clearances. Use the STEP motion function on the Teach Pendant (change the green arrow on the right side to select 100 - 0.1 mm steps sizes). When using this step motion, you must ensure the START + key is depressed until motion stops.
16. Return the diode to the surface position using the STEP motion function. Visually check the position to ensure it is correct.
17. Clear the room - deliver a warm-up fraction ION of 2000 Monitor Units (MU).
18. Extend the TP to the control console if possible, so that less trips into the room are required.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118 

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015

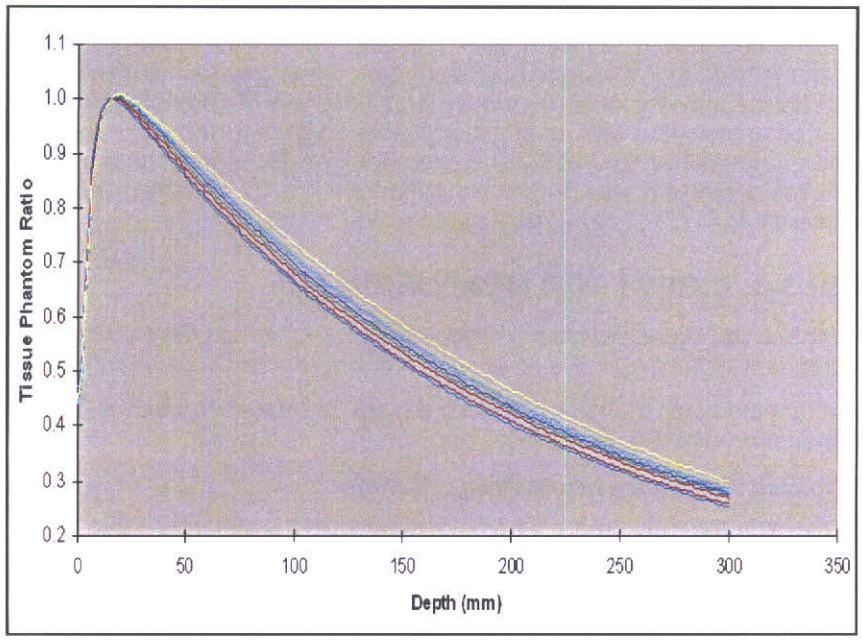




**Figure 3-6: *SAMPLE* TPR plots, normalized to 15 mm depth**

Tissue Phantom Ratio table for CyberKnife at Anytown, USA
12 Field Sizes (mm)
301 Depths (mm)

| | 5 | 7.5 | 10 | 12.5 | 15 | 20 | 25 | 30 | 35 | 40 | 50 | 60 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 0 | 0.8050 | 0.7670 | 0.7100 | 0.6900 | 0.6830 | 0.6720 | 0.6890 | 0.6720 | 0.6760 | 0.6950 | 0.6890 | 0.6780 |
| 1 | 0.8449 | 0.8063 | 0.7575 | 0.7383 | 0.7291 | 0.7183 | 0.7362 | 0.7077 | 0.7226 | 0.7375 | 0.7348 | 0.7255 |
| 2 | 0.8833 | 0.8445 | 0.8036 | 0.7853 | 0.7742 | 0.7636 | 0.7820 | 0.7435 | 0.7680 | 0.7790 | 0.7794 | 0.7717 |
| 3 | 0.9188 | 0.8808 | 0.8472 | 0.8298 | 0.8171 | 0.8067 | 0.8251 | 0.7793 | 0.8110 | 0.8185 | 0.8215 | 0.8152 |
| 4 | 0.9498 | 0.9139 | 0.8867 | 0.8704 | 0.8567 | 0.8465 | 0.8643 | 0.8151 | 0.8504 | 0.8552 | 0.8598 | 0.8548 |
| 5 | 0.9750 | 0.9430 | 0.9210 | 0.9060 | 0.8920 | 0.8820 | 0.8980 | 0.8510 | 0.8850 | 0.8880 | 0.8930 | 0.8890 |
| 6 | 0.9932 | 0.9670 | 0.9489 | 0.9354 | 0.9220 | 0.9122 | 0.9254 | 0.8862 | 0.9139 | 0.9161 | 0.9203 | 0.9170 |
| 7 | 1.0050 | 0.9850 | 0.9700 | 0.9580 | 0.9460 | 0.9370 | 0.9470 | 0.9170 | 0.9370 | 0.9390 | 0.9420 | 0.9390 |
| 8 | 1.0114 | 0.9965 | 0.9846 | 0.9740 | 0.9640 | 0.9564 | 0.9637 | 0.9400 | 0.9549 | 0.9567 | 0.9590 | 0.9559 |
| 9 | 1.0140 | 1.0030 | 0.9940 | 0.9850 | 0.9770 | 0.9710 | 0.9760 | 0.9570 | 0.9690 | 0.9700 | 0.9720 | 0.9690 |
| 10 | 1.0142 | 1.0061 | 0.9998 | 0.9928 | 0.9864 | 0.9815 | 0.9847 | 0.9704 | 0.9805 | 0.9798 | 0.9819 | 0.9793 |
| 11 | 1.0130 | 1.0070 | 1.0030 | 0.9980 | 0.9930 | 0.9890 | 0.9910 | 0.9810 | 0.9890 | 0.9870 | 0.9890 | 0.9870 |
| 12 | 1.0109 | 1.0065 | 1.0043 | 1.0009 | 0.9975 | 0.9945 | 0.9958 | 0.9892 | 0.9941 | 0.9922 | 0.9938 | 0.9924 |
| 13 | 1.0080 | 1.0050 | 1.0040 | 1.0020 | 1.0000 | 0.9980 | 0.9990 | 0.9950 | 0.9970 | 0.9960 | 0.9970 | 0.9960 |
| 14 | 1.0043 | 1.0029 | 1.0025 | 1.0015 | 1.0007 | 0.9997 | 1.0001 | 0.9983 | 0.9988 | 0.9986 | 0.9990 | 0.9985 |
| 15 | 1.0000 | 1.0000 | 1.0000 | 1.0000 | 1.0000 | 1.0000 | 1.0000 | 1.0000 | 1.0000 | 1.0000 | 1.0000 | 1.0000 |
| 16 | 0.9956 | 0.9963 | 0.9966 | 0.9978 | 0.9984 | 0.9994 | 0.9993 | 1.0010 | 1.0005 | 0.9999 | 0.9999 | 1.0005 |
| 17 | 0.9910 | 0.9920 | 0.9930 | 0.9950 | 0.9960 | 0.9980 | 0.9980 | 1.0010 | 1.0000 | 0.9990 | 0.9990 | 1.0000 |
| 18 | 0.9862 | 0.9876 | 0.9896 | 0.9917 | 0.9931 | 0.9957 | 0.9957 | 0.9998 | 0.9983 | 0.9977 | 0.9976 | 0.9987 |
| 19 | 0.9810 | 0.9830 | 0.9860 | 0.9880 | 0.9900 | 0.9930 | 0.9930 | 0.9980 | 0.9960 | 0.9960 | 0.9960 | 0.9970 |
| 20 | 0.9755 | 0.9781 | 0.9817 | 0.9841 | 0.9867 | 0.9902 | 0.9902 | 0.9961 | 0.9937 | 0.9937 | 0.9942 | 0.9952 |
| 21 | 0.9700 | 0.9730 | 0.9770 | 0.9800 | 0.9830 | 0.9870 | 0.9870 | 0.9940 | 0.9910 | 0.9910 | 0.9920 | 0.9930 |

Table continues to a depth of 300mm in 1 mm increments.

**Figure 3-7 SAMPLE ASCII TPR table**



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

189

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015


**19.** Using the TP, move the robot using world coordinates. Readings are required at approximately 20 depths to generate a TPR curve. *Appendix 3-3: Direct TPR Measurements, page 61* contains a sample spread sheet that may be used to record the readings. All readings must be corrected for the reference detector value. Measurements must be obtained for each secondary collimator.

**NOTE:** Do not use more than 301 data points, 0 to 300 mm.

**20.** The values for each collimator must be normalized to the depth of 15 mm.

**21.** Using a cubic spline fit, a TPR curve is generated. *Appendix 3-3: Direct TPR Measurements, page 61* displays the TPR measurement and interpolation Excel sheet. The spread sheet can be obtained from the Customer Support Physicst.

**22.** From the TPR curve, interpolated TPR values are generated to produce equidistant 1 mm data points. The TPR table requires 301 data points, from 0 to 300 mm, in 1 mm steps. (*Appendix 3-3: Direct TPR Measurements, page 61)*

**23.** Process the data normalized to 15 mm depth for each scan. TPR for any collimator is relative to the measurement at the reference depth (15 mm) (*Figure 3-6: SAMPLE TPR plots, normalized to 15 mm depth, page 10*). Therefore, the TPR at 15 mm depth is 1.0 by definition for each collimator. There will be 301 data points per collimator. Refer to the ASCII Sample TPR Data Table (*Figure 3-7 SAMPLE ASCII TPR table , page 10*).

**NOTE:** $d_{max}$ for the 5 mm collimator is 13 mm. For the 60 mm collimator it is 16 mm or 17 mm.

**24.** Convert the data to one table in the required ASCII format. Refer to the sample TPR table (*Figure 3-7 SAMPLE ASCII TPR table , page 10*). See *Appendix 3-2: TPR Table Example, page 60* for an example of a complete TPR data table.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118 

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015

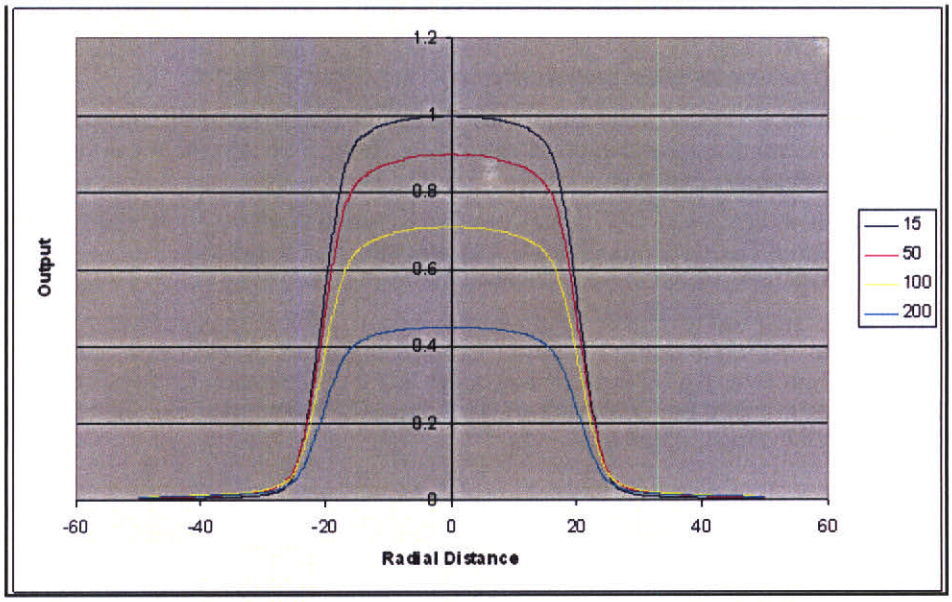




**Figure 3-8: *SAMPLE* OCR Measured Profiles**



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015


**25.** Verify that the table is correctly typed without extra spaces or line inserts as shown in the TPR table in *Figure 3-7 SAMPLE ASCII TPR table , page 10.*

1st line: Identifier for the local institution

2nd line: <*Number of Collimators* (integer)> and label

3rd line: <*Number of Depths* (integer)> and label

4th line: <*Field sizes in mm* (floating point)>

5th - nth line: <*Depth in mm* (integer)> <*TPR values* (floating point)>

**WARNING: Extra spaces or line breaks will generate serious errors in the SGI UNIX data. Patient treatments will be compromised. Print all tables from the TPS and confirm that they match the initial measured values.**

The Filename is *TMRtable.dat*

Location: Primary SGI workstation in */accuray/datafiles/site_df/beam_data*

**26.** All tables must be printed or plotted. Identify any errors and confirm the validity of the Unix beam data.

# OFF CENTER RATIO MEASUREMENTS

**OCR – Off Center Ratio** – OCR is the ratio of the absorbed dose at a given off-axis point relative to the dose at the central axis at the same depth. By definition, the central axis (CAX) value is 1.

These profiles are represented in the OCR measured profiles *Figure 3-8: SAMPLE OCR Measured Profiles, page 12.*

## OFF CENTER RATIO SCAN METHODS

The Off Axis Ratios are calculated from orthogonal sets of scans across the radiation field. They can be scanned using either the direct constant SAD or fixed SSD method. If the SSD method with a constant 80 cm target to water surface distance is used, the measurements will have to be geometrically corrected for an SAD setup. Using the TP to move the robot up and down the Z axis to obtain the profiles reduces the amount of data processing required, and can be done quickly and precisely. The chamber depth is then adjusted to maintain the 800 mm SAD distance. Some scanning systems can change water levels to maintain the 800 mm SAD levels.

Off Center Ratio Factors are all relative to the central axis dose so the OCR factor is 1.0 by definition for each depth and each collimator for a radial distance of 0 (at the central axis).

## MEASUREMENT REQUIREMENTS:

**Depths:** 5 depths such as 15 mm, 50 mm, 100 mm, 200 mm, and 300 mm are typical depths for extracranial radiosurgery.

**Resolution:** 1.0 mm for collimators greater than 20 mm. Use 0.5 mm or less for collimators 20 mm and less.

**Range:** 50 mm max on each side of central-axis except for secondary collimators 15 mm and less which ***must be*** measured to 30 mm each side of the central axis. Do not exceed more than 500 data points.

**Target to Detector Distance:** The SAD can remain fixed at 80 cm if the robot is moved using the TP in WORLD coordinates to adjust the distance every time the detector depth is changed. The scanning takes a little longer but the time required for data processing is significantly reduced, and associated errors are also minimized.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118 

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015


**5.0 collimator_size (mm)**
**5 depths (mm)**
**21 radial measurements (mm)**

| | 15 | 50 | 100 | 200 | 300 |
|---|---|---|---|---|---|
| 0.0 | 1.0000 | 1.0000 | 1.0000 | 1.0000 | 1.0000 |
| 0.5 | 0.9823 | 0.9828 | 0.9836 | 0.9827 | 0.9821 |
| 1.0 | 0.9270 | 0.9285 | 0.9301 | 0.9290 | 0.9289 |
| 1.5 | 0.8304 | 0.8323 | 0.8350 | 0.8358 | 0.8374 |
| 2.0 | 0.6932 | 0.6962 | 0.7013 | 0.7048 | 0.7081 |
| 2.5 | 0.5302 | 0.5356 | 0.5430 | 0.5502 | 0.5558 |
| 3.0 | 0.3701 | 0.3772 | 0.3858 | 0.3978 | 0.4060 |
| 3.5 | 0.2393 | 0.2471 | 0.2562 | 0.2700 | 0.2802 |
| 4.0 | 0.1477 | 0.1560 | 0.1644 | 0.1766 | 0.1870 |
| 4.5 | 0.0903 | 0.0986 | 0.1053 | 0.1158 | 0.1247 |
| 5.0 | 0.0569 | 0.0644 | 0.0696 | 0.0785 | 0.0859 |
| 5.5 | 0.0379 | 0.0446 | 0.0488 | 0.0560 | 0.0623 |
| 6.0 | 0.0271 | 0.0330 | 0.0366 | 0.0423 | 0.0474 |
| 6.5 | 0.0206 | 0.0260 | 0.0292 | 0.0338 | 0.0378 |
| 7.0 | 0.0166 | 0.0214 | 0.0243 | 0.0283 | 0.0316 |
| 7.5 | 0.0138 | 0.0183 | 0.0209 | 0.0246 | 0.0275 |
| 8.0 | 0.0120 | 0.0160 | 0.0184 | 0.0218 | 0.0246 |
| 8.5 | 0.0107 | 0.0144 | 0.0166 | 0.0196 | 0.0222 |
| 9.0 | 0.0097 | 0.0132 | 0.0152 | 0.0180 | 0.0202 |
| 9.5 | 0.0091 | 0.0122 | 0.0142 | 0.0168 | 0.0188 |
| 10.0 | 0.0086 | 0.0115 | 0.0133 | 0.0159 | 0.0177 |
| 10.5 | 0.0083 | 0.0109 | 0.0126 | 0.0152 | 0.0168 |
| 11.0 | 0.0079 | 0.0104 | 0.0121 | 0.0145 | 0.0162 |
| 11.5 | 0.0076 | 0.0100 | 0.0117 | 0.0139 | 0.0158 |
| 12.0 | 0.0074 | 0.0097 | 0.0113 | 0.0135 | 0.0154 |
| 12.5 | 0.0073 | 0.0094 | 0.0110 | 0.0132 | 0.0150 |

The table continues to a radial distnace of 30 mm.

**Figure 3-9 ASCII OCR Table Example**





Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015


## PROCEDURE 3-4: OFF CENTER RATIO BEAM PROFILE SCANNING

All measurements are done either at 800 mm SAD, or corrected from an SSD measurement to the 80 cm SAD equivalent. An example of a method to process the data using the PTW water scanning system is supplied at the end this module in Appendix 3-4.

**WARNING: Use the Measurement Requirement Range from the previous section. The dose calculation will extrapolate from the last two data points entered for each OCR curve. If the data is not acquired at a great enough distance from the central axis, dose will be incorrectly computed, and an inadequate dose will be delivered from those beams where points are distant from the central axis. This occurs frequently for non-isocentric beams.**

1. Acquire an orthogonal set of scans (in-plane and cross-plane) at each required depth listed above. Use the correct resolution appropriate for the collimator diameter.
2. After scanning is complete, process the data by taking the average of the two orthogonal scans. In *Appendix 3-4: Example - Processing OCR data in PTW MEPHYSTO MC2, page 62,* the PTW procedure for processing OCR data is described.

   **NOTE:** If an SSD setup was used, the data must be geometrically corrected to the SAD equivalent.

3. Then average each side to end up with the average of 4 half scans.
4. Renormalize to the central axis to produce the radial OCR data per collimator. The profiles should look like those in *Appendix 3-5: 5 mm OCR Plot, page 66.*

   **NOTE:** The radial distance of the 50% relative dose should be equal to the radius of the collimator.

5. Generate the OCR values in numerical form.
6. Then, type the numerical values in the precise ASCII format shown in the OCR table in *Figure 3-9 ASCII OCR Table Example, page 14.*

   Verify that the lines are as follows:

   1st line: <Collimator Size in mm (floating point)> and label

   2nd line: <*Number of Depths* (integer)> and label

   3rd line: <*Number of Measurements at each depth* (integer)> and label

   4th line: <*Depths in mm* (integer)>

   5th – nth line: <*Radial dist in mm* (floating point)> <*OCR factors* (floating point)>

7. The 5 mm collimator filename will be **OCRtable0**, and the 60 mm collimator will be the **OCRtable11** as required by the file naming system. An example of a complete OCR table can be found in *Appendix 3-6: 5 mm OCR Data Example, page 67.*

   **NOTE:** Confirm that the OCR values match those available from Customer Support Physicists before converting to UNIX.

   The location on the Primary SGI workstation is: /accuray/datafiles/site_df/beam_data.

   The filenames are: OCRtableX.dat.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118 194

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015

**Figure 3-10 Secondary Collimator**

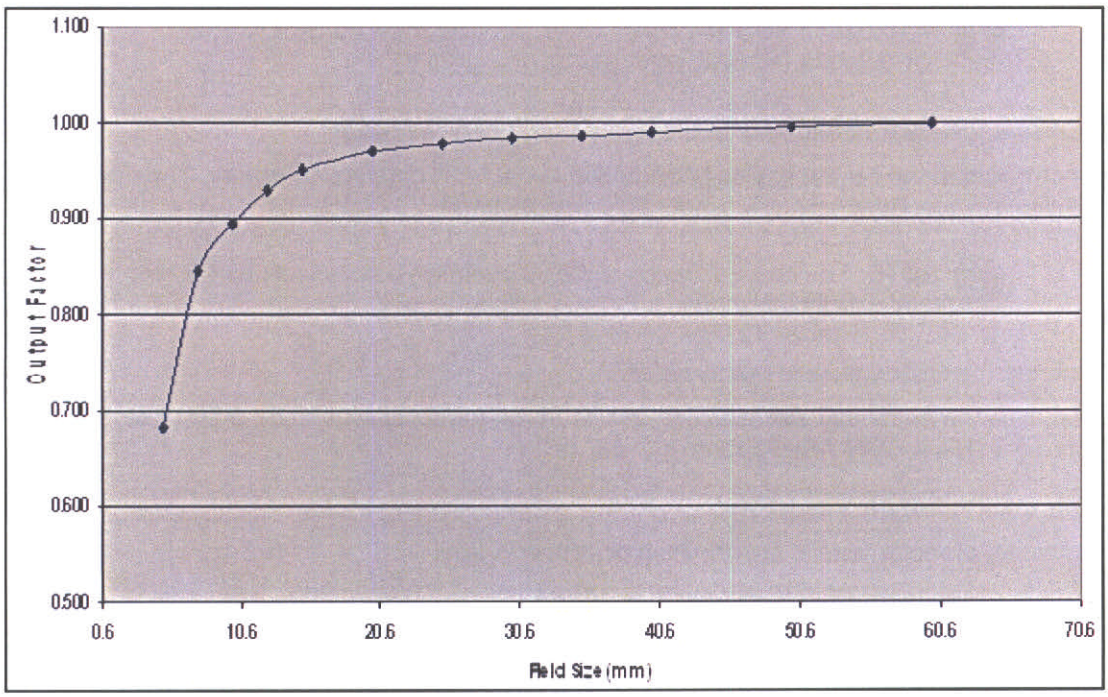



**Figure 3-11 *SAMPLE* Output Factor Plot**

Output factor Table for CyberKnife G4 at CK Center, Anytown, USA
12 Field Size (mm)
1 depth Size (mm)

| | 5.0 | 7.5 | 10.0 | 12.5 | 15.0 | 20.0 | 25.0 | 30.0 | 35.0 | 40.0 | 50.0 | 60.0 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 15 | 0.7200 | 0.8740 | 0.9140 | 0.9430 | 0.9530 | 0.9690 | 0.9760 | 0.9830 | 0.9860 | 0.9900 | 0.9950 | 1.0000 |

**Figure 3-12 *SAMPLE* Output Factor table**



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

195

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015


# OUTPUT FACTORS

**OF** – Output Factor – The ratio of the absorbed dose of a particular field size relative to the dose at a reference field size. The CyberKnife System reference field size is 60 mm.

The Field Size is determined by the secondary collimator dimension (*Figure 3-10 Secondary Collimator, page 16*). The size of the radiation field produced is defined at the CyberKnife reference SAD of 80 cm. The Full-Width Half-Maximum (FWHM), the distance between plus and minus 50% of the central axis maximum dose is the actual field size. The FWHM can be measured from the OCR profiles.

There are a number of issues that must be evaluated to obtain correct results. Also, detector setup geometry influences the accuracy and validity of the measurement result. see Robotic Radiosurgery Volume 1, Chapter 8, Table 1, and see Medical Physics Volume 32, #6, P. 2004 Abstract SU-FF-T238

## PROCEDURE 3-5: OUTPUT FACTOR MEASUREMENT METHOD

1. Set the small field diode at a depth of 1.5 cm.
2. The source to detector distance (SDD) must be 80 cm. The SSD will be 78.5 cm.
3. Be sure that the 5 mm collimator is perfectly centered to the detector. Search for the point of maximum reading. For the 400 MU/min LINAC, the expected range for the measured OF is from .68 to .72, with greater extremes in either direction dependent upon the detector used for the measurement. The detector must be small relative to the diameter of the field, therefore Film or MOSFETS will provide most accurate results relative to the expected values.

   **NOTE:** Take appropriate measures to correct for variability of detector types.

4. Measure the output for every collimator. Refer to the section, Detector Scatter in Appendix 3-7 for additional information regarding detector specifications.
5. Divide the readings by the 60 mm collimator output reading to determine the output factor for each collimator.
6. The output factor of the 60 mm collimator is 1.
7. Plot the values on the representative curve to confirm that the data is correct. The curves should be very similar to that in *Figure 3-11 SAMPLE Output Factor Plot, page 16.*
8. Type the measurements into the required ASCII format as indicated in *Figure 3-12 SAMPLE Output Factor table, page 16.* Appendix 3-8 contains a complete output factor, DM table and plot.

   Filename: *DMtable.dat*

   Location: Primary SGI workstation in /accuray/datafiles/site_df/beam_data
9. The Treatment Planning System requires the following beam data tables:
   - Output Factor table – one file.
   - Tissue Phantom Ratio table – one file.
   - Off-Center Ratio table – one file for each collimator.

   **NOTE:** After creating the files with the appropriate format and uploading them to the specified directory of the primary workstation, they must be converted to the UNIX forrmat using the "to_unix" command.

**WARNING: Verify that the file contents and format are correct by printing and/or plotting the data using the tools provided by your TPS. Use of incorrect data can result in patient mistreatment.**



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015

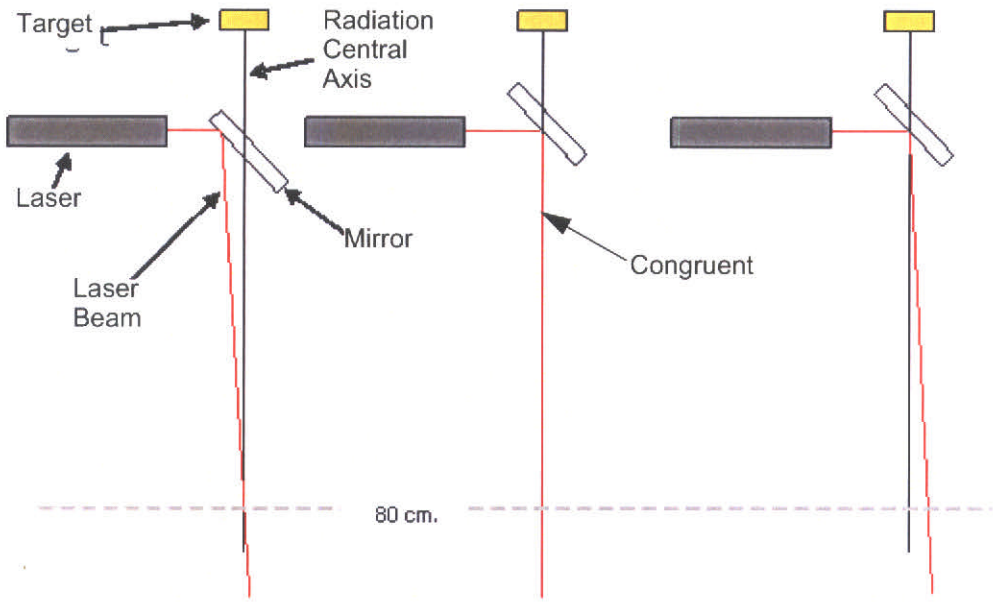




**Figure 3-13 Laser/Radiation CAX Congruence**

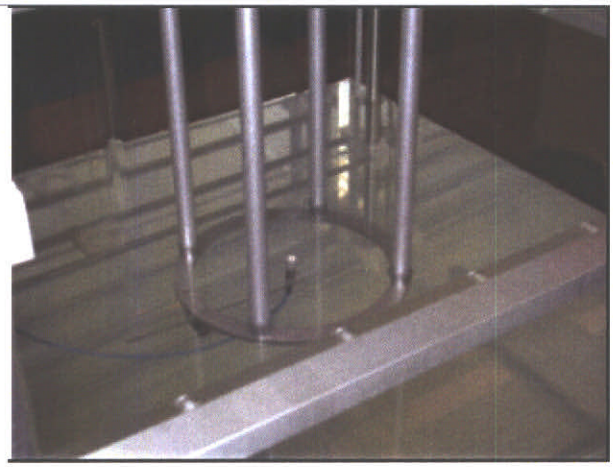


**Figure 3-14 Diode Water Surface Setup**



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

197

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015


## SUMMARY OF BEAM DATA MEASUREMENT REQUIREMENTS

For all measurements, the radiation central axis must be perpendicular to the water surface. The beam angle must be less than 0.2 degrees from perpendicular. First perform laser/radiation field CAX congruence tests described in *Procedure 3-1*. Note the laser position vector on the sheet of film relative to the actual radiation CAX. Congruence must be less than 1 mm at 80 cm SAD, and less than 2 mm at 160 cm SAD.

### TPR Measurements

**SETUP**: Fixed target to detector distance with 800 mm SAD. See *Figure 3-14 Diode Water Surface Setup, page 18.*

Acquire readings at 21 depths per the spreadsheet Beam Data Acquisition in *Appendix 3-3: Direct TPR Measurements, page 61*. Correct readings for the reference chamber readings.

Acquire the 5 mm collimator first to determine if your setup is correct. Generate a cubic spline fit curve and generate the values every mm and compare measured TPR values with the composite data values supplied by the Customer Support Physicist. If the 5 mm collimator has good agreement (≤ 3%) with the rest of the TPR data should be as good as the composite data.

### OCR Measurements

**SETUP**: May be done at 80 cm SSD, then convert data to SAD equivalent.

**Scan Parameters (See Table 3-1)** Use medium to slow scan speeds, and medium to large sample size, i.e. longer acquisition time per point measurement

**Table 3-1: Scan Parameters**

| **Collimator Size** | 5 and 7.5 mm | 10 to 20 mm | 25 to 60 mm |
|---|---|---|---|
| **Scan width** | +/- 300 mm | +/- 300 mm | +/- 500 mm |
| **Scan depths** | 15, 50, 100,200,300 mm | | |
| **Scan Spacing between measurement points** | 0.2 mm or 0.5 mm | 0.5 mm | 1 mm |
| **Equidistant** | Data Points MUST be equidistant and may not exceed a total of 500 total data points per scan. | | |
| **Data processing:** | Center the inplane and crossplane profiles at each depth and smooth the curves. Add inplane and crossplane scans. Average them, then fold or average again. *Appendix 3-4: Example - Processing OCR data in PTW MEPHYSTO MC2, page 62* contains the PTW $MC^2$ procedure for processing OCR profiles and generating data tables as an example. | | |

### Output Factors (DM Table) Measurement

**SETUP**: Water surface is 78.5 cm SSD.

Diode Detector Depth 15 mm to the detectors measurement plane.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015

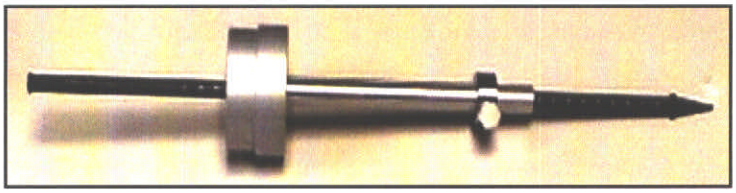



**Figure 3-15: Front Pointer**



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

199

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015


# DOSE CALIBRATION

## CYBERKNIFE ABSOLUTE DOSE CALIBRATION

There are a number of absolute dose calibration protocols available throughout the world. In the U.S., the current protocol is published by Task Group 51 of the American Association of Physicists in Medicine. IAEA 398 is very similar to this protocol and is used at many international sites. Task Group 21 is an older calibration protocol still used at some sites in the U.S. A negligible difference results using the different protocols. To perform the calibration with the CyberKnife System, some accommodations are needed to adapt the protocols to the 80 cm SAD distance for the 60 mm circular field secondary collimator.

One method of accomplishing this for the TG51 protocol is presented here, and the same method can be used with the IAEA 398 protocol. If further assistance is required, please contact customer support and ask for a physicist to supply commissioning information.

## GENERAL FORMALISM FOR TG51

The TG51 protocol is based on absorbed dose to water in a Co 60 beam and can be found in Medical Physics ys Vol 26 (9), 1999, 1847 – 1870. Measuring $k_Q$ is the only item that must be determined using two corrections for the Cyberknife configurations.

$$D_w^Q = M \quad N_{D,w}^Q$$

Dose in water equals the electrometer reading times the chamber factor times $k_Q$.

Electrometer Reading,

$$M = M_{raw} \prod P$$

Chamber Factor,

$$N_{D,w}^Q = N_{D,w}^{Co-60} \; k_Q$$

**Medical Physics Vol 26 (9), 1999, 1847 – 1870**

## BEAM QUALITY SPECIFICATION

The TG51 protocol requires that $k_Q$ must be determined from beam quality, using a percent depth dose measurement. The Cyberknife is a 6 MV beam with a $d_{max}$ of approximately 15 mm with minimal electron contamination. The Beam Quality Specification requires measurement of the PDD (Percent Depth Dose).

Setup Requirements for PDD measurement:

d=10 cm, SSD=100 cm, FS = 10x10 cm (@100 cm) where SSD is the source to surface distance and FS is field size, d = depth.

Since the CyberKnife maximum collimator size is 60 mm, how can $k_Q$ be obtained? First, convert the circular field size to the equivalent square field size (ESFS). Then, measure the PDD at the extended distance of 100 SSD with 60 mm collimator. Compare the resulting d10 PDD value with a standard reference such as the British Journal of Radiology (BJR) for the 6.75 cm equivalent square field size. From this, one can infer what the PDD would be for the equivalent 10 X 10 FS.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

200

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015


**Table 3-2: Square Field Size**

| Collimator Size (cm) | Eqv. Square FS (cm) @ 80cm SSD | Eqv. Square FS (cm @ 100cm SSD |
|---|---|---|
| 0.5 | 0.45 | |
| 0.75 | 0.68 | |
| 1.0 | 0.90 | |
| 1.25 | 1.13 | |
| 1.5 | 1.35 | |
| 2.0 | 1.80 | |
| 2.5 | 2.25 | |
| 3.0 | 2.70 | |
| 3.5 | 3.15 | |
| 4.0 | 3.60 | |
| 5.0 | 4.50 | |
| **6.0** | **5.40** | **6.75** |

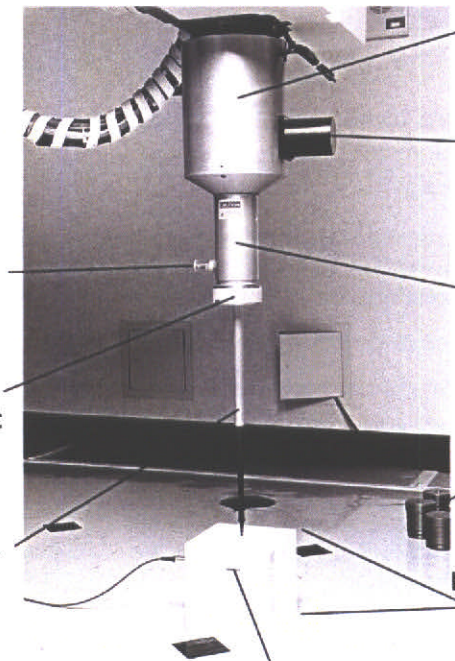



**Figure 3-16 Example of Verification of Dosimetry Calibration**



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

201

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015


To determine the equivalent square field size (ESFS) of the circular 60 mm collimator at 100 SSD, use the following information. CyberKnife fields are circular and defined at 80cm SSD. The diameter of the collimator is multiplied by 0.9 to determine the ESFS as in equation (Eq.1).

Convert the circular field size to the equivalent square.

ESFS (80) = .9 x Circular Field Size (Collimator @ 80 cm SAD)[1] **(Eq.1)**

For an extended SSD of 100 cm, the ESFS becomes larger by the relationship expressed in equation (Eq.2).

FS(100) = 100/80 x ESFS (80) **(Eq.2)**

ESFS (100) = 1.125 x ESFS (80)

So, the 60 mm collimator at 80 SAD is equal to the ESFS of 67.5 mm at 100 SSD. Refer to Table 3-2 on Page 3-22.

**CyberKnife ESFS**

| Collimator Size (cm) At 80 SSD = 6.0 cm | Eqv. Square FS (cm) @ 100 cm = 6.75 cm |
|---|---|

## PROCEDURE 3-6: CYBERKNIFE $K_Q$ BEAM QUALITY MEASUREMENT

1. Set up water tank or solid water phantom.
2. Measure at 100 cm SSD. Use the TP to manually drive the Robot. (Refer to Module 5 for details of manual robot operation).
   - Set robot normal to surface using laser and SSD=91 cm with front pointer (*Figure 3-15: Front Pointer, page 20*). Set up as in *Figure 3-16 Example of Verification of Dosimetry Calibration, page 22*
   - With the robot set to **WORLD** co-ordinates mode, move upwards 9 cm so that the linac target is 100 cm to the water surface.

   **CAUTION:** Alternatively, you could manufacture a front pointer suitable for SSD 100 cm, but do NOT push it too far in! Avoid this by making a stopper/flange. The mirror could be damaged.

3. Acquire a reading at 15 mm depth. Obtain a reading at 100 mm depth. Compute the PDD.
4. Compare the CyberKnife measured d10 PDD with the 6.75 mm equivalent from a known data source such as the BJR 25. From this value, the equivalent associated value for a 10x10 FS can be inferred.

After the beam energy has been determined, perform a hard calibration using the Absolute Dose Calibration of your choice such as TG 51 or IAEA 398 protocol.

The CyberKnife dose is then established to be 1 cGy equals 1 MU at 78.5 SSD and a depth of 15 mm.

1. From Day MJ & Aird EGA in BJR sup 25, 1996, p138-153. At 80 SSD, the 60 mm collimator is equal to a 5.4 cm equivalent square.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118 

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015

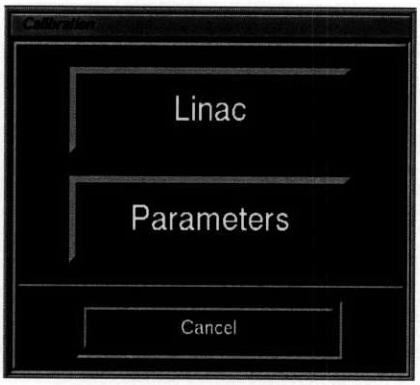




**Figure 3-17 Calibration Options**

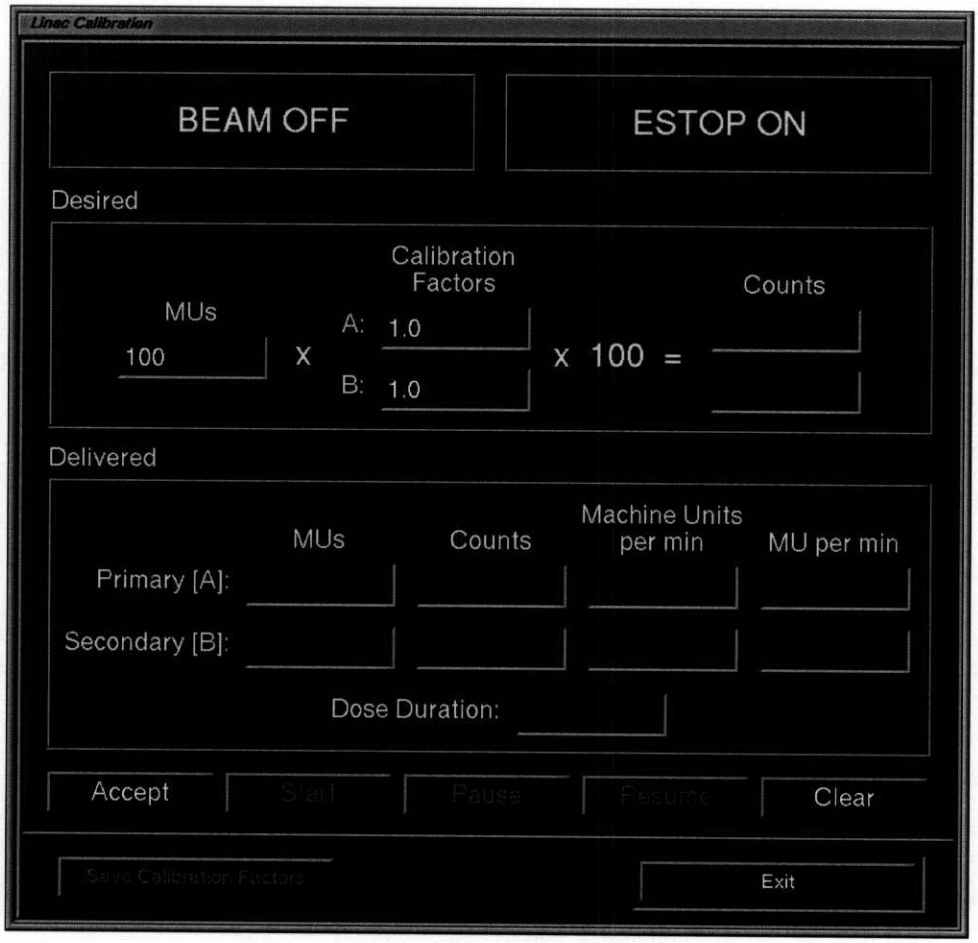



**Figure 3-18 LINAC Calibration Menu**



203
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015


# LINAC CALIBRATION

## Calibrating the LINAC from Physics Linac

(*Figure 3-19 Calibration factor Confirmation Message, page 26*) This procedure allows the user responsible for calibrating the CyberKnife System dosimeters to turn on the LINAC beam and measure dose with a standard radiation detector. The calibration is used to set factors (counts/MU) for dosimetry channels A and B.

### CyberKnife System Menu -> Physics -> Linac -> Calibration

To calibrate the LINAC, you must have at least Access Level 2.

Use the same setup as you use for your monthly or daily output check (*Module 5, Procedure 5-2 linac Daily Output Constancy Check*). *Figure 3-16 Example of Verification of Dosimetry Calibration, page 22*, shows a sample dosimetry calibration set up.

1. Turn on equipment power.

When the equipment power is on, the **PHYSICS** button on the CyberKnife System menu is active.

2. Click the **PHYSICS** button. The Calibration Options Menu opens (*Figure 3-17 Calibration Options, page 24*).

**WARNING: Do not modify the Calibration Factor unless you are the qualified Medical Physicist.**

3. Click the **LINAC** button.

When the LINAC calibration computer is ready, the LINAC Calibration window (*Figure 3-18 LINAC Calibration Menu, page 24*) appears with the **START**, **PAUSE**, **RESUME** and **SAVE CALIBRATION FACTORS** buttons inactive. In addition, the default value in the MU's text area is 100 and the values in the Calibration Factors text areas for dosimeters A and B are both 1.000.

4. To change the monitor units to be delivered, type the value in the text area under MU's and press **ENTER**. The text pointer moves to the Calibration Factors text area for dosimeter A. Type in the value. Press **ENTER** to move text pointer to the text area for dosimeter B. Type in the value.

   To clear all values, click **CLEAR**. The **ACCEPT** button becomes active and the **START**, **PAUSE** and **RESUME** buttons become inactive.

5. After the desired values are entered, click **ACCEPT**. The **START** button becomes active and the **ACCEPT** button becomes inactive.
6. Click the **START** button. The green E-Stop on sign becomes a red E-Stop off sign. A message instructing you to "Turn on High Voltage" appears. The **START** and **CLEAR** buttons become inactive.
7. Turn on the high voltage. Make sure the "radiation enable" key is in the "high voltage enable" key switch on the user panel and turned clockwise. Push the **ON** button in the High Voltage section of the user control panel. The high voltage is now on and radiation can be generated.
8. Once high voltage is on, the delivery of radiation begins. The green beam off sign becomes a red Beam on sign. **PAUSE** becomes active. The monitor units, counts, MU per minute and dose duration are shown in the Delivered section of the Linac Calibration window.

   To pause delivery of radiation, click **PAUSE**. The radiation beam terminates and the E-Stop is on. The green Beam off and E-Stop on signs are displayed. The **RESUME** button is active and **PAUSE** becomes inactive. If delivery has been paused, resume delivery of radiation by selecting **RESUME**. The system prompts you to turn on the high voltage. When high voltage is on, radiation continues to be delivered from where it was paused. The **RESUME** button becomes inactive and **PAUSE** is active.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

204

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015

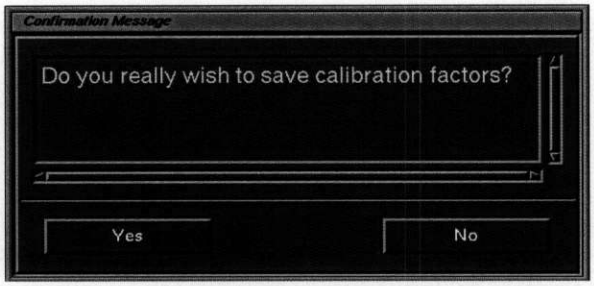




**Figure 3-19 Calibration factor Confirmation Message**



205
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015


9. When the delivered MU has been measured in one chamber, radiation delivery ceases. Use the measured data to update calibration factors.
10. When you are satisfied with the results of the calibration and ready to save the factors, click **SAVE CALIBRATION FACTORS**. The Confirmation Message appears *Figure 3-19 Calibration factor Confirmation Message, page 26*. It contains a message asking you to confirm the new calibration factors. Click **YES** to save the factors. Clicking **NO** returns to the Linac Calibration window.
11. Repeat the output and verify that the expected nC reading is obtained with the new calibration factors.

## Errors

If errors occur, an E-Stop is activated and the radiation beam terminates. Errors appear in the Linac Calibration Error Message. If the errors are recoverable, the calibration procedure can continue after the corrections are completed and the system reset. To reset system, click the **RESET** button. A message shows that the system is being reset. When the reset is completed, click **CONTINUE**. The error message disappears and the Linac Calibration window appears.

If errors are not recoverable, you must exit the Linac calibration process and restart the power. Clicking **CONTINUE** on the error message returns to the Linac Calibration window. This window has only the **EXIT** button active. Click **EXIT** to get the confirmation message. Click **YES** to start the exit sequence. During the exiting process, the electrical power to the Linac turns off.

## Viewing and Modifying Calibration Factors from The Parameters Screen

(*Figure 3-21 New Calibration Factors Entry Form, page 28*) You can view the current dosimeter calibration factors and modify them without calibrating the Linac.

**CyberKnife System Menu -> Physics -> Parameter -> New Calibration Factor**

## To view calibration factors

To view calibration factors, the Linac user must have at least Access Level 2.

Click the **PHYSICS** button on the CyberKnife System menu, click **PARAMETERS** button and the Calibration Factors window (*Figure 3-21 New Calibration Factors Entry Form, page 28*) appears. It contains the most recent factors and the date they were entered into the CyberKnife System database.

**WARNING: Do not modify the Calibration Factor unless you are the qualified Medical Physicist.**



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118 206

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015

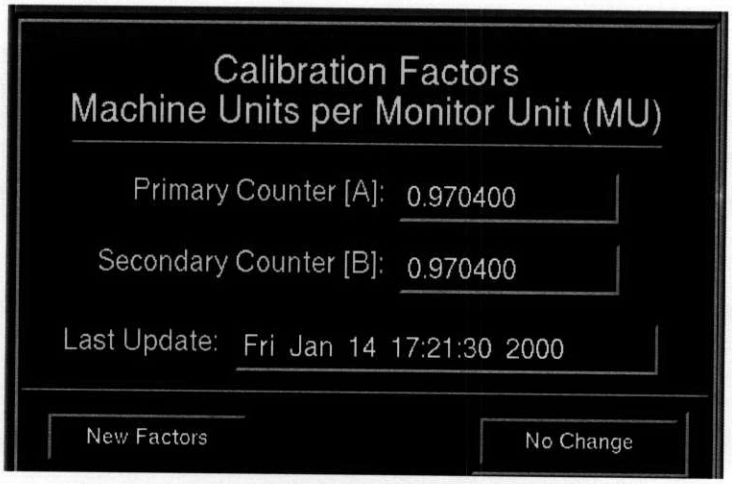




**Figure 3-20 Calibration Factors Verification**

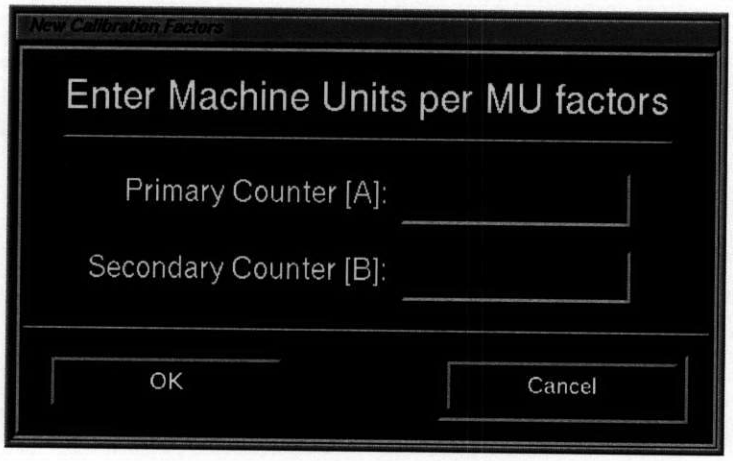



**Figure 3-21 New Calibration Factors Entry Form**

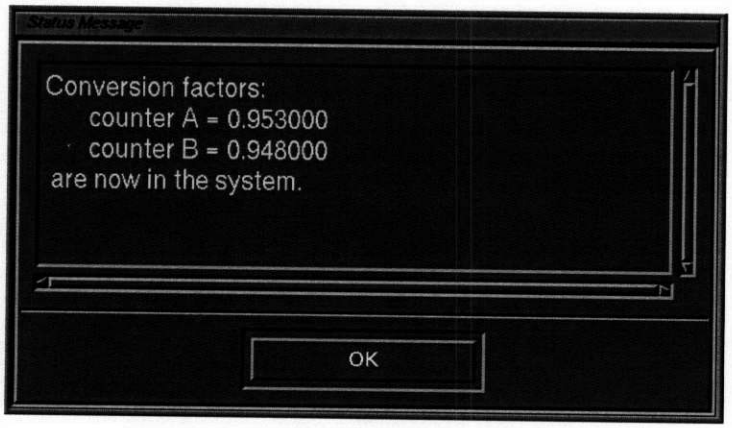



**Figure 3-22 Calibration Factor Status**



207
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015


## Modify calibration factors

1. Click the **NEW FACTORS** button on the Calibration Factors window (*Figure 3-20 Calibration Factors Verification, page 28*).

The Calibration Factors window disappears and the New Calibration Factors window (*Figure 3-21 New Calibration Factors Entry Form, page 28*) appears.

Clicking **NO CHANGE** on the Calibration Factors window redisplays the Calibration window.

2. To make a change, place the cursor in either the Primary Counter [A] or Secondary Counter [B] text area in the Calibration Factors window and type in the desired value.

The range for values entered is 0.5 and no larger than 2.0.

**WARNING: Do not modify the Calibration Factor unless you are the qualified Medical Physicist.**

3. When changes are completed, click **OK**.

The New Calibration Factors window disappears and the Status Message (*Figure 3-22 Calibration Factor Status, page 28*) appears. It states that the factors entered are now in the database.

4. Click **OK** to return to the Calibration Factors window.

Clicking **CANCEL** on the New Calibration Factors window redisplays the Calibration Window.

Click **OK** to return to the New Calibration Factors window to make corrections.

**WARNING: The software allows entry of calibration factors 0.5 to 2.0. 50% to 200% of the absolute dose calibration can be delivered to the patient. Serious harm to the patient may result if erroneous calibrations factors are entered.**

If out of range values are entered into the text areas of the New Calibration Factors window, and **OK** is clicked, the **Verification Message** (*Figure 3-20 Calibration Factors Verification, page 28*) displays the current allowable range of values of the calibration factors.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118 

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015


**NOTE:** Page Left Intentionally Blank



209 Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015


## LINAC OUTPUT CONSTANCY CORRECTION FACTOR DETERMINATION

Immediately after the absolute dose calibration is complete, setup the monthly calibration. Use a solid water phantom and determine the expected reading at a 5 cm or 10 cm depth at 80 cm SAD, which is typically used for this. Then a daily chamber reading in air must be taken to establish dose reading using the Bird Cage positioning chamber mounting device. The CyberKnife System uses ion chambers that are vented to atmosphere. So, changes in atmospheric pressure and X-ray head temperature can affect output, in addition to changes in the electronics. It is recommended that the output be checked at least daily. If the environment where the CyberKnife System is installed changes dramatically throughout a day, you may have to check more often.

A dedicated Farmer Baldwin type chamber with a 6 MV build up cap is to be used for this check. At the time of the initial beam absolute dose calibration, attach this chamber to the Bird Cage chamber holder. This is to ensure that the chamber is set up the same way each time a constancy check is performed. Compare the reading obtained in air with the build up cap and Farmer-Baldwin type chamber, and calculate a constancy correction factor for the daily QA setup, or establish a TPC corrected expected daily reading in air.

## PROCEDURE 3-7: CONSTANCY CORRECTION FACTOR

1. Insert the 60 mm secondary collimator.
2. Screw the Bird Cage onto the CyberKnife collimator housing.
3. Connect the Farmer-Baldwin chamber to the Bird Cage so that the center of the chamber is aligned with the front pointing laser.The chamber is fixed to 80 cm SAD.
4. Put a 6 MV buildup cap on the chamber.
5. Attach the triax cable to the chamber.
6. Take note of the temperature and pressure inside the treatment room.
7. Turn on the electrometer and verify the correct bias voltage
8. Login to the CyberKnife System workstation and proceed to the Physics Module.
9. Select the LINAC tab and enter 2000 MU to warm up the LINAC.
10. Take several chamber readings for 200 monitor units (MU's).
11. Calculate the temperature and pressure correction factor.
12. Average the readings.
13. Divide the readings average by the corrected Farmer-Baldwin chamber readings acquired in water at dmax during the absolute dose calibration for the same 80 SAD setup to establish the correction factor CF to correlate the daily T,P corrected Bird Cage readings with the absolute calibration.
14. Set up a quick energy check, if desired, by inserting 5cm of solid water or 2 cm of Al into the beam upstream of the chamber and set the LINAC to deliver 200 MU's.
15. Take two readings for each 200 MU delivery.
16. Calculate the ratio of the numbers obtained in Step 15, divided by the readings measured with the chamber and build up cap in air in Step 12 to establish the expected ratio for the monthly energy check.
17. Turn off the electrometer and remove the Bird Cage from the collimator.

    **Daily Factor = reading (nC) X $C_{TP}$ X CF**

    CF is the calibration factor from the Bird Cage reading on the day of absolute dose measurement.

    The daily factor will be the percent variance in beam output relative to the absolute dose calibration.
18. Repeat the above procedure, and substitute your solid water phantom with the chamber at a 5 cm or 10 cm depth to establish a monthly QA test setup (cross referenced to the absolute dose calibration).



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015

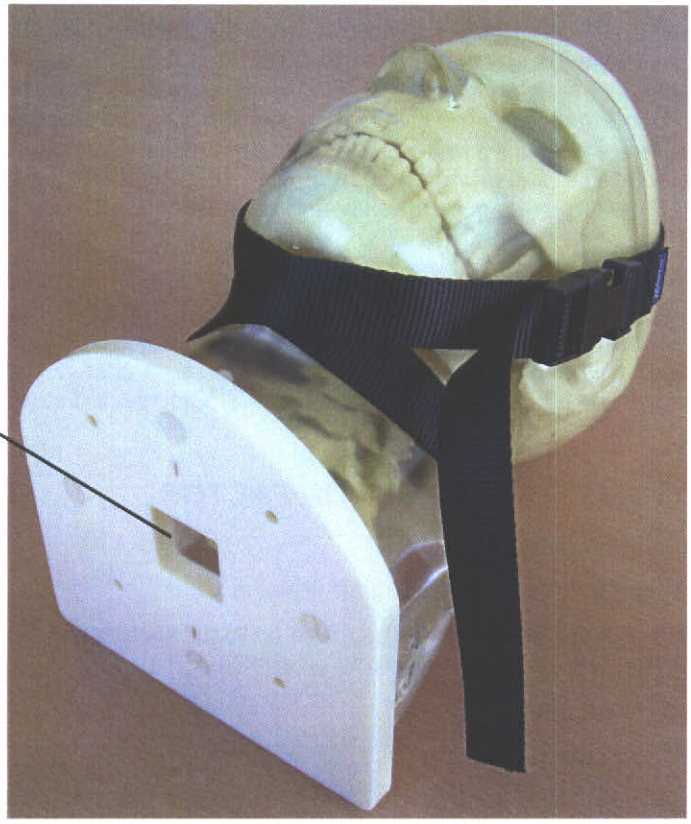




Figure 3-23 Anthropomorphic Xsight Phantom



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015


# CyberKnife System Targeting Accuracy

## END-TO-END TARGETING TEST DESCRIPTION

The end-to-end test (E2E) is designed to demonstrate the CyberKnife System geometric targeting accuracy. The Ball-Cube dose distribution recorded on film reflects the targeting accuracy based on radiation delivered to the phantom. The test integrates CT (Computerized Tomography) data acquisition, treatment planning, robot positioning, image processing, LINAC, and safety components of treatment accuracy. The E2E test mimics this entire treatment process by including all steps of a patient treatment. The treatment process includes a CT scan, importing the CT into the CyberKnife System, identifying the treatment target, designing a treatment plan, generating DRR's, and delivering the plan. After the plan is delivered to film inside the phantom, the centroid of the actual delivered dose distribution on the exposed film is compared with the planned dose distribution. Total positional error for each delivery modality is determined.

The CyberKnife system is delivered with the Xsight anthropormorphic head phantom and contains two Ball-Cube phantoms, one in the head and one mini-cube in the neck, the location is depicted in *Figure 3-23 Anthropomorphic Xsight Phantom, page 32.*

The E2E test is done either with the standard 2.5 inch "Ball-Cube" accessory or the mini 1.25 inch "Ball-Cube" accessory loaded with radiochromic film. The procedure for using the standard and Mini Ball-Cubes are similar. The film analysis software determines the film size and the analysis is performed relative to this.

During commissioning of the CyberKnife System, the E2E test should be performed for each treatment modality available at that site. These can include: 6-D Skull Tracking, 3-D Skull Tracking, Xsight Tracking, Synchrony Tracking, and fiducial delivery modes. An anthropomorphic head phantom with film loaded Ball-Cube inside should be used for skull tracking.

The Xsight system is delivered with the Xsight head phantom for spine tracking QA (*Figure 3-23 Anthropomorphic Xsight Phantom, page 32*).

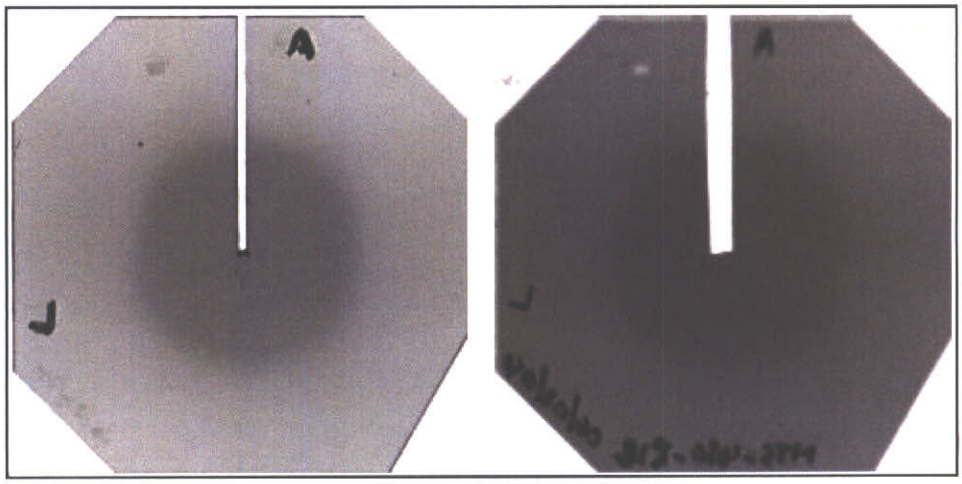
**Film analysis** can be performed either "visually" using just a ruler and graph paper or "digitally" using a transparency scanner and the Accuray film analysis software "End to end test tool". Visual film analysis can be performed in minutes and gives accuracy of about 1 mm. Digital analysis takes about 15 minutes and has an accuracy of +/- 0.3 mm. Digital film analysis using the "End-to-End test tool" is described in the "Film Analysis End-to-End Automation Tool" in Part 4 following.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015

**Figure 3-24 Ball-Cube Phantom**




**Acceptable Film Slot** **Defective Film Slot**

**Figure 3-25 Pre-cut Radiochromic Film**



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015


## MATERIALS REQUIRED FOR E2E TEST

1. **Phantoms** The anthropomorphic head phantom, shown in *Figure 3-23 Anthropomorphic Xsight Phantom, page 32* can be used for both 6-D and 3-D skull tracking modes. A neck attachment is available which allows placement of a miniature film cassette anterior of the C7 vertebra. The advantage of the anthropomorphic head is that it demonstrates the ability to track a humanlike skull.
2. **Standard Ball-Cube targeting tool** This tool is made of four pieces which connect together using threaded nylon rods and nuts. A 31.75 mm diameter acrylic ball is placed in the center of the cube. The standard Ball-Cube is placed in the cranium cavity of the head phantom (*Figure 3-24 Ball-Cube Phantom, page 34*).
3. **Mini Ball-Cube targeting tool** This tool is made of four pieces which connect together using nylon locator pins. A 19 mm diameter acrylic ball is placed in the center of the cube. The Mini Ball-Cube can be placed in the neck phantom and using the spacer accessory it can be placed in the head phantom.
4. **Radiochromic film** Accuray recommends either Gafchromic MD-22 precut film, Gafchromic MD-22 pre-notched or Gafchromic MD-55, which comes in 5 inch square sheets. The larger MD-55 films must be cut down to 2.5 inch square pieces with corners removed. Unless the pre-notched film is used, slots must be cut along the center line of the film as shown in *Figure 3-25 Pre-cut Radiochromic Film, page 34* so the films can be placed together in the film cube.
5. **Optical transparency scanner** (required for digital film analysis). One option is to use a 16-bit (or 48-bit color) scanner with the ability to generate consistent and accurate density and position measurements. The Epson Expression 1680 Professional - E1680-PRO is the recommended scanner. When using a photography scanner, one must be careful to perform regular calibration since these scanners do not guarantee spatial accuracy. An option is to use a medical imaging scanner such as the Vidar VXR-16. To use the Vidar scanner, the small pieces of radiochromic film must be placed in clear plastic pockets or taped to blank X-ray films or clear plastic sheets.
6. **End-to-End Test Tool software** Provided by Accuray.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015

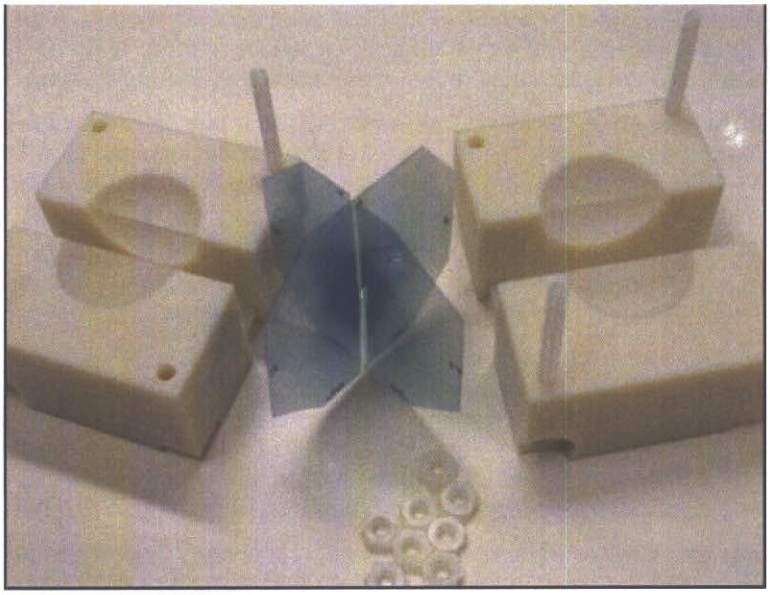



Figure 3-26 Film and Ball-Cube Phantom

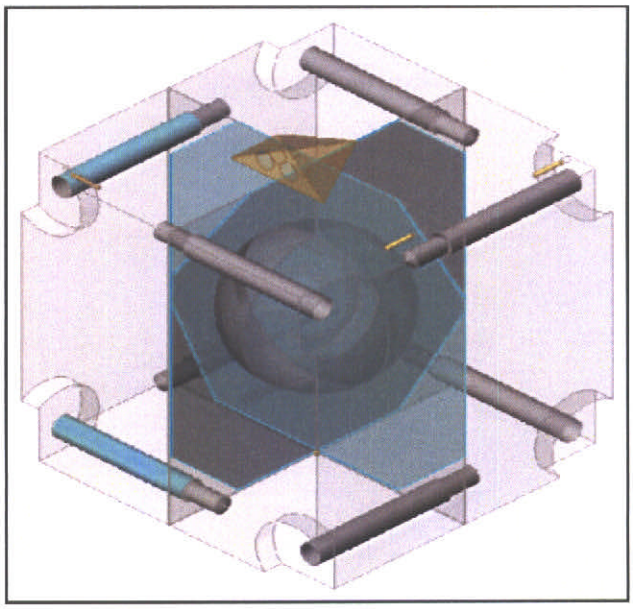


Figure 3-27 Ball-Cube Rendering



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015


## PROCEDURE 3-8: BALL-CUBE TEST PHANTOM PREPARATION

1. Pre-notched films have a smaller slot since they use a more precise cutting process. Or, cut a slot on each film if not pre-cut. The slot can be cut by marking a line on the film with a permanent marker and then cutting around the line with scissors. The best way to locate the line on the film is to trace it from a template. Figure 3-14 shows the dimensions and location of the slot. The cutting line should extend along the center of the film about 2 mm past the center of the film.
2. Load film cube with two pieces of film (*Figure 3-26 Film and Ball-Cube Phantom, page 36*).
3. Align film in cube.

   The axial film is aligned precisely with the anterior and left edges of the film cube. Likewise, the sagittal film is aligned with the anterior and superior edges of the film cube.

   One way to align the films with the edge of the cube is to first install the films in the cube without tightening the nuts. Next, tap the reference edges of the film cube on a hard flat surface so the films slide to these edges. Sometimes the film gets stuck and it is necessary to push the film from the opposite side using a piece of paper or a business card.
4. Label the film reference edges with a fine tip permanent marker. It is important that the labels on the films match the edges of the cube. The writing will be preserved in the scanned image for identification purposes.
5. Confirm correct film position in the cube as in *Figure 3-27 Ball-Cube Rendering, page 36.*

   To determine if the films are aligned with the edges of the assembled film cube, look at the reference edges from about a 45 degree angle with respect to the surface. The edge of the unexposed film should appear as a black line. If the film is below the surface the line will not appear. If it is sticking out too far you can see it sticking out and you can also feel it with your fingers. (This may take some practice.)
6. Tighten the nuts to secure the film.
7. Load the Ball-Cube into the phantom.

   The edge marked superior should be at the superior edge of the phantom, etc. Make sure that the cube is properly oriented within the phantom. *Figure 3-27 Ball-Cube Rendering, page 36* shows the proper orientation of the film cube in the phantom.

   - When performing Spine Tracking, *Figure 3-23 Anthropomorphic Xsight Phantom, page 32* shows where to insert the Mini Ball-Cube in the neck phantom.
   - For **spine tracking**, the CT center must be placed in the inferior portion of C5, or in the superior portion of C6 when generating the treatment plan.
8. Obtain a CT scan of the phantom containing a film cube loaded with film.

   To minimize measurement error due to localization, use 1.5 mm slice thickness or less, and use sequential axial slices. Helical acquisition CT's may not be as geometrically precise. Follow the appropriate Accuray procedure for CT scanning. Export the Ball-Cube CT AXIAL slices only to the CK system.

   If a multi slice scanner is used, confirm that the kVP is 120, and that minimum pitch is set.
9. Import the CT as "patient".

   From the main screen, select images. Import PATIENT images as TREATMENT mode instead of the SIMULATION mode so that TREATMENT mode is tested.
10. Use the On Target or MultiPlan Ball-Cube Test Planning Procedures to generate the Ball-Cube Test treatment plan. The procedure is described in Module 4 of this Physics Essentials Guide.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015


**NOTE:** Page Left Intentionally Blank



217
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015


**11.** Generate DRR's for the treatment and prescribe treatment.

**12.** Place phantom on table. Check DRR images. For Skull Tracking, acquire images. To make the live images and DRR images look similar, adjust image technique to make brightness and gradient gains within the range 0.9 to 1.1.

**13.** Deliver the treatment plan using the TREATMENT mode.

Do not use SIMULATION mode for these routine phantom tests. After the treatment is completed remove the Ball-Cube and the phantom. Always confirm the Ball-Cube was loaded properly into the phantom. Always confirm that the film was loaded properly into the Ball-Cube.

**14.** Check that the film is labeled properly.

Remember to keep the film away from fluorescent lights and the sun as much as possible. Exposure to these will darken the film over several hours. The film is less sensitive to incandescent lights.

**15.** Locate the center of the exposure on each piece of film.

The center of the axial film dose is measured with respect to the left and anterior edges. The center of the sagittal film dose is measured with respect to the anterior and superior edges.

**16.** Scan the film in a calibrated optical scanner. It is important to check the distance calibration of the scanner by scanning a precise ruler or graph paper in both horizontal and vertical orientation. Calculate the true pixels/inch. It is good practice to also perform visual analysis as described below and compare the results as a check against the error results.

**17.** Film Analysis

**A. Visual Check**

The center can be measured by laying the film over a cross drawn on graph paper and centering the dose spot on the cross. The film axes are aligned with the rotated cross but the film is positioned so that the exposure is centered on the vertical cross. Using two crosses keeps the film slot away from the axes used to position the film. To measure the dose centroid:

Center the exposed circle on the vertical cross (+).

Mark the positions of the two reference edges of the film on the rotated cross (X)

Remove the film and measure the distance from the center of the cross to the reference edge-marks.

This visual technique alone is not recommended for setting the targeting offset (Delta_man) during CyberKnife commissioning.

**B. Digital Analysis**

Refer to the section *Film Analysis with Automation Tool, page 45* for the procedure to follow for automated Ball-Cube test film analysis. Better accuracy can be achieved using the "digital" method outlined in that section.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118 

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015

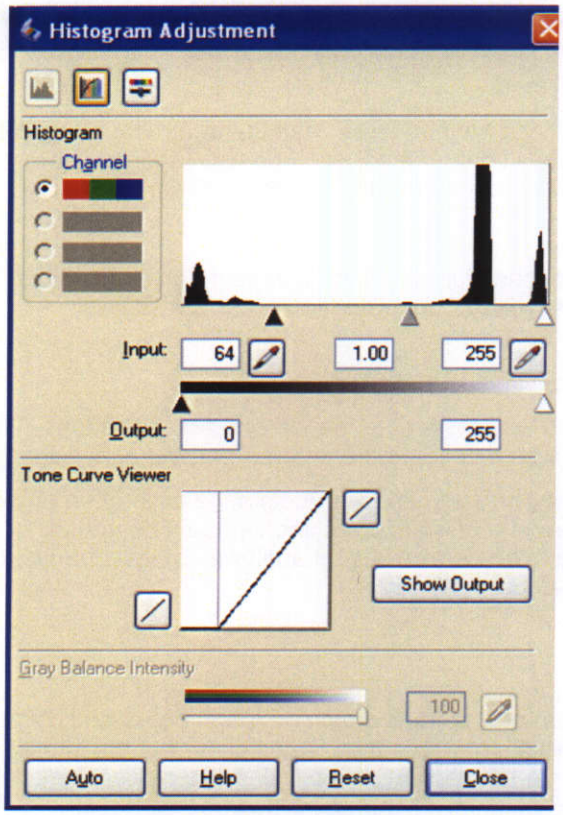




Figure 3-28 Histogram Adjustment

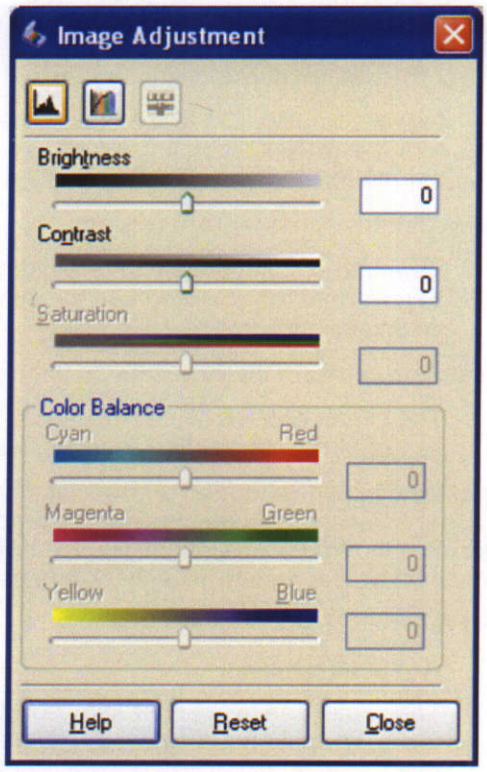



Figure 3-29 Image Adjustment

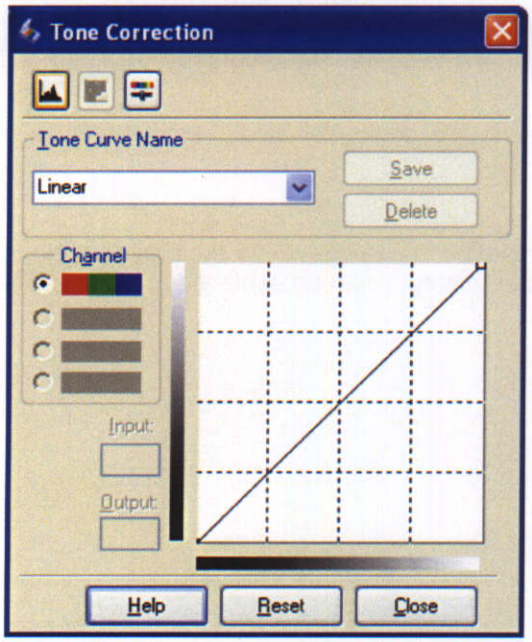



Figure 3-30 Tone Correction

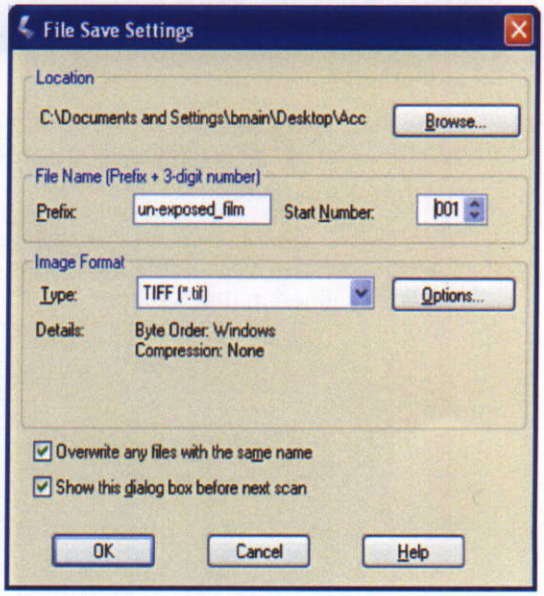



Figure 3-31 File Save Settings



219

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015


# FILM SCANNER SETUP

Contact Accuray for film scanners with appropriate accuracy and reproducibility. Examples include:

- VIDAR VXR-16
- Epson Expression 1680 Professional

**Epson Expression 1680 Professional**

This procedure applies to the Epson Scan software, which is included with the Epson Expression 1680 Pro. These notes were made based on version 1.01E.

1. Set "Mode" to "Professional Mode"
2. No corrections need to be made in the configuration tab found at the lower center of the field.
3. In the histogram adjustment window (*Figure 3-28 Histogram Adjustment, page 40*) set input to 64, 1.00, 255. This sets the input range for Optical Densities from about 0 to 1.
4. Set the output for 0 to 255 to use the entire 16-bit range. Although these numbers appear to apply to 8-bit they really refer to 16-bit operation. For example, 255 really means 65535.
5. Select Close.

The scanner often resets the window to factory settings so always check before saving the setup parameters.

Do not make adjustments to "Image Adjustment" or "Tone Correction" (*Figure 3-29 Image Adjustment, page 40* and *Figure 3-30 Tone Correction, page 40*).

6. From the main menu select "Configuration" and turn off "auto exposure".
7. From the pull down menu next to preview, deselect thumbnails.
   - When saving a file use "TIFF" format (standard uncompressed). See *Figure 3-31 File Save Settings, page 40.*
   - Use windows byte order.

**WARNING: Do NOT use auto calibration. Incorrect targeting accuracy values may result.**

8. Measure the pixels per inch.

Although you set the scanner for 300 dpi, there is no guarantee that the scanner is calibrated to exactly 300 dpi. You should scan a good quality ruler (*Figure 3-33 Ruler, page 42*) and measure the pixel dimensions manually in both vertical and horizontal directions. Image J is a good tool for doing this.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118 

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015

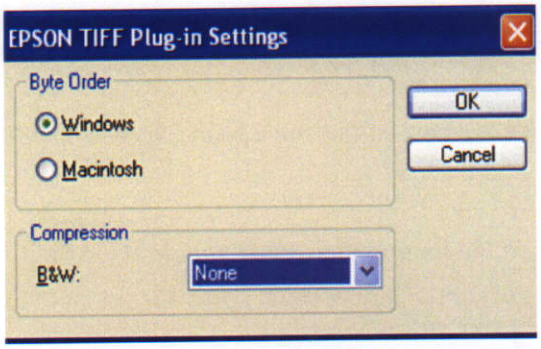




**Figure 3-32 Plug-in Settings**

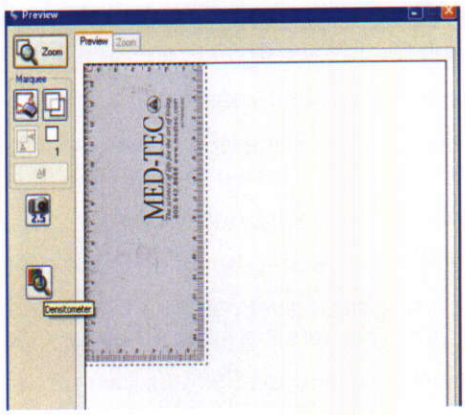



**Figure 3-33 Ruler**

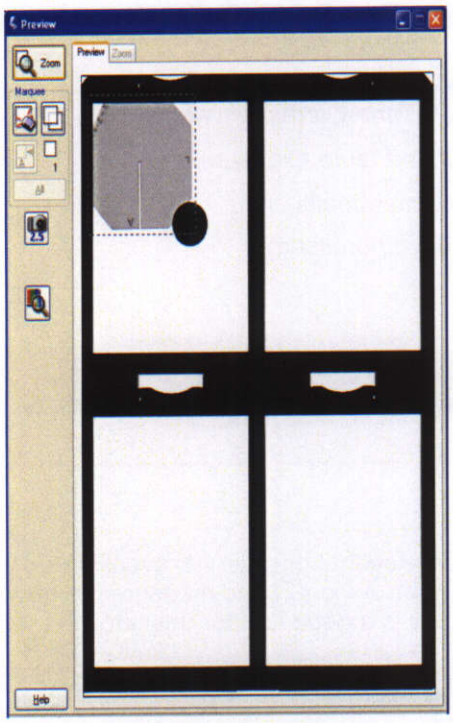



**Figure 3-34 Preview**

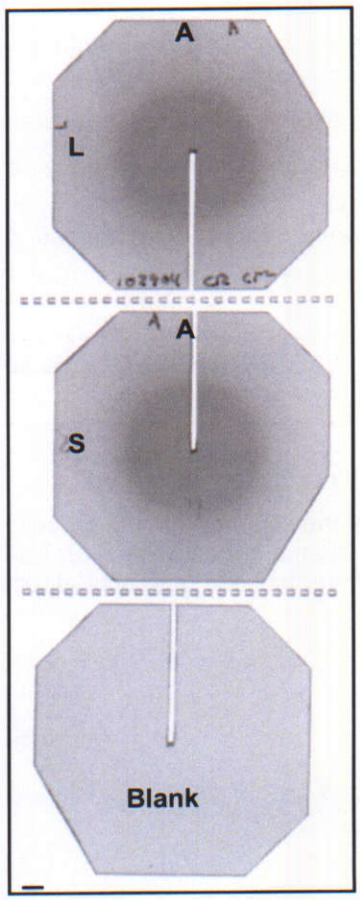



**Figure 3-35 3 Film Scanned Image**



221
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015


9. Place the film on scanner using one of two methods. Put the film inside clear plastic pockets (e.g., baseball card holders) and place it on the scanner.
10. If pockets are used set the distance to 0 by clicking on the button. Or you may use coins to elevate the film, however coins may interfere with the auto film analysis software. If the film is elevated set the focal distance at 2.5 mm (image below left side). A setting of 2.5 is the default for the transparency mode.
11. Use the preview window (*Figure 3-34 Preview, page 42*) to select the area to be scanned.
12. Once all the parameters are set up correctly, use the "Settings Name:" tool of the main window to save the setting for the future. These settings will include the scanning window.
13. Avoid having the edges of the film close to the edges of the sheet protector to make it easier for the film analysis software to identify the film edges.
14. Place the film according to the image, this can be managed in the film analysis software.

**NOTE:** Remember to include a blank film from the same batch for a background reading.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015


**NOTE:** Page Left Intentionally Blank



 Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015


# FILM ANALYSIS WITH AUTOMATION TOOL

## INTRODUCTION

The E2E (End-to-End) Automation software package allows rapid processing and analysis of scanned E2E film images.

## REQUIREMENTS

The E2E software requires a PC running at least Windows 2000.

Lots of memory and processing power is a plus. About 40 MB of hard disk space will be required, plus any space require for images to be scanned.

## INSTALL PROCEDURE

1. Place the E2E Install Disc into the CDROM drive.
2. Copy E2Esetup.zip to the directory where the E2E software should be extracted.
3. Using a decompression program, unzip E2E.zip.
4. Open up the $ROOT\End 2 End Software\bin\win32 directory, where $ROOT is the directory where the software was extracted.

Create a shortcut for End 2 End.exe in a location of choice. Executing this shortcut will launch the program.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015

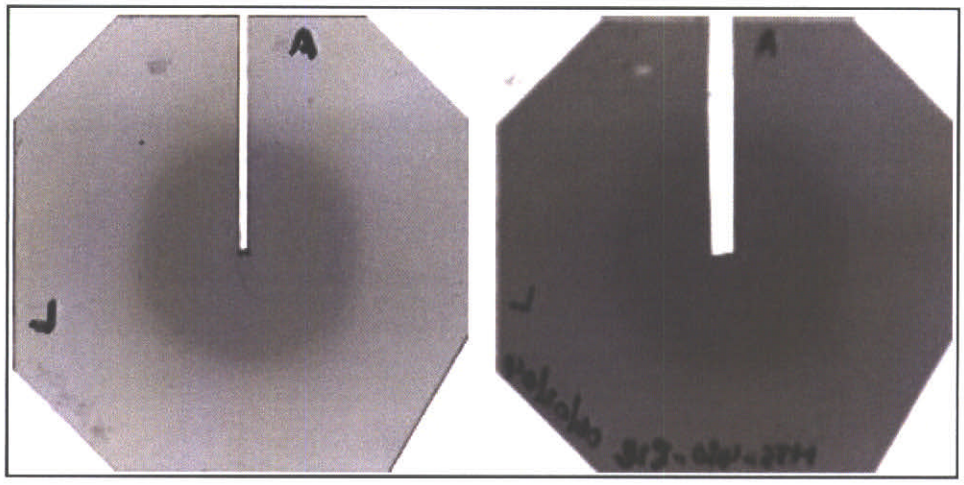




**Figure 3-36 Pre-cut Radiochromic Film.**

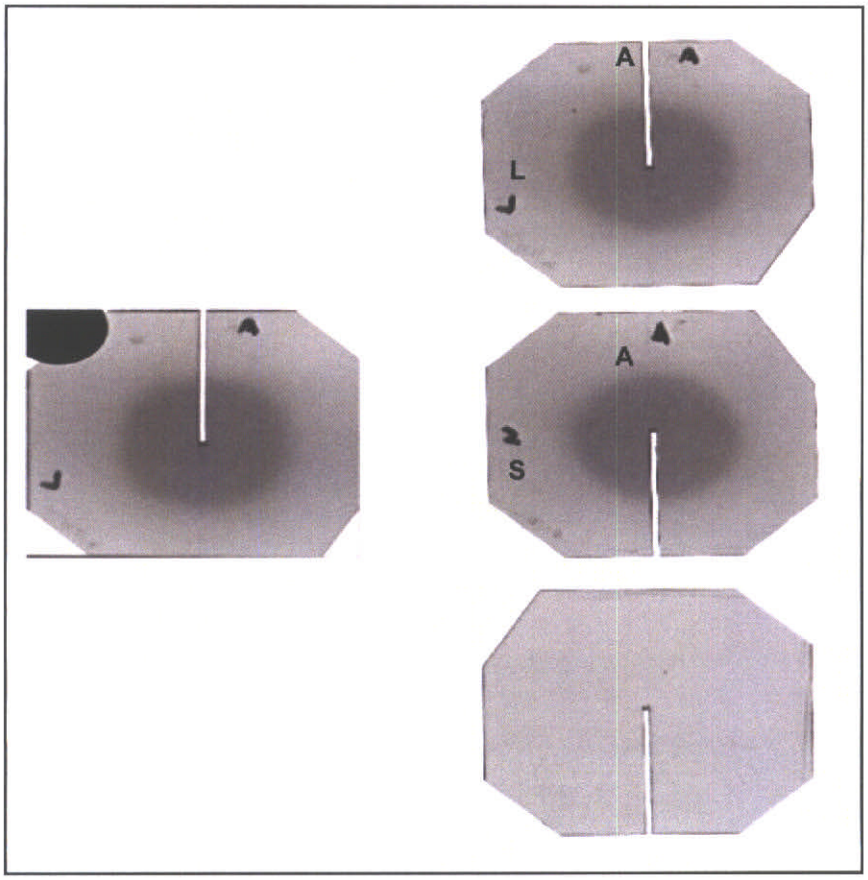



**Figure 3-37 Single Film image (left). 3 Film image (right).**



225

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015


# PREPARING IMAGES FOR ANALYSIS

Images of three films are required for end to end analysis. They are an anterior-left film, an anterior-superior film, and an unexposed background film.

## FILM SELECTION

The E2E software works best when laser cut film products are used. If a manual slot must be made, try to make it as narrow as possible (*Figure 3-36 Pre-cut Radiochromic Film., page 46*)

## PROCEDURE 3-9: FILM SCANNING

1. The films should be aligned such that, when scanned, the Anterior edge is on the top of the image and the Left/Superior edges are on the left. Furthermore, these edges should not vary more than 5° from the actual image edges (in other words, they should be parallel to the axes of the image, and cropped such that white or blank space is not in excess.
2. When placing the film on the scanner, be careful with handling them, as fingerprints can be detected in the scanning process.
3. Images can be scanned using two methods. (*Figure 3-37 Single Film image (left). 3 Film image (right)., page 46*)

   A. Each Film Individually

   If using a transparency holder or if perhaps interference is being noticed on scanned images, this method might be preferred. For this method, each film is saved as a separate file.

   B. Three Films Together

With this method, all three films are scanned as one large image.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015

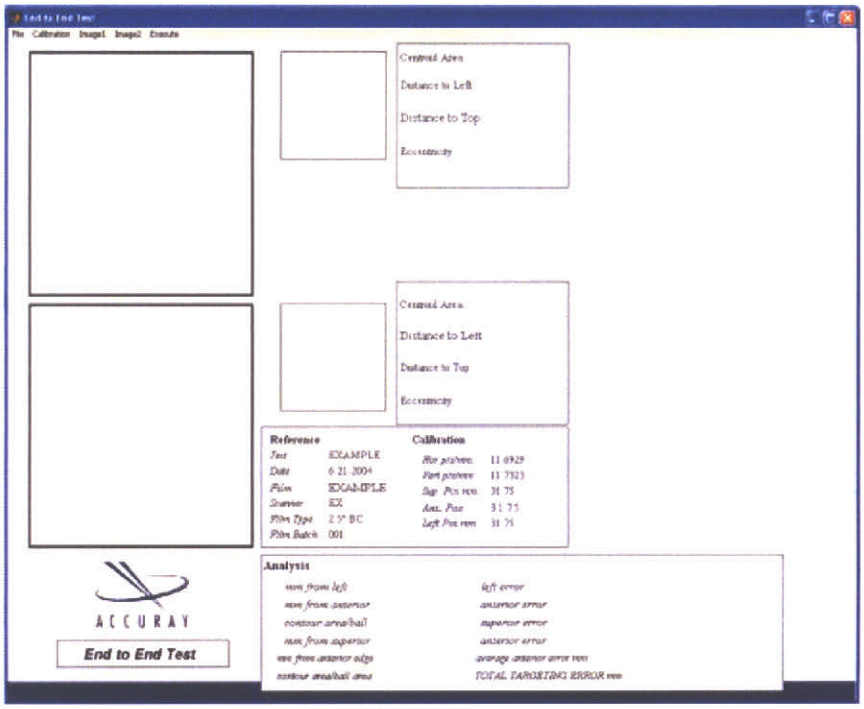




Figure 3-38 E2E User Interface (UI)

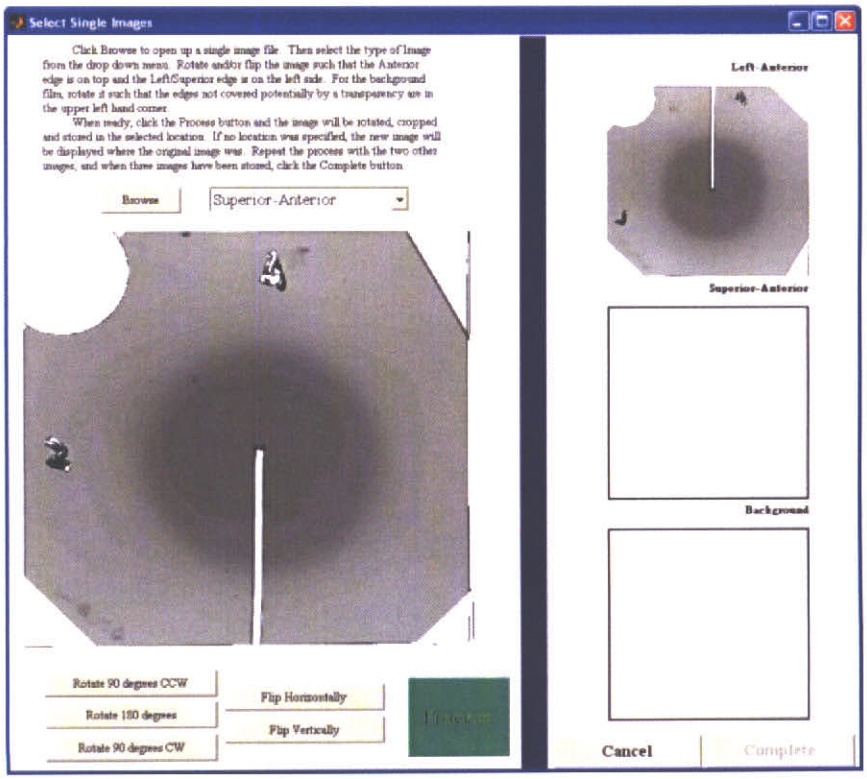



Figure 3-39 Select Single Images UI



227
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015


# RUNNING THE E2E PROGRAM

## STARTING E2E

Find the location of the E2E program and execute the program. The User Interface as in *Figure 3-38 E2E User Interface (UI), page 48* will appear.

The User Interface displays information. When an image set is loaded, the exposed film images will appear on the left. After running a contour analysis, the two boxes in the middle will show the contour region, and information about the regions will also be shown. If a multiple analysis is performed, the boxes in the middle will show the varying centroid locations, while the space on the far right will show the varying contours.

All of the commands needed to run this main User Interface can be found in the menu bars.

## LOADING IMAGES

### SINGLE IMAGES

1. To select a single image, click **FILE**, **OPEN SINGLE FILM**.

   Another user interface will load to import images.

2. Select Browse and select one of the three image files for the film set. The image will then load, allowing for the determination of the type of film. Use the drop down box to select the appropriate film.

3. Transform image.

   If any rotations or flips are needed to place the A and S/L edges in the correct location, use the Image1 and Image2 buttons to perform those transformations. Next, select Process, and alignment and cropping will be performed. When it is complete, the new image will be displayed on the right. Similarly, a value for AAD (Absolute Angle Difference) will be displayed, that shows the difference of the angles of perpendicular edges. For a finely cut edge, this should be close to zero degrees. If it is not within reason, then another edge should be used in rotation or the films should be cut better next time.

Repeat these steps two more times, at which point the Complete button in the bottom right will be enabled. Click on that to send the images to the main User Interface.

### THREE FILMS AT ONCE

1. To open an image of three films, click **FILE**, **OPEN 3 FILMS**. A dialog box will pop up asking for a file name.

2. After selecting the file, if previously the three films from this image set have been stored on the hard disk in the same folder, the program will ask if those images should instead be loaded. If this is desired, the rotated and cropped images will be immediately loaded and displayed.

   If this is the first time opening a data set, many preprocessing routines will be called upon the image. The **status bar** in the lower right of the User Interface will inform the user of which step is currently being processed.

## PROCESSING STEPS

1. Isolating Films

   The image is segmented such that the films are the foreground and the scanner glass is the background. The foreground regions are grouped and labeled, and the three largest regions are determined to be the three films. The three images are created by cropping around each film region.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118 

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015


**NOTE:** Page Left Intentionally Blank



229 Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015


2. Finding BG Film

   The standard deviation of each image is determined; the one with the lowest is determined to be the background film.

3. Aligning Films

   The films are aligned by analyzing the best edge of each image. By best edge, the angles along each perpendicular edges are measured, and the edge where these angles are most identical to each other is the edge on which the image is aligned.

4. After determining the proper rotation, the images are rotated and bilinearly interpolated. This is by far the most computationally intensive step, unless the original pre-separated image is excessively large, so for slower computers this could take significantly longer than the other steps.

   **NOTE:** As mentioned earlier, the maximum change in degree from horizontal is 5°.

5. Cropping Films

   Each rotated film is now assumed to have horizontal and vertical edges, so the films are cropped using those edges.

At this point, the user will be asked for calibration information about scanner. Type that in now and press **OK**.

# REORIENTING IMAGES

Any images that are improperly rotated or flipped can be transformed using the options under Image1 and Image2. Image1 is considered to be the upper image, while Image2 is the lower one.

Use Image1 and Image2 to confirm the proper labeling of each. Make sure the Left/Anterior Image is checked for the proper image, as well as for the Superior/Anterior Image. When one is changed, the other image will automatically be selected as the other option.

# MODIFYING INFORMATION

When the images are ready to go, it is important to make sure the other information about the films is correct.

## REFERENCE INFORMATION

Reference information does not affect the analytical process of this test in any way; if the results are to be printed afterwards, having this information on the printout is helpful.

To add or update the Reference Information, click **FILE**, **NEW REFERENCE INFORMATION**. A dialog box will open, where six different fields can be entered to describe information about the test. Click **OK** when finished, and the new data will be displayed in the Reference box of the main User Interface.

## TARGET BALL INFORMATION

The Target Ball diameter is used to describe the distance from the edge of the Ball-Cube to its center. There are two ball diameters: 31.75 mm and 15.875 mm.

If the Target Ball diameter is not correct, click **CALIBRATION**, **TARGET BALL CALIBRATION** and enter the correct information in millimeters. When OK is pressed, the new information will be displayed in the Calibration box of the main User Interface.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118 230

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015

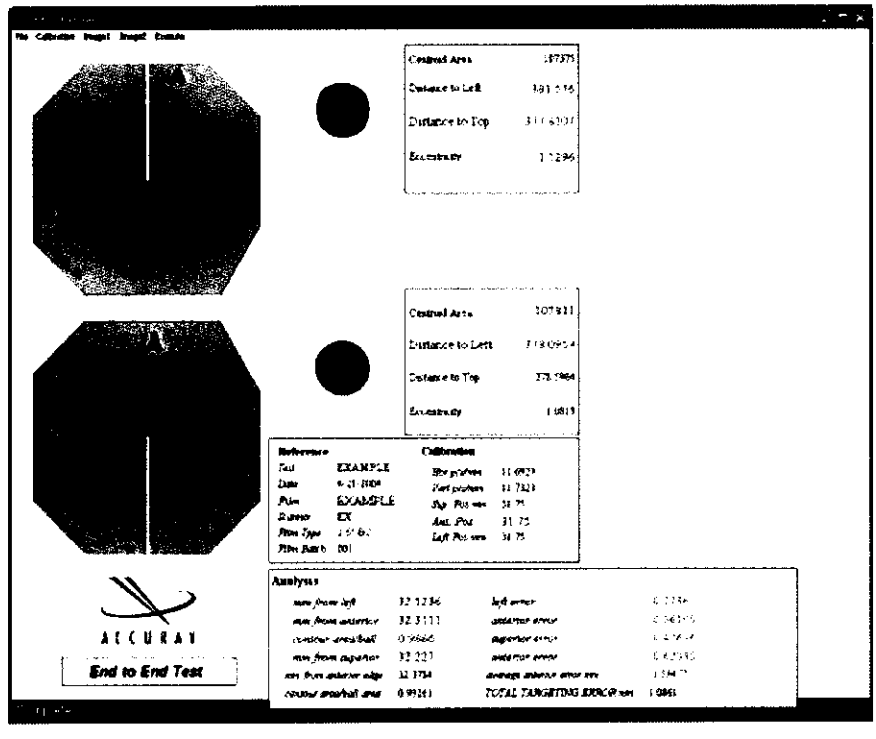




**Figure 3-40 E2E after Single Threshold Calculation**

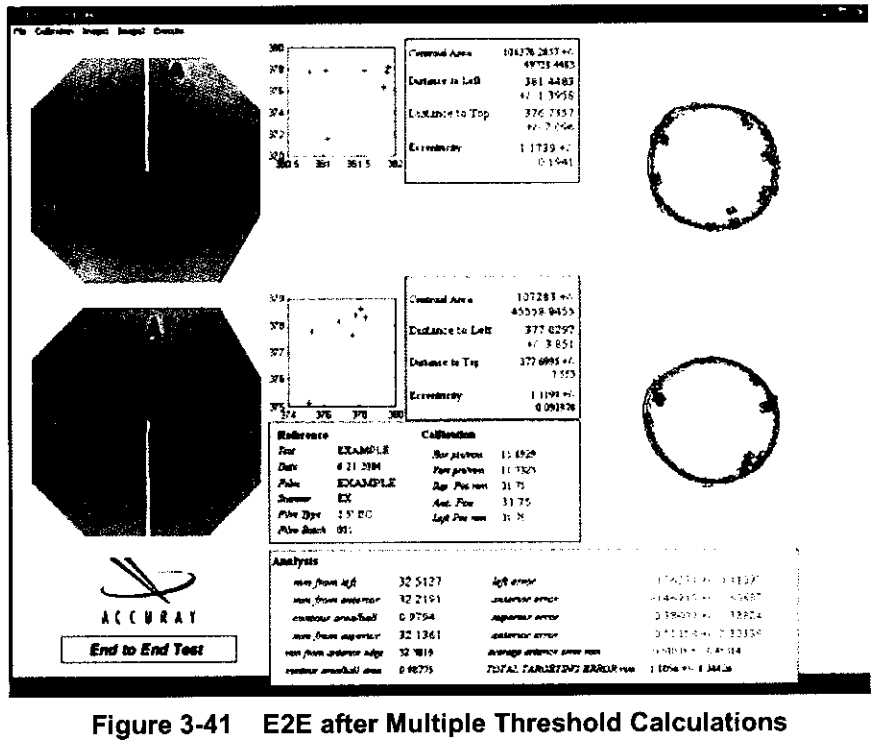



**Figure 3-41 E2E after Multiple Threshold Calculations**



231

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015


### Calibration Information

When running the Three Film Image setup or canceling the Calibration Information for the Single Film Image setup, the E2E program automatically determines the calibration by the physical size of the films (both x and y directions are averaged each time they are rotated).

To check and/or change these values in pixels per inch, click **CALIBRATION**, **SET DPI/MM**. This brings up a User Interface where the X and Y direction pixels can be entered. Clicking **OK** will save those settings, regardless of whether or not you rotate the images. Clicking **CANCEL** will keep the old settings, whether it was a previous manual calibration or the automatic.

**WARNING: Do NOT use auto calibration selection with E2E. The precision is inadequate and erroneous targeting data may result.**

## PERFORMING ANALYSIS

With all the settings set correctly, the threshold analysis can then be completed. Definitions are supplied for all terms used and are listed in *Table 3-3: Pixel Value Measurements, page 54* and *Table 3-4: Analysis Measurements, page 54.*

### SINGLE THRESHOLD

This method allows for the calculation of the centroid location and region area for a single threshold level. For the desired threshold level, the minimum pixel intensity value for both exposed films is determined as well as the mean background intensity from the unexposed film. Then the image is thresholded with the desired value (the default being 70%).

The final step is filling in the slot and deleting the rest of the image. From this image the centroid location, area, uncertainties, and other quantitative values are displayed in the Analysis box. In addition, on the black blob displayed for each image is a line that circles the approximate ideal dose region prescribed in the treatment plan.

To execute a Single Threshold, click **EXECUTE**, Once. A warning will pop up asking to ensure that the images were correctly rotated. Click **YES** to continue. See *Figure 3-40 E2E after Single Threshold Calculation, page 52*, which displays the E2E screen after analysis is complete.

### CHANGING THRESHOLD

The default threshold value is 70%. To change this, click **EXECUTE**, Threshold and select a contour level that is more desirable. If it is not there, click **CUSTOM** to pull up a User Interface to manually select a value. Keep in mind though that as the value strays from 65-75%, the accuracy of the area and centroid finder diminishes.

### MULTIPLE THRESHOLD

This method allows for multiple calculations to see how the contours and centroid locations change as the threshold levels increase or decrease. Unless only one threshold value is selected, the values of the centroid locations and errors are given as well as the value of three standard deviations above or below.

To execute Multiple Threshold, click **EXECUTE**, **MULTIPLE**. A warning will pop up asking to ensure that the images were correctly rotated. Click **YES** to continue. A contour selection User Interface will then appear. Follow the instructions to pick a contour range, and click **OK**. The multiple thresholds will be calculated, and a contour map will be displayed on the right. Furthermore, a map of the centroid locations will be displayed in the middle of the User Interface. See *Figure 3-41 E2E after Multiple Threshold Calculations, page 52.*

The contour selection User Interface also allows the ability to save both contour maps for further use. After the contours have been loaded, names for the files where these TIF images should be saved will be requested. Date should be included in the file name.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015


**Table 3-3: Pixel Value Measurements**

| | |
|---|---|
| centroid Area | number of pixels in main dark region of thresholded image |
| distance to left | x-location of centroid |
| distance to top | y-location of centroid |
| eccentricity | ratio of longest radius from centroid to the shortest |

**Table 3-4: Analysis Measurements**

| | |
|---|---|
| mm from left edge | distance to left edge, found by converting the a/l image's "distance to left" from pixels to mm |
| mm from anterior edge | distance to anterior edge, found by converting the a/l image's "distance to top" from pixels to mm |
| contour area/ball area | ratio of a/l ball area to the area determined using the target ball dimensions and calibration settings |
| mm from superior edge | distance to superior edge, found by converting the a/s image's "distance to left" from pixels to mm |
| mm from anterior edge | distance to anterior edge, found by converting the a/s image's "distance to top" from pixels to mm |
| contour area/ball area | ratio of a/s ball area to the area determined using the target ball dimensions and calibration settings |
| left error mm | error in mm – difference between "mm from left edge" and distance from target ball |
| anterior error mm | error in mm – difference between "mm from a/l anterior edge" and distance from target ball |
| superior error mm | error in mm – difference between "mm from superior edge" and distance from target ball |
| anterior error mm | error in mm – difference between "mm from a/s anterior edge" and distance from target ball |
| average anterior error mm | error in mm – average of two anterior error mm |
| total targeting error mm | square root of sum of square errors |



233
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015


## PRINTING

To print a record of the analysis, click **FILE**, Print. This will send a hardcopy to the printer.

## SAVING RESULTS TO A TEXT FILE.

After an analysis, either single or multiple, has been completed, the user has the option of saving the results to a text file by clicking **FILE**, **SAVE TO TXT FILE**...

A text filename will be sought, and at that location the data displayed on the User Interface (except the images) will be saved. If no analysis has been complete, no file will be created.

For the three film image set, another added option is the ability to save each individual film as a TIF file. The images saved will be the rotated and cropped versions (including any rotation, flipping, or designation as A/S or A/L). These images can then be examined using ImageJ or any other image viewing software.

## SHOWING DELTAMAN VALUES

After analysis, the suggested DeltaMan values can be displayed under Execute, Show Delta Man. Similarly, they will be displayed in the text file if that is saved.

## EXPORTING IMAGES

To export images, click **FILE**, **EXPORT IMAGES**.

## EXITING

Also upon closing the program, any reference information, dimension sizes of the main User Interface window, and last path location are saved for the next time E2E is run.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015

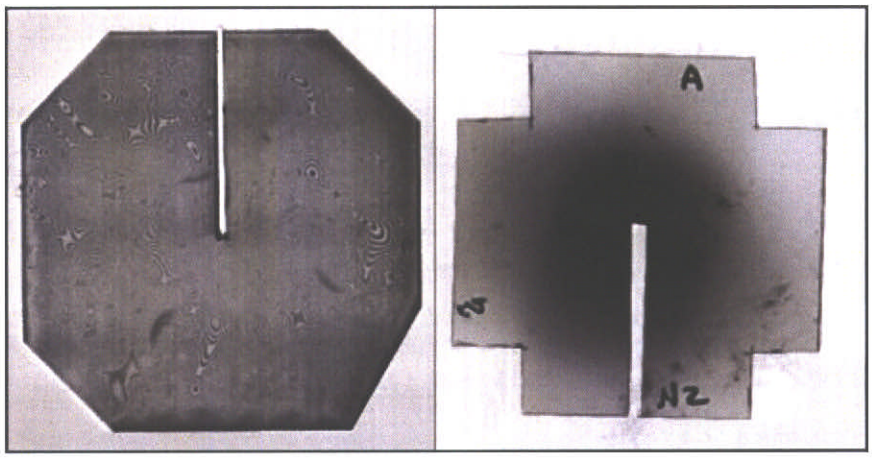




**Figure 3-42 Examples of optical interference fringes (left) and dust (right) on image quality. Both films were histogram equalized to enhance contrast.**

**Table 3-5: Effect of pixel error**

| Error, # of pixels | change in pix/in | | change in pix/mm | |
|---|---|---|---|---|
| | 2.5" | 1.25" | 2.5" | 1.25" |
| 1 | 0.4 | 0.8 | 0.015748031 | 0.031496063 |
| 2 | 0.8 | 1.6 | 0.031496063 | 0.062992126 |
| 3 | 1.2 | 2.4 | 0.047244094 | 0.094488189 |
| 4 | 1.6 | 3.2 | 0.062992126 | 0.125984252 |
| 5 | 2 | 4 | 0.078740157 | 0.157480315 |



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015


# SOLUTIONS TO COMMON PROBLEMS

Below are some known issues being resolved for future releases.

- **Noise from dust or fingerprints on the film or on the scanner:** Dust and fingerprints both can darken the film in such a way that interferes with the dark regions from X-ray exposure (*Figure 3-42 Examples of optical interference fringes (left) and dust (right) on image quality. Both films were histogram equalized to enhance contrast., page 56*). Keep the films as clean as possible. Usually the noise will be insignificant, but be aware of the possibility.
- **Cropping Errors:** The cropping algorithm relies on two directional high pass filters to determine the hard edges of each film. Sometimes the edges are not directly on the line that would be suggested from a manual crop, so if auto-calibration seems slightly off, cropping might be the reason, possibly warranting manually setting the calibration. See *Table 3-5: Effect of pixel error, page 56* for the effect of pixel error. Very rarely would an error greater than 2 pixels occur.
- Optical interference fringes: Use baseball card sleeves or coins in the corners to correct this problem (by vibrating the film from the glass).



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015


**NOTE:** Page Left Intentionally Blank



237
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015


# APPENDIX

## APPENDIX 3-1: RECOMMENDED EQUIPMENT

**Recommended Equipment**

The following tables summarize equipment requirements and recommendations for Beam Commissioning and Quality Assurance. It is the responsibility of the hospital to provide the following user equipment.

| Equipment Included with the CyberKnife System | |
|---|---|
| Ion chamber holder Bird Cage | 010181 |
| Anthropomorphic head phantom | 020417 |
| Ball-Cube film cassette (with fiducials) | 019364 |
| Gafchromic film MD-22 (pre-notched) | 019366 |
| Automatic Quality Assurance (AQA) | |

| Commissioning Equipment supplied by User | | |
|---|---|---|
| 3D Scanning Water Phantom System | PTW or Welhöfer or others | Required |
| 0.6cc Farmer-Baldwin type ion chamber, calibrated. One with 4-6MV buildup cap. | PTW 30013 | Required (two) |
| Micro ion chamber | Exradin A16 (or equiv.) | Required |
| Diode Detectors (water proof) | PTW T60008 | Required (two) |
| Survey Meter | Victoreen 450P (or equiv.) | Required |
| Thermometer | Various | Required |
| Solid Water Phantom with plugs drilled for ion chambers | Various | Required |
| Barometer | Various | Required |
| Film Scanner | Professional or Medical Film Scanner able to generate consistent and accurate position and accuracy measurements. | Required |
| Film analysis software | ImageJ - *http://rsb.info.nih.gov/ij/* | Required |

| Additional Equipment supplied by User | | |
|---|---|---|
| Radiochromic film | ISP Gafchromic MD-22 (Accuray P/N 017895 or MD-22 pre-notched by Accuray (P/N 019366) | Required |
| Anthropomorphic Body Phantom | Accuray | Optional |



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015


# APPENDIX 3-2: TPR TABLE EXAMPLE

Tissue Phantom Ratio table for the CyberKnife System at Anytown, USA
12 Field Sizes (mm)
301 Depths (mm)

| | 5 | 7.5 | 10 | 12.5 | 15 | 20 | 25 | 30 | 35 | 40 | 50 | 60 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 0 | 0.8050 | 0.7670 | 0.7100 | 0.6900 | 0.6830 | 0.6720 | 0.6890 | 0.6720 | 0.6760 | 0.6950 | 0.6890 | 0.6780 |
| 1 | 0.8449 | 0.8063 | 0.7575 | 0.7383 | 0.7291 | 0.7183 | 0.7362 | 0.7077 | 0.7226 | 0.7375 | 0.7348 | 0.7255 |
| 2 | 0.8833 | 0.8445 | 0.8036 | 0.7853 | 0.7742 | 0.7636 | 0.7820 | 0.7435 | 0.7680 | 0.7790 | 0.7794 | 0.7717 |
| 3 | 0.9188 | 0.8808 | 0.8472 | 0.8298 | 0.8171 | 0.8067 | 0.8251 | 0.7793 | 0.8110 | 0.8185 | 0.8215 | 0.8152 |
| 4 | 0.9498 | 0.9139 | 0.8867 | 0.8704 | 0.8567 | 0.8465 | 0.8643 | 0.8151 | 0.8504 | 0.8552 | 0.8598 | 0.8548 |
| 5 | 0.9750 | 0.9430 | 0.9210 | 0.9060 | 0.8920 | 0.8820 | 0.8980 | 0.8510 | 0.8850 | 0.8880 | 0.8930 | 0.8890 |
| 6 | 0.9932 | 0.9670 | 0.9489 | 0.9354 | 0.9220 | 0.9122 | 0.9254 | 0.8862 | 0.9139 | 0.9161 | 0.9203 | 0.9170 |
| 7 | 1.0050 | 0.9850 | 0.9700 | 0.9580 | 0.9460 | 0.9370 | 0.9470 | 0.9170 | 0.9370 | 0.9390 | 0.9420 | 0.9390 |
| 8 | 1.0114 | 0.9965 | 0.9846 | 0.9740 | 0.9640 | 0.9564 | 0.9637 | 0.9400 | 0.9549 | 0.9567 | 0.9590 | 0.9559 |
| 9 | 1.0140 | 1.0030 | 0.9940 | 0.9850 | 0.9770 | 0.9710 | 0.9760 | 0.9570 | 0.9690 | 0.9700 | 0.9720 | 0.9690 |
| 10 | 1.0142 | 1.0061 | 0.9998 | 0.9928 | 0.9864 | 0.9815 | 0.9847 | 0.9704 | 0.9805 | 0.9798 | 0.9819 | 0.9793 |
| 11 | 1.0130 | 1.0070 | 1.0030 | 0.9980 | 0.9930 | 0.9890 | 0.9910 | 0.9810 | 0.9890 | 0.9870 | 0.9890 | 0.9870 |
| 12 | 1.0109 | 1.0065 | 1.0043 | 1.0009 | 0.9975 | 0.9945 | 0.9958 | 0.9892 | 0.9941 | 0.9922 | 0.9938 | 0.9924 |
| 13 | 1.0080 | 1.0050 | 1.0040 | 1.0020 | 1.0000 | 0.9980 | 0.9990 | 0.9950 | 0.9970 | 0.9960 | 0.9970 | 0.9960 |
| 14 | 1.0043 | 1.0029 | 1.0025 | 1.0015 | 1.0007 | 0.9997 | 1.0001 | 0.9983 | 0.9988 | 0.9986 | 0.9990 | 0.9985 |
| 15 | 1.0000 | 1.0000 | 1.0000 | 1.0000 | 1.0000 | 1.0000 | 1.0000 | 1.0000 | 1.0000 | 1.0000 | 1.0000 | 1.0000 |
| 16 | 0.9956 | 0.9963 | 0.9966 | 0.9978 | 0.9984 | 0.9994 | 0.9993 | 1.0010 | 1.0005 | 0.9999 | 0.9999 | 1.0005 |
| 17 | 0.9910 | 0.9920 | 0.9930 | 0.9950 | 0.9960 | 0.9980 | 0.9980 | 1.0010 | 1.0000 | 0.9990 | 0.9990 | 1.0000 |
| 18 | 0.9862 | 0.9876 | 0.9896 | 0.9917 | 0.9931 | 0.9957 | 0.9957 | 0.9998 | 0.9983 | 0.9977 | 0.9976 | 0.9987 |
| 19 | 0.9810 | 0.9830 | 0.9860 | 0.9880 | 0.9900 | 0.9930 | 0.9930 | 0.9980 | 0.9960 | 0.9960 | 0.9960 | 0.9970 |
| 20 | 0.9755 | 0.9781 | 0.9817 | 0.9841 | 0.9867 | 0.9902 | 0.9902 | 0.9961 | 0.9937 | 0.9937 | 0.9942 | 0.9952 |
| 21 | 0.9700 | 0.9730 | 0.9770 | 0.9800 | 0.9830 | 0.9870 | 0.9870 | 0.9940 | 0.9910 | 0.9910 | 0.9920 | 0.9930 |
| 22 | 0.9649 | 0.9680 | 0.9725 | 0.9756 | 0.9786 | 0.9832 | 0.9831 | 0.9912 | 0.9877 | 0.9880 | 0.9891 | 0.9902 |
| 23 | 0.9600 | 0.9630 | 0.9680 | 0.9710 | 0.9740 | 0.9790 | 0.9790 | 0.9880 | 0.9840 | 0.9850 | 0.9860 | 0.9870 |
| 24 | 0.9551 | 0.9581 | 0.9634 | 0.9664 | 0.9695 | 0.9749 | 0.9750 | 0.9846 | 0.9805 | 0.9819 | 0.9830 | 0.9839 |
| 25 | 0.9501 | 0.9533 | 0.9587 | 0.9618 | 0.9650 | 0.9710 | 0.9712 | 0.9810 | 0.9771 | 0.9789 | 0.9800 | 0.9810 |
| 26 | 0.9451 | 0.9485 | 0.9539 | 0.9572 | 0.9607 | 0.9670 | 0.9675 | 0.9774 | 0.9738 | 0.9757 | 0.9771 | 0.9780 |
| 27 | 0.9401 | 0.9438 | 0.9490 | 0.9526 | 0.9564 | 0.9631 | 0.9638 | 0.9737 | 0.9704 | 0.9724 | 0.9741 | 0.9751 |
| 28 | 0.9350 | 0.9390 | 0.9440 | 0.9480 | 0.9520 | 0.9590 | 0.9600 | 0.9700 | 0.9670 | 0.9690 | 0.9710 | 0.9720 |
| 29 | 0.9299 | 0.9342 | 0.9390 | 0.9434 | 0.9475 | 0.9548 | 0.9560 | 0.9663 | 0.9634 | 0.9654 | 0.9676 | 0.9688 |
| 30 | 0.9249 | 0.9294 | 0.9339 | 0.9388 | 0.9430 | 0.9504 | 0.9519 | 0.9626 | 0.9597 | 0.9616 | 0.9641 | 0.9654 |
| 31 | 0.9199 | 0.9246 | 0.9289 | 0.9342 | 0.9383 | 0.9460 | 0.9477 | 0.9588 | 0.9559 | 0.9577 | 0.9604 | 0.9620 |
| 32 | 0.9149 | 0.9198 | 0.9239 | 0.9296 | 0.9337 | 0.9415 | 0.9434 | 0.9550 | 0.9520 | 0.9538 | 0.9567 | 0.9585 |
| 33 | 0.9100 | 0.9150 | 0.9190 | 0.9250 | 0.9290 | 0.9370 | 0.9390 | 0.9510 | 0.9480 | 0.9500 | 0.9530 | 0.9550 |
| 34 | 0.9051 | 0.9102 | 0.9142 | 0.9204 | 0.9243 | 0.9325 | 0.9346 | 0.9469 | 0.9440 | 0.9463 | 0.9493 | 0.9516 |
| 35 | 0.9003 | 0.9053 | 0.9096 | 0.9158 | 0.9197 | 0.9281 | 0.9302 | 0.9427 | 0.9400 | 0.9427 | 0.9457 | 0.9482 |
| 36 | 0.8955 | 0.9005 | 0.9050 | 0.9112 | 0.9151 | 0.9237 | 0.9257 | 0.9385 | 0.9360 | 0.9391 | 0.9421 | 0.9448 |
| 37 | 0.8907 | 0.8957 | 0.9005 | 0.9066 | 0.9105 | 0.9194 | 0.9213 | 0.9342 | 0.9320 | 0.9356 | 0.9386 | 0.9414 |
| 38 | 0.8860 | 0.8910 | 0.8960 | 0.9020 | 0.9060 | 0.9150 | 0.9170 | 0.9300 | 0.9280 | 0.9320 | 0.9350 | 0.9380 |
| 39 | 0.8813 | 0.8863 | 0.8915 | 0.8975 | 0.9015 | 0.9106 | 0.9127 | 0.9258 | 0.9240 | 0.9283 | 0.9314 | 0.9346 |
| 40 | 0.8765 | 0.8816 | 0.8870 | 0.8929 | 0.8970 | 0.9063 | 0.9085 | 0.9217 | 0.9201 | 0.9246 | 0.9278 | 0.9312 |
| 41 | 0.8718 | 0.8770 | 0.8824 | 0.8884 | 0.8926 | 0.9019 | 0.9043 | 0.9176 | 0.9161 | 0.9208 | 0.9241 | 0.9277 |
| 42 | 0.8671 | 0.8725 | 0.8779 | 0.8840 | 0.8882 | 0.8975 | 0.9002 | 0.9136 | 0.9122 | 0.9169 | 0.9205 | 0.9242 |
| 43 | 0.8624 | 0.8679 | 0.8734 | 0.8795 | 0.8839 | 0.8932 | 0.8961 | 0.9095 | 0.9083 | 0.9130 | 0.9168 | 0.9208 |
| 44 | 0.8577 | 0.8634 | 0.8688 | 0.8751 | 0.8796 | 0.8888 | 0.8920 | 0.9056 | 0.9044 | 0.9091 | 0.9131 | 0.9173 |
| 45 | 0.8530 | 0.8590 | 0.8643 | 0.8707 | 0.8752 | 0.8845 | 0.8880 | 0.9016 | 0.9005 | 0.9051 | 0.9095 | 0.9137 |
| 46 | 0.8484 | 0.8545 | 0.8598 | 0.8663 | 0.8710 | 0.8802 | 0.8840 | 0.8977 | 0.8966 | 0.9011 | 0.9058 | 0.9102 |
| 47 | 0.8438 | 0.8501 | 0.8553 | 0.8619 | 0.8667 | 0.8758 | 0.8800 | 0.8938 | 0.8927 | 0.8971 | 0.9021 | 0.9067 |
| 48 | 0.8392 | 0.8457 | 0.8509 | 0.8576 | 0.8625 | 0.8715 | 0.8760 | 0.8898 | 0.8888 | 0.8930 | 0.8984 | 0.9031 |
| 49 | 0.8346 | 0.8414 | 0.8464 | 0.8533 | 0.8582 | 0.8673 | 0.8720 | 0.8859 | 0.8849 | 0.8890 | 0.8947 | 0.8996 |
| 50 | 0.8300 | 0.8370 | 0.8420 | 0.8490 | 0.8540 | 0.8630 | 0.8680 | 0.8820 | 0.8810 | 0.8850 | 0.8910 | 0.8960 |
| 51 | 0.8255 | 0.8327 | 0.8376 | 0.8447 | 0.8498 | 0.8588 | 0.8640 | 0.8781 | 0.8771 | 0.8810 | 0.8873 | 0.8924 |
| 52 | 0.8209 | 0.8283 | 0.8332 | 0.8405 | 0.8456 | 0.8545 | 0.8600 | 0.8741 | 0.8731 | 0.8770 | 0.8837 | 0.8889 |

Continue to 300 mm depth




Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

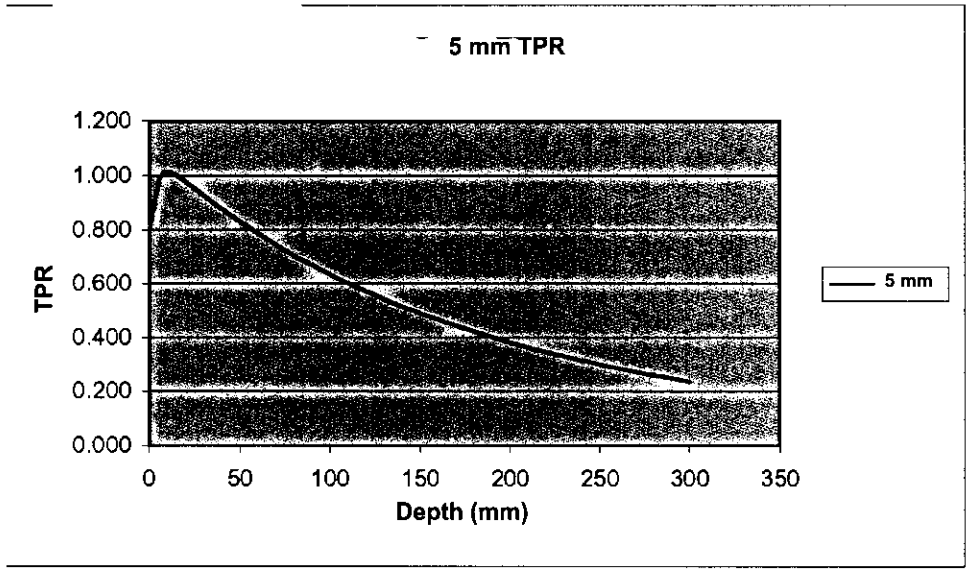
Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015


# APPENDIX 3-3: DIRECT TPR MEASUREMENTS

100 mu fraction
5 mm Cone

| step# | move | rel. pos | robot_z | 1 | 2 | avg | norm |
|---|---|---|---|---|---|---|---|
| 0 | | 0 | 1444.4 | 117.65 | 117.70 | 117.68 | 0.805 |
| 1 | 5 | 5 | 1439.4 | 142.53 | 142.54 | 142.54 | 0.975 |
| 2 | 2 | 7 | 1437.4 | 146.87 | 146.84 | 146.86 | 1.005 |
| 3 | 2 | 9 | 1435.4 | 148.23 | 148.21 | 148.22 | 1.014 |
| 4 | 2 | 11 | 1433.4 | 148.14 | 148.02 | 148.08 | 1.013 |
| 5 | 2 | 13 | 1431.4 | 147.21 | 147.28 | 147.25 | 1.008 |
| 6 | 2 | 15 | 1429.4 | 146.10 | 146.13 | 146.12 | 1.000 |
| 7 | 2 | 17 | 1427.4 | 144.74 | 144.72 | 144.73 | 0.991 |
| 8 | 2 | 19 | 1425.4 | 143.38 | 143.35 | 143.37 | 0.981 |
| 9 | 2 | 21 | 1423.4 | 141.81 | 141.75 | 141.78 | 0.970 |
| 10 | 2 | 23 | 1421.4 | 140.27 | 140.31 | 140.29 | 0.960 |
| 11 | 5 | 28 | 1416.4 | 136.62 | 136.58 | 136.60 | 0.935 |
| 12 | 5 | 33 | 1411.4 | 133.01 | 132.99 | 133.00 | 0.910 |
| 13 | 5 | 38 | 1406.4 | 129.43 | 129.37 | 129.40 | 0.886 |
| 14 | 12 | 50 | 1394.4 | 121.23 | 121.25 | 121.24 | 0.830 |
| 15 | 25 | 75 | 1369.4 | 105.75 | 105.69 | 105.72 | 0.724 |
| 16 | 25 | 100 | 1344.4 | 92.49 | 92.58 | 92.54 | 0.633 |
| 17 | 25 | 125 | 1319.4 | 81.21 | 81.20 | 81.21 | 0.556 |
| 18 | 25 | 150 | 1294.4 | 71.43 | 71.46 | 71.45 | 0.489 |
| 19 | 50 | 200 | 1244.4 | 55.65 | 55.64 | 55.65 | 0.381 |
| 20 | 50 | 250 | 1194.4 | 43.70 | 43.68 | 43.69 | 0.299 |
| 21 | 50 | 300 | 1144.4 | 34.51 | 34.53 | 34.52 | 0.236 |

all positions in mm






Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015


# APPENDIX 3-4: EXAMPLE - PROCESSING OCR DATA IN PTW MEPHYSTO MC²

Open the file containing the profile data, *Figure 1 . Single Depth In Plane and Cross Plane Scans, page 62.*

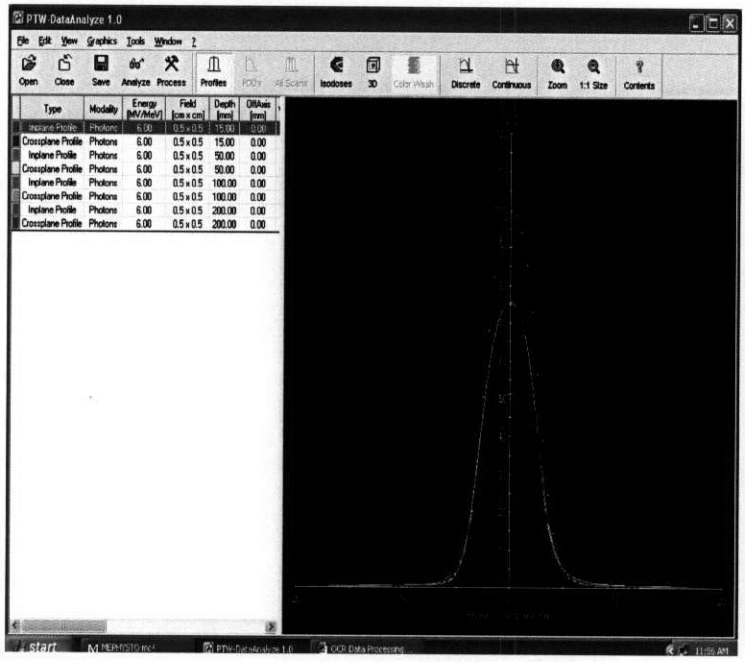



**Figure 1. Single Depth In Plane and Cross Plane Scans**

Delete all of the curves except for the in-plane and cross-plane curves for the depth to be processed. This is done by selecting the unneeded curves in the left screen while holding the SHIFT key, then right click and select DELETE SELECTED SCANS. There should be two curves remaining, an in-plane and cross-plane scan for the depth to be processed as shown in *Figure 2 . Select Scans to Process, page 62.*

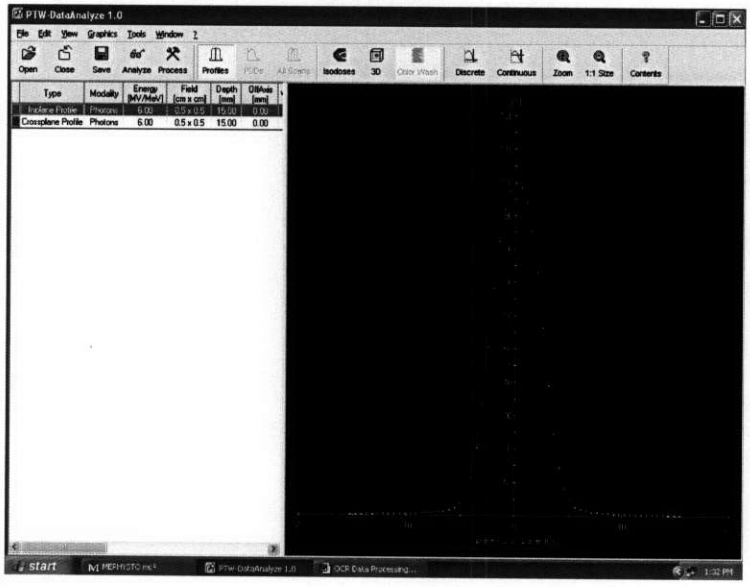



**Figure 2. Select Scans to Process**



241
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015


Highlight the in-plane and cross-plane curves in the left window. Select PROCESS, smooth and shift curves to CAX. Then right Mouse click and select CREATE > AVERAGE SCAN. Then click **OK**.

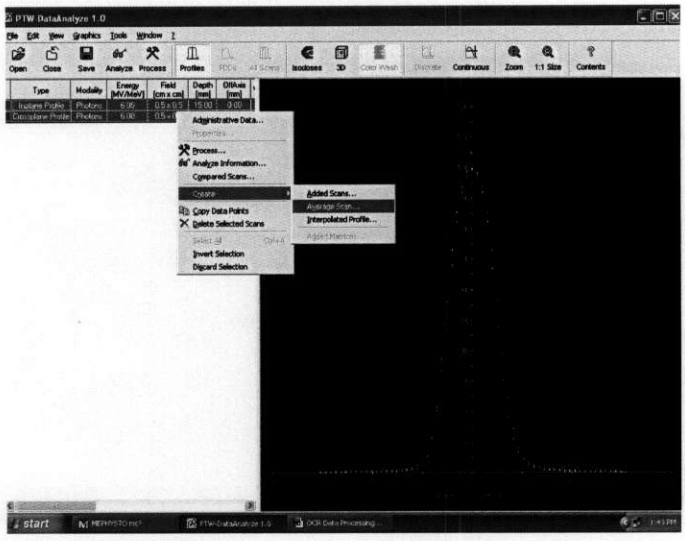



**Figure 3. Average Scan**

A third curve is created which is the average of the in-plane and cross-plane curves. Delete the in-plane and cross-plane curves so only the averaged curve remains and save this as a new file. Highlight the averaged curve and select PROCESS. SMOOTH the curve as required. Then click **ACCEPT** and save the file, e.g., 5 mm cone_15 mm depth_averaged_smoothed.

Open the file containing the averaged curve with the curve highlighted, click **PROCESS**.

Under the TOOLS menu, click **OPTIONS**, then select USE RIGHT HALF, *Figure 4 . Options to Select Half Scan, page 63*.

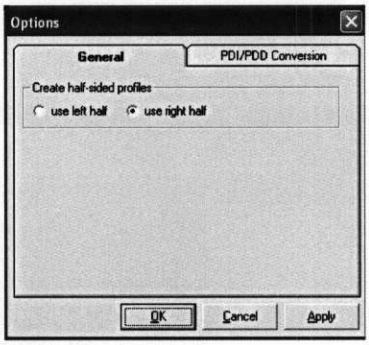



**Figure 4. Options to Select Half Scan**



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015


Then click **OK**.

Click **HALVE** then **ACCEPT**. The curve should look like *Figure 5 . Radial Beam Profile, page 64*, Radial Beam Profile.

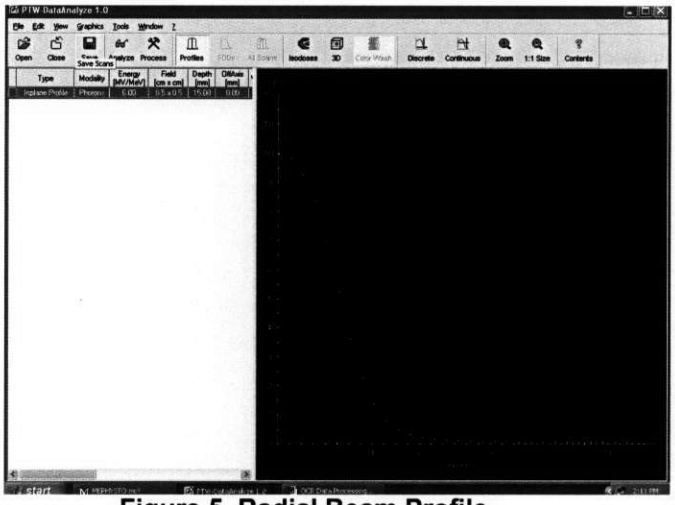


**Figure 5. Radial Beam Profile**

Save this file as the right half, e.g., 5 mm cone_15 mm depth_right half.

Close this file the reopen the averaged curve. Under the TOOLS menu, click **OPTIONS**, then select **USE LEFT HALF**.

Click **HALVE** then **MIRROR** then **ACCEPT**.

Save this file as the left half, e.g., 5 mm cone_15 mm depth_left half, then CLOSE it.

Open the right and left files in the same window by clicking **OPEN** then highlighting both files and clicking **OK**. Since the left half was MIRRORED, the two curves will appear in the same quadrant, see *Figure 6 . Average Half Profile, page 64*.

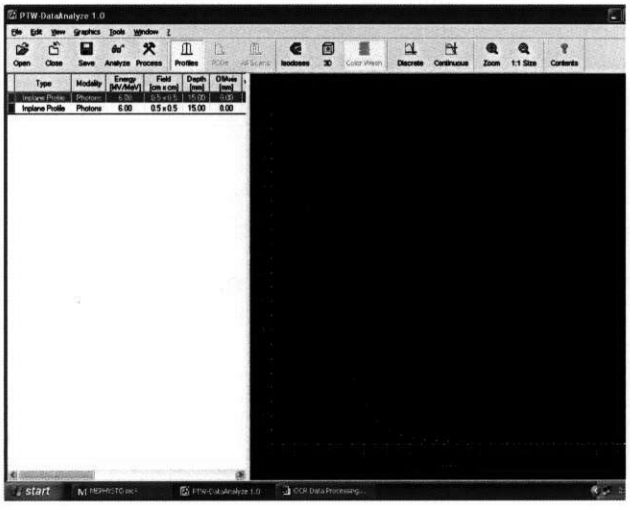


**Figure 6. Average Half Profile**



243

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015


Highlight the left and right curves, then right Mouse click. The select CREATE > AVERAGE SCAN. Then click **OK**, as in Figure 3.

The AVERAGE SCAN will appear as a new curve. Delete the left and right half curves and save the files as 5 mm cone_15 mm depth_OCR.

The finished curve should look like *Figure 7 . Averaged Half Beam Profiles, page 65.*

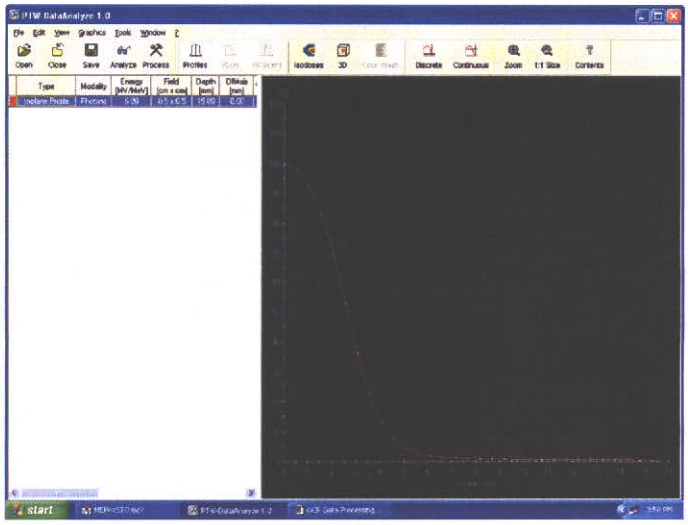


**Figure 7. Averaged Half Beam Profiles**

To export the data, highlight the curve and select PROCESS. Select the EDIT button. Right click in the data columns and SELECT ALL. Then, with all of the data highlighted, right click and select **COPY DATA POINTS**, *Figure 8 . Profile Data Points, page 65.* Then paste the data into Excel.

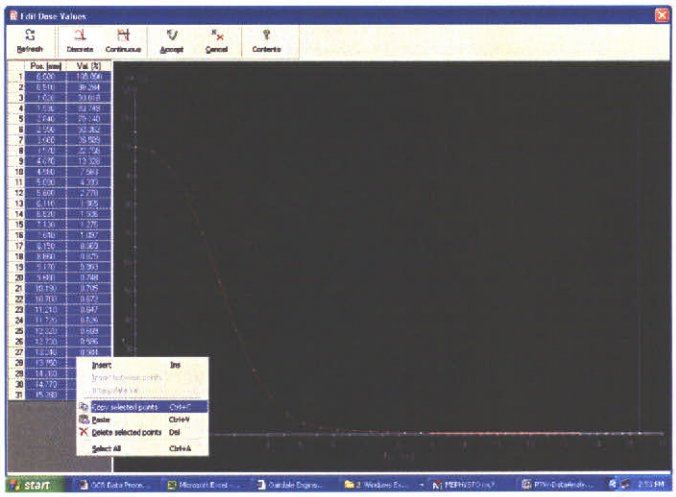


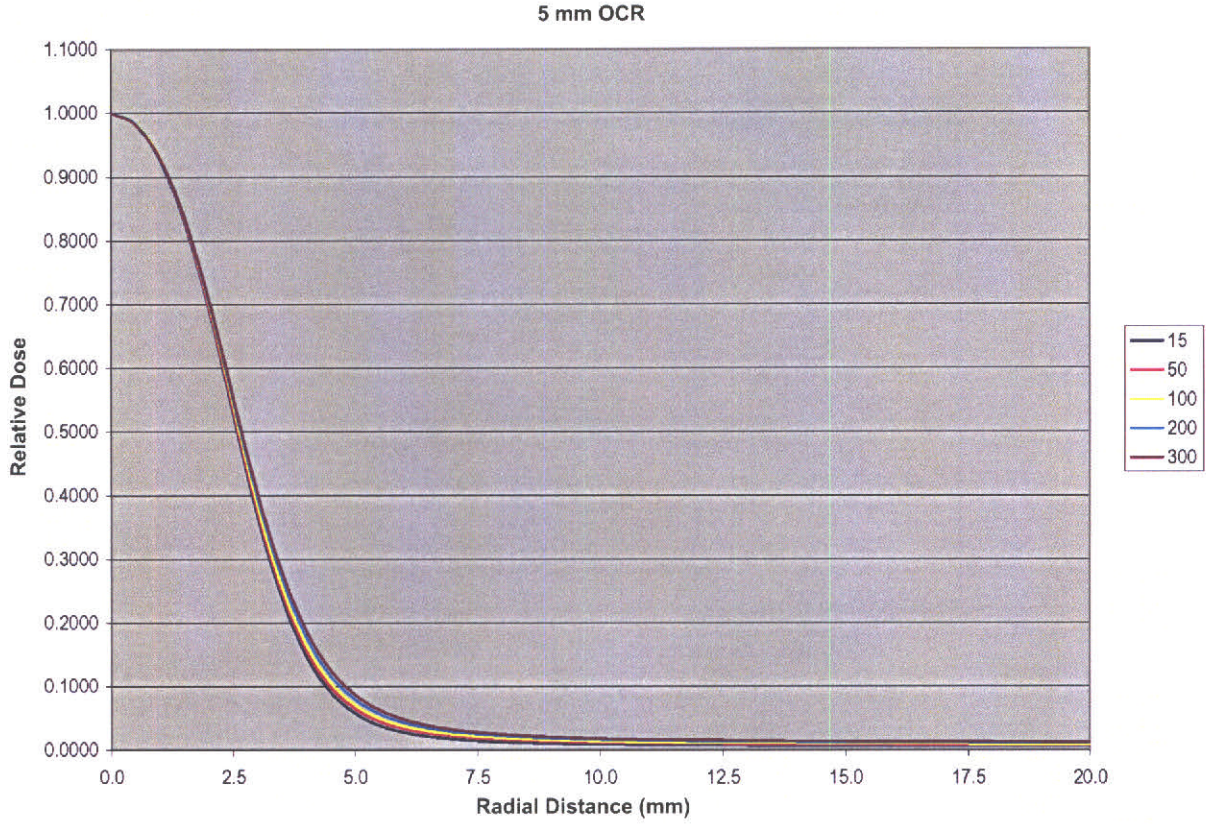
**Figure 8. Profile Data Points**



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015


# APPENDIX 3-5: 5 MM OCR PLOT






Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

245

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015

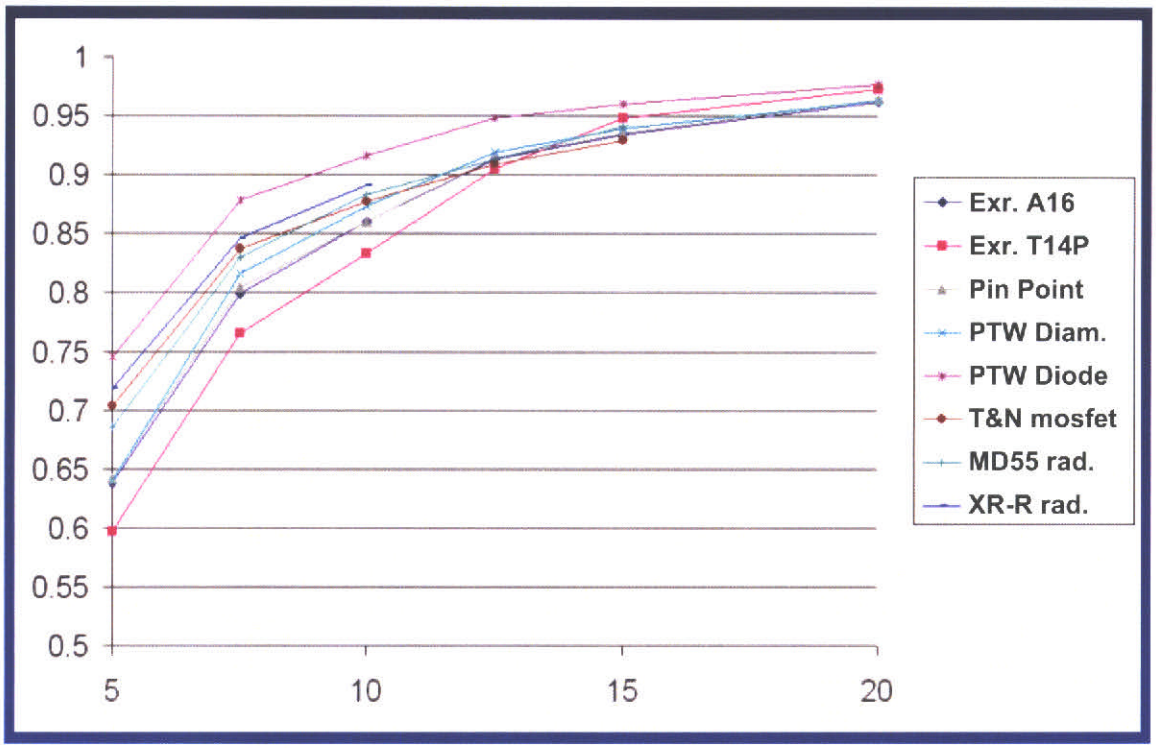




**Figure 9. Total Scatter Factors - results**



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015


# APPENDIX 3-6: 5 MM OCR DATA EXAMPLE

**5.0 collimator_size (mm)**
**5 depths (mm)**
**21 radial measurements (mm)**

| | 15 | 50 | 100 | 200 | 300 |
|---|---|---|---|---|---|
| 0.0 | 1.0000 | 1.0000 | 1.0000 | 1.0000 | 1.0000 |
| 0.5 | 0.9823 | 0.9828 | 0.9836 | 0.9827 | 0.9821 |
| 1.0 | 0.9270 | 0.9285 | 0.9301 | 0.9290 | 0.9289 |
| 1.5 | 0.8304 | 0.8323 | 0.8350 | 0.8358 | 0.8374 |
| 2.0 | 0.6932 | 0.6962 | 0.7013 | 0.7048 | 0.7081 |
| 2.5 | 0.5302 | 0.5356 | 0.5430 | 0.5502 | 0.5558 |
| 3.0 | 0.3701 | 0.3772 | 0.3858 | 0.3978 | 0.4060 |
| 3.5 | 0.2393 | 0.2471 | 0.2562 | 0.2700 | 0.2802 |
| 4.0 | 0.1477 | 0.1560 | 0.1644 | 0.1766 | 0.1870 |
| 4.5 | 0.0903 | 0.0986 | 0.1053 | 0.1158 | 0.1247 |
| 5.0 | 0.0569 | 0.0644 | 0.0696 | 0.0785 | 0.0859 |
| 5.5 | 0.0379 | 0.0446 | 0.0488 | 0.0560 | 0.0623 |
| 6.0 | 0.0271 | 0.0330 | 0.0366 | 0.0423 | 0.0474 |
| 6.5 | 0.0206 | 0.0260 | 0.0292 | 0.0338 | 0.0378 |
| 7.0 | 0.0166 | 0.0214 | 0.0243 | 0.0283 | 0.0316 |
| 7.5 | 0.0138 | 0.0183 | 0.0209 | 0.0246 | 0.0275 |
| 8.0 | 0.0120 | 0.0160 | 0.0184 | 0.0218 | 0.0246 |
| 8.5 | 0.0107 | 0.0144 | 0.0166 | 0.0196 | 0.0222 |
| 9.0 | 0.0097 | 0.0132 | 0.0152 | 0.0180 | 0.0202 |
| 9.5 | 0.0091 | 0.0122 | 0.0142 | 0.0168 | 0.0188 |
| 10.0 | 0.0086 | 0.0115 | 0.0133 | 0.0159 | 0.0177 |
| 10.5 | 0.0083 | 0.0109 | 0.0126 | 0.0152 | 0.0168 |
| 11.0 | 0.0079 | 0.0104 | 0.0121 | 0.0145 | 0.0162 |
| 11.5 | 0.0076 | 0.0100 | 0.0117 | 0.0139 | 0.0158 |
| 12.0 | 0.0074 | 0.0097 | 0.0113 | 0.0135 | 0.0154 |
| 12.5 | 0.0073 | 0.0094 | 0.0110 | 0.0132 | 0.0150 |
| 13.0 | 0.0071 | 0.0092 | 0.0108 | 0.0131 | 0.0147 |
| 13.5 | 0.0070 | 0.0090 | 0.0106 | 0.0128 | 0.0143 |
| 14.0 | 0.0069 | 0.0089 | 0.0104 | 0.0126 | 0.0141 |
| 14.5 | 0.0069 | 0.0088 | 0.0103 | 0.0124 | 0.0139 |
| 15.0 | 0.0068 | 0.0086 | 0.0101 | 0.0122 | 0.0137 |
| 15.5 | 0.0067 | 0.0084 | 0.0099 | 0.0119 | 0.0135 |
| 16.0 | 0.0067 | 0.0083 | 0.0097 | 0.0118 | 0.0134 |
| 16.5 | 0.0066 | 0.0082 | 0.0096 | 0.0118 | 0.0134 |
| 17.0 | 0.0065 | 0.0081 | 0.0095 | 0.0117 | 0.0134 |
| 17.5 | 0.0065 | 0.0080 | 0.0094 | 0.0115 | 0.0132 |
| 18.0 | 0.0064 | 0.0079 | 0.0093 | 0.0113 | 0.0130 |
| 18.5 | 0.0063 | 0.0079 | 0.0091 | 0.0113 | 0.0128 |
| 19.0 | 0.0063 | 0.0078 | 0.0090 | 0.0111 | 0.0127 |
| 19.5 | 0.0063 | 0.0077 | 0.0089 | 0.0110 | 0.0126 |
| 20.0 | 0.0063 | 0.0074 | 0.0087 | 0.0108 | 0.0125 |



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015

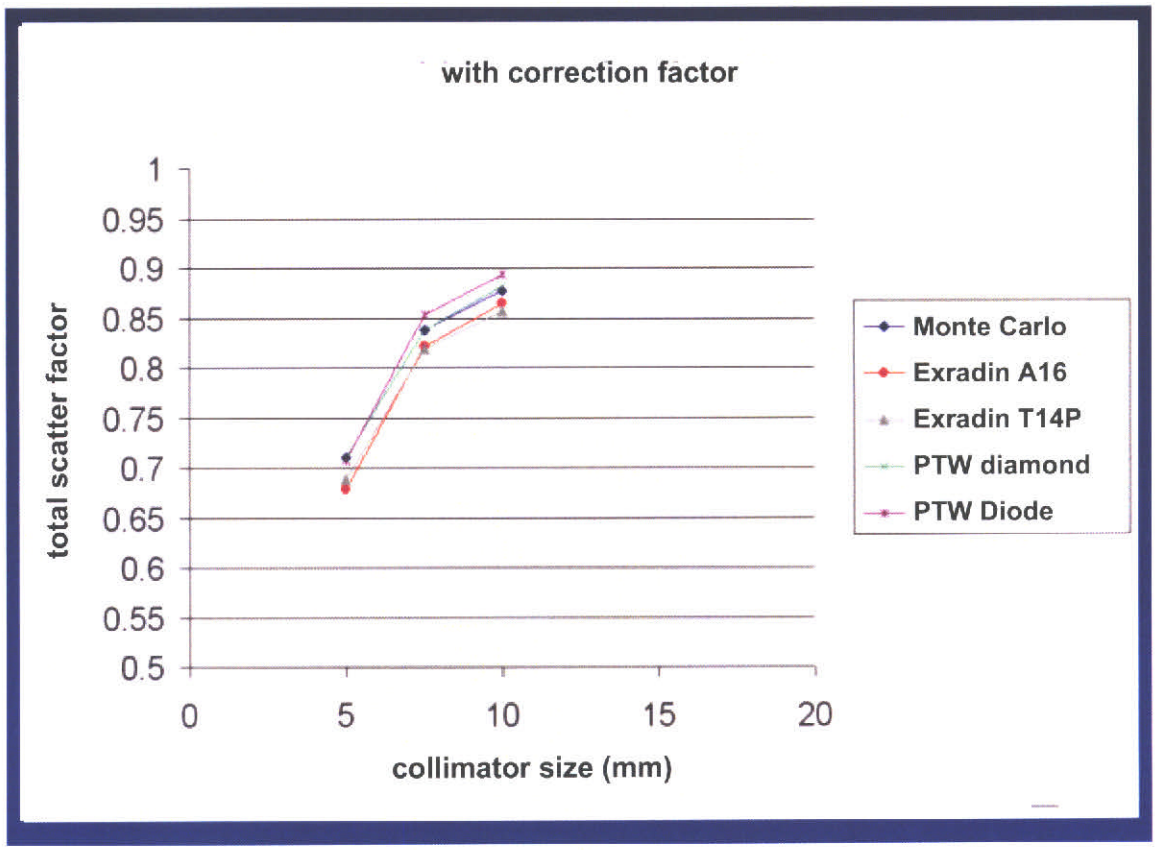




**Figure 10. Monte Carlo - Total Scatter Factors**



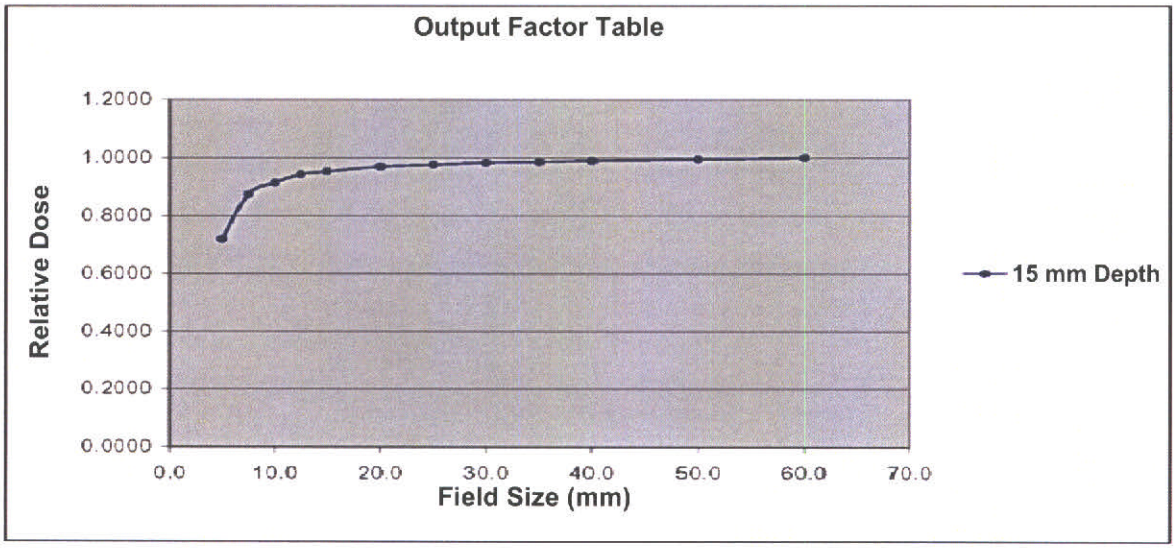
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015


# APPENDIX 3-7: OUTPUT FACTOR TABLE

Output factor Table for the CyberKnife System at Anytown, USA
12 Field Size (mm)
1 depth Size (mm)

| | 5.0 | 7.5 | 10.0 | 12.5 | 15.0 | 20.0 | 25.0 | 30.0 | 35.0 | 40.0 | 50.0 | 60.0 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 15 | 0.7200 | 0.8740 | 0.9140 | 0.9430 | 0.9530 | 0.9690 | 0.9760 | 0.9830 | 0.9860 | 0.9900 | 0.9950 | 1.0000 |






Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

249

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015


# MODULE 4:

# TPS COMMISSIONING AND QA

*© 2006 Accuray Incorporated. All rights reserved. The Accuray stylized logo, Accuray, CyberKnife, Xsight, CyRIS, InView, MultiPlan, and Synchrony are trademarks and/or registered trademarks of Accuray Incorporated in the United States and other countries.*

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015


# Table of Contents

**CyRIS™ MultiPlan™ (TPS)** ..... 3
TPS Data Verification ..... 3
Print tables and intercompare with expected values ..... 3
Procedure 4-1: Print Tables ..... 3
CT Geometric Accuracy ..... 5
Procedure 4-2: Confirm CT Geometric Accuracy ..... 5
Treatment Plan Generation for End to End (E2E) Ball-Cube Test ..... 7
Procedure 4-3: Generate the Ballcube Test Plan for End-to-End (E2E) Test on MultiPlan 1.5.x ..... 7
Treatment Delivery Dose Verification ..... 13
HOMOGENOUS PLAN ..... 13
Procedure 4-4: Plan to Solid Water (or other type) Phantom with Ion Chamber ..... 13
HETEROGENEITY PLAN ..... 15
Tutorials ..... 15
**Dose Calculation Options** ..... 17
Dose Calculation ..... 17
Standard Algorithm ..... 17
Isocontour AND DVH Calculation ..... 17
Coarse Dose Calculation ..... 17
Tissue Density Model Selection ..... 21
Dose Calculation, Manual ..... 23
CyberKnife Treatment Planning Data Fitting ..... 27



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

251

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015


# Module Description:

MultiPlan algorithm and commissioning procedures are described in this module.

# Module Objectives:

**Algorithms for:**

- Targeting
- Treatment Optimization
- Dose Calculation

**TPS Procedures:**

- Data Verification
- CT Geometric Accuracy
- Ball-Cube Test Plan Generation
- Treatment Dose Delivery Verification

**Dose Calculation:**

- Dose Grid
- Tissue CT Density Compensation
- Manual Dose Calculation
- TPS Data Fitting



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015


**NOTE:** Page Left Intentionally Blank



253
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015


# CyRIS™ MultiPlan™ (TPS)

## TPS DATA VERIFICATION

### PRINT TABLES AND INTERCOMPARE WITH EXPECTED VALUES

After the data has been converted to the UNIX format in the SGI primary workstation, the data tables must be printed and intercompared with the entered data.

**WARNING: Do not add extra line breaks, within or at the end of the tables. Otherwise, errors will be introduced into the treatment planning software.**

#### Procedure 4-1: Print Tables

1. Click the Print Button on the right tool bar. In the reference data section, check DM, TMR, and OAR. For the TMR and OAR, select "All collimators" from the pull down menu.
2. Collect the print outs, and compare with the appropriate *.dat file that was entered into the SGI.
3. If there are any extra line breaks, within or at the end of the table, or spaces, errors are introduced into the treatment planning software.
4. To review the files at a later date, open Windows Explorer, navigate to the directory C:\accuray\tmp\Reports\beam_data (for MultiPlan version 1.4.X or earlier) or C:\accuray\Reports\beam_data (for MultiPlan versions 1.5.0 and later.)



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015

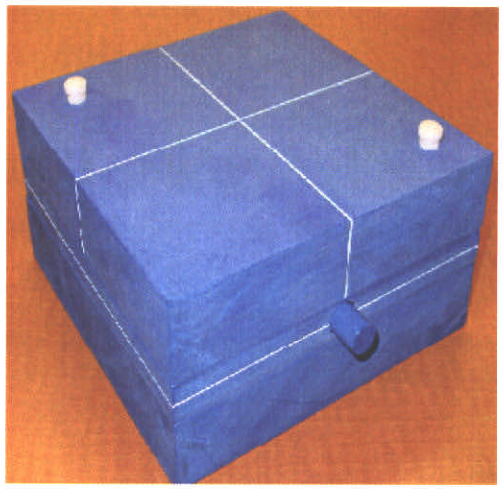



Figure 4-1 Accuray Small Solid Water Phantom with Implanted Fiducials

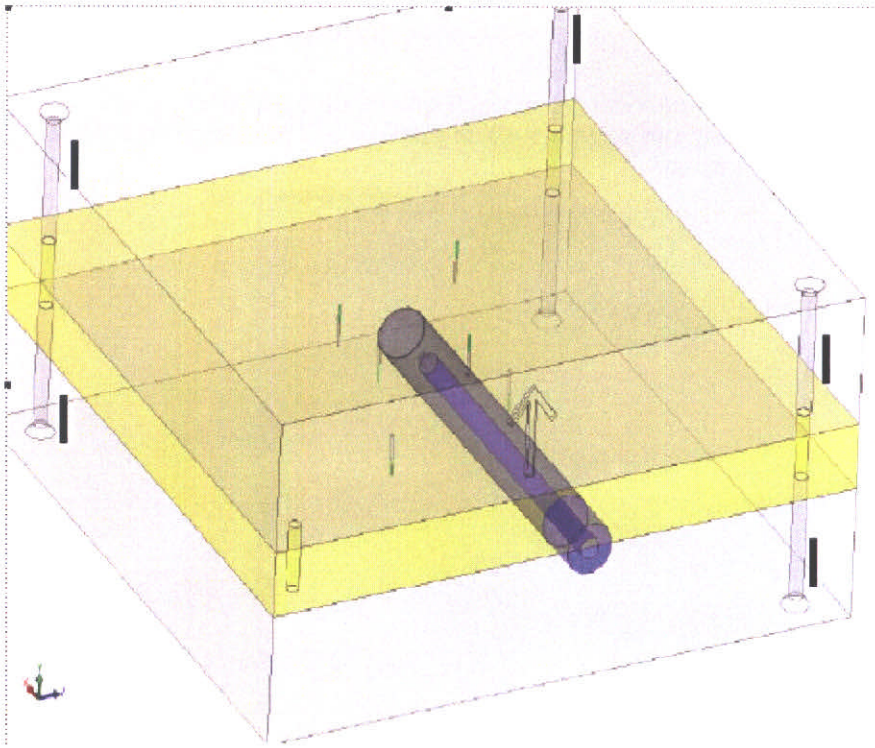


Figure 4-2 Accuray Small Solid Water Phantom with Implanted Fiducial



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015


# CT GEOMETRIC ACCURACY

The spatial accuracy of the simulation CT scanner must be verified. To do this, a CT image set must be acquired with BB markers such as the Beekley dots or fiducials placed a known physical distance (see Figures 4-1, 4-2). Any phantom can be used, though a solid water block is easier to use since it has regular geometry. In addition, the calibrated Farmer-Baldwin type chamber used for the absolute dose calibration can be included during the scan. A treatment dose delivery accuracy plan can also be generated for this phantom when the geometric measurements, distances between BB's, are determined from the TPS. The Ball-Cube is too small to obtain accurate results. The fiducials should be placed at least 150 mm apart LR and AP and at least 300 mm SI. The results of this measurement determine the greatest spatial inaccuracy of your CT scanner, and thus the treatment positioning accuracy.

## Procedure 4-2: Confirm CT Geometric Accuracy

1. Place Beekley dots or BB's on the surface of some kind of block or phantom if the Accuray small solid water phantom is not used.
2. CT scan the phantom with the fiducials. Slice thickness must be as thin as available because the greatest error will be in the superior/inferior direction. Do not use helical acquisition, only uniform slice spacing.
3. Import the CT as a patient.
4. Identify the fiducial location using TPS software.
5. From the ALIGN tab, select the <Mark Fiducial> step. Enter the type of fiducial as gold seeds. Check the auto center option. Double-click on each fiducial and record the x,y,z co-ordinates.
6. Using the ruler tool on the right side global tool bar, measure the distance between the fiducials.
7. Calculate the separation of the fiducials from the position table using the distance formula (below). Use at least one pair of fiducials in each direction (AL, SR, SI).

$$D12 = \text{sqrt}[(x1-x2) * (x1-x2) + (y1-y2) * (y1-y2) + (z1-z2) * (z1-z2)]$$

8. From the diagram, locate the fiducial pairs you are measuring and enter the known distances between them as in the sample data in Table 4-1.
9. Compare actual and CT image distances as measured with the global measuring tool.
10. Verify that the actual and CT distances agree within 1 mm.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015


**Table 4-1: Sample Distance between Fiducial Pairs**

| Marker pair | Actual distance (from diagram or measured with ruler) | CT image distance | error |
|---|---|---|---|
| SUP INF | 315.5 | 315.348 | 0.152 |
| Left Right | 312 | 312.039 | -0.039 |
| ANT POST | 167 | 166.913 | 0.087 |
| 6-4 delta z | 163.3 | 162.612 | 0.688 |
| 7-8 delta z | 141.5 | 141.029 | 0.471 |
| 5-6 delta x | 303 | 302.821 | 0.179 |



257
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015


# TREATMENT PLAN GENERATION FOR END TO END (E2E) BALL-CUBE TEST

To perform the targeting accuracy test using the ballcube phantom, treatment plans are generated using the MultiPlan Treatment Planning System. Plans must be produced using all treatment modes that have been purchased, including skull tracking, fiducial tracking, spine tracking, and motion tracking if available on the system.

## PROCEDURE 4-3: GENERATE THE BALLCUBE TEST PLAN FOR END-TO-END (E2E) TEST ON MULTIPLAN 1.5.X

### Launch the MultiPlan TPS

### Startup Wizard

1. Select the patient containing the Ball-Cube phantom. (During training at Accuray, click the Patient Name Phantom 1,1.)
2. At the top of the right (rt) side of the screen, click New Plan.
3. Click Next on the lower screen.
4. Highlight the desired CT study.
5. Click the SELECT EXAM button below the loaded images if the correct study is displayed.
6. Wait until the CT study ends loading.
7. The ALIGN tab will be high lighted.

### Align TAB

1. The first step on the left is **Treatment Parameters**.
2. In the left screen during training for example, select:
   Number of Stages = 1
   Treatment Anatomy = Body
   Tracking Mode = fiducial
   Treatment Mode = Automatic
   Beam on Time = 150 seconds which is default
   See table 4-3 for other modes
3. Go to the **FIDUCIALS** step.
4. Select Gold Seed_1 from Drop Down(DD) on the left side menu.
5. Check Auto Center.
6. Scroll through the transverse CT slices and double click on the fiducials. There are five.
7. Go to the **CT Center** step, where the images are automatically centered in the frame.

**NOTE:** When other Tracking Modes are selected during the Treatment Parameters step, the anterior and the superior image surfaces must be positioned relative to the frame edge.

- Skull: Use the lower image axis cursors to shift the Anterior and Superior images until there is 10 - 15 mm space from the fame edge.
- Skeletal Tracking: Set CT center at the inferior C5 spine or the superior C6 spine.

8. Select CONFIRM in the left screen when the images are correctly positioned.
9. Click on the CONTOUR tab.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015


**NOTE:** Page Left Intentionally Blank




Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015


## Contour TAB

**Contour the sphere.**

1. Begin at the left upper screen and select Volume of Interest (VOI) Tumor Site from the drop down. In properties, the name can be changed to Target.
2. To contour the target, locate the ball in the CT image.
3. Magnify the image in all three screens.
4. Use the Intensity button on the right side tool bar to enhance the contrast between the sphere and the cube.
5. Position cursor axes in center of ball at the maximum diameter.
6. CLK the blue Ellipse tool button, generate a target VOI of the ball by drawing the edge of the sphere.
7. CLK on the Ellipse, then CLK and drag to form a circle.
8. Click on the middle blue Rescale button to center the circle. CLK the yellow box on the right side to adjust the size of the circle as needed.
9. Scroll using the mouse thumb wheel to the top slice, and click in the screen.
10. Resize as needed and scroll down, resizing the circles as needed.
11. Repeat from the bottom slice.
12. Review the other image orientations and make the VOI contours as close to a sphere as possible, paying attention to top and bottom of sphere.
13. SAVE Plan by clicking the floppy disk icon on the right tool bar.

**Contour concentric shells around the sphere to control the dose gradient.**

1. Generate a NEW *critical* structure (NOT a Lesion), an "Inner Shell", by copying the target just completed. Using the 3D Copy button on the left screen, generate a shell VOI around the target.
2. In the screen that opens up, select New Shell Structure. The source VOI is target, and select a critical structure from the drop down. Destination VOI is Inner Shell. Continue. In the new screen, set the inner gap to 0mm, and the thickness to 5 mm.
3. Generate a NEW *critical* structure 2, Outer Shell. Select the target in the upper left screen. Using the 3D Copy tool, generate another shell VOI around the target as in step 3. Source VOI is target, and select another critical structure for the target volume. Destination VOI is Outer Shell. Set the inner gap to 5 mm, and the thickness to 5 mm.
4. Select the Outer Shell VOI, click <properties>, and change color so that the shells are easily seen.
5. SAVE the plan by clicking the diskette icon on the right edge tool bar.
6. Go to the PLAN tab.

## Plan TAB– Setup Step

1. Return the images to the original size by clicking the reset button on the right tool bar.
2. Resize the yellow dose calculation grid to the edges of the cube.
3. Do not change the defaults for homogenous.
4. Go to the ISOCENTRIC step.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015


**Table 4-2: VOI Constraints Table**

| | VOI Min Dose | Min Weight | Max Dose | Max Weight |
|---|---|---|---|---|
| **Head** Target | 2500 | 80 | 3000 | 50 |
| Critical Structure #1 Inner Shell | -- | -- | 800 | 50 |
| Critical Structure # 2 Outer | -- | -- | 300 | 50 |

**Table 4-3: Treatment Delivery Modality Values**

| Planning Constraints | Ball-Cube 6D Skull | Ball-Cube Fiducial | Ball-Cube Synchrony | Ball-Cube Xsight | Ball-Cube Xsight |
|---|---|---|---|---|---|
| Path | 800 | 800 | 800 | 900-1000 | 800 |
| Collimator Size | 30 mm | 30 mm | 30 mm | 15 mm | 20 mm |
| Dose, cGy | 3000 | 3000 | 3000 | 3000 | 3000 |
| $R_x$ IDL | | 80% | | 70% | 80% |
| Planning Algorithm | Simplex | Simplex | Simplex | Simplex | Simplex |
| Min MU | 5 | 5 | 5 | 5 | 5 |
| Max MU | 80 | 75 | 95 | 75 | -- |
| Ball_min Dose | 2400 | 2400 | 2400 | 2400 | 2400 |
| Ball Dose, max | 3000 | 3000 | 3000 | 3000 | 3000 |
| Constraint Dose, Inner shell max | 1200 | 1200 | 1200 | 1200 | 1200 |
| weight | 50 | 50 | 50 | 50 | 50 |
| Constraint Dose, Outer Shell max | 800 | 800 | 800 | 800 | 800 |
| Weight | 50 | 50 | 50 | 50 | 50 |



261 Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015


## Plan TAB– Isocentric

1. Magnify the images and position the cursor at the center of the ball
2. Check the "Conformal Plan" option so that dose is *not* calculated. The isocentric beam set that is generated can then be used to generate a conformal plan with this more limited beam set.
3. With the axis cursors centered within the sphere, select <Isocenter>New in the left screen.
4. Click edge of collimator, NOT near the the axis cursors, if the position needs to be better centered. • The default size of the collimator will approximately match the size of the ball for the 800 path.
5. Go to the conformal step.

## Plan TAB– Conformal

1. Do NOT check a collimator size or additional paths will be generated. When the Conformal Plan option is selected in the Isocentric Step, the beam set is retained for conformal planning. During training at Accuray, use steps 2-5, otherwise refer to tables 4-2 and 4-3.
2. Generate a treatment plan using the following parameters.

   Select Simplex as planning method.

   Large Ball-Cube:

   **BODY FIDUCIAL** 800 path, 30 mm collimator

   (900 - 1000 path, 25 mm collimator)

   **OR** Mini BC if generating an Xsight plan Refer to Table 3

   **Xsight HEAD 800 path**, 20 mm collimator
3. Set Min MU=5, Max MU=95 for example, but See Table 2 for actual values
4. Set the VOI dose constraint for the target (See Table 2), and select generate beams. Later enter the critical structure constraints if needed.
5. Prescription dose line = 75%. (75% is perfect for 800 path).
6. Click "Generate Beams".

## Settings TAB – Physics

1. Select "Target A" as the target VOI.
2. Set Target dose to 75%.
3. Click "Center Dose" button to center the dose the dose cloud to the target.
4. Proceed to the Plan Evaluate step. Type "3000" into the "Rx Dose (cGy) window", and "75" into the "Rx (%) window". Click the **PRESCRIBE** button.
5. Save the plan as a deliverable plan.
6. **PRINT** the plan using the printer icon on the right tool bar, and the beam data that was used for the dose calculations.
7. Use the beam data tables and perform a hand calculation.
8. Evaluate congruence of the results.

Delivered dose / planned dose = _____ should agree within + / - 2%.

9. On the SGI primary computer, generate the DRR's and Prescribe plan in the normal manner to deliver the plan to the Ball-Cube phantom.

For the delivery modalities, follow the same procedure using the values from the table for each modality (*Table 4-3: Treatment Delivery Modality Values, page 10*).



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015


**NOTE:** Page Left Intentionally Blank



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015


# TREATMENT DELIVERY DOSE VERIFICATION

## HOMOGENOUS PLAN

The overall treatment system performance relative to dose as well as the absolute dose calibration can be verified by planning and delivering a treatment plan of known prescription dose and isodose shape to a calibrated Farmer-Baldwin type chamber. The electrometer reading corrected for the temperature and pressure should correspond within 5% of the expected reading relative to the actual prescribed dose. Once the plan has been delivered, it can be repeated with a regular frequency to determine the CyberKnife dose delivery accuracy.

Patient dosimetry can be performed if a calibrated microchamber is available for use. Plans can be generated to test the small collimators and smaller, more structured and or irregular targets.

In addition, phantom overlay can be used to recalculate a patient plan to a phantom of choice where both the patient absolute dose and relative dose distribution can be verified using film.

### Procedure 4-4: Plan to Solid Water (or other type) Phantom with Ion Chamber

1. Use the method from the previous procedure 4-3. and generate a plan to the solid water phantom with the calibrated ion chamber in place.
2. Contour around the chamber 'to draw the target.
3. Select 3D copy and select shell structure.
4. Enter an isotropic volume of 8mm
5. Develop a plan so that the 98% dose covers the chamber entirely.
6. Save the plan.
7. Delivery and Dose Evaluation. At the primary workstation, generate the ion chamber plan DRR's.
8. Set up the phantom so that the ion chamber can be treated.
9. Deliver the plan and measure the delivered dose.
10. The measured dose will be within +/- 5% of the expected dose.
11. Perform a hand calculation of several beams to develop familiarity with the hand calculation Monitor Unit quality assurance check that is performed for patient treatment plan delivery.

**NOTE:** Be advised that the MultiPlan CT Density Model labeled homogenous actually treats any CT number less than 199 as a zero value. Therefore, you may note an effective depth less than the actual for some of the beams. If your clinic requires a true homogenous CT density model, generate a Custom CT density model that treats all CT numbers as a value of 1.0.

Planned dose _____ / Measured Dose _____ = Percent Difference.

Percent Difference must be less than 5%, and typically is approximately +/- 2%.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015


**NOTE:** Page Left Intentionally Blank



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015


## HETEROGENEITY PLAN

Repeat Procedure 4-4 using a phantom with an air cavity.

Confirm that the hand calculation matches the plan's expected value.

## TUTORIALS

During the physicist MultiPlan training sessions at Accuray, the following exercises will be completed.

1. Generate a Ball-Cube Plan for End to End Targeting Accuracy testing, and review large and mini Ball.
2. Print data tables for collimator used to generate the plan.
3. Perform hand calculation for plan.
4. Generate custom CT density model in the Settings Tab with "Homogeneous" model.
5. Repeat Steps 1. through 3. with a phantom containing a large air cavity.
6. Structure volume calculated in contour task properties step with DVH. If volume is not within Dose Calculation grid, it is not included in the DVH. Find cc of contoured sphere from plan done in step 1. Divide the value by 16,750 cc, how does this influence the target volume? the DVH?
7. Generate Dose Delivery Verification Plan.
8. Review the CI, homogeneity, coverage, and nCI values and their application to plan evaluation.
9. Generate an AQA plan.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015


$R_{800}$ is the radius scaled to distance of 800 mm from the source.

To find the true radius, use the relation:

$R_{SAD} = R_{800}$ (SAD/800)

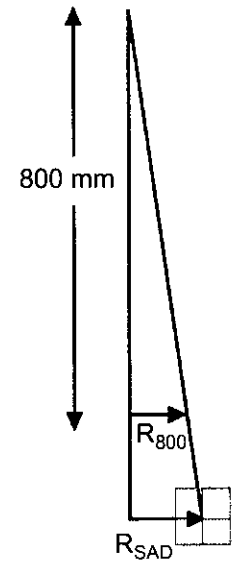



**Figure 4-3 Radius Definitions**

**Table 4-4: *SAMPLE* Ball-Cube Plan Beam Report**

Accuray Beam Data List Date/Time : 04/13/2006 17:36

Reference Point Information

Total Mu : 1700.0355
Total cGy : 988.6226
Refr Coord in CT system : X = 155.8594 Y = 157.5000 Z = 165.0000 (mm)
Refr Coord in Robot system : X = -0.4267 Y = -0.3020 Z = -34.3724 (mm)
Refr Coord in Patient system : X = -16.1328 Y = 17.7734 Z = 115.5500 (mm)

| Beam | ID | Path Collim | SAD | Depth cax | Depth eff | Radius 800 | ocr*inv2 *tpr*dm | cGy | Mu |
|---|---|---|---|---|---|---|---|---|---|
| 1 | 1 | 15.000 | 896.7953 | 62.9113 | 61.5113 | 0.62 | 0.625174 | 33.21 | 53.13 |
| 2 | 1 | 15.000 | 897.6134 | 93.8253 | 92.4253 | 1.99 | 0.532784 | 28.30 | 53.13 |
| 3 | 1 | 15.000 | 897.2223 | 85.2760 | 84.5760 | 1.53 | 0.556171 | 29.55 | 53.13 |
| 4 | 1 | 15.000 | 897.2081 | 50.4832 | 48.7450 | 1.55 | 0.661976 | 35.17 | 53.13 |
| 5 | 1 | 15.000 | 998.9850 | 43.3541 | 37.4541 | 2.50 | 0.565615 | 30.05 | 53.13 |
| 6 | 1 | 15.000 | 999.6666 | 43.8468 | 41.7468 | 2.61 | 0.551813 | 29.32 | 53.13 |
| 7 | 1 | 15.000 | 998.3474 | 46.2616 | 44.8616 | 2.28 | 0.546713 | 29.04 | 53.13 |
| 8 | 1 | 15.000 | 898.6721 | 44.5374 | 40.3374 | 2.67 | 0.680615 | 36.16 | 53.13 |
| 9 | 1 | 15.000 | 898.0978 | 46.0147 | 43.9147 | 2.39 | 0.671978 | 35.70 | 53.13 |
| 10 | 1 | 15.000 | 897.5951 | 48.4825 | 47.0825 | 2.00 | 0.664472 | 35.30 | 53.13 |
| 11 | 1 | 15.000 | 897.0002 | 57.0990 | 54.2297 | 1.19 | 0.646251 | 34.33 | 53.13 |
| 12 | 1 | 15.000 | 997.4623 | 57.1800 | 55.7800 | 1.68 | 0.522241 | 27.74 | 53.13 |
| 13 | 1 | 15.000 | 896.9297 | 64.6828 | 61.4048 | 1.03 | 0.625027 | 33.21 | 53.13 |



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015


# DOSE CALCULATION OPTIONS

## DOSE CALCULATION

The MultiPlan Treatment Planning System dose calculation is based on a ray tracing algorithm. This section describes the algorithm and its different variations.

## STANDARD ALGORITHM

The standard algorithm uses a ray-tracing function based on stored beam percent Tissue Phantom Ratio (TPR) and off-center ratios (OCR). The TPR values are separated into two tables, an output factor that depends only on the collimator, DM, and a tissue phantom ratio (TPR) table. Module 3 describes the methods for measuring the beam parameters and generating the data that comprise these tables.

At each point, the contribution D, in cGy, from each beam is given by the equation:

$$D = (800/SAD) * (800/SAD) * DM * TMR * OCR * MU$$

SAD is the source axis distance, along the central axis of the beam, to the point of the dose calculation, and MU is the number of monitor units for the beam.

The value for DM is found from the collimator size of the beam. The value for TMR is dependent on the field size and the depth of the point. Values are linearly interpolated from calculated points for the TPR. The value for OCR depends on the field size, beam depth, and radial distance between the point of interest and the beam central axis. Values for the OCR are also interpolated linearly, based on stored measured points. Interpolations are done based on perturbations of field size, depth, and radial distance from the central axis. The number of stored beam data points, the number of beams, and the beam geometry affect the amount of error associated with this dose calculation. Generally, more beams in a plan will yield smaller interpolation errors, because each beam's error should be random.

## ISOCONTOUR AND DVH CALCULATION

Dose volume histograms (DVH's), and minimum and maximum dose statistics for defined structures, are generated at native CT resolution, using linear interpolation on the dose values stored in the dose calculation grid. Isodose curves are generated using a curve-fitting algorithm, again using the values stored in the dose calculation grid. Therefore, using a dose calculation grid with smaller elements will yield more accurate DVH's and isodose curves, because interpolation inaccuracies are reduced.

Volumes of regions of interest (ROI) are calculated at native CT resolution, and are therefore generally unaffected by changes in the size of the dose calculation grid. However, note that the volumes of ROI's displayed with the DVH's reflect the volume of the intersection of the ROI with the dose calculation grid. Hence, if the grid is defined so that it does not completely enclose a given ROI, only a fraction of the volume of the ROI will be used for calculation of the corresponding DVH.

## COARSE DOSE CALCULATION

The coarse dose calculation volume is defined to cover the whole CT image. One dose voxel is an integer number of CT voxels in each coordinate direction, with this integer defined so that the resolution in any direction shall not exceed 32. For example, for a CT volume with dimension 512x512x100, the coarse dose voxels will be 8x8x4 CT voxels, giving a coarse dose volume resolution of 32x32x25. The coarse dose calculation volume is used in two ways:

(1) To determine the intersection of beam penumbrae with critical structures, thus allowing beams intersecting certain critical structures to be disabled.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015


**NOTE:** Page Left Intentionally Blank



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015


(2) To calculate the global maximum dose. In the event that the maximum dose found in the coarse dose calculation volume exceeds the maximum in the dose calculation grid, this will not be reflected in the displayed DVH's, i.e. the 100% dose value in the DVH's and dose statistics displayed in the Plan task will reflect the maximum dose in the calculation grid. However, the maximum dose from the coarse calculation volume will be written in the plan overview. Hence, it is recommended that you review the plan overview (create a deliverable plan, click on the Printer icon on the right-hand tool bar, and select "Plan Overview") to ensure that there is not a "hot spot" outside the calculation grid.

## OPTIMIZATION DOSE VOLUME

The optimization dose calculation volume is defined to cover the dose calculation grid. One dose voxel is an integer number of CT voxels in each coordinate direction, with this integer defined so that the resolution in any direction shall not exceed 32. For example, if the dose calculation grid encompasses 100 x 100 x 72 CT voxels, the optimization dose voxels will be 4 x 4 x 3 CT voxels, giving an optimization dose volume resolution of 25 x 25 x 24. The optimization dose calculation volume is used to calculate DVH's, minimum and maximum dose values, and isocontours, except in the Plan Evaluate step after calculation of the high resolution dose volume. Note that even when the high resolution dose volume is present, the optimization dose volume is used to calculate isocontours and DVH's in steps other than the Plan Evaluate step.

## HIGH RESOLUTION DOSE VOLUME

The high resolution dose calculation volume is defined to cover the dose calculation grid. One dose voxel is an integer number of CT voxels in each coordinate direction, with this integer defined so that the resolution in any direction shall not exceed 64. For example, if the dose calculation grid encompasses 100 x 100 x 72 CT voxels, the high resolution dose voxels will be 2 x 2 x 2 CT voxels, giving an optimization dose volume resolution of 50 x 50 x 36. The high resolution dose volume is generated by checking the "High resolution" box and clicking **CALCULATE** in the "Final Review" panel in the Plan Evaluate step. Once calculation is finished, DVH's, isocontours, and dose statistics shown in the Plan Evaluate step (but not other steps) will be calculated using the high resolution dose volume. Making any changes to the plan that affect the delivered dose will result in the high resolution dose volume being destroyed and needing to be recalculated. The sole exception to this rule is the use of the "Prescribe" feature in the Plan Evaluate step: in fact, it is recommended that you calculate high resolution dose before using "Prescribe". The high resolution dose volume must be present in order for a deliverable plan to be saved.

## POINT DOSE CALCULATION

By holding the left mouse button down and moving the mouse cursor over the 2D images, it is possible to get a value representing the dose in cGy delivered by the current plan to the point represented by the cursor. This displayed value has no inherent resolution limits, and is not affected by whether or not the cursor is within the dose calculation grid. The value is calculated by performing a real-time point dose calculation at the position defined by the cursor. Note that, because the dose calculation voxels have finite resolution, it is possible in some instances that the point dose value exceeds the maximum dose calculated in the dose volume (for example, when the true maximum falls between two calculation points).

## DENSITY COMPENSATION

The dose calculation algorithm has three methods for dealing with variable tissue density. Select the density correction algorithm with the PLAN Task, in the Setup step. The default method is to treat all tissue as either air or water. If an area is defined as air, accumulated depth through this is 0 mm. If an area is defined as water, 1 mm of transmission is treated as 1 mm of depth. Most tissue has density close to water, so this introduces small errors for individual beams. The density correction uses the relative physical depth of the beams as opposed to the geometric depth to adjust for the lower beam attenuation in air. Since the Cyberknife uses a large number of small beams with non-isocentric geometry, the oblique incidence through normal tissue along with the increased number of total beams used by the plan, the relative total error introduced by this approximation has been demonstrated to be in the 5% range.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015


**NOTE:** Page Left Intentionally Blank



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015


# TISSUE DENSITY MODEL SELECTION

The effective depth inhomogeneity correction algorithm is used for dose calculation. The effective depth is used during the lookup of TPR and OAR data. There are standard CT density models, labeled lung homogenous, and Body Standard. Custom CT Density Models can also be added.

**1. Homogenous** All CT numbers greater than 199 are assigned a density of 1 mm.

**NOTE:** Be advised that the MultiPlan CT Density Model labeled homogenous actually treats any CT number less than 199 as a zero value. Therefore, you may note an effective depth less than the actual for some of the beams. If your clinic requires a true homogenous CT density model, generate a Custom CT density model that treats all CT numbers as a value of 1.0.

All voxels with a CT number within a user definable range have a relative electron density which is also user definable (typically for lung this value is 0.2 – 0.3). Voxels with CT numbers outside this range are considered water or air, according to these parameters.

**2. Lung**

The CT number can be selected to model areas that will be treated as lung tissue. Generally, these areas have density that is between air and water. The algorithm determines which voxels have CT number between two user-defined parameters. The default range is 200 – 800. Voxels that lie within this range have density values set by the user that may differ from 0.0 and 1.0.

The default setting is the equivalent depth of 0.3 mm depth/1 mm of beam transmission. For treatment plans in the thoracic region of the body, this method generally yields lower dose calculation errors than when treating all tissue as either water or air.

The dose calculation model does not consider effects related to electron disequilibrium, for example backscatter at soft-tissue/bone interfaces.

**3. Body Standard**

This density model is designed with three piece wise linear components to model attenuation by three different types of matter: air, soft tissue, and bone. Voxels with a CT number less than 200 are treated as air, i.e., they have no attenuation associated with them. Voxels with CT number from 200 to 1200 are modeled as having linearly increasing relative density from 0.2 to 1.2, representing soft tissue of varying density. Voxels with CT number from 1200 to 2500 have linearly increasing density from 1.2 to 1.77, representing bone. Voxels with intensity greater than 2500 have constant relative density of 1.77.

**4. Custom CT Density Models**

For versions of MultiPlan 1.5.0 or earlier, DO NOT enter more than nine data points when entering a custom CT density model. Measurement of the CT# per known density can be measured for the treatment planning CT scanner at the site used to scan CyberKnife patients. The measured density values can then be entered into a model for patient planning. The CT calibration data is entered from the SETTINGS task tab on the upper right of the screen.

**WARNING: The depth calculation can be inaccurate in the presence of a significant CT artifact. Low CT number streaks into the patient may lead to underestimation of depth, and high CT number streaks outside the patient or into lung/air cavities may lead to overestimation of depth.**



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015


# Calibration Point

When at calibration point, doseis calcululated as follows:

1 cGy = 1 MU at:

800 mm SAD

15 mm depth water

60 mm collimator

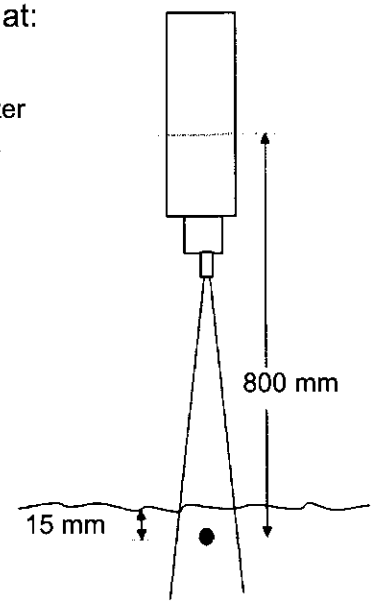



**Figure 4-4 Calibration Point Location**

# Dose calculation

When not at calibration point, dose is calculated as follows:

$$RAD/MU = OCR_{800}(coll, R_{800}, D_{***})*(800/SAD)^{*}(800/SAD)*TPR(field\ size, D_{eff})*DM(field\ size)$$

**Figure 4-5 Dose Calculation Equation**



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015


# DOSE CALCULATION, MANUAL

The absolute dose calibration is conducted so that the CyberKnife output, with the 60 mm collimator at 800 mm SAD and depth = 15 mm, is 1cGy per 1 MU at 15mm depth for the 60 mm collimator (*Figure 4-4 Calibration Point Location, page 22*).

The dose at all other points is determined from the following equation;

**RAD/MU=**

**OCR(coll, R800, D eff) * (800/SAD) * TPR(FS, eff depth) * DM(FS@SAD)**

**Radius, R** is the radial distance from the central axis. The radius for the calculation points can be printed for the geometrically collected value, R 800, or for the actual radius, R SAD From the PRINT Tab in Multiplan 1.5.0 or later. The beam report provides the choice of true radius, or the radius scaled to 800mm SAD, R800 (*Figure 4-5 Dose Calculation Equation, page 22*).

Actual or True radius uses the relation **$R_{SAD} = R_{800}$(SAD/800).**

**Actual field size, FS**, at reference point = **(SADref/800)*(field size at 800)**

The actual field size is used for the TMR and DM tables and must be calculated from the information in the patient treatment file. Refer to notes in *Figure 4-6 MultiPlan Dose Calculation Equation, page 24.*



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015


# MultiPlan Dose Calculation

When **not** at calibration point, doseis calcululated as follows:

$$RAD/MU = OCR_{800}(coll, R_{800}, D_{eff})*(800/SAD)^2*TPR(field\ size, D_{eff})*DM(field\ size)$$

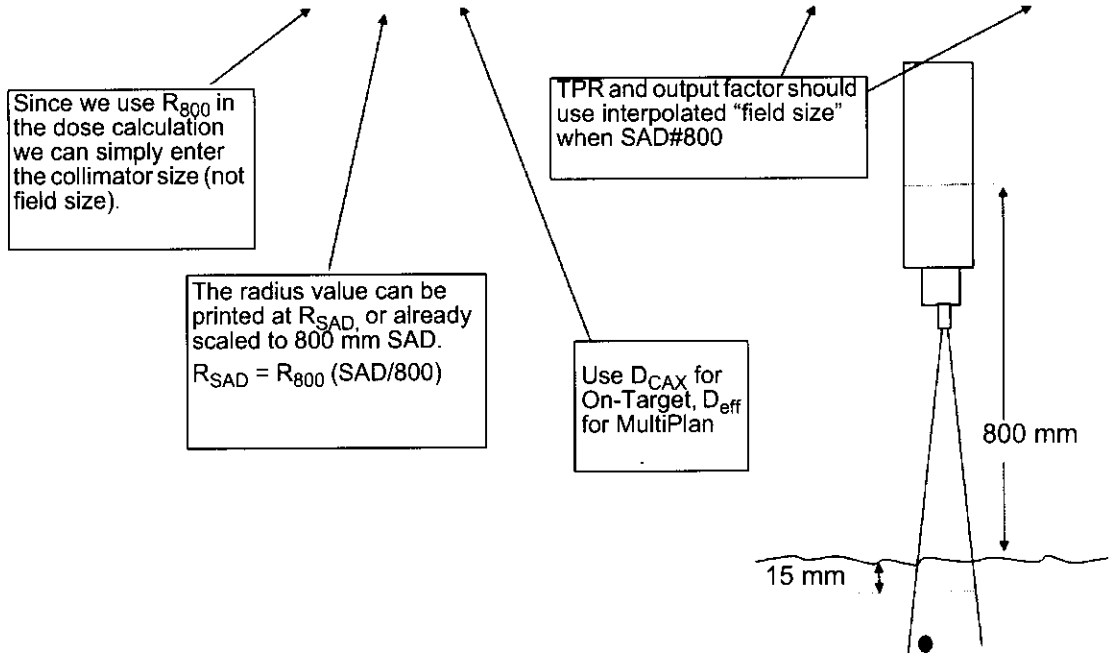



**Figure 4-6 MultiPlan Dose Calculation Equation**



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015


**OCR factor** Use the R800 radius and the effective depth to look up the OCR for the R 800 radius. OCR values greater than 60 mm radius are set to zero in all versions of MultiPlan.

For MultiPlan 1.4, scale the $R_{SAD}$ radius (actual radius for the SAD) to the size it is at 800mm SAD. Using the effective depth, look up the OCR for the $R_{800}$ radius.

**TPR factor** Use the actual field size and effective depth to look up the TPR factor. Interpolate between values as needed. TPR values greater than 300mm use the 300mm value. MultiPlan versions 1.5.0 and earlier have TPR values at effective depths greater than 300mm set to zero.

**Output Factor, DM** Use the calculated actual field size. See Figure 4- 6 **MultiPlan Dose Calculation Equation**

From the beam report found at **Path:** C:\accuray**tmp**\reports\beams for Multiplan versions before 1.5.0. **Path:** C:\accuray\reports\beams for MultiPlan versions 1.5.0 and later. For Multiplan versions 1.5.0 and earlier TPR values greater than 300 mm are set to zero. For Multiplan versions 1.5.1 and later TPR values greater than 300 mm use the value at 300 mm depth.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015


**NOTE:** Page Left Intentionally Blank



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015


# CYBERKNIFE TREATMENT PLANNING DATA FITTING

This summary assumes MultiPlan version 1.5.1 or later and On-Target. Data fitting for On-Target and MultiPlan are identical except where noted.

- **Output Factor less than 5 mm**

  Linear extrapolation by first two values (5 mm and 7.5 mm)

- **Output Factor greater than 60 mm**

  Linear extrapolation of last two values (50 mm, and 60 mm collimators).

- **TPR depth greater than last entered depth point**

  On-Target: last value used for all depths greater than last value

  MultiPlan: Last two entered values extrapolated to 300mm effective depth. The 300mm value is then used as a constant to infinity. TPR values at greater than 300mm effective depth are set to zero. For Multiplan versions 1.5.0 and earlier TPR values greater than 300 mm are set to zero. For Multiplan versions 1.5.1 and later TPR values greater than 300mm use the value at 300mm depth.

- **TPR field size less than 5 mm**

  MultiPlan: Linear extrapolation of first two values.

- **TPR field size greater than 60 mm**

  MultiPlan: Linear extrapolation of last two values

- **OCR Depth less than first measurement**

  Linear extrapolation of first two depth measurements

- **OCR Depth between measurements**

  Linear interpolation

- **OCR Depth greater than last entered data point**

  On-Target: Linear extrapolation out to 300 mm then constant thereafter.

  MultiPlan: Linear extrapolation using the last two values out to 300 mm then constant thereafter

- **OCR Radius greater than last entered value**

  On-Target: Average of last three entered radius values, extended to 50 mm radius.

  At greater than 50 mm radius, OCR is set to zero.

  MultiPlan: Average of last three entered radius values, extended to infinite radius.

  At greater than 50 mm radius, 50 mm value is used



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015





Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015


# MODULE 5:

# QUALITY ASSURANCE TESTS AND SCHEDULE

© 2006 Accuray Incorporated. All rights reserved. The Accuray stylized logo, Accuray, CyberKnife, Xsight, CyRIS, InView, MultiPlan, and Synchrony are trademarks and/or registered trademarks of Accuray Incorporated in the United States and other countries.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118 

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015


# Table of Contents

**Introduction** ..... 3
Quality Assurance Schedule ..... 3
Introduction ..... 5
Equipment QA Benefits ..... 6
QA Benefits ..... 7
**Quality Assurance Procedures** ..... 9
Daily ..... 9
Procedure 5-1. DAILY Quality Assurance ..... 9
DL-A. Safety Interlocks Check ..... 9
DL-B. System Status Check ..... 9
DL-C. LINAC Output Constancy Check ..... 11
Procedure 5-2: LINAC Daily Output Constancy Check ..... 11
DL-D. Robot Perch Position Laser Check ..... 11
DL-E. X-ray Tube Warmup ..... 13
Procedure 5-3: Daily X-ray Tube Warmup ..... 13
DL-F. AQA TOOL ..... 13
Procedure 5-4: Daily QA Test ..... 13
AQA Hardware Components ..... 13
AQA Overview ..... 15
Procedure 5-5: AQA Targeting Accuracy Test Procedure ..... 15
Procedure 5-6: Deliver Simulation to AQA shadow phantom ..... 17
**Film Analysis Software** ..... 21
AQA Software Components ..... 21
Running the AQA Program ..... 21
Starting AQA ..... 21
Loading the Images ..... 21
Adjusting the Images ..... 23
Processing the Images ..... 25
Settings ..... 27
Printing and Saving Analysis Results ..... 29
**Monthly Quality Assurance** ..... 31
Monthly ..... 31
MN- G. Beam Parameters Check ..... 31
MN- H. Qualitative Check of Robot Targeting Accuracy ..... 31
Visual qualitative Robot Targeting Accuracy Test (With BB in Simulation Mode) ..... 33
Procedure 5-7: Robot Targeting Accuracy with BB Test (in Simulation Mode) ..... 33



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

281

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015


MN-H. Monthly "Ball-Cube" Targeting Test Procedure ..... 33
Materials Required for Monthly Ball-Cube Test ..... 35
Procedure 5-8: Monthly Ball-Cube Test ..... 37
Visual Check ..... 37
Quarterly Quality Assurance ..... 39
Quarterly ..... 39
QT - K. Imaging System Alignment ..... 39
Procedure 5-9: Imaging Alignment ..... 39
Treatment Mode ..... 39
Service Mode ..... 39
Analysis ..... 39
Couch Position Accuracy Checks ..... 41
Procedure 5-10: Couch Position Accuracy Check ..... 41
QT - L. Linac Laser Alignment ..... 43
Procedure 5-11: Linac Laser/Radiation Field Alignment Check ..... 43
Procedure 5-12: Linac Laser Mechanical Alignment Check ..... 43
QT – N. TLS Tracking ..... 45
Procedure 5-13: TLS Tracking ..... 45
Annual Testing Requirements ..... 47
Appendix ..... 49
Detailed Instructions Using On Target Treatment Planning ..... 51
Procedure 5-14: Planning the AQA Test (not required for each daily test) ..... 51



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015





Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015


# Module Description:

Introduction to the CyberKnife® Quality Assurance (QA) program.

# Module Objectives:

**Learn the recommended QA program**

**Learn the test schedule**

**Learn the procedures, including:**

- Ball-Cube Targeting Accuracy test,
- Auto Quality Analysis (AQA) daily targeting test,

and

- Xsight™ Skeletal Tracking System



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015


**NOTE:** Page Left Intentionally Blank



285
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015


# INTRODUCTION

## QUALITY ASSURANCE SCHEDULE

Table 5-1 indicates the recommended type and frequency of test procedures designed to document the geometric and dosimetric precision and accuracy of the Cyberknife Radiosurgery System. Practicing medical physicists are aware of the importance of a well documented quality assurance program. Since the Cyberknife is a technology that may be unfamiliar to new users, it is imperative that the QA program be performed without fail as recommended. A functional equivalent for any procedure may be substituted where measurements in the clinic support the Physicist's determination.

**Table 5-1: CyberKnife QA Schedule**

| QA Tests | Frequency | | |
|---|---|---|---|
| | Daily, DL | Monthly, MN | Quarterly, QT |
| A. Safety Interlocks Check | X | | |
| B. System Status Check | X | | |
| C. LINAC Output Constancy Check | X | | |
| D. Robot Perch Position Laser Check | X | | |
| E. X-ray Tube Warmup | X | | |
| F. AQA test (visual check), film weekly | X | | |
| G. Beam Parameter Check energy, symmetry | | X | |
| H. Qualitative Check of Robot Targeting Accuracy | | X | |
| I. Monthly "Ball-Cube" Targeting Test Procedure | | X | |
| J. Imaging Alignment | | X | |
| K. Couch Position Accuracy Checks | | | X |
| L. Linac laser mechanical alignment | | | X |
| M. Target localizing System | | | X |
| N. Quarterly Radiation Safety Report | | | X |
| **New System AND after major service changes or annually, whichever occurs first.** | | | |
| Robot mastering check | | | |
| End-to-End (E2E)Tests for all Treatment Modes | | | |
| TPS: beam data check with single beam plan & measurement | | | |
| TPS (calculation check) | | | |
| Safety system tests | | | |
| CT geometric accuracy | | | |
| Annual Report | | | |



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

286

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015


**NOTE:** Page Left Intentionally Blank



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015


# INTRODUCTION

There are many professional guidelines that address the linear accelerator (LINAC), treatment planning system, and radiosurgery quality assurance (QA) and associated professional standards of practice. CyberKnife system introduces new technologies not commonly encountered in radiosurgery: Robotics and Real-Time Image Guidance. Accuray has developed several QA methodologies to ensure high quality CyberKnife treatments and maximum patient safety using these new technologies.

This module introduces procedures unique to the CybeKnife system. The recommended frequencies are considered to be the essential minimum. Conventional, additional or equivalent tests may also be performed as necessary. An example of this would be patient specific dosimetry verification.

As traditionally practiced, quality assurance tests are used to document and ensure the on-going correct performance of any medical radiation device and also to identify non-compliance with a defined performance criteria as soon as it might be manifested. This practice also applies to the Cyberknife system treatment planning and delivery systems.

The quality assurance tests and their recommended frequency are presented in *Table 5-1: CyberKnife QA Schedule, page 3*. The procedures for all tests are described in the subsequent pages.

To support your comprehensive QA program, Accuray customer service engineers will request your records to determine the current performance status of your system. They will provide a written record of all work completed along with any relevant testing they have completed to maintain optimal compliance with the system specifications.

The CyberKnife program is readily incorporated into the institutional Radiation Safety and Quality Management Programs. It is recommended that the results of the quarterly and annual testing be presented with the quarterly and Annual Radiation Safety Reports so that the results are available for administrative oversight.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015


# EQUIPMENT QA BENEFITS

- Easier to maintain system in optimal condition over the life of the equipment.

**RELIABILITY**

- Reduces time to troubleshoot and repair problems.

**UPTIME**

- Ensures accurate prescription delivery to the target.

**SAFETY**

- Documentation satisfies regulatory and professional standards of practice guidelines.

**RISK REDUCTION**

**Figure 5-1 CyberKnife QA Benefits**



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015


## QA Benefits

The slide in *Figure 5-1 CyberKnife QA Benefits, page 6* is presented during the radiation therapists training for the daily QA activities. It is beneficial to the Cyberknife program to have this reinforced by the CyberKnife physicist as the radiosurgery program develops. Reliability of system performance, including high uptime and safe delivery, along with the well documented QA program results in risk minimization for the human use of medical radiation and robotic radiosurgery.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015


**NOTE:** Page Left Intentionally Blank




Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015


# QUALITY ASSURANCE PROCEDURES

## DAILY

### Procedure 5-1. DAILY Quality Assurance

**DL - A. Safety interlocks Check**

**DL - B. System Status Check**

**DL - C. LINAC Output Constancy**

**DL - D. Perch Position Laser Check**

**DL - E. X-ray Tube Warmup**

**DL - F. AQA**

### DL-A. Safety Interlocks Check

Important safety interlocks must be checked on a daily basis. At a minimum, the door interlock and the operator panel E-stop button must be checked daily.

1. In the Physics Screen, run the system at 100 monitor units (MU).
2. While the beam is on, open the treatment room door. The radiation should stop and a red E-stop banner should appear on the SGI screen describing the error.
3. Close the door, recover from the error, and continue to run the radiation.
4. Again, while the beam is on, press the operator panel E-stop mushroom switch. Once again, the radiation should stop and an error message is displayed on the SGI screen.
5. This process can be repeated to check other interlocks as scheduled, and recover as appropriate.

### DL-B. System Status Check

The parameters shown in Table 5-2 must be checked daily to ensure that the CyberKnife is within specifications and to monitor any operating parameter drift. The values returned should be recorded and saved. This data is extremely useful to Accuray Field Service when diagnosing problems.

| Parameter Check | Location | Allowed Range |
|---|---|---|
| SF6 Pressure (psi) | J-Box | > 30 psi |
| Water Pressure (psi) | Chiller side | 80 ± 5 psi |
| Water Temperature (°C) | Chiller front panel | 19 ± 2 °C |
| Water Flow Rate (gpm) | Chiller flow meter | 0.6 gpm |
| Steering Coil 1 (amps) | MCC Front Panel | No drift |
| Steering Coil 2 (amps) | MCC Front Panel | No drift |
| Steering Coil 3 (amps) | Inside MCC | No drift |
| Steering Coil 4 (amps) | Inside MCC | No drift |
| Magnetron Heater (VAC) | Modulator | 9.5 ± 0.2 (standby) |
| Gun Heater (VAC) | Modulator | 5.8 ± 0.2 |
| Ion Pump (μA) | Modulator | N/A |
| Magnetron Tuner | MCC Front Panel | N/A |
| Dose Rate (Mu/min) | MCC Front Panel or SGI Physics Mode (use one or the other, do not alternate) | 600 Mu/min<br>400 Mu/min<br>300 Mu/min |

**Table 5-2: System Status Check List**



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015


**NOTE:** Page Left Intentionally Blank




Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015


## DL-C. LINAC Output Constancy Check

The ion chambers are vented to atmosphere. That means changes in atmospheric pressure and x-ray head temperature can affect system output. Check outputs daily. Additional checks throughout the day may be required if dramatic environmental changes occur. Note that the daily constancy check confirms that the dosimetry electronics and all additional factors that have the potential to influence dose output accuracy are also being evaluated. Do not adjust the calibration factor based only on environmental changes. A dedicated Farmer-Baldwin chamber should be used for this check.

## Procedure 5-2: LINAC Daily Output Constancy Check

1. Insert the 60 mm secondary collimator.
2. Screw the Bird Cage onto the CyberKnife collimator.
3. Connect the Farmer chamber to the Bird Cage so that the center of the chamber is aligned with the front pointing laser.
4. Put a 6 MV buildup cap on the chamber.
5. Attach the triax cable to the chamber.
6. Take note of the temperature and pressure inside the treatment room.
7. Turn on the electrometer and verify the correct bias voltage.
8. Login to the CyberKnife system workstation and proceed to the Physics Module.
9. Select the LINAC tab and enter 2000 to warm up the LINAC.
10. Take several chamber readings of 200 monitor units.
11. Calculate the temperature, pressure correction.
12. Average the readings and calculate the output using the temperature and pressure correction, $C_{T,P}$ and the calibration factor, $C_F$.

    **Daily Factor = Reading, (nC)** X $\mathbf{C_{T,P}}$ X $\mathbf{C_F}$

    $\mathbf{C_F}$ = calibration factor from the bird cage reading on the day of absolute dose measurement.
13. Adjust the Calibration Factors to attain 1.00 MU=1.0 centiGray(cGy) (within 1%).
14. Confirm the calibration by taking one or two more readings and recalculating output.
15. Press the **SAVE CALIBRATION FACTORS** Button to save the adjustments for treatment.
16. Turn off the electrometer and remove the birdcage from the collimator.

## DL-D. Robot Perch Position Laser Check

Mark where the laser light hits the floor when the robot is in perch at the time of installation. Everyday thereafter, you can check the laser to confirm that the robot mastering is unchanged.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015

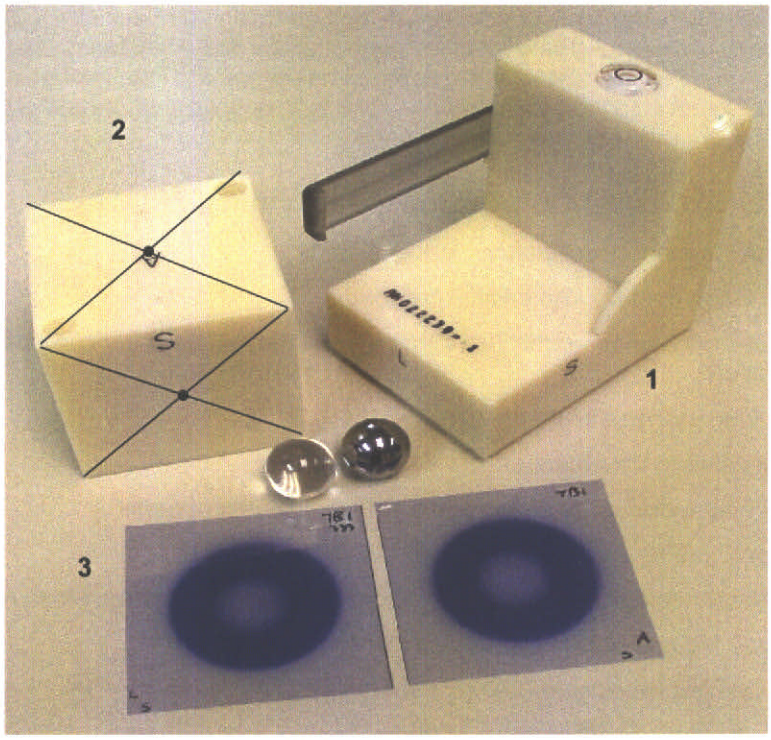




Figure 5-2 AQA hardware components.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

295

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015


## DL-E. X-ray Tube Warmup

Condition and warm up the X-ray Source (XRS) tubes. The intent is to minimize target (anode) cracking due to thermal shock.

If the unit has not been energized for a period of eight hours or more, it is necessary to start at a kVp considerably lower than the highest kVp normally used on a given tube in order to re-align the internal distribution of charges.

**CAUTION:** Adherence to the above two procedures will also minimize target cracking due to thermal shock. Thermal shock can cause a target to fracture, and in extreme cases, the target may break apart, causing damage to the insert and/or tube housing.

Warmup the tubes by taking a series of four, 1/10-second radiographic exposures, using the lowest mA station for the large focal spot (200mA) on the X-ray control. Start with a kVp of 80 and increase by 10 kVp increments to the maximum. Exposures are to be spaced approximately 20 seconds apart.

### Procedure 5-3: Daily X-ray Tube Warmup

1. From the system menu, click **Physics**
2. Click **TUBE WARMUP**
3. Click **START**
4. Click the **EXIT** button

## DL-F. AQA TOOL

The Automatic Quality Assurance tool is designed to check robot mastering daily by vizualizing where the laser light strikes BB's on the center of the anterior and superior surfaces. A two path treatment can be delivered to film using different orthogonal X-ray exposures. From the results of the films, the robot mastering and radiation dose constancy can be analyzed and determined from the results of the AQA film test.

### Procedure 5-4: Daily QA Test

### AQA Hardware Components

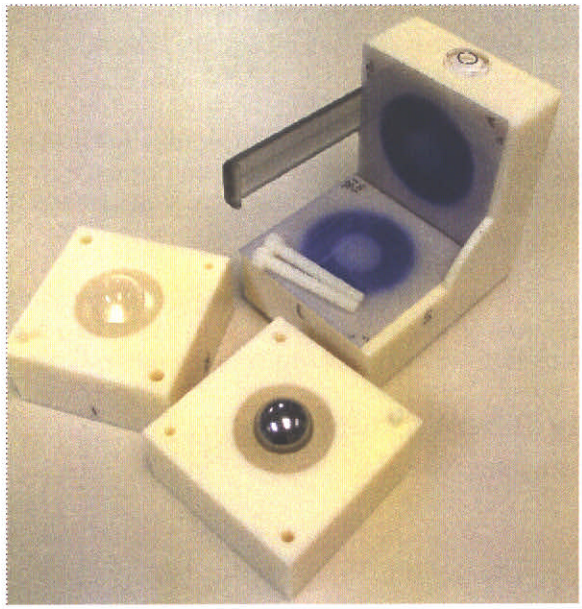
(*Figure 5-2 AQA hardware components., page 12*)

1. Shadow phantom with interchangeable steel and plastic ball.
2. Shadow phantom base. (Phantom and base are available in black or tan.)
3. Pre-cut EBT film.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015

*Shadow phantom opened showing both steel and acrylic target balls. The acrylic is used for CT scan and tungsten is used to create a shadow in treatment.*

**Figure 5-3 2.5-inch Shadow Phantom**

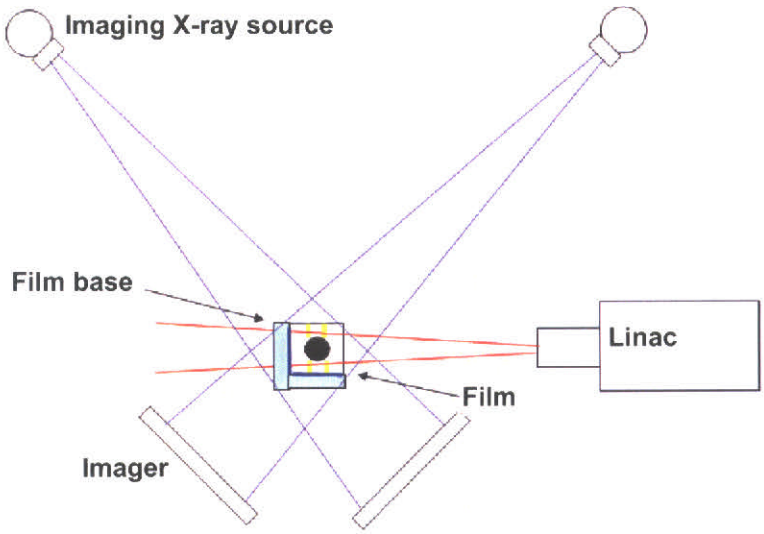



**Figure 5-4 Diagram showing arrangement for a symmetric Automatic QA tool**



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015


## AQA Overview

The AQA tool is based on the gantry-LINAC Stereotactic QA technique of placing a radiopaque ball at the treatment isocenter and observing the concentricity of the beam and shadow of the ball. You can purchase off-the-shelf software such as RIT 113 (Radiological Imaging Technology, Inc., Colorado Springs, Colorado, USA) to perform the analysis.

For a non-isocentric image-guided system like CyberKnife, the technique must be modified. The ball is not mechanically placed precisely at the room isocenter. Instead, load the ball in a small plastic phantom containing fiducials. This is called a **Shadow Phantom (Figure 5-3 2.5-inch Shadow Phantom, page 14)** .The image guidance of the CyberKnife is used to direct the therapy beam at the ball. Since the ball is spherically symmetric, this technique can determine the translational targeting error, which is a combination of tracking and delivery error.

**NOTE:** This type of shadow phantom cannot distinguish between tracking and targeting error. The symmetric shadow phantom cannot determine rotational targeting error.

## Procedure 5-5: AQA Targeting Accuracy Test Procedure

1. The AQA path set contains two nodes. The nodes are located anterior and to the right of the phantom. This two-node path is calibrated using the results of 3 AQA tests instead of the standard laser calibration.
2. A CT scan is made of the ball phantom where the 0.75 inch tungsten ball is replaced with a plastic ball, like the one used in the standard CyberKnife Ball-Cube (ABS cube, Acrylic ball).

**NOTE:** There is an acrylic shell in the phantom so the acrylic target ball is 1.25 inch. Use a 9/64 inch allen wrench to open the shadow phantom.

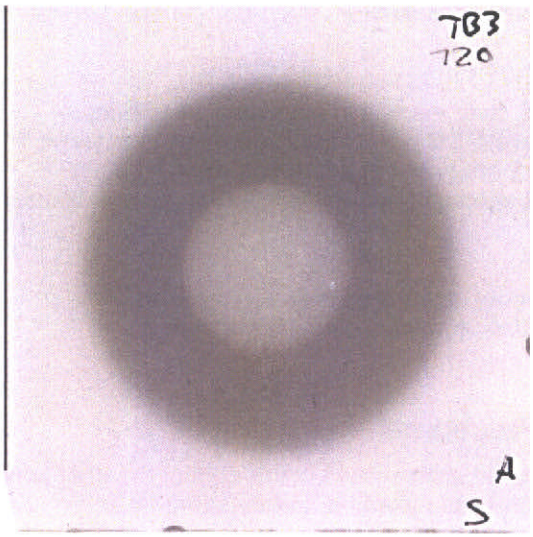
3. Using the acquired CT scan of the shadow phantom, a treatment plan is made that places the treatment isocenter at the center of the ball. MultiPlan users may use the dose centering function while making the plan. The maximum dose to the film is set for 250 cGy as this produces a clear image on EBT film.
4. The shadow phantom is opened and the plastic ball is replaced by the steel ball.
5. Films are placed between the shadow phantom and the phantom base.
6. The phantom is placed on the table as in Figure 5-4 Diagram showing arrangement for a symmetric Automatic QA tool, and the two beam treatment is delivered to expose the films.
7. Films are scanned with attention to maintaining a consistent film orientation in the scanner.
8. Images analyzed for concentricity of shadow with beam using the AQA film analysis tool.
9. Resulting targeting error is recorded in the Accuray QA logbook.

The film image (*Figure 5-5 Image of 1.25 inch steel ball in plastic ball phantom., page 16*) was acquired at 80 cm SAD using Gafchromic EBT film. The maximum exposure on the film if the ball was absent would be 250 cGy. In this film the "A" and "S" are labels identifying the anterior and superior sides of the film.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118 

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015


*The long axis of the film is identified either by a thin black line along the long axis edge or a cut-out with long dimension along the long axis.*

**Figure 5-5 Image of 1.25 inch steel ball in plastic ball phantom.**

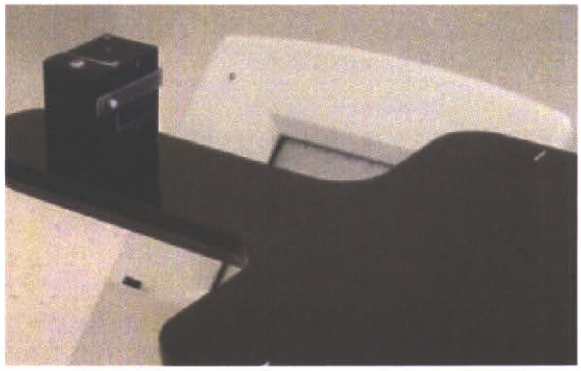
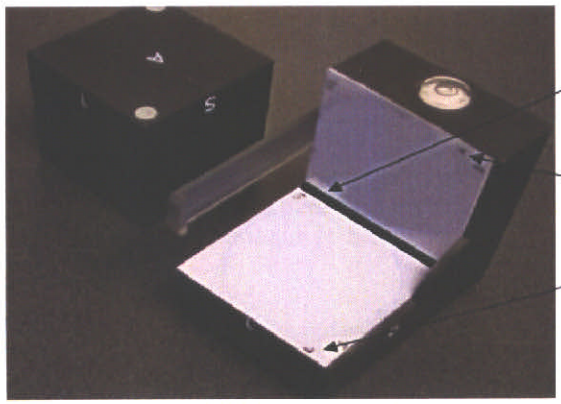


**Figure 5-6 Support Table**

**Figure 5-7 Plastic Arm**



**Black line drawn on edge of film for registration (line enhanced in figure)**

**Vertical film labeled on Anterior and Superior edges.**

**Horizontal film labeled on Left and Superior Edges.**

**Figure 5-8 Edge of Films**



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015


## Procedure 5-6: Deliver Simulation to AQA shadow phantom

1. If the LINAC has not been warmed up, deliver 1500 MU. Do not leave EBT film in the treatment room when the LINAC is on unless it is being used for a test.
2. Confirm that the LINAC has been calibrated and that the calibration factors have been correctly entered into the system using the Physics/Parameters window.
3. Place the AQA tool and base on the patient support table (*Figure 5-6 Support Table, page 16*).
4. Remove the shadow phantom from the base. Bend the plastic arm (*Figure 5-7 Plastic Arm, page 16*) back several mm to release the phantom.
5. Load two pieces of unexposed EBT film between the Shadow phantom and the base. Position the films so that the single black edge (or notch) of the films (*Figure 5-8 Edge of Films, page 16*) touch each other.
6. Coarsely align the phantom using the room lasers (*Figure 5-9 Room Lasers, page 18*). Align the yaw axis with extra care since yaw can not be automatically aligned using couch. Install the 35 mm collimator.
7. Enter simulation mode from the 9-button menu by clicking on the **SIMULATION** button.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015

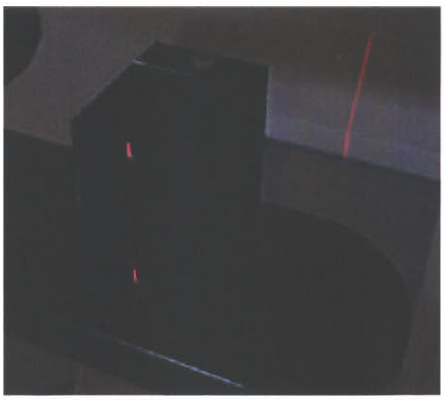



Figure 5-9 Room Lasers

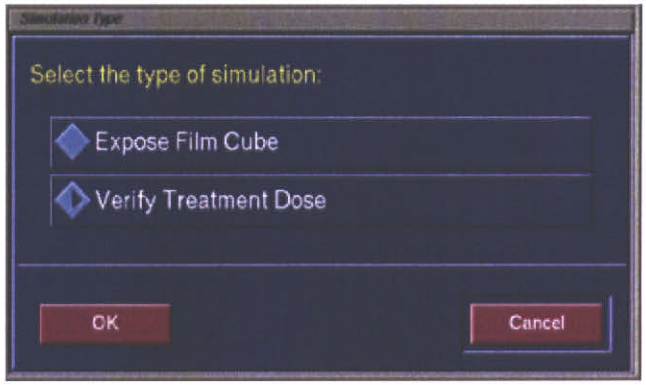



Figure 5-10 Simulation type

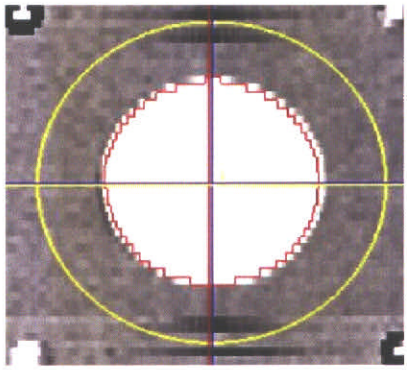


Figure 5-11 Align

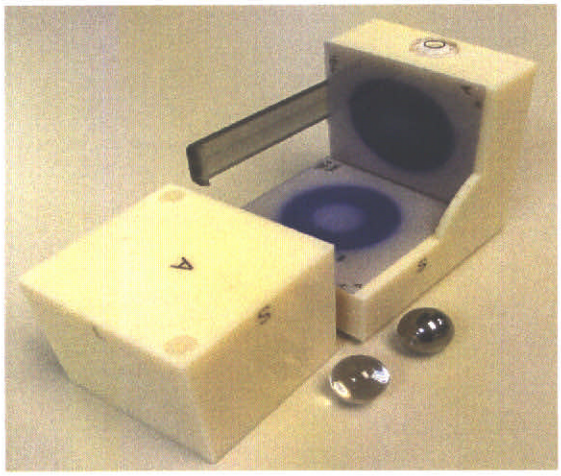


Figure 5-12 Remove Shadow Phantom



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015


8. Make sure to select **Verify Treatment dose** (*Figure 5-10 Simulation type, page 18*) instead of **Expose Film Cube**.
9. Select the daily AQA test plan.
10. From the patient alignment window click the **ACQUIRE** button to capture an image.
11. Use couch to align the shadow phantom (*Figure 5-11 Align, page 18*). Get the error on each axis less than 0.5 mm and 0.5 degrees.
12. Deliver the treatment simulation.
13. Remove the shadow phantom from the table (*Figure 5-12 Remove Shadow Phantom, page 18*) and confirm that the films are labeled correctly.
14. Scan the film in separate files with the following parameters:
    - Grayscale
    - 300 DPI (VIDAR uses 285 dpi)
    - 16bit
    - Tiff or BMP
    - auto-calibration off.
15. Orient the films with the black line along the long direction of the scanner bed and with the superior edge away from the scanner hinge. Scanning the films in the same orientation is critical to achieve a repeatable process both in dose and in targeting error. (If necessary, another orientation can be used as long as it is repeated on each test.)



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118 

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015

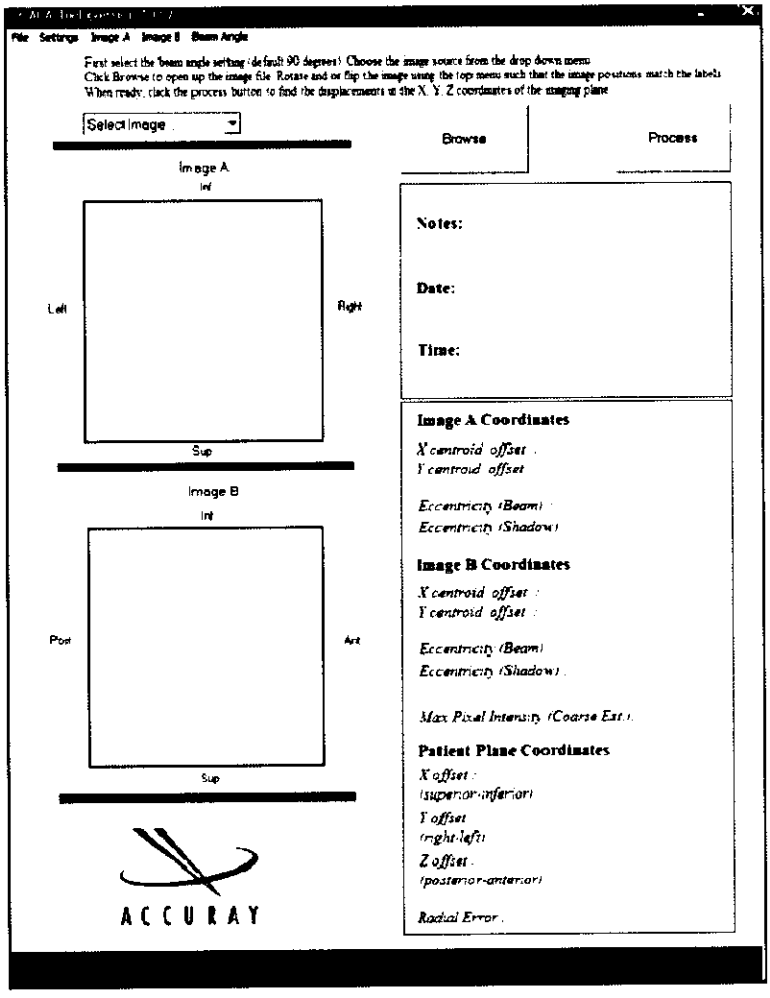




**Figure 5-13 AQA Graphical User Interface**

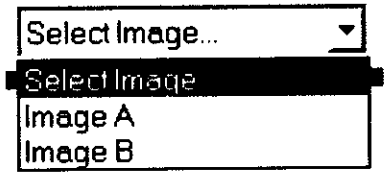



**Figure 5-14 Select Image**

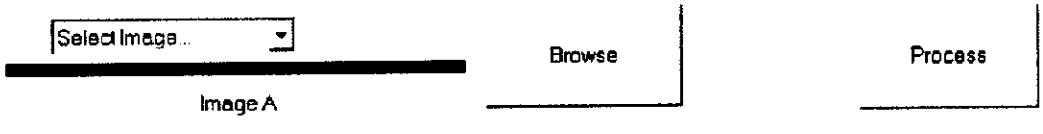



**Figure 5-15 Browse**



303 Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015


# FILM ANALYSIS SOFTWARE

## AQA SOFTWARE COMPONENTS

1. AQA film analysis tool
2. AQA path

The AQA software is developed for use with the AQA tool film images.

## RUNNING THE AQA PROGRAM

### Starting AQA

Launch the AQA program. (*Figure 5-13 AQA Graphical User Interface, page 20*).

### Loading the Images

The brief set of instructions for loading, adjusting and processing the images are displayed at the top of the UI window.

The beam angle setting should remain at 90° for the current version of the AQA tool.

1. Select image type from the pull down menu on the upper left hand corner (*Figure 5-14 Select Image, page 20*).

   For an AQA test:

   **Image A** represents the image with edges corresponding to the Right, Superior, Left, and Inferior directions

   **Image B** represents the image with edges corresponding to the Posterior, Inferior, Anterior and Superior directions.

2. After selecting the image type, click the **BROWSE** button next to the pull down menu (*Figure 5-15 Browse, page 20*). (Clicking the **BROWSE** button before selecting the image type will cause an error message to appear on the bottom of the window.)
3. The File Selection menu will open. Go to the directory where the scanned image file is saved and select the image file by clicking **Open**. After selecting the file, the image will be displayed in the corresponding window on the left hand side.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015

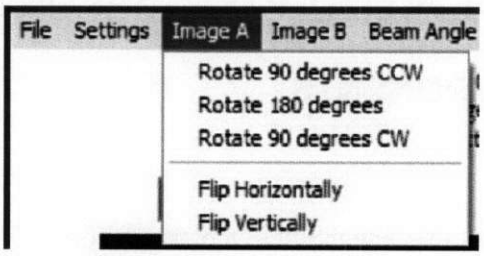




**Figure 5-16 Pull Down**

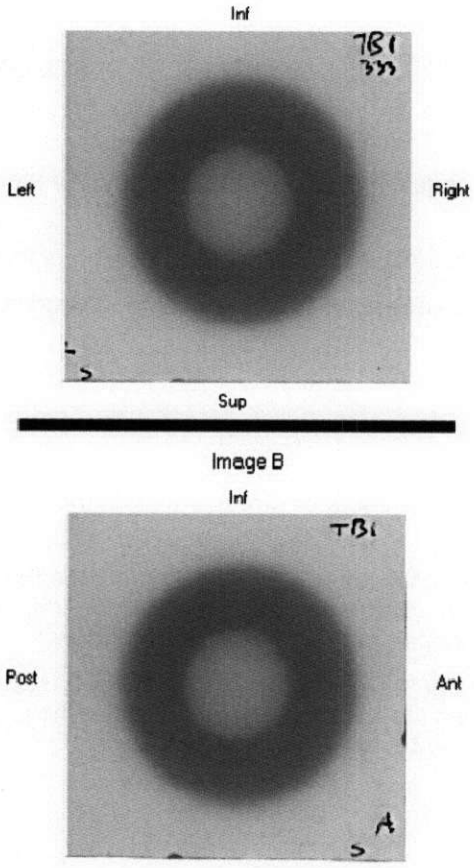



**Figure 5-17 Images correctly aligned for the processing**



305

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015


## Adjusting the Images

The algorithm requires images be oriented in a certain way. Images should be labeled prior to scanning to indicate which direction each edge corresponds to.

The image display windows on the left hand side have abbreviations of directions as a guide (*Figure 5-16 Pull Down, page 22*). Loaded images should be rotated such that the labels on the sides must match the labels on the scanned films.

Rotate and flip operations are available for both images from the top menu. To rotate Image A 90° in the counter clockwise direction, first select **Image A** and **Rotate 90 degrees CCW** options from the top menu (*Figure 5-17 Images correctly aligned for the processing, page 22*). *Figure 5-18 Process operations screen, page 24* shows images correctly aligned for processing.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015

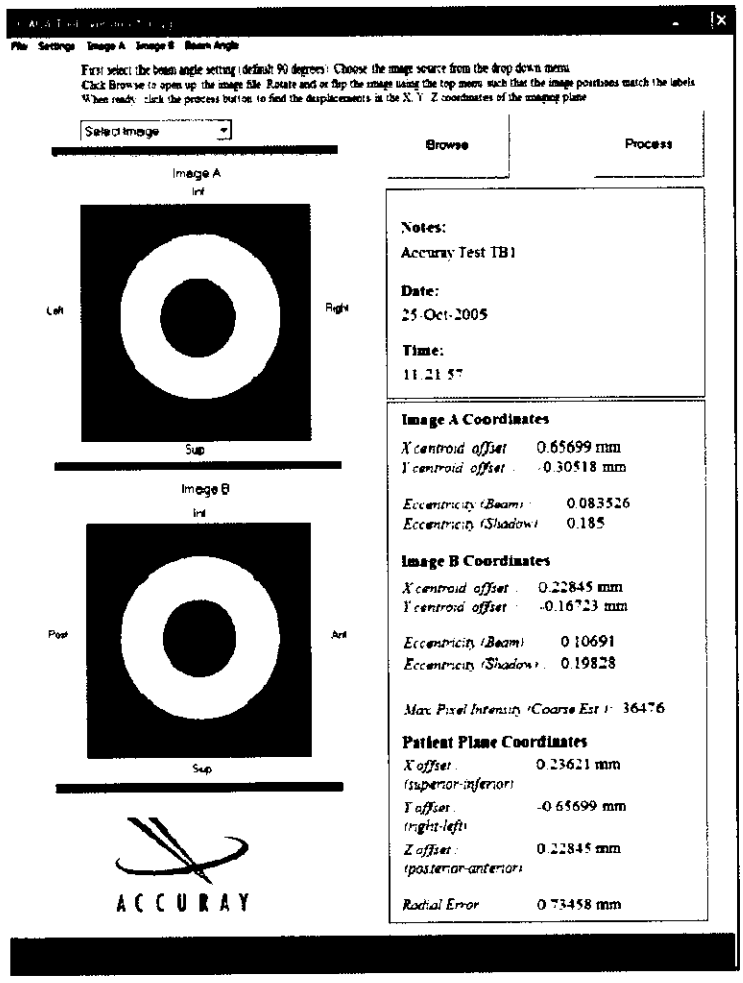




**Figure 5-18 Process operations screen**



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

307

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015


## Processing the Images

After loading both images and rotating them for the correct alignment, click the **PROCESS** button on the upper right hand corner of the GUI (*Figure 5-18 Process operations screen, page 24*). This will start the image processing operations.

Tracking accuracy data is displayed in pixel units. Pixel intensity at the beam centroid location is displayed.

Images on the left side are replaced by the processed images that show the detected beam region in white and ball shadow in black. *Figure 5-18 Process operations screen, page 24* shows a sample output after the Process operation.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015

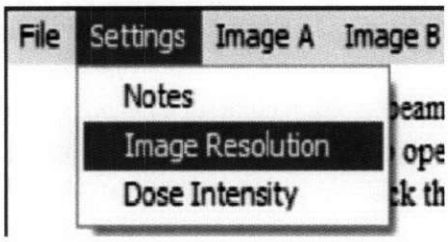




**Figure 5-19 Resolution pull down**

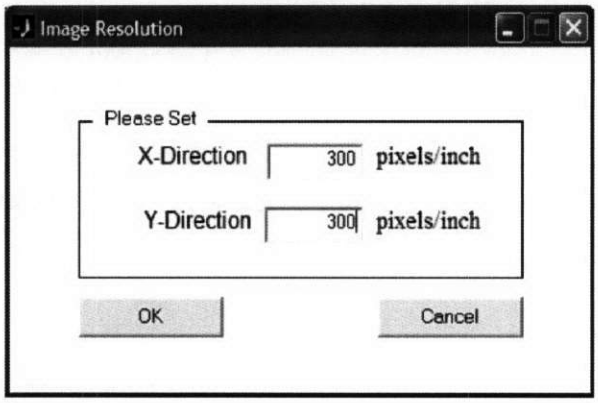



**Figure 5-20 Image Resolution**

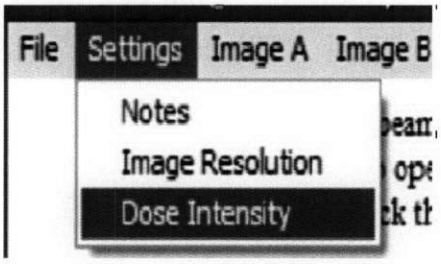



**Figure 5-20 Setting Dose Intensity**

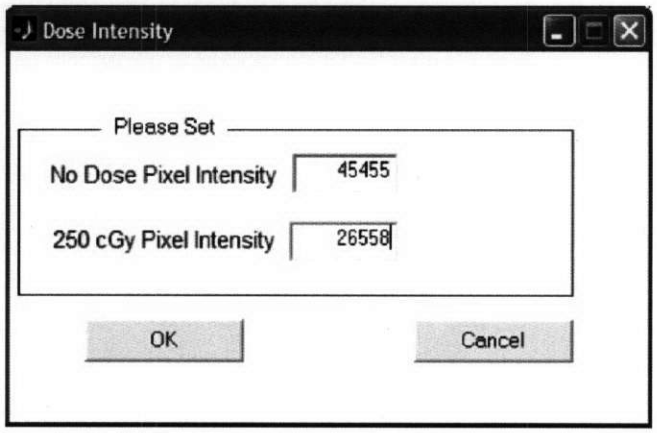



**Figure 5-22 Dose Intensity**

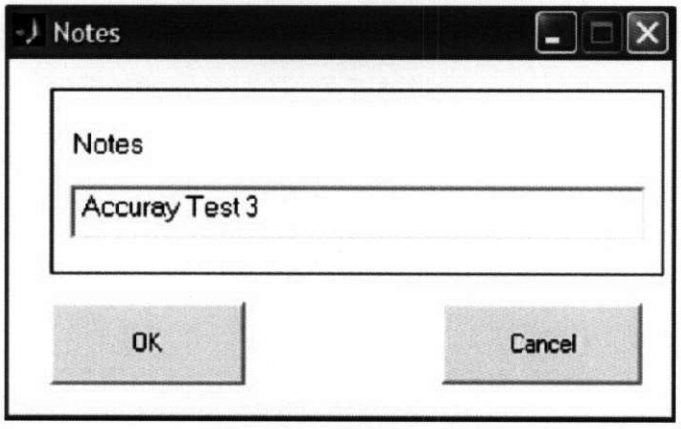



**Figure 5-23 Notes**



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

309

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015


## Settings

1. Select the **Settings** option from the top menu (*Figure 5-19 Resolution pull down, page 26*) and **Image Resolution** in order to generate the offset information in millimeters (mm).
2. Enter pixels/inch resolution in X (horizontal) and Y (vertical) directions (*Figure 5-20 Image Resolution, page 26*).
3. Select the **Settings** option from the top menu and **Dose Intensity** (*Figure 5-20 Setting Dose Intensity, page 26*) in order to generate the dose intensity information in cGy.
4. Enter the pixel intensity values on the scanned film (*Figure 5-22 Dose Intensity, page 26*) when No Dose and 250 cGy Dose is applied.

Image Resolution information is necessary to convert from pixels to mm's. The pixels/inch values in the x and y direction are obtained by scanning a ruler with the same scanner. Radial error is also calculated after the resolution information is entered by the user.

Dose Intensity settings are used to calculate the dose intensity at the beam centroid. To convert the pixel intensity value at the beam centroid to a dose intensity value, the pixel intensities of the films are used when no dose is applied and when 250cGy is entered.

5. Select the **Settings** option from the top menu and **Notes** (*Figure 5-23 Notes, page 26*) in order to enter notes on the GUI window for further reference.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015

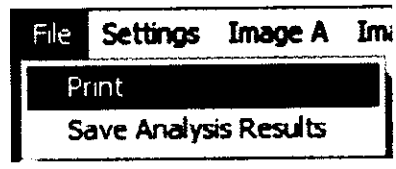




**Figure 5-24 File Print Pull Down**

**Figure 5-25 Save Analysis Results Pull Down**



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015


## Printing and Saving Analysis Results

1. Select the **File** option from the top menu and **Print** (*Figure 5-24 File Print Pull Down, page 28*) in order to print the interface window at any time.
2. Select the **File** option from the top menu and **Save Analysis Results** (*Figure 5-25 Save Analysis Results Pull Down, page 28*) in order to save the processing results to a file.

The option opens up a File Selection menu so the user can browse to a directory and name the output file. The resulting file is a text file that includes all the information displayed on the UI, the names of the image files and the date and time of the analysis.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015


**NOTE:** Page Left Intentionally Blank



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015


# MONTHLY QUALITY ASSURANCE

## MONTHLY

**MN- G. Beam Parameters Check. Energy. Symmetry.**

**MN- H. Qualitative Check of Robot Targeting Accuracy**

**MN- I. Monthly "Ball-Cube" Targeting Test Procedure**

**MN- J. Imaging Alignment**

## MN- G. BEAM PARAMETERS CHECK

It is important to monitor a few beam characteristics on a monthly basis, such as beam symmetry, flatness, and penumbra. Use the following procedure:

1. Set up a piece of Ready-Pack film. Place the film under 5 cm of buildup that is setup to 80 cm SSD.
2. Install the 40 mm collimator.
3. Expose the film with an appropriate amount of monitor units so as to not cause saturation.
4. Develop the film.
5. Analyze the film flatness. It should be less than 18% in both orthogonal directions.
6. Analyze the beam symmetry using the TG 45 method (comparing profile heights at 80% of the beam width to each other).
7. Analyze the penumbra. The 80% - 20% penumbra should be less than 4.5mm in both directions.

## MN- H. QUALITATIVE CHECK OF ROBOT TARGETING ACCURACY

A visual qualitative test of the robot targeting accuracy can be done using a BB test via the Simulation mode. Simulation mode can deliver a plan with or without radiation. During the simulation exercise, all software programs are functioning.

**Source to Axis (Isopost) Distance** –The isopost is a rigid device used to verify that the robot is pointing at the geometric center of the treatment delivery system, though there is no equipment that revolves about the tip.

The distance from the LINAC target to the isopost **(IP)** is 80 cm. The term SAD is used to describe this distance, though there is actually no axis in this non-isocentric treatment delivery device. The isopost physically defines the geometric point to which the robot, LINAC, imaging system, and treatment table are centered. The nodes are defined relative to the isopost. During treatment delivery, the LINAC can point at the target from any allowed angle and distance as optimized by the TPS. In other words, during any conformal treatment, the beams do not have to point to the center of the target. They can point to the target boundary or anywhere within the target volume as optimized by the TPS, and none of the beams have to pass through the "isopoint".

When the isocentric treatment mode is selected, a subset of approximately 100 of the beams point at the isopost defined point (isopoint) in space.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015


**NOTE:** Page Left Intentionally Blank



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015


# VISUAL QUALITATIVE ROBOT TARGETING ACCURACY TEST (WITH BB IN SIMULATION MODE)

This is a quick visual check to see that all subsystems are working properly. This test is sometimes referred to as the ***BB test***. Because this test is qualitative it is most useful for the early stages of targeting alignment, usually during acceptance and commissioning.

## Procedure 5-7: Robot Targeting Accuracy with BB Test (in Simulation Mode)

1. Be sure that the LINAC laser is properly aligned.
2. Power-on the system.
3. Place a small metal BB on the headrest and line it up close to isocenter using the wall lasers. A 2 mm *Beekley Y-spot* can be used for this purpose.
4. Create a new plan (from any CT set of which phantom CTs have been loaded).
5. Select a body/fiducial treatment.
6. Locate one fiducial in the appropriate location of the phantom.
7. Calculate and Save the plan.
8. Create ***phantom*** DRR's.
9. Select *simulation* and advance to the patient alignment interface and align the BB close to (0,0,0). *Note*: it will be necessary to turn the X-ray technique way down since there is no phantom material around the fiducial.
10. Go to the imaging parameters interface and select the BB test mode.
11. Follow the prompts on the screen and teach pendant to advance through the BB test.
    - On the Teach Pendant, *sim node* will advance to the next node and pause there. *Sim all* will go through all the nodes in the path, pausing briefly at each node.

# MN-H. MONTHLY "BALL-CUBE" TARGETING TEST PROCEDURE

The monthly test is designed to demonstrate and document the on-going CyberKnife® targeting accuracy of the system. The robot, image processing, LINAC, and the safety subsystem are tested for an approximate 50 beam plan with high accuracy results. The monthly test is designed to document the constancy of the targeting accuracy, and requires delivery of a previously planned phantom treatment.

The centroid of the actual delivered dose distribution on the exposed film is compared with the planned dose distribution to determine total error for alternating delivery modalities. The monthly test is done either with the standard 2.5 inch "Ball-Cube" accessory or the mini 1.25 inch "Ball-Cube" dependent upon the treatment modality being tested. The procedure for using the standard and Mini Ball-Cubes are similar. Since the film analysis software determines the film size, the correct analysis is always performed relative to the scanned film size.

The treatment modality targeting accuracy specific to the site, e.g. 6-D Skull Tracking, 3-D Skull Tracking, Xsight tracking, and fiducial tracking modes, will be tested and documented at least three times annually. An anthropomorphic head phantom with film cube inside should be used for skull tracking. The Xsight system is delivered with a clear head phantom for spine tracking QA.

On an annual basis, the complete "end to end" test should be conducted for each modality and include new CT scans, planning, and dose delivery.

**Film analysis** should be performed "digitally" using the transparency scanner and the Accuray film analysis software ("End to end automated test tool"). Digital analysis takes about 15 minutes and has an accuracy of +/- 0.3 mm.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118 316

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015

Figure 5-26 Ball-Cube in Xsight Phantom

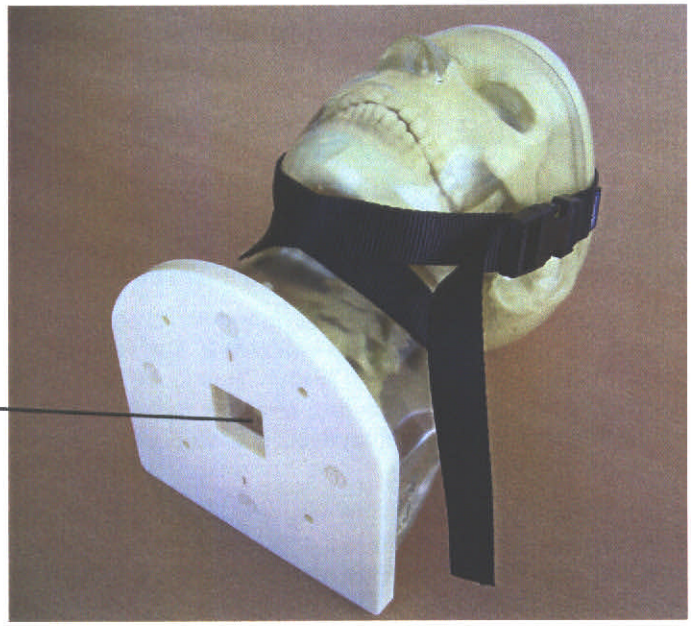



Figure 5-27 Anthropomorphic Xsight Phantom



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015


## Materials Required for Monthly Ball-Cube Test

1. **Phantoms**
2. **Standard Ball-Cube targeting tool** (*Figure 5-26 Ball-Cube in Xsight Phantom, page 34*)
3. **Or, the Mini Ball-Cube targeting tool** (*Figure 5-27 Anthropomorphic Xsight Phantom, page 34*)

   **Neck Phantom Accessory** if spine tracking is to be tested.
4. **Radiochromic film.** Accuray recommends either Gafchromic MD-22 precut film, Gafchromic MD-22 pre-notched or Gafchromic MD-55, which comes in 5 inch square sheets.
5. **Optical transparency scanner** (required for digital film analysis).
6. **End to End Automated Test Tool software.**



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015

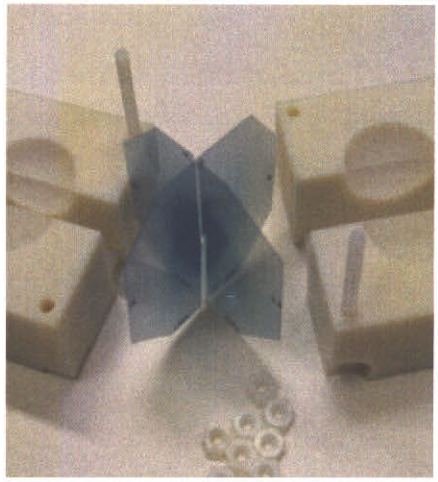



Figure 5-28 Film Cube

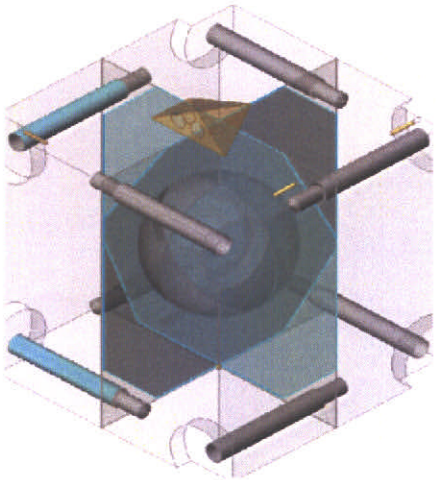


Figure 5-29 Film Cube Rendering



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015


## Procedure 5-8: Monthly Ball-Cube Test

1. Pre-notched films have a smaller slot since they use a more precise cutting process. Or, cut a slot on each film if not pre-cut. The slot can be cut by marking a line on the film with a permanent marker and then cutting around the line with scissors. The best way to locate the line on the film is to trace it from a template. The cutting line should extend along the center of the film about 2 mm past the center of the film.
2. Load film cube with two pieces of film as shown in *Figure 5-28 Film Cube, page 36* and *Figure 5-29 Film Cube Rendering, page 36*.
3. Align film in cube to ensure it will fit.
4. Remove film and label the film reference edges with a fine tip permanent marker. The writing will be preserved in the scanned image for identification purposes.
5. Load the Ball-Cube into the phantom.
   - If performing **neck QA** use the neck phantom accessory.
   - For **spine tracking**, the CT center must be placed in the inferior portion of C5, or in the superior portion of C6.
6. Select the Ballcube treatment plan
7. Place phantom on table. Check DRR images. Be sure space at anterior and superior is 10 – 15 mm. Acquire images and adjust imaging technique (kV, mA, ms) to make the live images and DRR images look similar. Alternately, adjust image technique to make brightness and gradient gains within the range 0.9 to 1.1.
8. Deliver the treatment plan using the Treatment mode.

   Do NOT use SIMULATION mode for these routine phantom tests. Check that the film is labeled properly as you unload the ballcube.

   **NOTE:** Keep film away from fluorescent lights and the sun. Exposure to these will darken the film over several hours. The film is less sensitive to incandescent lights.

9. Scan the film in a calibrated optical scanner. Confirm the distance calibration of the scanner by scanning a precisely dimensioned graph paper for both horizontal and vertical dimension. Calculate the true pixels/inch. It is good practice to also perform visual analysis as described below and compare the results as a check against the error results.
10. Follow the steps in the "End-to-End Automation Tool" procedure described in module 3 of this manual for automated Ball-Cube film analysis.

## Visual Check

The center can be measured by laying the film over a cross drawn on graph paper and centering the dose spot on the cross. The film axes are aligned with the rotated cross but the film is positioned so that the exposure is centered on the vertical cross. Using two crosses keeps the film slot away from the axes used to position the film. To measure the dose centroid:

Center the exposed circle on the vertical cross (+).

Mark the positions of the two reference edges of the film on the rotated cross (X)

Remove the film and measure the distance from the center of the cross to the reference edge-marks.

Better accuracy can be achieved using the film analysis software supplied with the system.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015


**NOTE:** Page Left Intentionally Blank



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015


# QUARTERLY QUALITY ASSURANCE

## QUARTERLY

**QT - K. Imaging system alignment**

**QT - L. Linac laser mechanical alignment**

**QT - M. Target localizing**

## QT - K. IMAGING SYSTEM ALIGNMENT

**Imaging Alignment**

It is necessayr to check the imaging system mechanical alignment to document that it is performing within the specifications. This is especially important if there has been major maintenance of any sort in the treatment room or an earthquake or other possible significant perturbation of the camera stands or ceiling mounted x-ray sources. To do so, use the following procedure:

### Procedure 5-9: Imaging Alignment

1. Attach the isopost to the camera stand.
2. Exit the treatment room and close the door.
3. An image of the isopost can be acquired either from a treatment plan or using service mode.

**TREATMENT MODE**

1. From the main SGI screen, open a treatment plan.
2. Adjust the imaging technique to 60kVp, and 50 mAs and acquire image. Adjust the X-ray parameters so that you get a good image of the isocrystal.
3. Use zoom to 400%, center cross-hairs and snapshot image.
4. Verify that the isocrystal is at the center pixel ± 2 pixels.

**SERVICE MODE**

1. Turn the Key on the ESCC to *Service*.
2. On the ESCC, bypass all the interlocks except the door switch and Estop buttons,
3. On the TLSPC, start the TLS Controller Software
4. Turn on the imaging system and set the mode to "fiducial"
5. With isopost installed, adjust the imaging technique kVp to 80, and 50 mAs.
6. Acquire image.
7. Adjust the X-ray parameters if needed so that you get a good image of the isocrystal.
8. Use zoom to 400%, center cross-hairs and snapshot image.
9. Verify that the isocrystal is at the center pixel ± 2 pixels.

**ANALYSIS**

1. Confirm that isocrystal is with 1 mm of center of cross-hairs.
2. Record results.
3. Exit service mode and remove the isopost.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015


**NOTE:** Page Left Intentionally Blank



323 Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015


## Couch Position Accuracy Checks

This test is designed to show that the couch calibration is still within specifications for rotations and translations. Use the following procedure to check table calibration:

## Procedure 5-10: Couch Position Accuracy Check

1. Press the **HOME** button on the hand controller while pressing the enable switches. Continue to hold the button until the table has stopped moving.
2. Using a digital level, check the Head U/D and Roll L/R angles and confirm that they are 0° ± 0.3°.
3. Inspect the right side of the couch to ensure that the couch has fully retracted and the movement stop limit switch has been engaged on the vertical bar.
4. On the forward portion of the vertical lift, verify that the interrupter blade is positioned between the two arms of the sensor. The top of the blade may not be flush with the top of the black sensor.
5. For left/right travel, use a tape measure or other measuring device to check that the center of the vertical lift is positioned to within 5 mm of the center of the couch base. It may be convenient to make a mark on the base of the couch that matches up with one of the retractable covers and just check that the mark continues to line up with the cover.
6. If any position is out of specification, manually move the axis approximately five cm for a translation or approximately 3° for a rotation and then press the Home switch again until motion stops. Recheck to see if the position is in specification. If the position is still out of specification, contact Accuray.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015


**NOTE:** Page Left Intentionally Blank



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015


# QT - L. LINAC LASER ALIGNMENT

**Linac Laser/Radiation Field alignment check**

Once the mechanical alignment is verified (above), it is important to verify that the laser is indeed coincident with the radiation field. Use for example the following procedure:

## Procedure 5-11: Linac Laser/Radiation Field Alignment Check

1. Install the laser secondary collimator.
2. Place a sheet of Ready-Pack diagnostic film on a flat surface.
3. With a mirror, adjust the robot trajectory so it is perpendicular with the film by reflecting the laser back to the hole in the collimator.
4. Using the front pointer, adjust the SAD to 800 mm.
5. Remove the front pointer and install the 60 mm collimator.
6. Expose the film with the appropriate number of monitor units so as to not saturate the film. For XV film, Use about 25 monitor units (without buildup).
7. Using a sharp pin, poke a hole in the film where the laser hits. This must be done very carefully so as to not shift the film inside the envelope.
8. Develop the film and measure the location of pin hole with respect to the radiation field. This can be done using the software tool ImageJ

This should not differ more than 2mm from the center of the radiation field.

**Linac Laser Mechanical Alignment Check**

The CyberKnife uses a point laser that is coincident with the radiation field as a QA tool. The laser is reflected off an adjustable mirror. The alignment must be checked periodically. Use the following procedure to check the mechanical alignment:

## Procedure 5-12: Linac Laser Mechanical Alignment Check

1. Install the laser secondary collimator.
2. Move the robot so that the collimator is approximately 40cm from a flat surface (floor or table). Place a piece of paper on the surface.
3. Allow the collimator to rotate by releasing the stop pin and hold.
4. Rotate the collimator housing through its full range and mark the furthest extent of the laser as it walks across the paper.

   It should walk no more than 1 mm. Although this is a subjective test, the next section describes a more quantitative technique



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015


**NOTE:** Page Left Intentionally Blank



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015


# QT – N. TLS TRACKING

**TLS Tracking**

The TLS subsystem is responsible for measuring and reporting patient motion.

## Procedure 5-13: TLS Tracking

1. Obtain a CT of a phantom.
2. Create a plan.
3. Make DRR's
4. Make a Prescription.
5. Place a phantom on the treatment table.
6. Advance through the *Treatment* menus to the patient alignment interface.
7. Re-align the phantom to get the couch offsets close to zero.
8. Using the couch digital readouts, move the phantom to several different positions in all three translational axes.
9. At each position, take an image and compare the TLS estimate to the actual couch offset.
10. Subtract the "zero-position" offsets from the data.
11. Record results.

The RMS of all the errors should be no more than 2 mm.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015


**NOTE:** Page Left Intentionally Blank



329 Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015


# ANNUAL TESTING REQUIREMENTS

The CyberKnife program is readily incorporated into the institutional Radiation Safety and Quality Management Programs. It is recommended that the results of the quarterly and annual testing be presented as part of the quarterly and Annual Radiation Safety Reports so that the results are available for administrative oversight.

- Evaluate monthly and quarterly trends for compliance with system performance specifications.
- Ensure Robot mastering check using Srch1 and Srch2 to quantitatively document robot targeting accuracy is performed by the Service Engineer.
- Perform End to End Tests by acquiring new CT studies, generating new treatment plans, deliver the treatments for each modality and document treatment delivery accuracy results for all Treatment Modes. Plans generated at this time can be delivered on a monthly basis to document system targeting accuracy during treatment delivery.
- CT geometric accuracy must be documented for the new phantom CT studies.
- TPS: beam data check with single beam plan & measurement
- TPS (calculation check)
- Safety system tests



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015


**NOTE:** Page Left Intentionally Blank



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015


# APPENDIX



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015

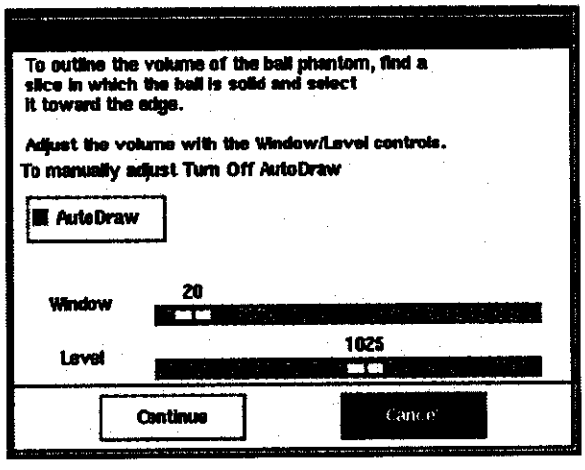




**Figure 5-A1 Delineate Ball**



333 Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015


# DETAILED INSTRUCTIONS USING ON TARGET TREATMENT PLANNING

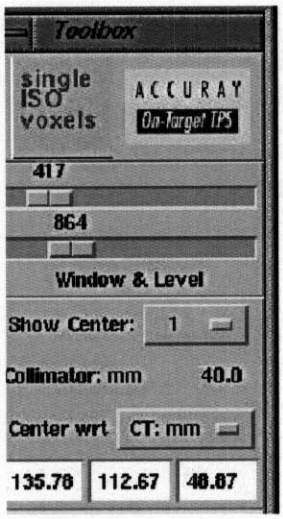
## Procedure 5-14: Planning the AQA Test (not required for each daily test)

1. Place the acrylic ball in the shadow phantom. Remove the steel ball if it was installed.
2. Load film into the shadow phantom
3. Acquire a CT scan of the AQA shadow phantom and film base with the anatomic direction labels (left, superior etc.) aligned as if for a supine patient. Use the standard CT protocol for head treatments in place at the installation site. Typical parameters will be DFOV= 20-25 cm, 100-400 mA, 1 – 1.5 mm axial slice thickness.
4. Transfer the CT scan to CyberKnife using the "Images" utility from the 9-button menu screen.
5. Import the CT scan as a patient.
6. Remove the plastic ball from the shadow phantom and place the steel ball inside.
7. Use the On Target hidden menu function to copy CT to phantom.
8. Open a treatment plan using the newly acquired CT scan.
9. When the Set Anatomy/Imaging parameters dialog box pops up, Choose the Type of Treatment AQA and Template Paths QA800, Fiducial Tracking and Automatic Update and 1 Fraction.
10. Use the imaging pull-down menu to select Locate Fiducials.
11. Set the number of fiducials to 4
12. Set the type of fiducials to GOLD_SEED_1
13. Locate the four fiducials contained in the shadow phantom and then close the Identify Fiducials window.
14. Before doing any other planning functions, open **Setup Ballcube Test** from the hidden menu.
15. Use the view selection sliders to center the three view windows on the target ball in the shadow phantom.
16. Follow the instructions on the **Delineate Ball** window to auto-contour the 1.25 inch plastic ball (*Figure 5-A1 Delineate Ball, page 50*).
17. If contouring is complete, click the red **CANCEL** button to exit the Delineate Ball menu box and also exit the Setup Ballcube Test mode.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015


*Tool box showing X,Y,Z position of treatment isocenter after adjusting yellow circle inferior by 0.13 mm. The present z-value is 48.87 mm, the z-value before alignment was 49.00 mm.*

**Figure 5-A2 Tool Box**

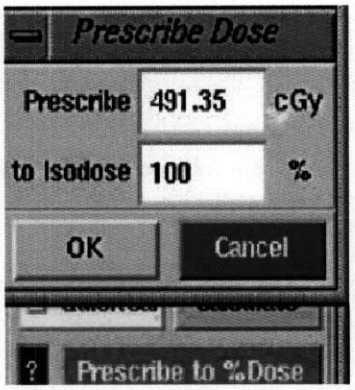



**Figure 5-A3 Prescribe dose**

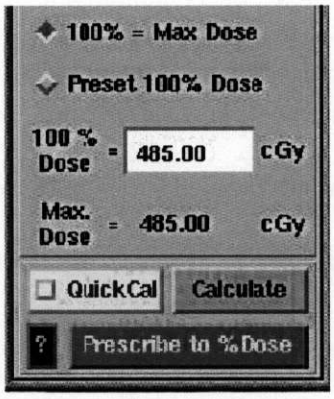



**Figure 5-A4 Calculate**



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015


18. Before doing any other panning select the green **SINGLE CENTER** button from the Toolbox.
19. Choose the 30 mm collimator in the Single Center Beam Assignment Window (*Figure 5-A7 Single Center Beam Assignment, page 56*).
20. The 30 mm collimator is used to allow easier alignment with the ball since it has a similar size. Change to the 40 mm collimator later in the procedure. Click the green **NEXT** button.
21. Enter the dose 500 cGy (this will be scaled in a later step to get a max dose on the film of 250 cGy) (*Figure 5-A3 Prescribe dose, page 52*).
22. Use the Zoom (+) tool to zoom in on the target ball in all three views.
23. Turn off the dose distributions on each window to allow easier viewing of the yellow circle with respect to the red tumor contouring line.
24. If the yellow circle is not centered (*Figure 5-A5 Yellow circle before alignment (yellow circle is 0.13 mm Superior of alignment), page 54*) in the target contour (jagged red line), make small (sub-mm) adjustments to the z-coordinate of the target in the Toolbox until they are aligned. The best way to determine alignment is to observe how the yellow circle is centered on the inside corners of the red target contour line (*Figure 5-A6 Yellow circle after alignment, now centered in inside corners of red contour line., page 54*).



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015

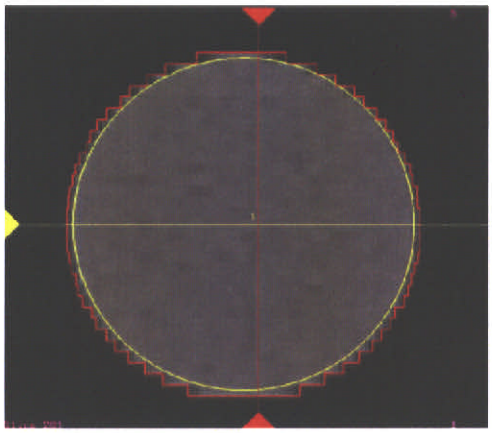



**Figure 5-A5 Yellow circle before alignment (yellow circle is 0.13 mm Superior of alignment)**

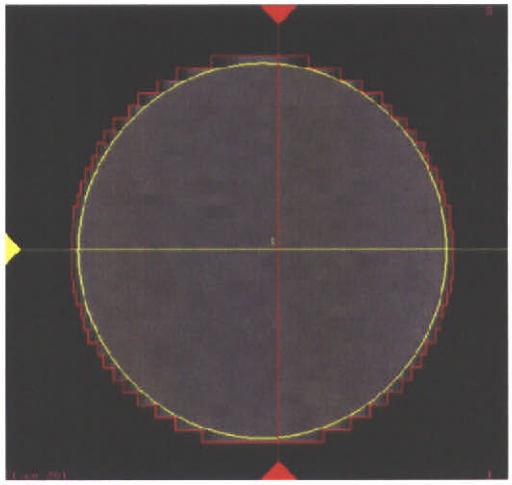


**Figure 5-A6 Yellow circle after alignment, now centered in inside corners of red contour line.**



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015


25. Record the (X,Y,Z) coordinates which are displayed in the Toolbox (*Figure 5-A2 Tool Box, page 52*). These should be checked to make sure the plan is not accidentally changed.
26. Select the green **SINGLE CENTER** button and change the collimator size from 30 mm to 40 mm. (The 30 mm collimator is used to align the isocenter. The 40 mm collimator is used for radiation delivery.)
27. Click **CALCULATE** to calculate the plan dose and make sure the X,Y,Z coordinates have not been changed.
28. Click on the film and determine the max dose on each of the two films. If the average maximum dose is not 250 cGy, scale the max treatment dose using the **PRESCRIBE TO %DOSE** button: (*Figure 5-A3 Prescribe dose, page 52*) so that the film receives 250 cGy.
29. In axial window, click on film to observe maximum dose and verify that the maximum dose is 250 cGy (+/- 2 cGy).
30. Click **CALCULATE** (*Figure 5-A4 Calculate, page 52*).
31. Save the plan as AQA_daily_test_plan.
32. Select the **DRR** button from the 9 –button screen.
33. Select the plan AQA_daily_test_plan.
34. Press the **PHANTOM** button to create phantom DRR's.
35. Press **CANCEL** to exit DRR generation.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015

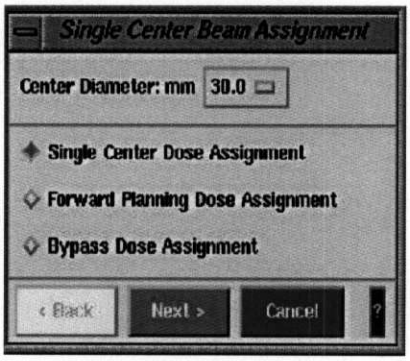




**Figure 5-A7 Single Center Beam Assignment**

**Figure 5-A8 Single Dose Wizard**

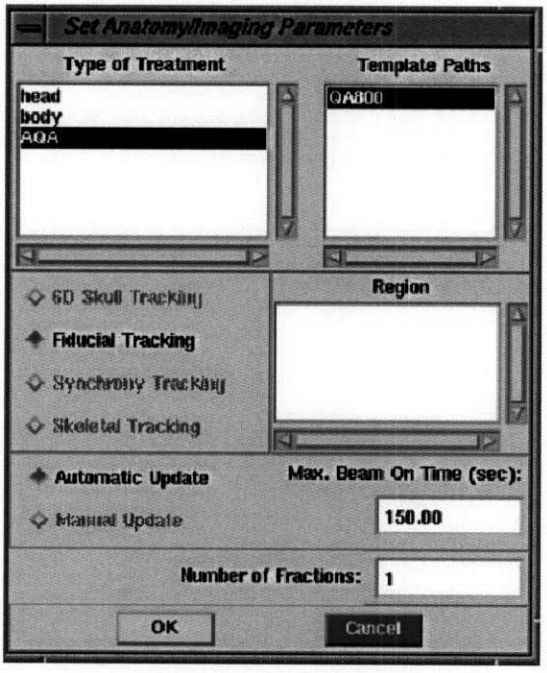



**Figure 5-A9 Imaging Parameters**



339

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015


# MODULE 6: QA PRACTICUM

© 2006 Accuray Incorporated. All rights reserved. The Accuray stylized logo, Accuray, CyberKnife, Xsight, CyRIS, InView, MultiPlan, and Synchrony are trademarks and/or registered trademarks of Accuray Incorporated in the United States and other countries.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118 

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015


# Table of Contents

Robot Operation ..... 3
Controller Power-up ..... 3
Teach Pendant ..... 3
Jogging ..... 5
Safety Considerations ..... 5
Procedure 6-1: Moving the Robot Manually ..... 7
Procedure 6-2: Move the Robot to "PRCH" (Perch) ..... 7
Procedure 6-3: Turning the Laser ON and OFF Via the Teach Pendant ..... 9
Beam Measurements ..... 9
Water Tank Setup for Beam Scanning ..... 9
Procedure 6-4: Water Tank Setup ..... 9
Robot Targeting Visual Check (or Centering to Isopost) ..... 10
Procedure 6-5: Robot Targeting Accuracy with BB Test ..... 10
System Alignment ..... 11
Imaging Alignment ..... 11
Linac laser alignment ..... 11
Laser Mechanical Alignment Check ..... 11
Procedure 6-6: Mechanical alignment ..... 11
Procedure 6-7: LINAC Laser/Radiation Field Congruence Check ..... 12
TLS Tracking ..... 12
Procedure 6-8: TLS Tracking and Table Movement Correspondence ..... 12
Robot mastering check ..... 12
Training Checklist ..... 13



341 Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015


# Module Description:

Practice the QA procedures introduced in Module 5.

# Module Objectives:

- Develop skills to operate the robot manually.
- Perform beam measurement dry run.
- Deliver BB test path for qualitative targeting accuracy check.
- Review the Ball-Cube and AQA film analysis programs.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015

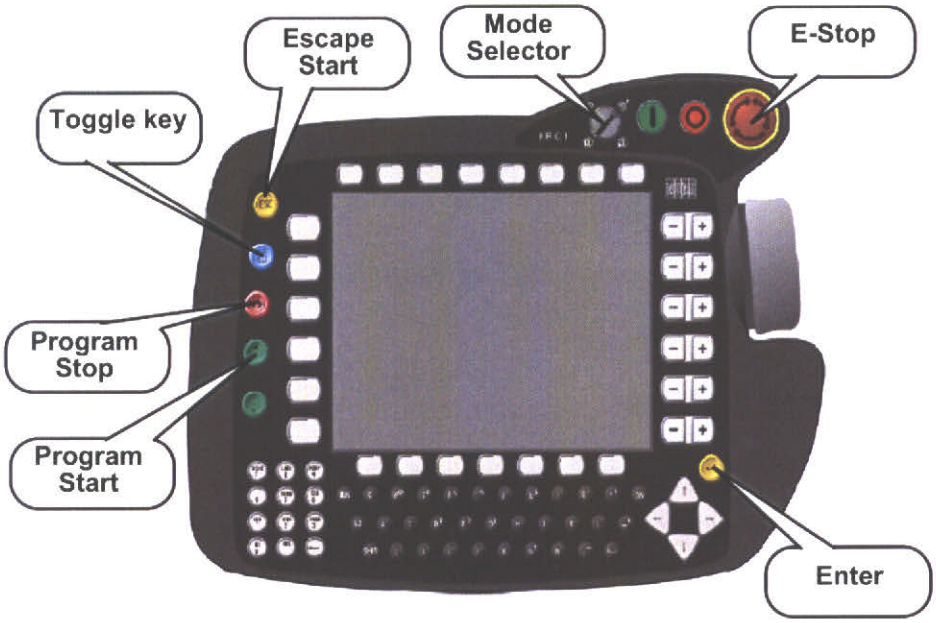




Figure 6-1 Teach Pendant

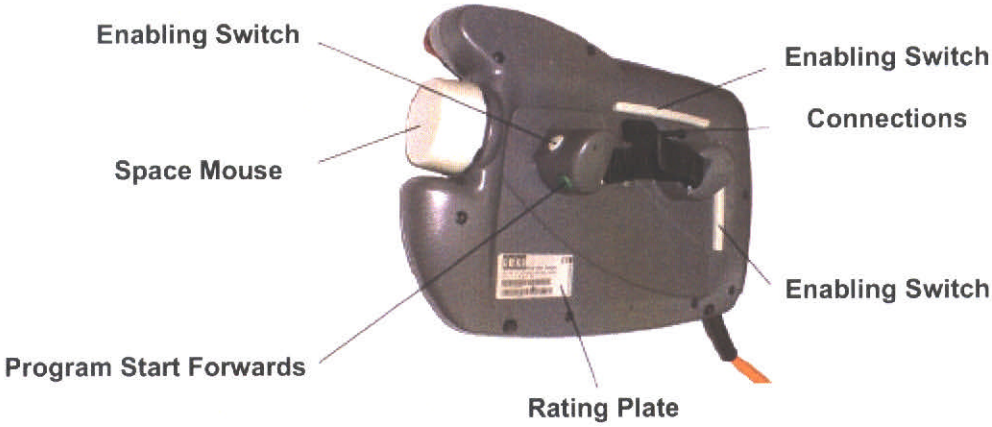



Figure 6-2 Teach Pendant (View from behind)



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015


# ROBOT OPERATION

This section is a quick reference for operating the robot.

## CONTROLLER POWER-UP

The main disconnect switch is on the controller cabinet. When this handle is in the UP position, the switch is closed and if power is supplied to the cabinet, the controller will start. The robot's boot-up usually takes about 2-3 minutes.

To power off the controller, put the handle in the DOWN position. It takes approximately 30-60 seconds for the controller to shut down. It is recommended to wait at least 60 seconds after powering off the robot before initial power up.

## TEACH PENDANT

*See Figure 6-1 Teach Pendant, page 2.*

All enabling switches on the Teach Pendant are three-position switched. If they are released, the drives are disabled. If they are held too tightly, the drives are disabled as well. They should be held in the middle position for the drives to be enabled. See *Figure 6-2 Teach Pendant (View from behind), page 2* for a view of the Teach Pendant from behind.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015


| | | |
|---|---|---|
| | **T1** | Low speed teach mode |
| | **T2** | High speed teach mode |
| | **Automatic** | Runs programs |
| | **External** | Runs programs from SGI computer |

**Figure 6-3 Mode Selection (Different Operating Modes)**

No Jogging allowed

Jog with space mouse

Jog using soft keys (right side of display)

**Figure 6-4 Jog Modes**

Individual axes

World coordinate frame

Base coordinate frame

Tool coordinate frame

**Figure 6-5 Jog Coordinate Frames**




Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015


## Jogging

Jogging can only be performed in T1 or T2 mode. See *Figure 6-3 Mode Selection (Different Operating Modes), page 4.*

### Jog Modes

Jog mode soft key is located on the left side of the display. Pressing it changes the Jog mode as indicated in *Figure 6-4 Jog Modes, page 4.*

### Jog Coordinates

Jogging can be performed in one of the frames shown in *Figure 6-5 Jog Coordinate Frames, page 4.* Pressing the soft key on the left side of display can change the frame. All modes, except the first one, are Cartesian coordinate systems.

# SAFETY CONSIDERATIONS

**WARNING: Maintain at least 3 ft. distance from robot when operating the robot manually. Overhead structures such as the X-ray tubes can be struck by the gun box on the top of the robot. The robot can be driven into bulkheads along walls.**

**CAUTION:** The PDP or safety zone parameters are not active when using the teach pendant. When moving the robot, focus on the robot rather than looking at the teach pendant.

If the teach pendant system does not respond, check to see if the E-Stop button is depressed halfway.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015


**NOTE:** Page Left Intentionally Blank




Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015


## Procedure 6-1: Moving the Robot Manually

1. Move key from automatic mode to manual mode (select either **T1** or **T2**).
2. Select **ACKN** or **ACKN ALL** (soft key located at bottom right corner of display screen.
3. Press the top left soft key until the following robot jog icon appears.
4. Change the speed of the robot by selecting the soft key located at the lower right side of display screen (2nd from bottom).

**CAUTION:** Select 50% or less for the speed of robot travel, to prevent collisions.

5. Depress and hold enable switch halfway to activate teach pendant. the middle status indicator turns green (located at bottom left side of display screen) When enable switch is depressed, buttons along right hand side of screen will change to + / - corresponding to each of the 6 robot joints.
6. Move robot as desired using the **+** / **-** buttons for each individual joint.

**CAUTION:** Keep your eyes on the robot at all times, not the teach pendant, when robot joints are in motion, to prevent collisions.

Reset the mode selection by moving the key from manual mode (**T1** or **T2**) to automatic external mode.

## Procedure 6-2: Move the Robot to "PRCH" (Perch)

1. Move key from automatic mode to manual mode (**T2**).
2. Select **ACKN** or **ACKN ALL** (right bottom corner of display screen).
3. Use blue toggle key to highlight top of screen.
4. Select **CK MAIN** menu in left menu column (highlights in blue) by using the arrow keys.
5. Open menu by selecting the **ENTER** key (**YELLOW** button).
6. Use arrow keys to highlight the **prch** program.
7. Launch the **prch** program by using the **ENTER** key.
8. Depress and hold enable switch halfway until button turns green.
9. Press **GREEN +** button once and release after message "programmed path reached (BCO)" appears in message window.
10. Press **GREEN +** button a second time. Hold until robot returns to perch position as indicated by black button.

Reset the mode selection by moving the key from manual mode automatic external mode.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015


Figure 6-6 Scanning Setup with Reference Diode

Figure 6-7 Water Tank for Beam Scanning



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015


### Procedure 6-3: Turning the Laser ON and OFF Via the Teach Pendant

1. Switch key to manual mode **(T2)**.
2. Select **MONITOR** soft key above display screen.
3. Use arrow keys to select **I/O**, then press <Enter>.
4. Use arrow keys to select **DIGITAL OUTPUTS**, then press <Enter>.
5. Depress and hold enable switch halfway until red button changes to a green button.
6. Wait for the "Change" option on the menu at the bottom of screen to become active, then select **CHANGE**; wait a few seconds to verify laser has turned on.
7. Switch key back to automatic mode
8. Repeat sequence outlined above to turn the laser off.

# BEAM MEASUREMENTS

## WATER TANK SETUP FOR BEAM SCANNING

For direct 800 mm SAD measurements, the tank can be no more than 20 cm from the floor, or it can be set on the floor. For fixed 800 mm SSD setups, the distance to the floor is less critical because the robot remains stationary.

A reference diode must be used for all scanning. *Figure 6-6 Scanning Setup with Reference Diode, page 8.*

### Procedure 6-4: Water Tank Setup

1. Be sure the LINAC is level.
   - Make sure that the laser is aligned. To perform mechanical alignment check, rotate the collimator housing with the laser on to confirm that it does not walk.
   - Use the reflection of the laser from the water surface to establish that the beam is perpendicular to the surface.
2. Be sure the phantom is level.
   - Confirm that the rails are truly perpendicular to the walls of the tank.
   - Use a level that is verified to be correct, compare levels etc.
3. Be sure the detector is set correctly at the water surface.

   **NOTE:** Chamber and diode position determine the width of the OCR due to the resolution of the penumbra.

   - Look from below the surface
   - Use an alignment tool if available
   - Scan Chamber across the surface of the water to confirm that the depth in the x and y axes is constant across the scan field.
4. Confirm the central axis of the beam and the detector correspond in the x and y plane. Take readings in each direction to determine the beam center, then set the 0,0,0 of the scanning system.
5. Verify that the chamber is on the beam central axis.
   - Using the 5mm secondary collimator, run the chamber up and down making sure the laser hits the same spot on the chamber at all depths.
   - If need be, adjust the 0,0,0 of the scanning system to correspond with the maximum readings obtained along the x and y axis at dmax and 20 cm depth for final chamber centering.
6. Be sure that the electrometer is set so that the entire scan distance gives a good signal.
7. Use a reference chamber mounted as in *Figure 6-7 Water Tank for Beam Scanning, page 8.*



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015


# ROBOT TARGETING VISUAL CHECK (OR CENTERING TO ISOPOST)

A visual qualitative test of the robot targeting accuracy can be done using either a testpath function from the treatment mode, or a BB test via the Simulation mode. Simulation mode can deliver a plan with or without radiation. During the simulation exercise, all software programs are functioning.

When testpath is used, only the robot software is functioning; all other software is turned off. The tests, though similar, therefore have different purposes and applications.

## Procedure 6-5: Robot Targeting Accuracy with BB Test

This is a quick visual check to see that all subsystems are working properly. This test is sometimes referred to as the ***BB test***. Because this test is qualitative it is most useful for the early stages of targeting alignment, usually during acceptance and commissioning.

1. Be sure that the LINAC laser is properly aligned.
2. Power-on the system.
3. Place a small metal BB on the headrest and line it up close to isocenter using the wall lasers. A 2mm *Beekley Y-spot* works very nicely for this purpose.
4. Create a new plan (from any CT set of which phantom CTs have been loaded).
5. Select a body/fiducial treatment.
6. Locate one fiducial at its default location.
7. Select *single center* and locate the center to be at the default location (robot coordinates 0,0,0).
8. Calculate and Save the plan.
9. Create ***phantom*** DRR's.
10. Select *simulation* and advance to the patient alignment interface and align the BB close to (0,0,0). *Note*: it will be necessary to turn the x-ray technique way down since there is no phantom material around the fiducial.
11. Go to the imaging parameters interface and select the BB test mode.
12. Follow the prompts on the screen and teach pendant to advance through the BB test.

On the teach pendant, *sim node* will advance to the next node and pause there. *Sim all* will go through all the nodes in the path, pausing briefly at each node.




Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015


# SYSTEM ALIGNMENT

## IMAGING ALIGNMENT

It is sometimes advisable to check the imaging system mechanical alignment. This is especially important if there has been an earthquake or other significant perturbation of the camera stands or ceiling mounted x-ray sources. To do so, use the following procedure:

1. Attach the isopost to the camera stand.
2. Exit the treatment room and close the door.
3. Turn the Key on the ESCC to *Service*.
4. On the ESCC, bypass all the interlocks except the door switch and Estop buttons.
5. On the TLS PC, start the TLS Controller Software.
6. Turn on the imaging system and set the mode to "fiducial".
7. Adjust the imaging technique to kVp to 60, and 50 mAs and acquire image. Adjust the X-ray parameters so that you get a good image of the isocrystal.
8. Verify that the isocrystal is at the center pixel ± 2 pixels.
9. Close the TLS Controller program.
10. Un-bypass the ESCC interlocks.
11. Remove the isopost.
12. Alternately an image of the isopost can be acquired using the treatment delivery system.
13. With isopost installed, acquire image, use zoom to 400%, center cross-hairs and snapshot image.
14. Confirm that isocrystal is with 1 mm of center of cross-hairs.
15. Record results.

## LINAC LASER ALIGNMENT

### Laser Mechanical Alignment Check

The CyberKnife System uses a point laser that is coincident with the radiation field as a QA tool. The laser is reflected off an adjustable mirror. The alignment must be checked periodically both mechanically and relative to the radiation field. Use the following procedures to check the alignment.

### Procedure 6-6: Mechanical alignment

1. Install the laser secondary collimator.
2. Move the robot so that the collimator is approximately 80 cm from a flat surface (floor or table). Place a piece of paper on the surface.
3. Allow the collimator to rotate by releasing the stop pin and hold.
4. Rotate the collimator housing through its full range and mark the furthest extent of the laser as it walks across the paper.

   It should walk no more than 1mm. Although this is a subjective test, the next section describes a more quantitative technique



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015


### Procedure 6-7: LINAC Laser/Radiation Field Congruence Check

Once the mechanical alignment is verified (above), it is important to verify that the laser is indeed coincident with the radiation field. Use for example the following procedure:

1. Install the laser secondary collimator.
2. Place a sheet of Ready-Pack diagnostic film on a flat surface.
3. With a mirror, adjust the robot trajectory so it is perpendicular with the film by reflecting the laser back to the hole in the collimator.
4. Using the front pointer, adjust the SAD to 800 mm.
5. Remove the front pointer and install the 60mm collimator.
6. Expose the film with the appropriate number of monitor units so as to not saturate the film. For XV film, Use about 25 monitor units (without buildup).
7. Using a sharp pin, poke a hole in the film where the laser hits. This must be done very carefully so as to not shift the film inside the envelope.
8. Develop the film and measure the location of pin hole with respect to the radiation field. This can be done using the software tool ImageJ
9. This should not differ more than 2mm from the center of the radiation field.

## TLS TRACKING

The TLS subsystem is responsible for measuring and reporting patient motion.

### Procedure 6-8: TLS Tracking and Table Movement Correspondence

1. Obtain a CT of a phantom.
2. Create a plan.
3. Make DRR's.
4. Make a Prescription.
5. Place a phantom on the treatment table.
6. Advance through the *Treatment* menus to the patient alignment interface.
7. Re-align the phantom to get the couch offsets close to zero.
8. Using the couch digital readouts, move the phantom to several different positions in all three translational axes.
9. At each position, take an image and compare the TLS estimate to the actual couch offset.
10. Subtract the "zero-position" offsets from the data.
11. Record results. The RMS of all the errors should be no more than 2 mm.

#### ROBOT MASTERING CHECK

Robot mastering is done after maintenance and at least annually to generate the quantitative results of robot targeting accuracy. The testpaths are named SRCH 1 and SRCH 2.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015


# TRAINING CHECKLIST

1. **Use Teach Pendant To: Perch, Jog, And Drive Robot Manually For Z Axis.**
2. **Water Tank Setup**
3. **Robot Targeting Visual Test With Run Test Path**
4. **System Alignment:**
   - **Imaging**
   - **Laser Mechanical Alignment**
   - **Radiation Field CAX/ Laser Light Congruence**
5. **TLS Tracking and Table Movement Correspondence**
6. **Review Equipment Requirements List**



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015




Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015


# MODULE 7:

# BASIC UNIX REVIEW

*© 2006 Accuray Incorporated. All rights reserved. The Accuray stylized logo, Accuray, CyberKnife, Xsight, CyRIS, InView, MultiPlan, and Synchrony are trademarks and/or registered trademarks of Accuray Incorporated in the United States and other countries.*

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015


# Table of Contents

**Basic UNIX and System Administration Practical ..... 3**
Basic UNIX Commands ..... 5
Helpful Shortcuts ..... 7
The Cyberknife File system: File Editing and Security ..... 9
Transferring Files using ftp ..... 11
ASCII Conversions ..... 13
Screen Dumps ..... 15
TAR and ZIP ..... 17



357
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015


# Module Description:

Review basic UNIX commands and learn the file locations for commonly used directories.

# Module Objectives:

- Exercise UNIX commands.
- Learn simple UNIX procedures to manage and move UNIX files.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015


**NOTE:** Page Left Intentionally Blank



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015


# BASIC UNIX AND SYSTEM ADMINISTRATION PRACTICAL

The following information provides the tools needed to work successfully with UNIX. The most common task that you will perform is to TAR and ZIP FTP files to Accuray so that we can help you solve any technical problems or application issues you might be experiencing with the system.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015


**NOTE:** Page Left Intentionally Blank



361
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015


# BASIC UNIX COMMANDS

To open a UNIX command shell, move the cursor onto the blue background, right mouse click and select 'shell'.

Basic commands;

- To see your current directory:"pwd"
- To list the contents of this directory:"ls" (or "ls –l" for more details)

If this runs to more than one screen then use the command "ls | more" or "ls –l | more".

The pipe symbol "|" is found just under the backspace key. This shows the results of the ls command one screen at a time,

Use the Enter key to advance one line, Spacebar to advance one page, or 'q' to quit.

- To change directory"cd *new directory*" use "cd .." to move to the next parent directory, "cd /" to move to the root directory, and just "cd" to move to your home directory. "cd .." to move one directory higher.
- To read the contents of a file"more filename". Navigate the file as explained above.
- To copy a file "cp source filename destination_filename"
- To move a file "mv filename" - then path (e.g. /usr/tmp)
- To delete a file "rm filename"
- To open a calculator "xcalc"
- To see the help page for a command"man command". Navigate the help pages using Enter, Spacebar, and 'q' as with the more command.
- To close the shell window "exit" or double click on the top-left window button
- To reset a TPS graphics error"gclear" (when the contours turn grey)



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015


**NOTE:** Page Left Intentionally Blank




Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015


# HELPFUL SHORTCUTS

- When typing a file or directory name, you can "complete" the name by typing the <esc> key, if there is no ambiguity. So, for instance, to go to the directory site_prog:
  - Open a shell.
  - "cd sit<esc>"
  - The computer will fill in the rest, so that it reads: cd site_prog
  - Type return
- To copy and paste, highlight a line of text with the left mouse. Use the middle mouse to paste.
- The command "!! <enter>"; repeats the last command you did.
- The command "!{char_set}"; repeats the last command that begins with the char_set selected. For instance, if you just did the command:

  nedit clean_image.dat

  and have closed and exited and want to continue editing that file, type:

  !ned

  and the computer will implement the command:

  nedit clean_image.dat

## Practical

Try moving between a few directories and reading the contents of some files.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015


**NOTE:** Page Left Intentionally Blank



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015


# THE CYBERKNIFE FILE SYSTEM: FILE EDITING AND SECURITY

The Cyberknife System uses several directories to store programs and data. The most relevant are

/usr/accuray/database/patients stores all patient data (CT, DRRs, plans, etc)

/usr/accuray/datafiles/site_df/beam_data beam data files

/usr/accuray/wkstn home directory

To check the amount of free disk space use the command "df -h/". If space is short you can archive patient data to storage media (see later).

To edit a text file use "nedit filename". This opens a windows type file editor.

Note that Cyberknife System employs a file security system that will disable Cyberknife if certain files are modified or deleted. This is to prevent the possibility of planning or treatment errors occurring due to inadvertent file system changes. If this occurs you will see an 'Invalid System Configuration' ESTOP message when you try to start the TPS. This is an unrecoverable error, and you should contact Accuray Service.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015

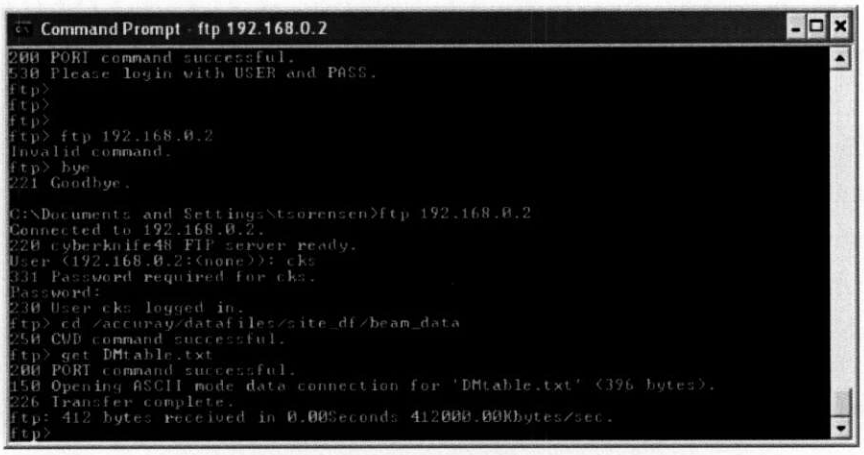




**Figure 7-1: Command Shell in FTP Mode**



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015


# TRANSFERRING FILES USING FTP

To Transfer files from a PC to the SGI:

On the PC, get the command prompt; (See *(Figure 7-1:, Command Shell in FTP Mode , Page 10)*)

- Navigate to the directory where the files are saved on the PC
- 'ftp CK IP address'(you can get the IP address from your system administrator or installation engineer)
- Log in to the CyberKnife (cks; cks)
- Navigate to the directory where the files are to be sent
- If the files are binary files, e.g. images, use the "bin" command to set for binary transfer
- Use the "put" command to transfer the files: (note "mput" can be used for multiple files, e.g. "mput *.dat")
- Enter "bye" to quit



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015


**NOTE:** Page Left Intentionally Blank




Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015


# ASCII CONVERSIONS

Convert Windows ASCII files to UNIX ASCII

In the SGI shell, use the "to_unix" command

e.g. 'to_unix DMtable.txt DMtable.dat'

Convert UNIX ASCII files to Windows ASCII

In the SGI shell, use the "to_dos" command

e.g. 'to_dos DMtable.dat DMtable.txt'



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015

**Figure 7-2: Using the Media Recorder**

**Figure 7-3: Using Image View to change a file format**



371

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015


# Screen Dumps

In a shell window "mediarecorder". When the mediarecorder program starts, close the original shell window. See *(Figure 7-2:, Using the Media Recorder, Page 14).*

By default screen dumps will be stored in home directory, but you can edit this.

Adjust the dotted rectangle to encompass the screen area you want to capture (you may need to move the mediarecorder window out of the way. When ready hit the record button (red circle). Repeat for as many images as needed.

These images are stored in the UNIX rgb format, which is not readable by Windows applications. To convert them use "imgview" See *(Figure 7-3:, Using Image View to change a file format, Page 14).* From the File menu open the relevant rgb image, then save as – using a standard tiff or jpeg format. You can now FTP the files to a PC.

## Practical

Save a Screen Dump showing a CyberKnife plan, and convert the file to jpeg. Then delete the rgb and jpeg files.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015


**NOTE:** Page Left Intentionally Blank




Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015


# TAR AND ZIP

You may wish to send planning system files to Accuray. The easiest way to do this is to use the TAR command to produce an archive file, then compress that file, then ftp it. The reverse process can be used to receive planning system files from Accuray.

To make and compress an archive file of an entire directory and all its subdirectories:

- Navigate to the directory, i.e. cd/usr/accuray/database/patients
- Type: tar -cvf <file or directory name>.tar <file or directory name>
- Type gzip<file or directory name>.tar to compress tar file.

FTP the file to Accuray or other sites.

To uncompress and extract files from an archive;

- 'cd' to the directory where the file is located.
- To uncompress: type gunzip<file or directory name>.tar.gz
- Type: tar -xvf<file or directory name>.tar
-

## Practical

Use tar to make an archive of the /usr/accuray/tmp directory (and all its subdirectories) in the /tmp directory. Use gzip to compress this file. Now unzip the file and extract all the files, still within the /tmp directory. Finally delete all files in /tmp.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015





Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015


# MODULE 8:

# SYNCHRONY™

*© 2006 Accuray Incorporated. All rights reserved. The Accuray stylized logo, Accuray, CyberKnife, Xsight, CyRIS, InView, MultiPlan, and Synchrony are trademarks and/or registered trademarks of Accuray Incorporated in the United States and other countries.*

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015


# Table of Contents

Quality Assurance ..... 2
Synchrony Motion Table Routine QA Procedure ..... 2
Purpose ..... 2
Film Dosimetry ..... 2
Procedure to Generate Optical Density vs. Dose Calibration Curve ..... 2
Routine QA Procedure Using Synchrony Motion Table ..... 3
Deliver Ball-Cube Plans ..... 4
Film Analysis ..... 8
Synchrony Motion Table Maintenance ..... 9
Controls ..... 9
Fuse Replacement ..... 9
Charging the Batteries ..... 9
Replacement Parts ..... 10
Battery Replacement ..... 10
Battery Disposal ..... 10
Cleaning the Motion Table ..... 10



377
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015


# Module Description:

General introduction to the Synchrony™ Tracking Algorithms and Quality Assurance procedures.

# Module Objectives:

To learn the Synchrony QA Methodology and Quality Assurance procedures.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015


# QUALITY ASSURANCE

## SYNCHRONY MOTION TABLE ROUTINE QA PROCEDURE

### Purpose

Verify the proper operation of Synchrony™ tracking at a clinical site. This is done by comparing the targeting accuracy and dose profile of static and moving End-To-End (E2E) tests.

Both positioning accuracy and radiation distribution shape will be measured.

**Materials**

1. Accuray standard E2E test ball-cube Assembly
2. 1 box of Gafchromic MD-55-2 (20 sheets, 2.5 x 2.5 inches, pre-notched)
3. 1 Accuray Synchrony Motion Tracking QA Tool
4. One flatbed transparency scanner (e.g. Epson Expression Model 1680 or similar)
5. Current version of Accuray's E2E analysis software
6. Current version of NIH ImageJ freeware image analysis tool

**Methods**

Overview: Using the new Accuray Synchrony QA Motion table two End-to-End tests are performed using standard and extreme motion.

1. Use at least two LED markers with maximum AP motion.
2. Take images at every other (non-blocked) node.
3. Elevate target at least 3" with Styrofoam block to facilitate fiducial extraction

The proposed End-to-End tests are:

1. Static: No-motion (ideal)
2. Full motion with 30° phase shift between AP chest movement and SI tumor movement.

## FILM DOSIMETRY

### Procedure to Generate Optical Density vs. Dose Calibration Curve

One piece of Gafchromic film is used to develop a dose calibration curve for the local transparency scanning system. An absolute dose calibration curve for E2E dose profile corrections must be established.

1. Prepare a standard set of radiochromic calibration films from the same film batch. Cut a sheet of film in 1 cm squares.
2. Expose them to 500, 1000, 1500, 2000, 3000 cGy at 1.5cm depth, 800 mm SAD, in a unit density plastic or solid water phantom.
3. Scan these films with an unexposed piece of film from the same box (for a zero dose point) after waiting at least 24 hours.
4. Measure the optical densities.

379 Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015


5. From this data, calculate the relation between pixel intensity and dose in cGy. In most cases a linear relation of the form shown below is sufficient.

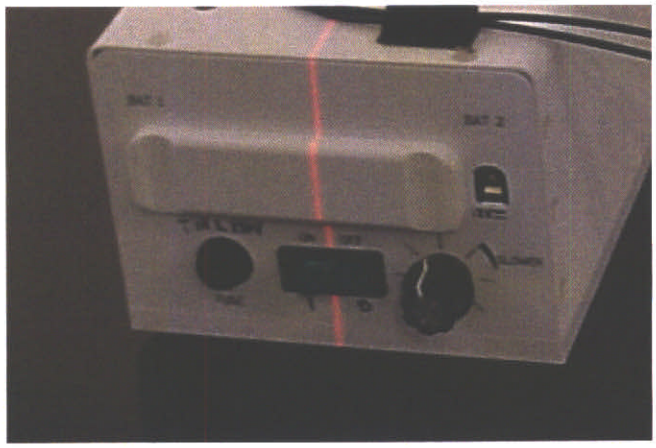
   Dose = constant*log[$P_{bkgr}/P_{exp}$] where,

   $P_{bkgr}$ is the background film pixel intensity and

   $P_{exp}$ is the exposed film pixel intensity

## ROUTINE QA PROCEDURE USING SYNCHRONY MOTION TABLE

1. **Charge at least one battery pack on the motion table,** using the provided charger. Use the sliding switch to select the desired battery pack to charge. The switch automatically sets the other battery pack for driving the table, thus the unit can be charged and operated at the same time.

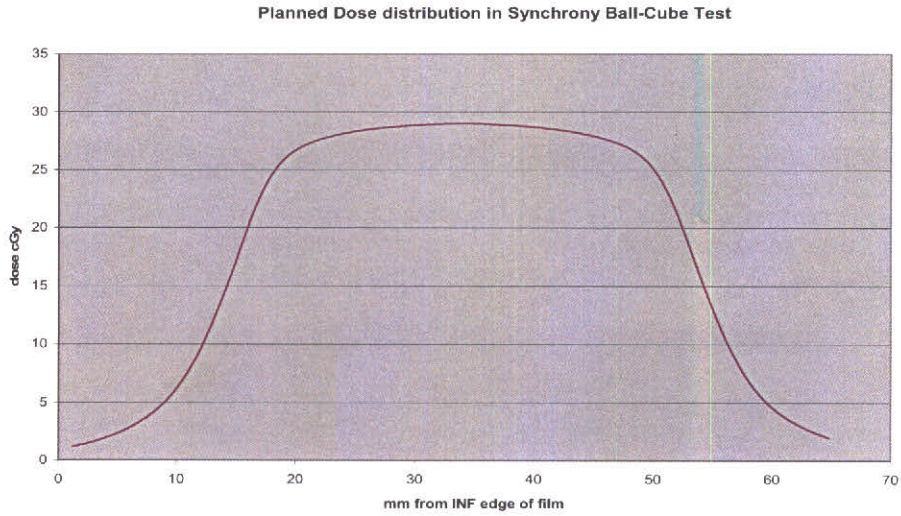


2. **Obtain a CT study of the Ball-Cube Phantom.** CT Positioning: Place the ball-cube phantom so that the phantom is in the proper anatomical orientation (i.e. anterior is facing up) parallel to the centerline axis of the CT couch, flat on the table. The ball-cube must be loaded with film (dose from the CT will be insignificant). Use 120 kVp, and thin slices. Use minimum pitch if a multi-slice scanner is used.
3. **Generate a Synchrony/Fiducial End-to-End test** plan using standard Accuray procedures. This plan will be copied and repeated for all measurements in this protocol.
4. **Export the RTDICOM dose** format using the DICOM export function from the MultiPlan right side global tool set.
5. Create profiles through the center of the target in each direction. This will be overlaid with the film results produced later.



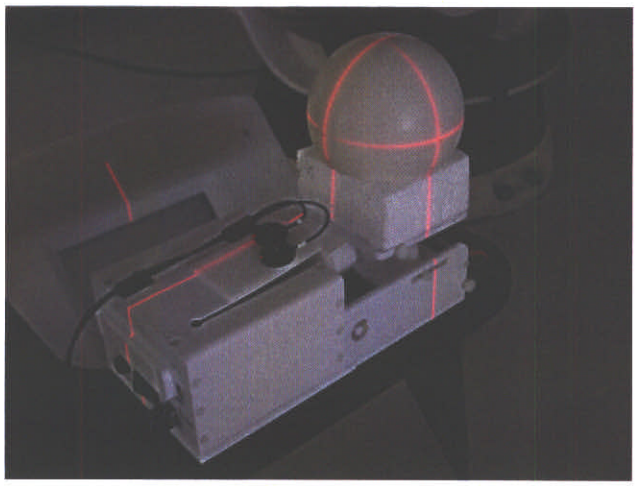
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015


## Deliver Ball-Cube Plans

Perform your standard Cyberknife dose calibration procedure such that all E2E tests are performed with as accurate a dose as possible. First, deliver the plan without motion to establish the expected targeting accuracy. Then deliver the plan with the motion table.

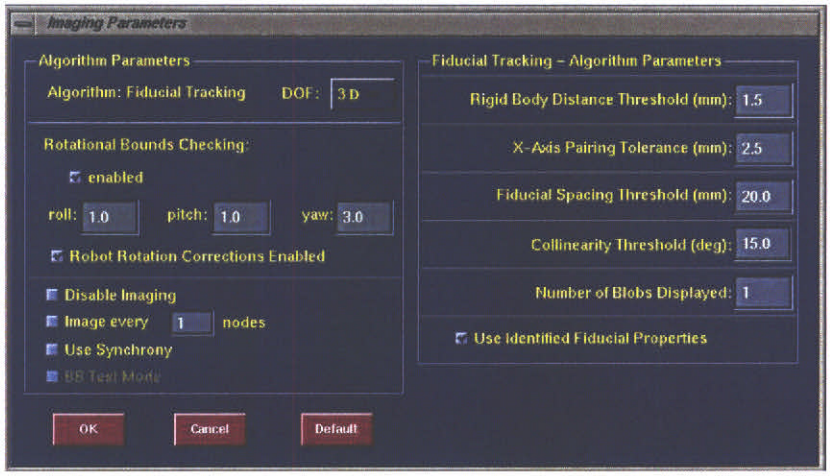




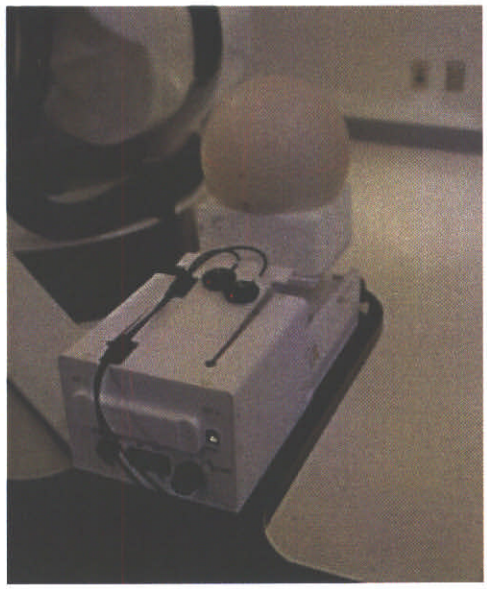
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015


1. Place the motion table and ball phantom on the CyberKnife couch. Use a 5 cm styrofoam block to elevate the ball-cube phantom above the motion table surface to minimize the image interference of the fiducials with the motion table components.
2. Deliver your End-to-End test plan with fiducial tracking to the SYNCHRONY Ball-Cube phantom with **no** target motion. Disable motion tracking and use Synchrony mode. ("Use Synchrony" unchecked).




3. Remove film, minimize exposure to UV. Scan after 24 hours.
4. Place the motion table and ball phantom on the CyberKnife couch. Use a 5 cm styrofoam block to elevate the ball phantom to minimize the image interference of the fiducials with the motion table components. Reproduce the setup orientation of the ball phantom from step 1 above (on CT couch).

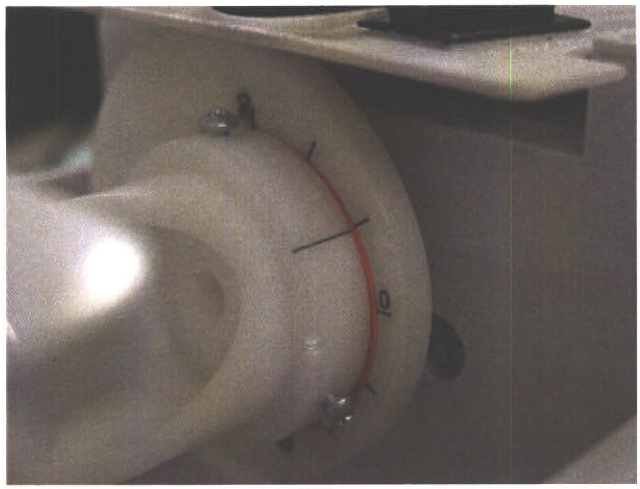


5. Load the ball-cube with Radiochromic film per standard Accuray procedure.
6. Verify the motion table phase shift is set to 30 degrees.

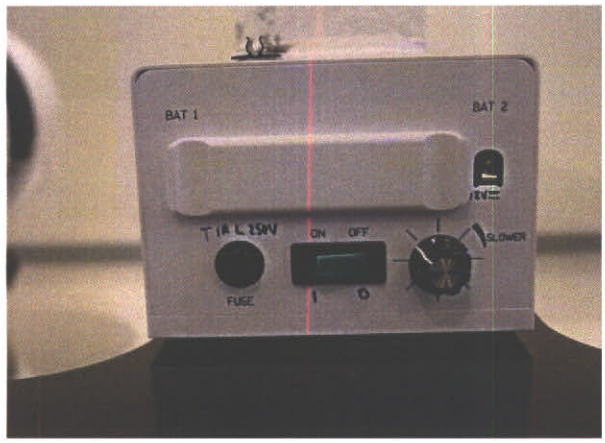


Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015

7. Turn on the motion table using the green toggle switch.

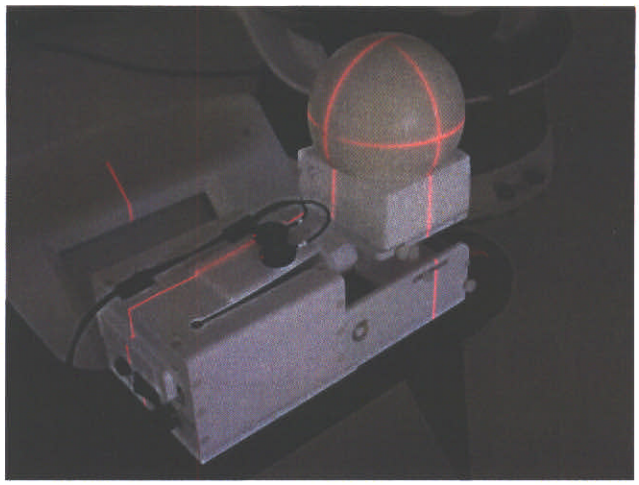



8. Verify by sweep second hand or stopwatch that the variable speed motor control produces a motion frequency between 15 and 16 cycles per minute. Adjust the speed with the dial to the right of the toggle switch.
9. If room lasers are available, use them to center the SI motion of the ball phantom with the room center. Also center LR and AP positions. Also position the Synchrony tracking "LED's" for maximum motion (i.e. at top of vertical motion ramp).

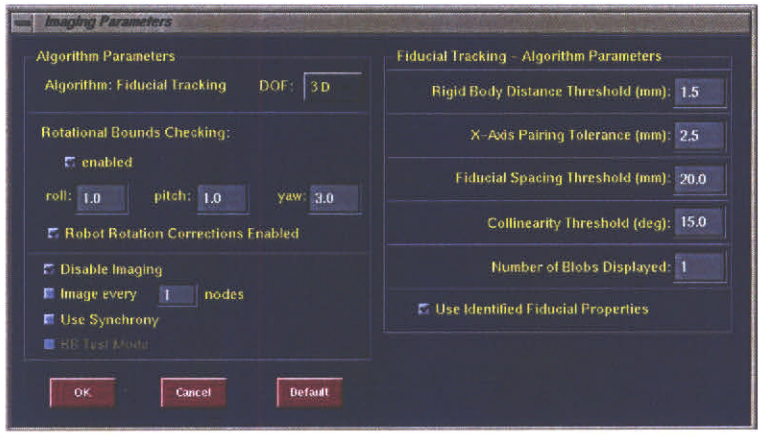


Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015

**10.** Check the Disable Imaging box on the Imaging Parameters screen so the model motion will remain constant.




**11.** Deliver the same End-to-End test plan as created in step 3 to the phantom, now with the phantom moving.

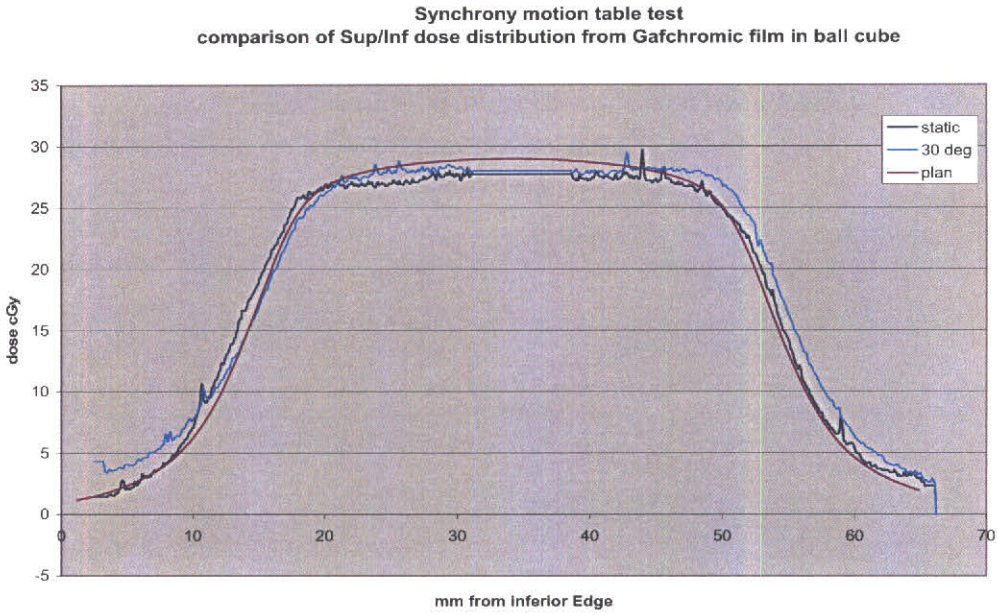


Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015


# FILM ANALYSIS

1. Scan all resulting radiochromic targeting result films as near to 24 hours after exposure.
2. Overlay the measured dose profiles of the static and moving phantom tests. Also include the plan dose from the RT/DICOM file. The figure below shows an example of overlay. In this example, the synchrony model points were not properly distributed, resulting in a deviation of the measured 30-degree curve (upper right side of curve). This kind of deviation can be avoided by proper distribution of the model points in phase space.



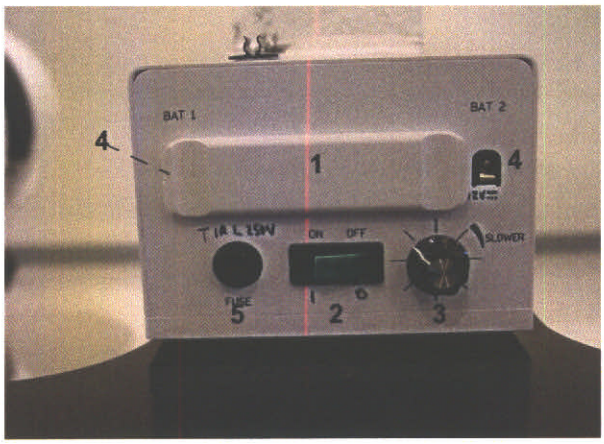



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015


# SYNCHRONY MOTION TABLE MAINTENANCE

## CONTROLS




1. Battery selection switch – Used to select which battery runs the device; the other battery is selected for charging.
2. Power on switch – Used to turn on the motion table
3. Speed control – used to adjust the speed of the motion table
4. DC jacks – used to connect AC adaptor for battery charging
5. Fuse holder – contains fuse for motor

## FUSE REPLACEMENT

Replace fuse with a 5 mm x 20 mm T1AL250V fuse only

## CHARGING THE BATTERIES

When the speed of motion desired cannot be attained, switch the battery selection switch to the unused battery, and charge the depleted battery as follows.

1. Connect the AC adaptor supplied with the unit to the exposed DC jack.
2. Plug the adaptor into the wall.
   The battery will charge in 3 to 4 hours. For maximum battery life, do not leave the adaptor connected to the unit after battery charging is complete. The table can be run (on the battery not being charged) during battery charging if desired.

The battery charging adaptors that is used with the unit are GlobTek Inc. Model GT-341-12-500D for 120VAC, 60Hz (North America); or GT-3T41-12-500D-3 for 230VAC 50 Hz (Europe)



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015


## REPLACEMENT PARTS

The fuse, traction band, replacement batteries, and battery charging adaptors are available from Accuray. Please contact customer service at 408-716-4600.

## BATTERY REPLACEMENT

When the unit can no longer run the table for the desired length of time after being recharged, the battery pack(s) will need to be replaced. When the replacement pack(s) have been received, they can be installed as follows.

1. Remove the 10 nylon screws that hold the cover onto the base.
2. Remove the old battery pack(s) by disconnecting the wires at the in-line connector (pulls apart) and pulling the pack(s) from their Velcro mounts.
3. Install the new pack(s) by pressing them into place, and connecting the wires.
4. Reinstall the cover and secure it with the nylon screws.

## BATTERY DISPOSAL

DO NOT dispose of old battery packs in the regular trash. These NiCd battery packs should be taken to appropriate facilities for correct disposal, or handled as directed by state or local waste handling laws.

## CLEANING THE MOTION TABLE

It is recommended that periodic cleaning of the motion table be done using a soft cloth dampened with a mild detergent solution, or an alcohol wipe.

**NOTE:** The use of high level disinfectants (e.g. Cidex) may discolor the unit.

RECEIVED
2006 SEP 29 A 9:51
FDA/CDRH/ODE/PMO



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015

K 067967



ACCURAY

**Enabling Full-Body Radiosurgery Using Image-Guided Robotics**

**Accuray Worldwide Headquarters**
1310 Chesapeake Terrace
Sunnyvale, CA 94089 USA

**Accuray Worldwide Manufacturing**
1310 Orleans Drive
Sunnyvale, CA 94089 USA

1383 Shorebird Way
Mountain View, CA 94043 USA

**Accuray Europe**
Tour Atlantique
1, Place de la Pyramide
F 92911 Paris La Défense cedex
Tel: +33 1 55 23 20 00 Fax: +33 1 55 23 20 39

**Authorized Representative**
MedNet GmbH
Borkstrasse 10
D-48163 Münster, GERMANY
Tel: +49 (251) 32266-0 Fax: +49 (251) 32266-22

**Customer Support +1 (877) 668-8667**

CE 0197

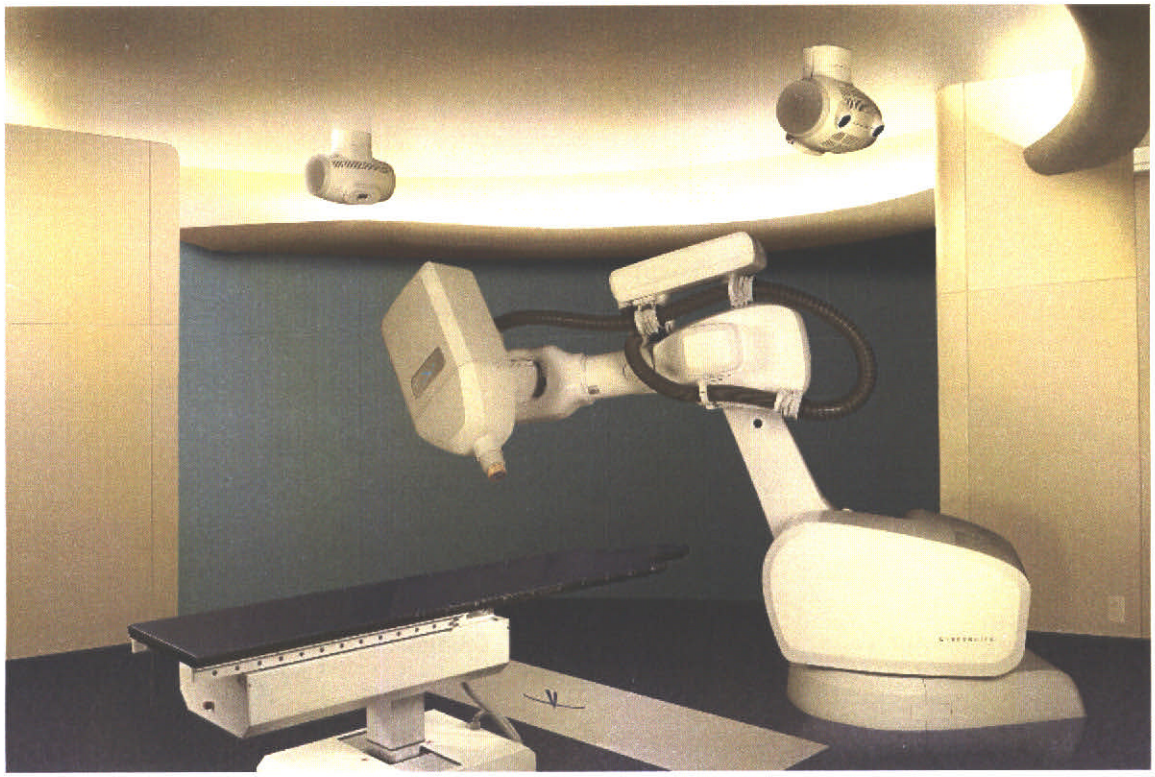
K23



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015





© 2005 Accuray Incorporated. All Rights Reserved. The Accuray stylized logo, Accuray, CyberKnife, Express, CyRIS, InView, MultiPlan, and Synchrony are trademarks and/or registered trademarks of Accuray Incorporated in the United States and other countries.

This document contains proprietary information that belongs exclusively to Accuray, Incorporated, and should not be distributed without prior written consent from Accuray.

The principals, officers, representatives, subsidiaries, employees, agents, heirs and assigns of Accuray, Incorporated, assume no responsibility or liability, either express or implied, for injury, death, or losses to consumers, users or service personnel resulting from improper handling of the CyberKnife® System by untrained or otherwise unqualified personnel.

Accuray Incorporated expressly denies any responsibility or liability for deliberate misuse or tampering with CyberKnife System components by persons not employed directly by Accuray, Incorporated. This warranty voids all others to the contrary, either expressed or implied, regardless of form, content, or source.

The anticipated useful life of the CyberKnife is seven to 10 years depending on utilization and proper performance of preventive and corrective maintenance.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



**WARNING: In the United States, law restricts this device to sale by or on the order of a physician.**

**Notice:**

**This User's Manual contains instructions for multiple features of the CyberKnife System. Since some features of the CyberKnife System are optional, some of the instructions in this manual may not apply to your system.**

**The availability of options is dependent on regulatory approvals in a particular country and varies from country to country.**

**The content of the User's Manual may vary since Accuray, the manufacturer, may modify them from time to time without giving notice to customers.**



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118 390

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



# REGULATORY COMPLIANCE

The CyberKnife System is classified by the following:

- Protection against electric shock: Class I, permanently connected
- Applied part: Patient treatment table only, Type B
- Protection against harmful ingress of water: IPXO - no protection against ingress of water
- Methods of sterilization or disinfection: Not required
- Degree of safety in the presence of flammable mixtures: Not suitable for use in the presence of flammable mixtures
- Mode of operation: Continuous

The CyberKnife System has been tested for compliance to the following standards:

| Standard Number | Standard Title |
|---|---|
| EN 60204-1:1997 | Safety of machinery - Electrical equipment of machines – Part 1: Specification for general requirements |
| EN 60601-1:1990 /A1:1993 /A2:1995 | Medical electrical equipment, Part 1: General requirements for safety |
| IEC 60601-1-1:2000 | Medical electrical equipment, Part 1-1: General requirements for safety – Collateral standard: requirements for medical electrical systems |
| EN 60601-1-2:2001/A1:2005 | Collateral standard: Electromagnetic compatibility – requirements and tests |
| EN 60601-1-3:1994 | Collateral standard: General requirements for radiation protection in diagnostic X-ray equipment |
| EN 60601-1-4 1996 /A1:1999 | Collateral standard: Programmable electrical medical systems |
| EN 60601-2-1:1998 | Particular requirements for safety – Specification for electron accelerators in the range 1 mev to 50 mev |
| EN 60601-2-46:1998 | Particular requirements for safety – Specification for operating tables |
| EN 60825-1:1994/ A11:1996 /A2:2001 | Radiation safety of laser products, equipment classification, requirements and user's guide |
| EN 60950:2000 | Safety requirements for information technology equipment |
| EN 61010-1:2001 | Safety requirements for electrical equipment for measurement, control, and laboratory use – Part 1: General requirements |
| EN 62083:2001 | Medical electrical equipment – Requirements for the safety of radiotherapy treatment planning systems |
| EN 61508-1:1998 | Functional safety of electrical/electronic/programmable electronic safety-related systems – Part 1: General requirements |
| EN 60976:1998 | Medical electrical equipment – Medical electron accelerators – Functional performance characteristics |





Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



# TREATMENT PLANNING USER'S MANUAL

## Table of Contents

1. Safety
2. Overview
3. Patient Preparation
4. Patient Data & Image Administration
5. System Administration
6. Patient Archive and Restore System
7. CyRIS™ MultiPlan™
8. CyRIS™ InView™ (OPTION)
9. Treatment Planning System
10. Treatment Planning
11. Glossary
12. Technical Bulletins
13. White Papers

P/N 023999A-ENG

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015







Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



# Safety
## Table of Contents


Safety Precautions and Warnings ..... 1
- Warning, Caution and Note Symbols ..... 1

Overview ..... 2
- Equipment Symbols ..... 3

Emergency Procedures ..... 4
- Emergency Stop Procedure (E-Stop) ..... 4
  - Emergency Stop Failure ..... 6
  - E-Stop Button Failure ..... 6
- Emergency Power Off ..... 6
- Power Failure ..... 7
- Accelerator Malfunction ..... 7
- Fire or Fumes ..... 7
- Treatment Table Failure ..... 8
- Unexpected Manipulator Arm Motion ..... 8

Safety Precautions ..... 9
- X-ray Radiation ..... 9
- Pacemakers ..... 10
- Electromagnetic Interference ..... 10
- Laser Radiation ..... 11
  - Laser Warning Labels ..... 12
- Sulfur Hexafluoride ..... 12
- Implosion ..... 13
- Explosion ..... 13
- Electric Shock ..... 14
  - Observe the following precautions to avoid electric shock ..... 14
- Heavy Equipment ..... 15
- Hot Surfaces ..... 16

Facility Responsibilities ..... 17
- General Use ..... 17
- Safety Operations ..... 17
- Emergency and Safety Training ..... 18
- Radiation Overdose ..... 18




Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118 394

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015





395

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



# SAFETY

## SAFETY PRECAUTIONS AND WARNINGS

Safe operation of the CyberKnife® System requires careful attention to the serious hazards associated with the use of the Linear Accelerator, ways to avoid or minimize the hazards and familiarity with emergency procedures. Additional hazards associated with movement of the robot are also present. Untrained or careless operation of the CyberKnife System can damage the system, its components or other property causing poor performance, or leading to serious bodily injury and possibly death. Anyone who operates, services, maintains, or is otherwise associated with the CyberKnife System must read, understand and be thoroughly familiar with the information in this manual and take precautions to protect themselves, patients, their associates and the equipment. Specific warnings and cautions are given with the instructions in this module.

**WARNING: The CyberKnife System can emit lethal doses of high energy radiation. The assemblies contain high voltage circuits that can deliver lethal electrical shocks. Always observe safety precautions when operating or working on or around the CyberKnife System.**

Address any questions regarding the safe and efficient use of the CyberKnife System directly to Accuray, Incorporated.

### Warning, Caution and Note Symbols

**WARNING: Describes actions or conditions that could result in injury or death to personnel.**

**CAUTION:** Describes actions or conditions that could result in damage to the equipment.

**NOTE:** Provides more information about a subject.

This module provides emergency procedures for the CyberKnife System. Anyone who uses the CyberKnife System should read this guide.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



# OVERVIEW

This module provides information about the emergency procedures and safety features of the CyberKnife System and describes safe operating practices.

Review the following information before using the equipment.

**Emergency Procedures** Describes what to do in emergency situations.

**Safety Precautions** Describes how to avoid hazards.

**Facility Responsibilities** Describes user responsibilities for the training and safety of the staff and patients who come into contact with the CyberKnife System.

**WARNING: The CyberKnife System is a highly complex product. It is your responsibility to operate the equipment knowledgeably and safely and to ensure the service of each component that may be required. Improper operation or service can result in injury and even death.**

**WARNING: Do not alter the software or any of the components in the CyberKnife System. Results of these actions could cause injury or death.**





Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



# Equipment Symbols

The CyberKnife System labeling includes several symbols designed to convey safety and usage information. Below are the symbols and their description.

| | |
|---|---|
| CE 0197 | CE mark |
| TÜV Rheinland of North America, Inc. C US | United States and Canada product safety certification mark (NRTL approval) |
| | WARNING: Alerts the user to potential serious outcomes (death, injury, or adverse events) to the patient or user. |
| | Electric shock hazard |
| | Caution, hot surfaces |
| | Read manual |
| | Caution, foot crush hazard |
| | Caution, hand crush hazard |
| 3 ~ | 3 Phase alternating current |
| IPX0 | Not protected against ingress of liquids |
| | Type B equipment |
| REF | Part number or reference number |
| SN | Serial number |
| | Date of manufacture |



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



# EMERGENCY PROCEDURES

You are responsible for on-site procedures that follow the guidelines outlined here. The following emergencies are described:

- General emergency stop procedure.
- The emergency stop button does not work.
- The Linac X-ray beam does not shut off.
- Power failure.
- Fire or fumes are detected.
- The treatment table does not operate properly.
- The manipulator arm moves in an unexpected way.

Being prepared for an emergency is essential to operate this equipment safely.

## Emergency Stop Procedure (E-Stop)

If the CyberKnife System detects an error in its operation, it executes a system emergency stop (E-Stop). If any situation has the appearance of an emergency, immediately stop the equipment by pressing an E-Stop button. Pressing an E-Stop button stops motion and radiation, but does not turn off power to the equipment.

**To turn off power to all equipment in a non-urgent situation:**

**Step 1.** After pausing the operation, click **ABORT** on the display.

**Step 2.** Or in an emergency cut the power at the main circuit breaker by pressing the **EMERGENCY POWER OFF** (EPO) button or facility main breaker, as applicable. (*see section, Emergency Power Off, page 6*).

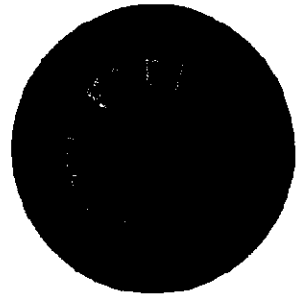


**Figure 1 System E-Stop Button**

Patient treatment table motions are disabled when an E-Stop is in effect. If the E-Stop is *not* caused by depressing one of the table E-Stop switches, manual controlled motion is possible by using the hand controller.



399

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



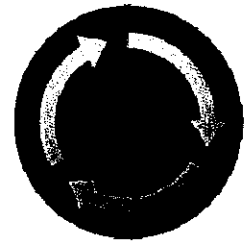


**Figure 2 EPO (Emergency Power Off) Button**

The CyberKnife System also has an emergency power off (EPO) system that uses a similar button. The appearance of the E-Stop and EPO buttons may differ from the above figures depending on the particular system.

**To cease operation immediately**

Press the nearest E-Stop button

E-Stop buttons are located on the following

- User control panel
- Linac control panel
- Robot teach pendant
- Additional locations chosen during installation.

Clicking **PAUSE** and pressing an E-Stop button have the same function.

When the pause button is selected the system goes to the following status:

- The Linac high voltage power shuts down so that **no radiation is emitted**.
- The Linac filament power remains on so that the Linac can resume operations without undue delay.
- The manipulator stops moving and remains in its current location. The power to the manipulator remains on.
- The imaging X-ray sources turn off so that **no radiation is emitted**.
- The user control console workstation remains on and receives status reports from the components.

When the status indicates that the radiation is off, you can enter the treatment room. The user control console monitor displays a window indicating that you may resume or abort the treatment. **ABORT** cancels the treatment at the incomplete stage and generates a "makeup" treatment plan, which enables you to resume treatment at any time (*see module, Makeup Fractions in the Treatment*). **RESUME** continues the treatment from the point when it stopped.

**NOTE:** You can easily reverse an E-Stop by clicking **RESUME** on the software menu. Do not hesitate to press the E-Stop or **PAUSE** even if you are unsure of the severity of the situation.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118 

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



## Emergency Stop Failure

**Software E-Stop System Failure**

When any controller in the CyberKnife System detects an error, it sends a message to the system to execute an E-Stop. A message is displayed on the user control console monitor "Undergoing E-Stop Trip Sequence"

If this message is on the user control console monitor and the manipulator, Linac, or imaging system are still operating, the software emergency-off system has failed and you must manually stop the system.

**To execute the Emergency Off system manually:**

**Step 1.** Press the nearest physical E-Stop button.

**NOTE:** You must monitor the system at all times and manually initiate an E-Stop if an unsafe condition is imminent.

## E-Stop Button Failure

If you press the E-Stop button during an emergency and the manipulator is still moving, or the control console still indicates that the Linac beam or the imaging X-rays are on, the emergency off system has failed. You must manually stop the system.

**To manually stop the system:**

**Step 1.** Press an EPO button, or turn off the main circuit breaker in your facility.

**NOTE:** All users must know the location of the main circuit breaker.

# Emergency Power Off

CyberKnife Systems have an emergency power off (EPO) system that removes power from all non-computer-related equipment when actuated. Systems without power distribution units do not have an EPO system. Power must be removed by opening the main facility breaker through the means provided at the particular site. These sites should disregard references to the EPO button in this guide and use the site-specific means of removing power. The control button for the activating switch is shown in *Figure 2 EPO (Emergency Power Off) Button, page 5*. These switches are located by the user control computer, in the treatment room, on the power distribution unit and in additional locations chosen during installation.

**NOTE:** The computer equipment, e.g., user control computer, system PC, Synchrony™ computer and networking equipment, are powered from a UPS (uninterruptible power supply). To remove power from these items, the UPS must be turned off with its front panel power switch. After operating the EPO switch, follow the steps in *section, Power Failure, page 7* for loss of system power.



401

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



## Power Failure

The CyberKnife System operates from 3-phase electrical power. If the power fails, all treatment actions stop. In the event of a partial loss of power, resulting in abnormally low voltage on one or more phases of the input power, the system performs an emergency power off, (*see section, Emergency Power Off, page 6*). Use the following emergency shutdown procedure to protect the patient. For starting up after a power outage, *see module System Startup, section, Power-up Due to Power Interruption.*

**To recover from a power failure:**

**Step 1.** If necessary, turn on emergency lighting.

**Step 2.** Enter the treatment room and carefully help the patient off the treatment table.

**Step 3.** When power is restored, start the CyberKnife System using the normal start-up procedures as applicable to the specific situation.

**Step 4.** If power loss is likely to continue longer than approximately 30 minutes, shut down the system components powered from the UPS, (*see module, System Shutdown*).

## Accelerator Malfunction

If the dose in the Parameter Display window exceeds by 1% or 1 cGy the treatment dose at a node and an E-Stop was not automatic, the Linac has not functioned properly. You must turn off the Linac.

**To turn off the Linac:**

**Step 1.** Press the nearest E-Stop button.

## Fire or Fumes

If you smell smoke or fumes, or if you detect a fire, initiate the emergency shutdown procedure below.

**To shut down immediately:**

**Step 1.** Press the nearest EPO button.

**Step 2.** Activate the fire alarm in the facility.

**Step 3.** Attend to the patient.

**Step 4.** Evacuate everyone from the facility according to facility protocols.

**Step 5.** If in treatment mode, verify that the system has executed the abort sequence. All the treatment information is recorded automatically and the remaining undelivered dose will be saved into the "makeup" treatment plan for use later.

**Step 6.** If the smoke or fumes are coming from the computer equipment, manually turn off the uninterruptible power supply.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118 402

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



## Treatment Table Failure

The CyberKnife System treatment table uses a hand-held motor control and electro-mechanical actuators. These actuators have sufficient friction and mechanical stops to prevent a runaway condition.

**WARNING: If a malfunction occurs when a patient is on the table, do not attempt to use the control that malfunctioned (if possible), because the cause of the problem (e.g., an electrical malfunction) may endanger the patient and others.**

Instructions for operating the treatment table are found in the *module, Treatment Room Operations*.

## Unexpected Manipulator Arm Motion

If the manipulator arm moves in any unanticipated way, shut down the system by pressing the nearest E-Stop button and contact Accuray.



403 Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



# SAFETY PRECAUTIONS

This section describes the hazards and safety precautions associated with the CyberKnife System. If the equipment is not operated safely, the following hazards could result in injury or death for patients and personnel.

- X-ray radiation
- Radio-frequency radiation
- Electromagnetic interference
- Laser radiation with power up to 1 mW at 632 nm (class II)
- Ozone
- Sulfur hexafluoride
- Implosion
- Explosion
- Electric shock
- Heavy equipment
- Hot surfaces

**WARNING: Many of these hazards are not visible.**

It is unsafe for anyone other than trained personnel to operate the CyberKnife System. Anyone working with the system must be aware of the hazards listed here. Only trained personnel should perform user functions.

**WARNING: You should NOT perform any maintenance not specifically listed as user functions.**

## X-ray Radiation

**WARNING: If the equipment is not operated properly, you can receive a harmful, even lethal, dose of radiation in a short time without knowing it is being received. Radiation exposure can damage some types of cardiac pacemakers.**

The CyberKnife System emits X-rays from both the Linac for treatment and the imaging system to determine the patient's real-time location.

**Protection from X-rays**

The following safety precautions are required:

- Radiation hazard warnings must be posted in appropriate locations.
- Only qualified personnel may operate and service the equipment.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118 404

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



- Radiation monitoring devices must be worn at all times while working with the CyberKnife System.
- When treatment is in progress, no one but the patient should be in the treatment room.
- Before entering the treatment room, be certain that the Linac and imaging system is not emitting radiation. Check and ensure that the HV ON light on the control console is off.
- Remove the safety interlock key from the console before leaving the console area to prevent unauthorized operation. Use this key, NOT a duplicate, to bypass the treatment room door interlock.
- Monitor the parameter display window during a treatment and commence emergency shut off procedures if the system does not terminate when the dose at a node exceeds the prescribed dose by 1% or 1 cGy.
- Pay attention to objects that may lie between the Linac and the patient. Such objects may attenuate and scatter radiation. Such objects may include shadow trays or blocks, side rails, spinal attachments, various panels and filters. If possible, remove these objects or make the necessary dose corrections.

## Pacemakers

Implement the following precautions when patients or personnel have cardiac pacemakers:

- Prominently display warnings regarding potential damage to pacemakers.
- If a patient or staff member has a pacemaker, contact the pacemaker manufacturer about the possibility of damage from radiation. The frequency of the microwaves used by the Linac in the CyberKnife System is approximately 9 GHz.
- Even after the manufacturer has indicated safe operation of a pacemaker when exposed to radiation, monitor their operation, particularly the pulse generators, when near an ongoing CyberKnife System treatment.

## Electromagnetic Interference

The low levels of electromagnetic radiation from the Linac may cause electromagnetic interference (EMI) to surrounding equipment and to patients and technical personnel who have cardiac pacemakers. In addition, EMI from other nearby equipment, such as microwave hypothermia and diathermy equipment, may interfere with the dose counter in the CyberKnife System, shielding by the walls of the treatment room may lessen this risk.

The following precautions further protect the CyberKnife System from electromagnetic interference from other equipment and protect other equipment from interference from the CyberKnife System components.

- Keep all doors, panels and covers in place while you are operating the CyberKnife System.
- Stop any treatment if you detect fluctuations in outputs, inputs and power or notice any obvious erroneous readings. These fluctuations indicate possible EMI between CyberKnife System components or from other nearby equipment.
- Follow the Pacemaker precautions from the *section, Pacemakers, page 10.*



40S Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



## Laser Radiation

The Linac uses laser radiation — narrow beams of bright red light. These Lasers are both in the Linac X-ray head and in some installations, on the X-ray sources (part of the imaging system). These lasers aid alignment of the patient for treatment and alignment of the manipulator for Linac calibration. Each laser consists of two components, the plasma tube and the power supply. The tubes used have a maximum of 1 mW output power, thus a Class 2 rating.

**WARNING: Use of controls, adjustments, or performance of procedures other than those specified herein, may result in hazardous laser radiation exposure.**

**WARNING: The light from a laser beam can damage the retinas of the eyes. Never look directly into the laser beam. Advise patients not to look into the laser beam.**

**WARNING: Replacement of the laser tube must be done only by Accuray service engineers.**



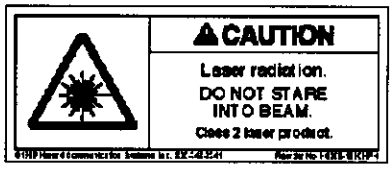
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8116

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015

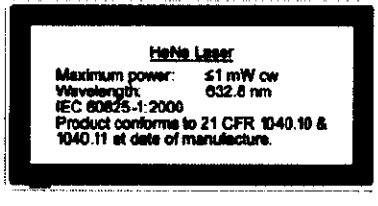


## Laser Warning Labels

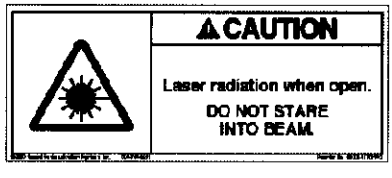
There are four types of laser warning labels used in the CyberKnife System:




**Warning Legend.** Indicates that the laser is Class 2 and to not stare into the beam. Affixed in the vicinity of each laser housing.




**Laser Information Label.** Affixed in the vicinity of each laser housing and describes the technical details of the lasers.




**Warning Legend.** Warning of exposure to laser light if covers are removed is affixed on each removable cover.

**Laser Aperture Label.** Is placed at apertures where laser light exits the equipment.

## Sulfur Hexafluoride

Sulfur hexafluoride ($SF_6$) is a colorless, odorless gas used in the CyberKnife System as an electrical insulator. It is stored in a metal container under high pressure. If the metal container ruptures, the gas or liquid will escape rapidly. Sulfur hexafluoride is nonflammable and is considered to be nontoxic, but it can act as a simple asphyxiate by displacing air. Contact with the liquefied gas may cause frostbite; $SF_6$ gas is denser than air and accumulates on the floor if released.

If the CyberKnife System detects a loss of $SF_6$ gas pressure, it will generate an E-Stop.

**WARNING: You can be asphyxiated from sulfur hexafluoride in high concentrations, or be injured by the escaping gas or liquid or by the container itself.**

- Handle the sulfur hexafluoride container carefully.
- Do not allow the temperature of the sulfur hexafluoride container to exceed 125° F (52° C).
- Store extra containers in a dry, well-ventilated location.
- Shut the valve on the gas bottle after filling the RF system.





Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



**FIRST AID: If inhaled**, move the victim to fresh air. If not breathing, give artificial respiration, preferably mouth to mouth. If breathing is difficult, give oxygen. Call emergency. **If contact** with the liquefied gas occurs, treat for frostbite.

## Implosion

The windows that separate the vacuum in the Linac and magnetron from the waveguide, can shatter inwardly, if they are struck or jolted excessively. Damage may occur to the equipment because of the casing. Shattering glass should not harm the operator or patient.

The cathode ray tube (CRT) in the user control console monitor, system PC and the thyratron tubes in the Linac modulator could also implode.

**WARNING: You can be cut and injured by flying debris from an implosion.**

Only trained service personnel should service these or any part of the system.

## Explosion

The system must never be operated in the presence of flammable anesthetics or other flammable or explosive substances. Electrical arcs that can occur during the normal operation of switches, circuit breakers, push buttons and other circuit components can ignite vapors and gases.

**WARNING: You can be cut and injured from the pressure of an explosion or from flying debris caused by an explosion**

- If flammable substances are present before the system is turned on, do not turn it on.
- If flammable substances are detected after the system has been turned on, pause the system. **Do not turn the system off**.
- If flammable substances are detected during a treatment, open the treatment room door to cause an E-Stop. An E-Stop must be generated to evacuate the patient, but no other operations should be performed.

**If flammable substances are detected:**

**Step 1.** Evacuate all persons immediately.

**Step 2.** Ventilate the room to clear the air of the flammable vapor or gas.

**Step 3.** Remove any volatile liquids that are producing flammable vapors to a safe storage area.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8148

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



# Electric Shock

Some CyberKnife System components operate with voltages up to 40,000 volts. Be cautious at all times during operation.

**WARNING: As with any equipment that uses high voltage, the residual voltage in the components can shock you after the equipment has been turned off. Only qualified service personnel should remove equipment covers.**

The following equipment may have residual high voltage:

- Power from the facility circuit breaker.
- Power lines to each component.
- User control console and system PC monitor CRT.
- Capacitors in various power supplies, several of which remain charged for long periods.
- When a laser is energized, the red wire from the laser power supply has a potential greater than 1 kV.

## Observe the following precautions to avoid electric shock

- Keep all equipment doors and covers closed during operation.
- Do not bypass any safety interlocks.
- Never attempt to tamper with instrumentation circuitry or disconnect a CyberKnife System cable at any time.
- Only authorized personnel shall service the high voltage components or any part of the system.
- Conductive fluids should not be spilled onto any part of the equipment.
- Discharge all high voltage storage components prior to servicing or disconnecting from the supply.



409 Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



## Heavy Equipment

Many CyberKnife System components are heavy, particularly the treatment table and manipulator. The motors that control the table and the manipulator are very powerful. When these components move, they have substantial inertia. Observe utmost care to prevent moving components from hitting you, the patient, other personnel, or other equipment.

**WARNING: Collision with the manipulator or any other heavy component can seriously injure or kill you or the patient.**

**CAUTION:** Collisions among components can damage equipment.

- Use caution when components are moving.
- During treatment, carefully watch while the manipulator is moving. If you see the manipulator moving too close (within 2 inches or 5 cm) to any object, press the nearest E-Stop button immediately.
- Observe the manipulator's safe movement envelope when you are in the treatment room and when adding objects to the treatment room. The safe movement envelope is the set of configurations the robot can assume without colliding with objects defined at installation. These objects include the floor, ceiling, treatment table/patient area and camera stands.
- Keep adequate clearance between you and the treatment table during table movements to avoid possible injury.
- If any equipment collides with the patient or another component, stop the treatment, attend to the patient, record the accumulated dosage and call Accuray to service the equipment before any further use.
- Use caution when handling the secondary collimators, dropping could cause serious injury to your feet. Never replace collimators where they could fall on any part of a patient.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118 410

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



## Hot Surfaces

Many components of the CyberKnife System operate at high temperatures. When equipment covers are removed, hot surfaces are accessible.

**WARNING: You can be seriously burned from touching high temperature surfaces.**

Take caution not to touch the following components when they are hot:

- Thyratron tubes
- Any light bulbs
- Transformers
- Resistors
- Magnetron
- Laser tubes
- Manipulator Motors

During operation of the CyberKnife System and during a reasonable cool-down period after turning the equipment off, avoid any bodily contact with these or other components that seem warm when approached. Be aware that the thyratron, magnetron and Linac filaments remain on while the equipment is in the stand-by mode.

Only qualified service personnel should remove any equipment covers.



411 Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



# FACILITY RESPONSIBILITIES

This section describes your responsibilities for setting up emergency and safety procedures for the CyberKnife System operations.

## General Use

Use the following guidelines for routine use of the CyberKnife System:

1. Keep a logbook of all unusual events related to system operation.
2. Always observe the standard start-up and shutdown procedures, being certain to disable the equipment by the documented procedures only.
3. Test emergency stop procedures monthly.

## Safety Operations

You must provide and train your technical, service and support staff in the following safety operations:

1. Fire extinguishers should be present in the treatment room and near the user control console.
2. The treatment room and user control console area must have emergency lighting. In addition, flashlights must be on site as a back-up during emergencies.
3. Hazard signs, regarding radiation exposure, high voltage, laser light hazards and pacemaker hazards, must be posted where appropriate, near the treatment room, near the user control console and on the system components.
4. Radiation monitoring badges should be worn at all times while in the treatment room.
5. Dangers to people with pacemakers must be ascertained by following the guidelines described earlier in this chapter.
6. Video and audio monitoring are mandatory whenever a patient is in the treatment room. This monitoring equipment is required in addition to the radiation monitoring equipment incorporated in the CyberKnife System.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118 412

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



## Emergency and Safety Training

All personnel who work with the CyberKnife System must have initial training and periodic refresher courses for the following:

1. Emergency off procedure (E-Stop).
2. Emergency power off (EPO) procedures
3. Location of the main circuit breaker as a backup for emergency power off.
4. Evacuation procedures and egress routes in case of fire, fumes, or other threatening situations.
5. Emergency procedures in case of earthquake or other natural disasters likely in the facility's location.
6. Emergency lighting system activation and the location of backup flashlights.
7. How to assist a patient to get down from the treatment table and out of the facility.
8. List of people to contact in case of a fire, medical, or technical emergency.
9. How to restart the CyberKnife System after an emergency shut down.

## Radiation Overdose

The CyberKnife System uses dual redundant dose monitoring systems, which stop treatment upon reaching the prescribed dose.

If the treatment is stopped manually because of a failure in the automatic shut-off by the dose monitoring system, the equipment must be checked and serviced by a qualified technician before any further treatments are performed.

**In the case of a radiation overexposure:**

**Step 1.** Seek emergency treatment for the victim.

**Step 2.** Contact local radiation safety officer according to facility protocols.

**Step 3.** Notify the local, state and federal authorities in accordance with your institutional procedures.

**Step 4.** Consult with medical experts in radiation treatment.

**Step 5.** Notify Accuray as quickly as possible.



413 Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



# Overview
## Table of Contents


**CyberKnife® Radiosurgery System** ..... 1

**CyberKnife System Overview** ..... 2

- **Indications for Use** ..... 2
- **The CyberKnife System Includes** ..... 2
  - Imaging and Computer Systems ..... 2
  - Treatment Planning and Operator Control Systems ..... 4
  - Linac and Control Systems ..... 4
  - Robotic Manipulator ..... 5
  - Power Distribution Unit (PDU) ..... 5
  - DICOM RT Open Architecture ..... 5
  - Express™ Throughput Solution ..... 5
  - User Control Console ..... 5

**CyberKnife System Components** ..... 7

- **Treatment Planning and Delivery Workstations** ..... 7
  - Main Treatment Planning and Delivery Workstation ..... 7
    - Main SGI Computer ..... 7
    - Linac Control Panel ..... 7
    - Main Intercom Box and Phone (supplied by customer) ..... 7
    - Closed Circuit TV (CCTV) Monitoring System (supplied by customer) ..... 7
    - Synchrony™ System (Optional) ..... 7
    - Xsight™ Spine Tracking System (Optional) ..... 7
    - Printer ..... 8
    - CyRIS™ InView™ Image Fusion and Contouring Station (Optional) ..... 8
- **Treatment Room** ..... 8
  - Robot (Manipulator) ..... 8
  - Linear Accelerator (Linac) ..... 8
  - Patient Alignment Couch ..... 8
  - Target Locating System (TLS) ..... 8
    - X-ray Sources and Generators ..... 8
  - Synchrony Respiratory Tracking System (Optional) ..... 9
  - Miscellaneous Equipment (Supplied by customer) ..... 9
- **Equipment Room** ..... 9
  - Power Distribution Unit (PDU) ..... 9
  - Chiller ..... 9
  - Robot Controller ..... 9
  - Modulator ..... 9




Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



Modulator Control Chassis (MCC) ..... 9
Interface Control Chassis (IFCC) ..... 10
Dual 19-inch Rack ..... 10
E-Stop Control Chassis (ESCC) ..... 10
Target Locating System Control Chassis (TLSCC) ..... 10
SMART Uninterruptible Power Supply (UPS) ..... 10
Target Locating System (TLS) Computer ..... 10
Synchrony Computer ..... 10
17" High Resolution CRT Monitor, Keyboard and Mouse ..... 10
Firewall ..... 10



415 Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



# OVERVIEW

## CYBERKNIFE® RADIOSURGERY SYSTEM

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

416

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



# CyberKnife System Overview

The CyberKnife System is an integrated turnkey radiosurgery system that combines continuous image-guidance technology with computer-controlled robotics to precisely deliver a prescribed dose of radiation. It utilizes a compact linear accelerator attached to a computer-controlled robotic arm to target a precise number of beams of radiation very accurately at a lesion from many different directions. The patented image-guidance technology correlates intra-operative X-rays with previously acquired CT images of the lesion and surrounding tissue to precisely target each beam of radiation. This approach results in a high dose of radiation concentrated within and conforming to the lesion, where the beams converge. In contrast, surrounding normal tissue receives a relatively minimal, less-injurious radiation dose from which it can quickly recover.

## Indications for Use

**The CyberKnife System is intended to provide treatment planning and image-guided stereotactic radiosurgery and precision radiotherapy for lesions, tumors and conditions anywhere in the body when radiation treatment is indicated.**

## The CyberKnife System Includes

### Imaging and Computer Systems

**Imaging System**- The imaging system includes the following hardware:

1. Two X-ray Sources
2. Two Digital X-ray Detectors
3. One Localizing Frame
4. One ISO Post Calibration Tool
5. Two Detector Windows (not shown in the image below)
6. Two Protective Window Coverings (not shown in the image below)

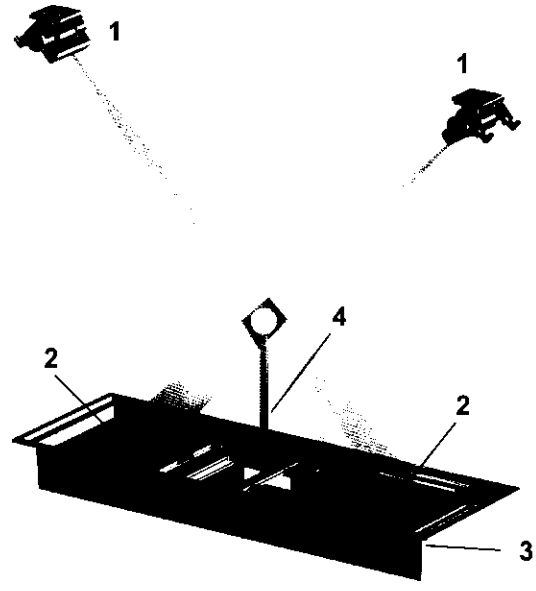


417 Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



**NOTE:** The imaging system is mounted either flush with or slightly above the treatment room floor.




**Target Locating Subsystem (TLS)** - Employs two X-ray sources mounted overhead, which provide orthogonal images. The images are digitized and compared to images synthesized from the patient's CT data (DRR's). The TLS system provides real-time precision information about the location of the treatment target.

All of these components are aligned within the imaging plane and are symmetric about the ISO post.

**X-ray Sources**

The two X-ray sources are mounted over head and create the X-ray beams for imaging the patient.

**Digital X-ray Detectors**

Two high sensitivity digital X-ray detectors are mounted within a localizing frame to ensure a high degree of alignment and accuracy between all of the imaging components.

**ISO Post Calibration Tool**

The ISO Post calibration tool mounts directly into this localizing frame and is the reference point for calibrating the robot and imaging system.

**Detector Windows**

The two detector windows are made of carbon graphite material to ensure X-ray translucency and high strength. They are designed to support up to a 500 lb. load and protect the detectors. There is a protective covering material that protects the detector windows and seals the imaging pit from fluid spills. The coverings can be replaced if they become too scratched or damaged.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118 

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



**CAUTION:** Care must be exercised not to drop any heavy or sharp objects onto the detector windows. For instance, secondary collimators should not be changed over the detector windows. If a heavy object has been dropped on the detector window an ACCURAY service call must be made to assess the structural damage.

**CAUTION:** Never jump onto the detector windows.

**CAUTION:** Do not operate the system without the detector windows in place.

**CAUTION:** Avoid walking on the detector windows. Do not slide heavy objects across detector windows.

**CAUTION:** Scratches can degrade the X-ray images to the point where skull or fiducial tracking may fail. If necessary, replace the protective film at regular maintenance intervals.

## Treatment Planning and Operator Control Systems

- **Operator Control Subsystem** - Provides treatment planning capability and automated control of the treatment process according to the treatment plan. It is a tightly coupled, symmetric, shared memory, multi-processing architecture design using RISC technology, custom VLSI and ASIC components to provide both high performance computing and high performance graphics.
- **Treatment Planning Subsystem** - State-of-the-Art treatment planning system. A highly interactive software package capable of developing inverse and forward treatment plans.

## Linac and Control Systems

- **Linear Accelerator (Linac)** - The Linac consists of an electron gun and a series of microwave cavities under vacuum. The X-band Linac provides a collimated beam of 6 MV X-rays. The compact size allows unique robotic manipulation that provides greater degrees of freedom.
- **X-Ray Head** - The assembly contains the Linac, magnetron, microwave wave-guide components, the pulse transformer, water circulating connections and a gas pressurizing connection for the wave-guide.
- **Secondary Collimators** - (in millimeters: 5,7.5,10,12.5,15,20,25,30,35,40,50,60, pinhole and blank) Interchangeable collimators allow for greater flexibility and conformability during the treatment planning process.
- **Modulator** - This assembly contains the HV pulse-generating circuits that drive the Radio Frequency (RF) system located in the X-ray head.
- **Chiller** - The chiller cools the Linac and consists of a re-circulating pump, a water reservoir and a refrigeration unit with chiller and temperature regulating control (used to maintain a stable operating temperature), water temperature indicator and status lamps. This is a closed loop system that does not require external facility connections.



419 Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



- **Target Locating System Control Console (TLSCC) and Computer** - This unit controls the diagnostic X-ray sources and imaging panels in acquiring images, as well as conducting image correlation to determine patient displacement during treatment.
- **Interface Control Chassis** - An interface control system, which provides near-real-time control of hardware components and relays status information to the multi-processing computer.

## Robotic Manipulator

- Accuray's robotic system (manipulator) carries and aims the Linac providing automated positioning in six-degrees of freedom.

## Power Distribution Unit (PDU)

- The PDU is the AC power source for the entire CyberKnife System. Uses a 208VAC, 3 phase, 150 amp input.

## DICOM RT Open Architecture

- Import DICOM RT image sets (CT, MR and PET) and RT structure sets.

## Express™ Throughput Solution

- Provides radiosurgery precision with greater throughput.

## User Control Console

The user control console equipment for the CyberKnife System, includes the following:

- Workstation monitor with keyboard and mouse.
- Treatment room monitoring equipment.
- Operator control console panel.
- Radiation generator controller used to calibrate the Linear Accelerator (Linac).



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118 

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



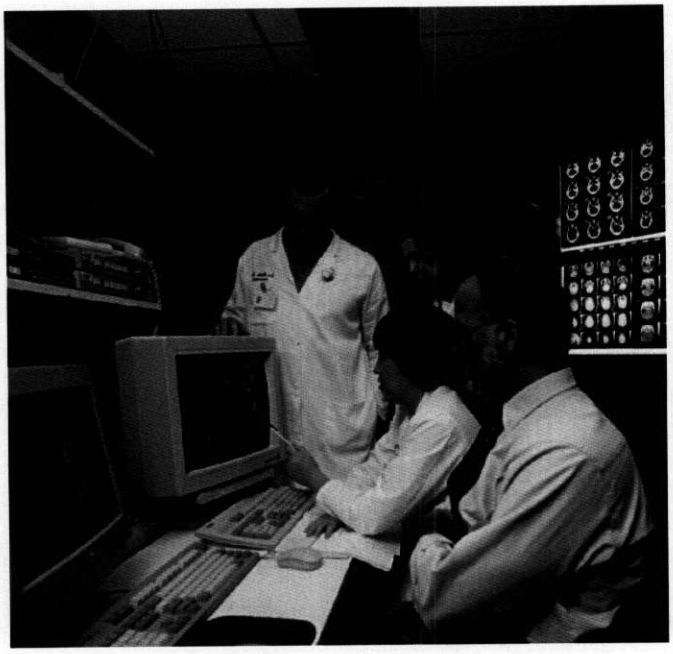


**Figure 1 User Control Console Equipment**



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



# CyberKnife System Components

## Treatment Planning and Delivery Workstations

The treatment planning and delivery stations can be configured in many ways.

## Main Treatment Planning and Delivery Workstation

This station is used for operating and monitoring primary treatment delivery to the patient.

The station includes the following:

### Main SGI Computer

- CRT monitor (or optional flat panel monitor).
- One keyboard and mouse.
- The actual SGI computer itself, is usually located in the equipment room.

### Linac Control Panel

Control box.

### Main Intercom Box and Phone (supplied by customer)

### Closed Circuit TV (CCTV) Monitoring System (supplied by customer)

- Usually comprised of a Quad Multiplex Monitor, used for viewing the patient in the Treatment room.
- It is recommended that there be four CCTV cameras located in the Treatment room, two high and two low, with two of them capable of pan/zoom (one high and one low).

### Synchrony™ System (Optional)

When the Synchrony System is installed, then an additional flat panel monitor, keyboard and mouse are located next to the main treatment and planning system.

A physics conduit port should exist between the control room and the treatment room. It can also be used for remote patient monitoring.

### Xsight™ Spine Tracking System (Optional)

The Xsight Spine Tracking System enables tracking of skeletal structures in the body for accurate patient positioning and radiation beam delivery in the CyberKnife® System. Xsight provides the capability to deliver radiation treatments to the human body without the need for implanting fiducials. Xsight is capable of accurately and automatically tracking a wide range of skeletal structures, including the cervical spine, and most of the thoracic and lumbar spine. Xsight is capable of tracking non-rigid deformations typically observed in multiple vertebral structures.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118 

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



### Printer

2550n HP Color Laser Printer (or comparable - normally located with the secondary treatment planning workstation).

### CyRIS™ InView™ Image Fusion and Contouring Station (Optional)

If the CyRIS InView option is selected, it may be located in any room. There may be more than one of these. Each system is comprised of a:

- Standard desktop computer system, with a computer, LCD flat panel monitor, keyboard and mouse.

### CyRIS™ MultiPlan™ Treatment Planning System

The CyRIS MultiPlan is a full purpose treatment planning system. It is specifically designed to optimize the flexible nature of the robotic treatment delivery system.

## Treatment Room

The treatment room contains the Robot, Linac, Patient Positioning Equipment and Target Locating System.

### Robot (Manipulator)

A six-axis robot used for positioning and pointing the Linear Accelerator for patient treatment.

### Linear Accelerator (Linac)

The Linac is attached to the end of the robot and delivers the radiation treatment to the patient.

### Patient Alignment Couch

- The couch is used to position the patient for treatment.
- The maximum capacity of the couch is 350 pounds (770 Kg).
- Includes a couch top, head base plate, hand control pad and readout display.
- Includes up to 2 indexed CT overlay kits (CT overlay + head base plate). Additional overlay kits can be purchased, as needed.

### Target Locating System (TLS)

#### X-ray Sources and Generators

- The X-ray sources are used to track patient positioning.
- They are attached to the ceiling on each side of the table.
- The X-ray generators, which supply high-voltage power to the X-ray sources, may be located in either the treatment room or the equipment room.



423 Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



### Synchrony Respiratory Tracking System (Optional)

Synchrony is used to monitor patient breathing and adjust the Linac position to match the motion of the target lesion.

- The Synchrony camera array is mounted to the ceiling near the foot of the treatment couch.
- The Synchrony Fiber Optic Interface Box, to which the Synchrony Tracking Markers are connected, is mounted on the couch.

### Miscellaneous Equipment (Supplied by customer)

- The treatment room also contains the following; phone, intercom system and patient monitoring cameras. It also includes the medical gas lines, if desired by the customer. All of these components are supplied by the customer.
- A physics conduit port should exist between the treatment room and the control room. It can also be used for remote patient monitoring.

## Equipment Room

The equipment room is located adjacent to the shielded walls of the treatment room and is intended to hold the bulk of support equipment needed for planning and treatment. This equipment includes the facility power interface, E-Stop assembly, primary and target locating computers and robot controller. The room is cooled with a customer-supplied A/C unit.

### Power Distribution Unit (PDU)

- The PDU supplies power to all components of the CyberKnife System.
- The customer supplies the power input to the PDU.

### Chiller

The chiller is a closed loop system that cools the Linac.

### Robot Controller

The robot controller controls the robot positioning.

### Modulator

The modulator provides a pulse to the magnetron so it can produce RT energy.

### Modulator Control Chassis (MCC)

The MCC contains the modulator and Linac control circuits, as well as the fault circuitry and an interface card allowing control by the CyberKnife System.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118 

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



## Interface Control Chassis (IFCC)

The IFCC functions as an interface between the CyberKnife System and the Linac. The IFCC also handles most digital processing of the dosimetry signals as well as generating a variety of fault signals. It also monitors the sense potentiometers for the collimator.

## Dual 19-inch Rack

### E-Stop Control Chassis (ESCC)

The ESCC performs a wide variety of hardware functions, as well as functioning as a central point for E-Stop signals.

### Target Locating System Control Chassis (TLSCC)

This is an interface between the Target Locating System (TLS) PC and the imaging system.

### SMART Uninterruptible Power Supply (UPS)

Provides backup power to the system control computers.

### Target Locating System (TLS) Computer

Also known as the System PC, it is primarily used to control the TLS and interface between the TLS and the SGI.

### Synchrony Computer

### 17" High Resolution CRT Monitor, Keyboard and Mouse

### Firewall



425 Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



# Patient Preparation
## Table of Contents


**Patient Setup** ..... 1
- **Patient Setup Safety Considerations** ..... 3
- **Immobilization** ..... 5
  - Head and Neck Immobilization ..... 5
    - Head and Neck Immobilization Without Fiducials ..... 5
    - Head and Neck Immobilization for Fiducial Tracking/Xsight™ Treatments ..... 6
  - Body Immobilization ..... 6
  - Using the Synchrony™ Vest (Optional) ..... 8
    - CT/MR/PET Acquisition ..... 9
    - Treatment Delivery Setup ..... 10
  - Reassess Patient Positioning ..... 11
- **Acquire Treatment Planning Image Studies** ..... 11
  - CT Imaging Guidelines ..... 11
  - MRI Imaging Guidelines ..... 13
- **Attaching the Headrest to the CT Machine** ..... 14
- **Setting the CT Scanning Parameters** ..... 14
- **Key DICOM Identifiers** ..... 14

**Fiducial Placement Principles** ..... 15
- **Supplies** ..... 16
  - Soft Tissue Supplies ..... 16
  - Spine and Bone Supplies ..... 16
    - Fiducial Kit for Spine ..... 17
- **Fiducial Placement Procedure** ..... 18
  - Post Placement Guidelines ..... 18
  - Lung ..... 18
    - Outline of Procedure ..... 18
    - Potential Complications ..... 20
    - Points To Consider ..... 20
    - Conclusion ..... 20
  - Pancreas/Liver ..... 21
    - Outline of Procedure ..... 21
    - Potential Complications ..... 22
    - Points To Consider ..... 23
    - Conclusion ..... 23
- **Cleaning and Sterilization** ..... 23
  - Sterility ..... 23




Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

426

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015





427 Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



# PATIENT PREPARATION

## PATIENT SETUP

To treat a patient with the CyberKnife® System, Accuray recommends following the procedure as shown in *Figure 1 Treatment Process, page 2*.

**Important steps to take before treating a patient with the CyberKnife System:**

**Step 1.** Log into the console and power up the CyberKnife System.

**Step 2.** Load the imaging studies (i.e., CT, MRI) which will enter patient information.

**Step 3.** Check CT center and move as needed.

**Step 4.** Fuse images as required.

**Step 5.** Generate one or more treatment plans.

**Step 6.** Generate DRR's (Digital Reconstructed Radiographs) any time after treatment plan has been created and prior to beginning treatment. Generation of DRR's requires approximately 3 minutes for extracranial plans and 20 minutes for intracranial plans. Be sure to allow sufficient time before treatment to generate DRR's.

**Step 7.** Load and recalculate final plan on Treatment Delivery System.

**Step 8.** Prescribe treatment plan.

**Step 9.** Calibrate and enter appropriate dosimeter factors as described in *module, QA/Calibration, section, Calibrating the Linac.*



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118 

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



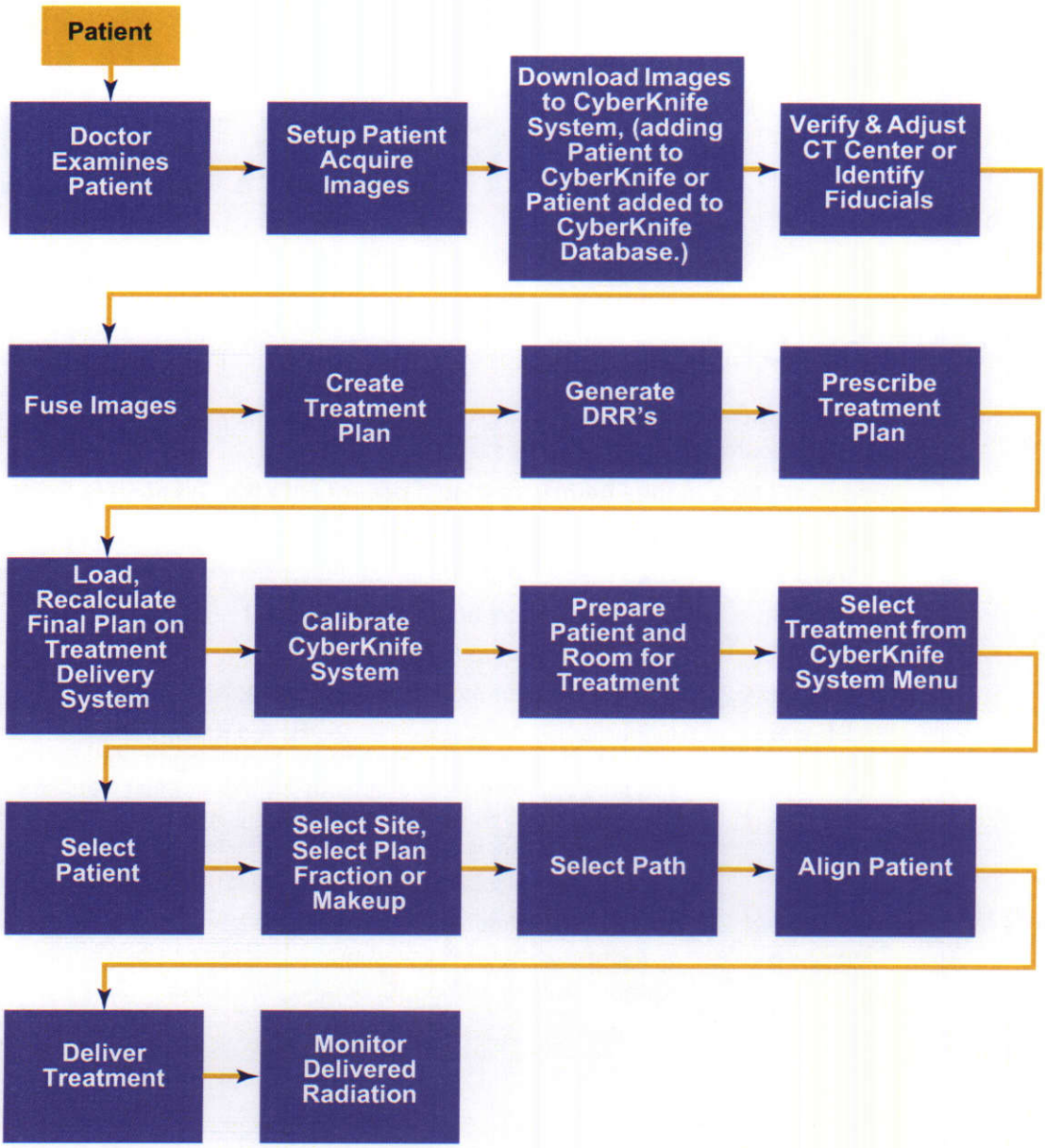



**Figure 1 Treatment Process**

**NOTE:** It is essential to have patients in the same position for treatment as they were during CT scanning. A reproducible patient position is the primary requirement during preparation of a patient for the CT scan.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



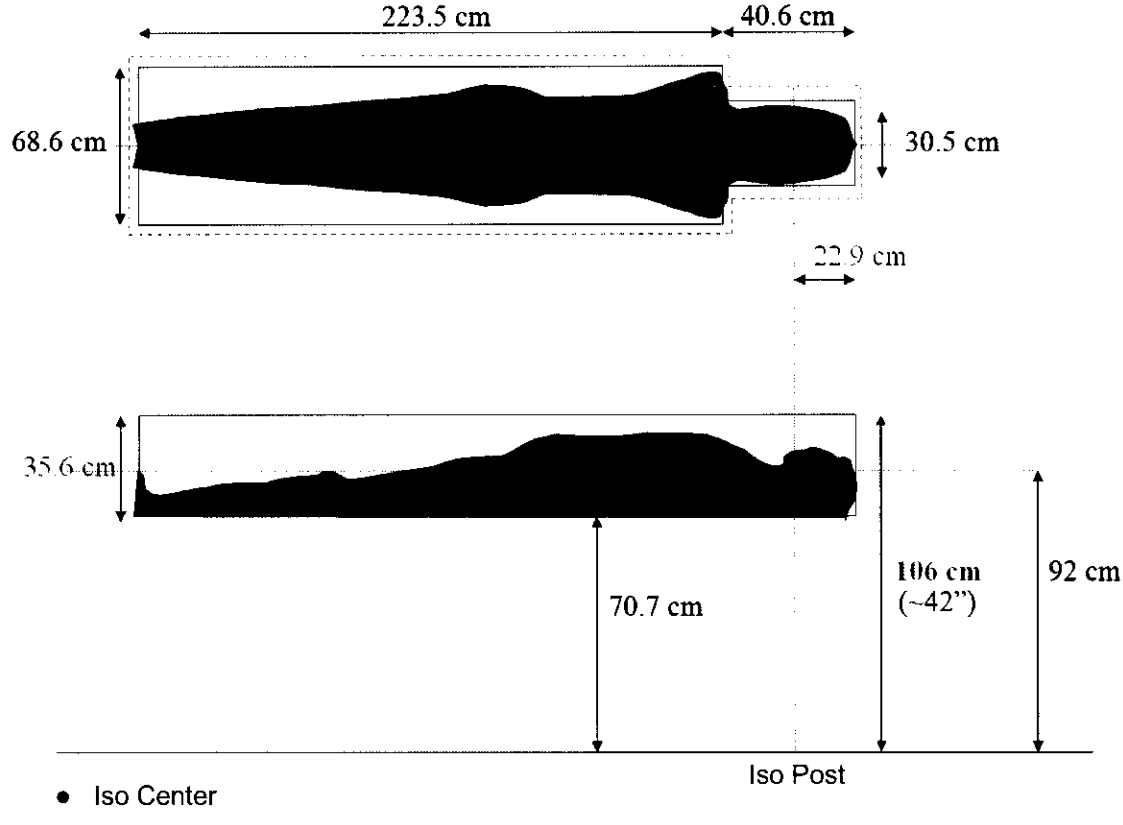
**WARNING: Position the patient and all devices within the PDP Model. Anything extending outside the boundaries of the PDP model increases the risk of collision with the manipulator.**

## Patient Setup Safety Considerations

With patient in treatment position, verify that patient does not violate the safe zone as specified below:

1. No part of the patient or couch may extend >111 cm (~44 inches) from the floor (*Figure 2 Patient Safety Setup Dimensions for Head Treatment, page 3*).

**PDP Model: Head Treatments**




PDP program adds 5 cm to the boundary of the head model. If any part of the manipulator enters the boundary zone, an error will be triggered and manipulator motion will cease.

**Figure 2 Patient Safety Setup Dimensions for Head Treatment**



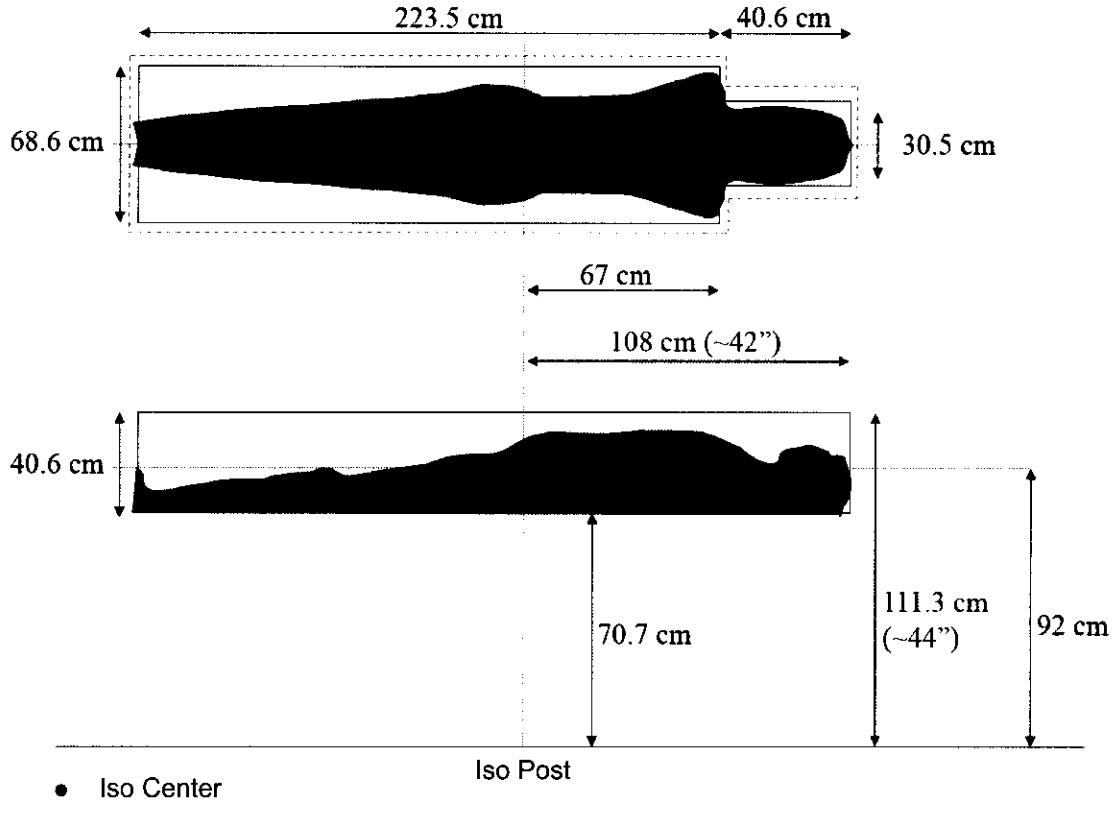
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



2. No part of the patient or couch may extend >108 cm (~42 inches) superior from the nominal isocenter (*Figure 3 Patient Safety Setup Dimensions for Body Treatment, page 4*).

**PDP Model: Body Treatments**




PDP program adds 10 cm to the boundary of the body model.

**Figure 3 Patient Safety Setup Dimensions for Body Treatment**

**WARNING: Do NOT place pillows and/or objects in area, common errors can occur that cause safe zone violations.**

1. Pillows under the patient's head may raise head above the 111 cm height limit.
2. Positioning patient with arms raised above head can cause elbows to exceed the 111 cm height limit or the 108 cm superior limit.
3. Using too large a wedge under the patient's knees may elevate them above the 111 cm height limit.
4. Treating lesions below L-4 head first supine (HFS) may cause the patient's head to extend >108 cm from the nominal isocenter.



431 Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



# Immobilization

**WARNING: Head and neck treatments require that the neck of the patient is immobilized. There are some techniques that help with immobilization, however, it should be recognized by the user that complete immobilization is not achievable. Therefore all users should understand that it is never completely possible to immobilize a person's neck, therefore Accuray strongly recommends that the user use caution and visually check for patient movement throughout treatment. It is the user's responsibility to decide what is best for their patient.**

If pre-CT immobilization is done on the Cyberknife treatment couch it is important to be sure the couch pitch and roll is at zero (0) during the immobilization process.

## Head and Neck Immobilization

### Head and Neck Immobilization Without Fiducials

**Step 1.** Thermoplastic mask should fit snugly to minimize movement. (Mask thickness of 2.4 mm is recommended)

- **a** Mask should extend below patient's chin.
- **b** Mold bridge of nose to reduce lateral movement.
- **c** Bubble wrap over headrest can increase patient comfort.
- **d** Using shims under mask flange can accommodate for future shrinkage.
- **e** Mark laser lines to assist in setup reproduction.

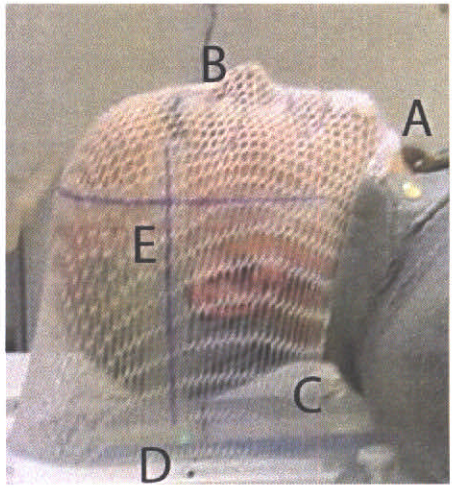



**Figure 4 Thermoplastic Mask**



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



## Head and Neck Immobilization for Fiducial Tracking/Xsight™ Treatments

**Step 1.** Make aquaplast mask as above.

**Step 2.** A C-spine collar can be used in conjunction with a mask for better immobilization of the neck. Ensure that the C-Spine collar does not contain any metal or radiopaque material which may interfere with the visualization of the fiducials or the spine.

**Step 3.** Conduct an imaging test to evaluate visualization of fiducials or spine prior to CT.

## Body Immobilization

**Step 1.** Set up patient for treatment.

- **a** Use knee sponge, bolster or other means to stabilize legs and feet; re-evaluate position for patient comfort and safety.
- **b** Consider placement of arms:
  - Upper body treatment site - placed at sides.
  - Lower body treatment site - holding sternum ring, crossed at chest, overhead.
- **c** Position the patient Feet First Supine (FFS) if superior limit of 106 cm is exceeded.

**WARNING: Verify that placement of patient extremities does not violate the PDP zone (see section, *Patient Setup Safety Considerations, page 3*).**

**Step 2.** Make immobilization device to replicate setup position (alpha cradle or vacuum bag can be used).

- **a** Upper body immobilization (bottom of sternum and superior):
  - Include patient head and shoulders extending inferior toward pelvis.
  - Include arm position and imprint of fingers when possible.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



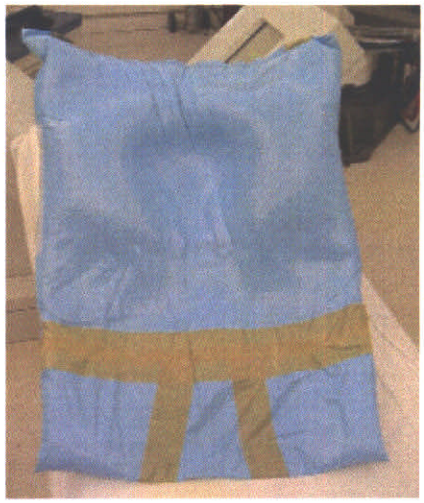


**Figure 5 Alpha Cradle for Upper Body**

**b** Lower body immobilization (bottom of sternum and inferior):

- Extend device below patient knees and include heel imprint.
- Place knee sponge or bolster under immobilization device for patient.

**Figure 6 Alpha Cradle for Lower Body**

**NOTE:** For patients with fiducials, evaluate patient position and fiducial visualization by acquiring a treatment image:

**Step 1.** Set up patient in treatment position using newly created immobilization device.

**Step 2.** Position patient's treatment area into image detector field.

**Step 3.** On the treatment workstation, open a phantom plan designed using fiducial tracking.

**Step 4.** Acquire live treatment image.

**a** Ignore fiducial errors. These occur due to difference between patient and phantom fiducials.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



**Step 5.** Verify number and location of fiducials against details from physician op notes and films.

- **a** Reposition patient as needed to bring fiducials into imaging field.
- **b** Check for obscured, overlapping or unusable fiducials.

**Step 6.** Repeat steps 4 and 5 as necessary to determine quality of fiducial placement and patient setup.

**Step 7.** Using room lasers for reference, mark patient position on immobilization device.

## Using the Synchrony™ Vest (Optional)

**Step 1.** Select the appropriate Synchrony Tracking Vest size for the patient.

**Table 1: General Guidelines**

| | |
|---|---|
| **Small Vest** | Height < 5'5" (1.68 m) |
| | Weight < 130 lbs (59 Kg) |
| **Medium Vest** | Height 5'5" – 6'0" (1.68 – 1.83 m) |
| | Weight 130 – 180 lbs (59 – 81.6 Kg) |
| **Large Vest** | Height > 6'0" (1.83 m) |
| | Weight > 180 lbs (81.6 Kg) |

**Figure 7 Synchrony Tracking Vest**



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

435

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



**Step 2.** Take the Vest out of the pouch.

**Step 3.** Instruct the patient to put on the Synchrony Vest or, if unable, assist the patient to put on the Vest:

1. Unzip the back of the Vest and detach the Velcro tab at the bottom, back of the Vest.
2. Ensure the two drawstrings are in the loosest position.
3. Remove all clothes from upper body. (Jog bra with no metal inserts or fasteners is permissible if necessary for large breasted patients.)
4. Slip Vest over head of patient.
5. Slip arms into arm holes of the Vest.
6. Fasten Velcro tab at the bottom, back of the Vest.
7. Pull the string attached to the zipper or the zipper itself down to the bottom of the Vest.
8. Detach the Velcro tab at the bottom of the Vest to ensure the zipper has been pulled all the way to the bottom and re-fasten the Velcro tab.
9. Pull the whole Vest down as far as possible and cinch the bottom drawstring for a snug fit – this will aid in preventing the Synchrony Vest from riding up.

**Step 4.** Create an immobilization device using an alpha cradle or vacuum bag following standard procedure. Use of the indexing table will facilitate patient setup.

**Step 5.** With the patient lying down on the table (supine or prone), cinch the mid-thoracic drawstring for a snug fit – this will prevent "tenting" of the Vest ensuring it follows the contour of the patient's body.

## CT/MR/PET Acquisition

Patients must wear the Synchrony Tracking Vest during pre-treatment scanning. Follow standard protocol guidelines for the appropriate pre-treatment scan for extracranial applications. Instruct the patient to breathe normally until acquiring the scan, at which time the patient must hold their breath at end of normal expiration. If the patient cannot hold their breath for the entire scan, ensure that one of the scan segments includes the entire target and the fiducials.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



## Treatment Delivery Setup

**Step 1.** Mount the Fiber-Optic Interface Box under the head portion of the table top.

**Step 2.** Position the patient on the immobilization device in the approximate treatment position.

**Step 3.** Instruct the patient to relax and breathe normally.

**Step 4.** Evaluate the patient's breathing to identify the location of maximum body motion during respiration.

- In the supine position this is most typically the diaphragm area, but possibly the lower thoracic (for "chest breathers") area or the abdominal area (for "stomach breathers.")
- In the prone position this is most typically the thoracic area but can also be in the lumbar area.

**Step 5.** Apply the 3 Tracking Markers onto the white Velcro strips on the Synchrony Vest at the location of maximum body motion due to respiration.

**Step 6.** Connect the Tracking Marker Harness connector to Fiber-Optic Interface Box.

**Step 7.** Lower the camera so that it is directly in-line with the patient (not angled from the side of the patient) and is approximately 6-7 feet (2 meters) from the floor.

**Step 8.** Continue to adjust the position of the Tracking Markers and Camera Array until the Tracking Markers are visible by the Camera Array which is confirmed by very fast blinking action from each of the Markers. This can best be viewed by standing directly under the Camera Array looking at the Markers. (A good test is to place your hand in front of one of the three cameras in the Camera Array and compare the beams emanating from the Markers. When not seen by the Camera Array, the beams are steadily lit, when seen by the Camera Array the beams blink rapidly.) This can also be confirmed by reviewing the breathing waveforms displayed on the Synchrony PC (*see module, Synchrony.*)

**NOTE:** Keeping the camera low will reduce the incidence of the robot obscuring the Tracking Markers from the Camera Array.

**CAUTION:** Moving the Camera Array forward can increase the risk of potential robot collisions with the Camera Array.

**Step 9.** Evaluate the application of the Tracking Markers by reviewing the waveforms displayed and the correlation error values from the model created. (*see module, Synchrony.*)

- If the correlation error is close to 5 mm consider turning off a Marker or repositioning the Markers and/or Camera Array, rebuild the model and evaluate the correlation error maintaining it as close to 0 mm as possible.
- Watch the Markers through a couple of breathing cycles to ensure the Markers stay within view throughout the breathing cycle.

**Now the patient set-up is complete and fiducial identification can occur.**



437

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



## Reassess Patient Positioning

**Step 1.** Reassess patient position after localization of the implanted fiducials on the acquired images.

**Step 2.** Ensure that the patient's anatomy does not exceed the anterior or superior limits as stated under Patient Setup Safety Considerations (*see section, Patient Setup Safety Considerations, page 3*). If the patient's anatomy exceeds the superior limit of 106 cm, consider scanning and treating FFS. If the patient's anatomy exceeds the anterior limit of 112 cm, every attempt should be made to reposition the patient so as not to exceed this limit. If this is not possible, it is recommended that the treatment paths are simulated using the teach pendant prior to treatment delivery.

# Acquire Treatment Planning Image Studies

**WARNING: Some scanners may orient patient data differently when the patient position is other than HFS. Image studies from scanners should not be used unless the correct orientation of the patient in the Treatment Planning System has been verified. Treatments based on incorrect oriented patient data can lead to death or injury of the patient.**

## CT Imaging Guidelines

1. Bring immobilization devices to CT to replicate setup for the CT scan
2. Basic CT parameters:
   - **a** IV Contrast may be used when indicated.
   - **b** Gantry angle = 0.
   - **c** Maximum 300 slices.
   - **d** kVp = 120 mAs = scanner maximum (minimum 400).
   - **e** Contiguous 1.0 - 1.5 mm slice thickness.

**NOTE:** Variable slice thickness is not supported.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



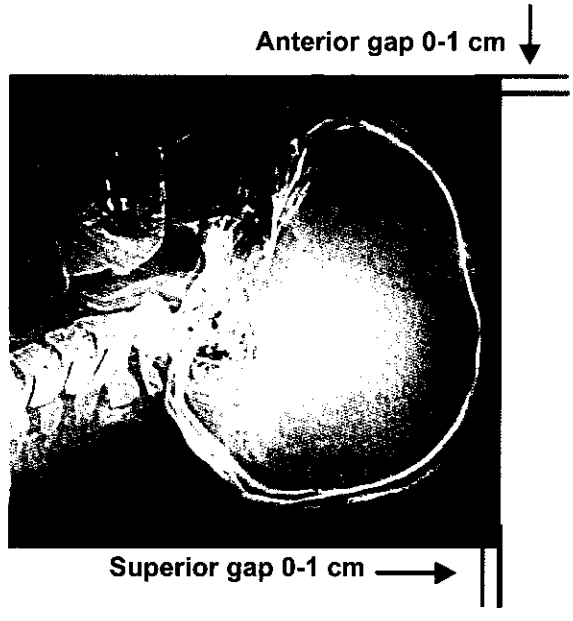



**Figure 8 Treatment Image**

3. CT rules for skull tracking studies:
   - **a** Set windows to soft tissue levels.
   - **b** Set Field of View (*Figure 8 Treatment Image, page 12*).
     - Patient must be centered laterally in the FOV.
     - FOV must include the chin and extend 0-1 cm superior past top of skull.
     - FOV must include the headrest and extend 0-1 cm anterior past the tip of nose.
4. CT rules for fiducial tracking:
   - **a** Set windows to bone levels.
   - **b** Set Field of View.
     - Patient must be centered L/R and ANT/POST in the FOV.
     - Tumor should be centered in the INF/SUP direction with a minimum 10-15 cm scanned in either direction.
     - FOV should include the entire patient circumference (use the largest field of view possible) - anatomy left out of scan will cause beams to be excluded by the TPS.
5. Push images to the Treatment Planning System:
   - **a** Send only AXIAL slices.
   - **b** Patient ID on CT must match the ID used in the CyberKnife System exactly.
     - Spaces and punctuation (dashes, slashes, commas, etc.) may not be used in the patient ID.



439 Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



## MRI Imaging Guidelines

1. Immobilization devices are not necessary
2. Basic MRI parameters:
   - **a** IV Contrast may be used when indicated.
   - **b** True AXIAL scan plane only (angle = 0).
   - **c** Maximum 300 slices.
   - **d** 512 x 512 square acquisition.
   - **e** Contiguous 1.0 - 3.0 mm slice thickness or volume scan.

   **NOTE:** Variable slice thickness is not supported.

3. MRI rules for intracranial studies:
   - **a** Set windows to visualize anatomy.
   - **b** Set Field of View to replicate CT.
     - Patient must be centered laterally in the FOV.
     - FOV must include the chin and extend 0-1 cm superior past top of skull.
     - FOV must include the headrest and extend 0-1 cm anterior past the tip of nose.
4. MRI rules for extracranial studies:
   - **a** Set windows to visualize anatomy.
   - **b** Set Field of View.
     - Patient must be centered L/R and ANT/POST in the FOV.
     - Tumor should be centered in the INF/SUP direction.
     - FOV should include the entire patient circumference.
5. Push images to the Treatment Planning System:
   - **a** Send only AXIAL slices.
   - **b** Patient ID on MRI must match the ID used in the CyberKnife® system exactly.
     - Spaces and punctuation (dashes, slashes, commas, etc.) may not be used in the patient ID.

   **NOTE:** When collecting images from more than one series, it is necessary to push the scans separately (Not necessary with SW Version 4.3.0.1 or later). The first scan must be imported prior to pushing the second scan to avoid combining the scans as one series.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



## Attaching the Headrest to the CT Machine

Headrest orientation is critical to patient alignment and must be reproduced as closely as possible. You must record the orientation of the headrest after it is attached to the CT table and the patient, with head restraint, is securely positioned. Use the digital level to measure the orientation of both the long and short sides of the headrest.

Record the headrest orientation and duplicate it when you position the patient for treatment.

## Setting the CT Scanning Parameters

When CT scanning, place the patient in the supine position and scan head-first or feet-first. The position that the patient is scanned should be the same as the position you will use to treat the patient. The CyberKnife System does not support scans of patients positioned prone or on their sides. It supports Head-First Supine (HFS) and Feet-First Supine (FFS).

## Key DICOM Identifiers

You should refer to the CyberKnife DICOM Conformance Statement (Accuray P/N 19055) to understand fully how the CyberKnife System handles the import of DICOM images. One key identifier is used to classify imported DICOM data. All patient data is linked by a unique Medical ID. To maintain all image studies under one patient in the database, the images should all have the same Medical ID. If this is not possible, the AccuFusion program does allow you to fuse image studies assigned to different patient Medical IDs.

**NOTE:** Multiple series from the same image study will be linked together in the CyberKnife System database. If a study is to be done in multiple segments and then combined, they should have the same Image Study UID. Each segment can have a different Image Series UID.



441 Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



# FIDUCIAL PLACEMENT PRINCIPLES

In order to treat the patient with ease and accuracy, there are a few key principles that need to be taken into consideration when implanting the fiducial markers for patient treatments with the CyberKnife System. Sample fiducial configuration can be seen in *Figure 9 Example Configuration of 5 Fiducials, page 15*.

- Minimum of 2.0 cm distance between fiducials (max. distance 5-6 cm from lesion).
- Non-collinear placement (X-ray plane); Right Anterior Oblique (RAO)/Left Anterior Oblique (LAO) or Right Post-anterior Oblique (RPO)/Right Left-anterior Oblique (LPO) images acquired during patient treatments.
- A minimum 15 degree angle between any grouping of 3 fiducials should be used.

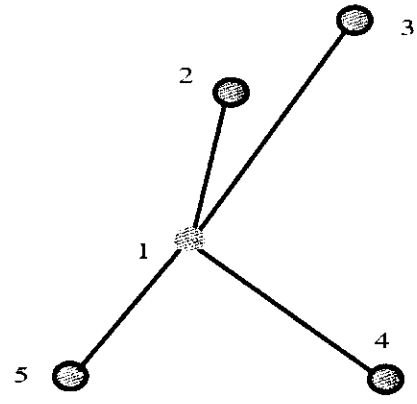



**Figure 9 Example Configuration of 5 Fiducials**

**NOTE:** You may find that some of the fiducials are unusable, for example due to any of the following reasons: (i) migration, (ii) close placement of fiducials - closer than 2.0 cm, i.e. fiducials 1,2, (iii) less than 15 degree angle between any set of 3 fiducials, i.e. fiducials 2,1,3. This type of fiducial placement adversely affects tumor localization and treatment accuracy. Fiducial placements that meet the requirements listed above are recommended so that the CyberKnife System can track and treat tumors with sub-millimetric accuracy.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



# Supplies

## Soft Tissue Supplies

**Figure 10 Gold Seeds, Biopsy Needle**

4 - 6 Gold seed fiducial markers (3 options)

- **Option 1**: Alpha Omega P/N SMG0242-025. 25 gold seeds/vial, 0.8 mm x 5 mm, packaged non-sterile. 19G thin walled biopsy needle, 10-11 or 15 cm length (*Figure 10 Gold Seeds, Biopsy Needle, page 16*)
- **Option 2**: Med-Tec P/N MT-NW-887-816. 3 gold seeds/package, 1.6 mm x 5 mm, packaged non-sterile.
- **Option 3**: Med-Tec P/N MT-NW-887-825. 3 - 17G needles preloaded with 1 gold seed marker per needle, 1.2 mm x 5 mm, sterile.

Needle aspiration kit and/or chest tube insertion kit (optional)

## Spine and Bone Supplies

- 4 - 6 stainless steel fiducial markers (*Figure 11 Stainless Steel Fiducial Markers, page 16*).

**Figure 11 Stainless Steel Fiducial Markers**



443

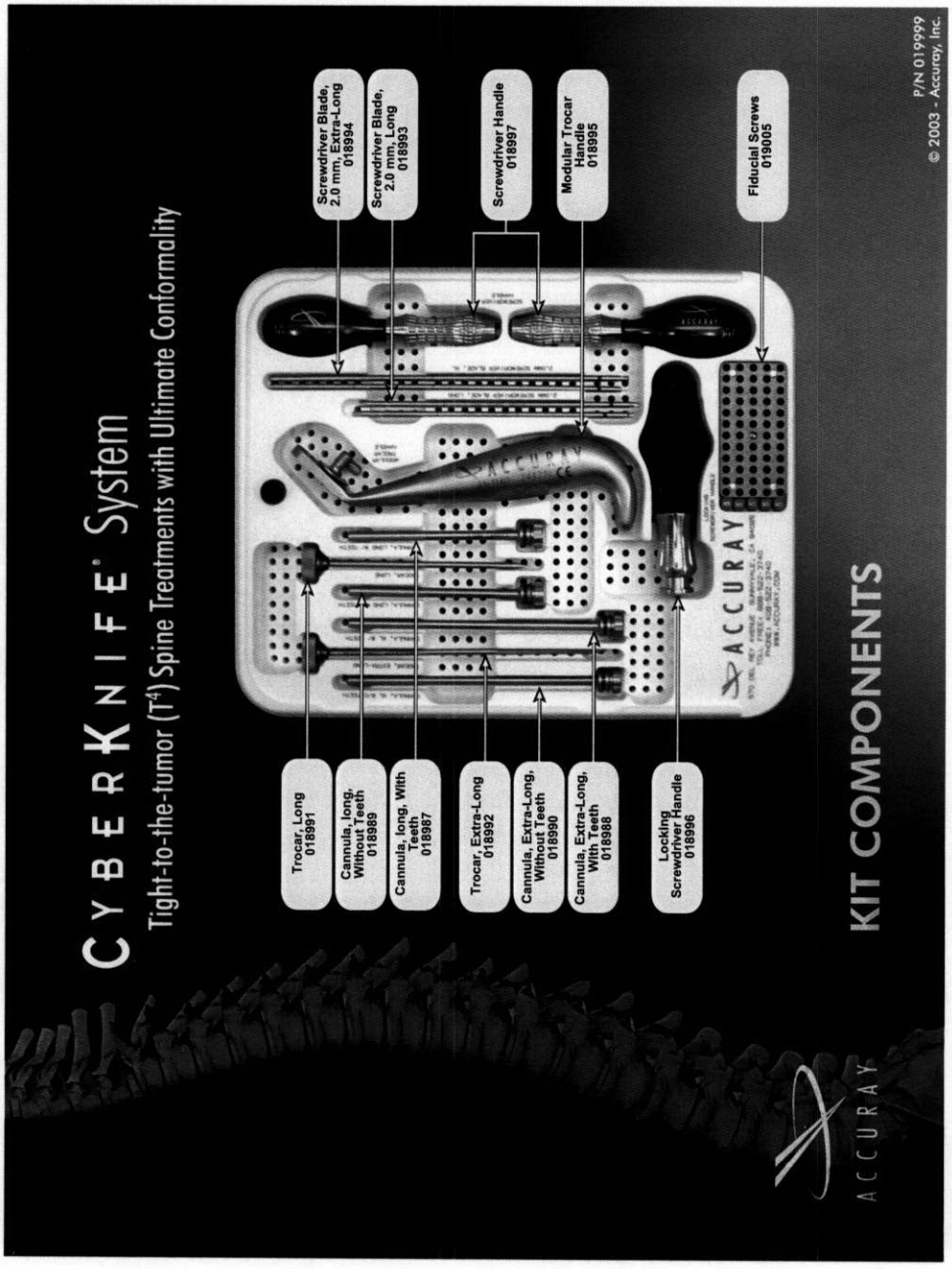
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



- Accuray P/N 019005. Single screw/pk, 2.0 mm x 5 mm, packaged non-sterile.
- Accuray P/N 019006. 5 screws/pk, 2.0 mm x 5 mm, packaged non-sterile.
- Accuray P/N 019007. 10 screws/pk, 2.0 mm x 5 mm, packaged non-sterile.
- Fiducial instrument kit. Accuray P/N 018985. Non-sterile.

## Fiducial Kit for Spine






Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



# Fiducial Placement Procedure

**NOTE:** Accuray does not make recommendations as to any particular fiducial placement procedure. The fiducial placement procedures presented here are developed by the medical professionals listed and are only presented here as guidelines.

## Post Placement Guidelines

For fiducials implanted for the treatment of spinal lesions, it is advised to wait 24-48 hours before acquiring the CT scan therefore enabling resolution of any localized pain or swelling. For soft tissue lesions, 1 week is recommended to allow adequate time thereby minimizing fiducial migration.

**NOTE:** It is imperative that the time between CT scanning and treatment delivery is kept to a minimum for soft tissue lesions; recommend time span is 24-48 hours. This will aid in reducing the incidence of fiducial extraction errors related to fiducial migration during treatment delivery.

## Lung

The treatment of lung lesions using the CyberKnife System requires the implantation of gold seeds referred to as fiducial markers. This outline reviews the procedure for placement of fiducial markers using a percutaneous approach with CT guidance. In order to track lesions in 6D (translational and rotational movements), a minimum of 3 fiducials are required for the software to track the lesion. It is recommended to place a minimum of 4 fiducials, 1 more then is required for tracking in 6D and no more than 6. This recommendation is based on a study of the tracking accuracy possible in the presence of uncertainties in fiducial localization both in the CT scan and live radiographic images. (*Murphy MJ Fiducial-based targeting accuracy for external-beam radiotherapy Med Phys 29(3) 334-344 (2002).*)

### Outline of Procedure

*Lung information provided by Stephen T. Kee M.D., Associate Professor of Interventional Radiology, Stanford University Medical Center.*

The fiducial placement procedure is very similar to a CT guided lung biopsy. Anyone who has experience with CT guided lung biopsies should be well aware of the methods employed and potential complications of the placement of needles in lung tissue. Perform the procedure utilizing the exact same methods used for a CT guided lung biopsy; the main difference being that once the needle is placed in the lesion, fiducials are implanted rather than taking tissue out. The complications and challenges are almost identical.

The first step is to obtain a detailed informed consent during which the patient is made aware of complications pertinent to placement of any needle within the lung, namely pneumothorax and hemorrhage. The incidence of pneumothorax with a single visceral pleural puncture is approximately 15-30%; this increases if multiple visceral punctures need to be performed. Hemorrhage can occur any time a needle is placed within the lung tissue resulting in hemoptysis.



445 Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



The patient is placed on the CT table in either the supine or prone position depending on the best approach to be used to access the lesion. The procedure is performed using conscious sedation and the patient should be monitored following hospital protocol for such a procedure. Images are acquired to locate the lesion and assess the approach and puncture site. The area is prepped using sterile technique and local anesthetic is injected at the intended puncture site. Under CT fluoroscopic guidance, the biopsy needle is advanced into the target lesion. The smallest gauge biopsy needle through which the gold seeds will fit should be used.

**NOTE:** The 19-gauge thin-wall needle is recommended for the Alpha Omega gold seeds. In our practice, an increased incidence of a pneumothorax using the larger gauge needle has been noted.

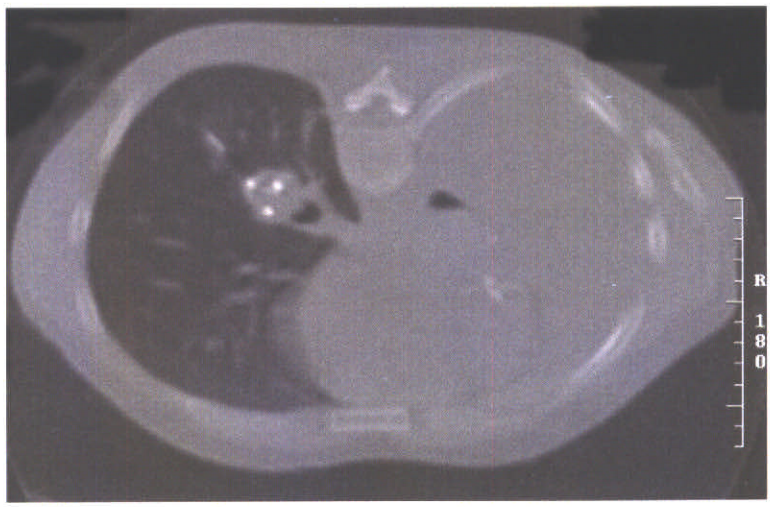



**Figure 12 Proper Fiducial Placement with 3 Gold Seeds**

When deciding what trajectory to use in order to place the needle within the lesion, the ideal route allows for placement of multiple fiducials within the lesion without having to puncture the visceral pleural multiple times. There is a significantly lower incidence of pneumothorax should the visceral pleura be transversed once rather than multiple times. When placing the needle within the lesion attempt to advance the needle to the back wall of the lesion and place the first fiducial in this location. Withdraw the needle from the initial fiducial placed, verify with imaging then implant the second fiducial. Angle the needle medial or lateral for placement of the other fiducials repeating the process described above on the opposing side of the lesion. Whenever possible, every attempt should be used to place the fiducials within the lesion as long as the fiducial placement guidelines are met (*Figure 12 Proper Fiducial Placement with 3 Gold Seeds, page 19*). CT scanning can be used to verify proper fiducial placement. Image patient at the end of the procedure to assess for complications. Obtain a chest X-ray 3 hours after the procedure to ensure no late onset of pneumothorax.

**NOTE:** Most lung lesions measure 3-5 cm in diameter making it possible to place 4-6 fiducials within the lesion with a single visceral puncture. In an extremely large lesion, it may be necessary to place multiple needles within the lesion to achieve adequate positioning of the fiducials.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



## Potential Complications

Pneumothorax - occurs in approximately a 30% of all biopsy cases; less than 10% require treatment. A small pneumothorax can be observed and if stable in size requires no further treatment. A pneumothorax greater than 20-30% requires either aspiration or placement of a chest tube. Aspiration of air from a pneumothorax can be done through a sheathed needle while the patient is still on the CT table. Placement of a chest tube usually requires the patient to be supine and is often performed after the post-procedure chest X-ray. In our experience at Stanford, placement of a chest tube has been required in a minimum of cases, less than 5%. Should a chest tube be required, this usually requires an overnight admission to a step down unit with continuous wall suction. A chest X-ray is performed the next day. If the pneumothorax be resolved and stable, the patient is discharged.

Hemoptysis - occurs in approximately 10-50% of cases whenever a needle is introduced into the lung. It is less common in patients who do not have a biopsy, therefore, it is rarely observed with fiducial placement procedures. Prior to the procedure evaluate if the patient is taking anti-coagulants. Should hemoptysis occur, the major concern is the patient's alarm at seeing that they are coughing up blood. Typically this complication ceases spontaneously due to the low blood pressure within the pulmonary arteries. It is usually not life threatening. It is important to adequately inform the patient during consent and remain calm while rendering the appropriate supportive care.

## Points To Consider

The major downside with performing fiducial placement in the lung is the difficulty of obtaining a good trajectory to place the needle within the lesion while taking into consideration the surrounding anatomy, i.e. ribcage. Anyone who has performed multiple lung biopsies should be able to adequately guide the placement of a needle into the lesion without great difficulty. CT and CT fluoroscopic guidance is recommended for the placement of fiducials as it allows for better visualization of the entire lung and lesion and enables the operator to rapidly identify complications during the procedure.

If a pneumothorax should develop during the procedure attempt to complete the fiducial placement procedure if at all possible. It may be necessary to place a chest tube during the procedure to re-inflate the lung. If the patient is stable and can tolerate it, the procedure should be resumed and completed. Should a pneumothorax develop during the placement of the first needle consider leaving it in place and introduce a second needle into the lesion to complete the procedure.

Another point to consider is the often used statement that "the enemy of good is perfect". During the procedure the goal is to get multiple fiducials placed into the lesion in the best locations. It is not absolutely necessary to get 5 fiducials in the most perfect place within the lesion to treat the patient. Placement of 3 fiducials within or adjacent to a tumor will be sufficient to track and treat the patient. Therefore, should the procedure become more complicated than expected, or should the patient become unable to tolerate a long procedure rapidly placing 3 fiducials, adhering to the fiducial placement principles, in and around the tumor should be adequate in most cases.

There is always the possibility of placing a fiducial within a significant sized pulmonary vein which could become a serious complication as it may travel and become lodged in the heart, lungs or brain. This has not occurred but is possible therefore, it is mentioned in this section. It is important to include this as a potential complication when obtaining patient consent. Documentation of the discussion between the physician, patient and preferably a relative is recommended.

## Conclusion

The key to success is to adequately inform the patient, perform the procedure with caution using the standard approach for needle biopsies, be prepared for potential complications and be familiarized with the fiducial placement principles.





Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



# Pancreas/Liver

*Pancreas and Liver information provided by Stephen T. Kee M.D., Associate Professor of Interventional Radiology, Stanford University Medical Center.*

## Outline of Procedure

The risks of the procedure are essentially identical to those of an image guided biopsy, however, depending upon the number of needle repositions required in order to adequately place the fiducials these risks may be somewhat higher. Most of the risks associated with placement of needles in soft tissues is hemorrhage, these risks are kept to a minimum if a single needle puncture can be used in order to place multiple fiducials and if adequate imaging is obtained prior to the procedure in order to identify potential hazards. A detailed informed consent outlining the potential complications to the patient should be the first step.

The diagnostic imaging technique of choice is CT or CT-fluoroscopy, however, other operators have performed this procedure using ultrasound guidance and this is quite feasible particularly for large lesions. If the patient is considered a candidate for treatment with the CyberKnife System while in the operating room, placement of the fiducial markers using direct visualization could be an option.

The patient is placed on the CT table in either the supine or prone position depending on the best approach to be used to access the lesion. The procedure is performed using conscious sedation and the patient should be monitored following hospital protocol for such a procedure. Images are acquired to locate the lesion and assess the approach and puncture site. The area is prepped using sterile technique and local anesthetic is injected at the intended puncture site. Under CT guidance, the biopsy needle is advanced into the target lesion. The smallest gauge biopsy needle through which the gold seeds will fit should be used.

**NOTE:** The 19-gauge thin-wall needle is recommended for the Alpha Omega gold seeds. When deciding what trajectory to use in order to place the needle within the lesion, the ideal route allows for placement of multiple fiducials within the lesion without having to reposition the needle multiple times. There is a significantly lower incidence of hemorrhage should the organ involved be transversed once rather than multiple times. When placing the needle within the lesion attempt to advance the needle to the back wall of the lesion and place the first fiducial in this location. Withdraw the needle from the initial fiducial placed, verify with imaging then implant the second fiducial.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



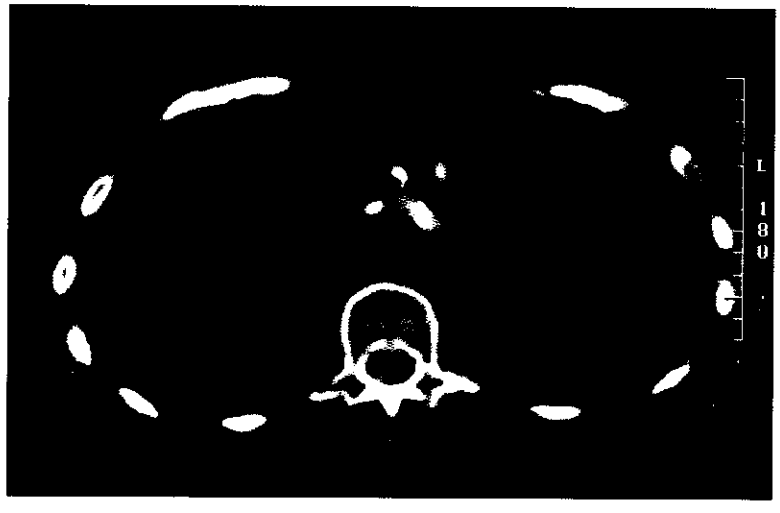



**Figure 13 Proper Fiducial Placement with 4 Gold Seeds**

Angle the needle medial or lateral for placement of the other fiducials repeating the process described above on the opposing side (or wall) of the lesion. Whenever possible, every attempt should be used to 4-6 fiducials within the lesion as long as the fiducial placement guidelines are met (*Figure 13 Proper Fiducial Placement with 4 Gold Seeds, page 22*). This can prove to be challenging with lesions less than 3 cm in diameter. With smaller lesions, it is acceptable to place fiducials in the organ tissue surrounding the lesion. CT scanning should be used frequently to verify proper fiducial placement.

## Potential Complications

Hemorrhage is the most likely complication when puncturing the liver, pancreas and other soft tissue regions in the body. Use of a small, gauge needle and knowledge of critical structures surrounding the lesion should minimize this complication. Should the concern of hemorrhage be present for whatever reason following placement of the last fiducial, a small amount of gel-foam slurry can be injected into the needle as it is being removed to immobilize the track. The gel-foam slurry is created by cutting up small amounts of gel-foam, mixing with either saline or lidocaine.

Transgression of a section of bowel when advancing the needle towards a lesion particularly for pancreatic lesions is a possibility. There are usually no necessary precautions to be taken if the stomach or small bowel is to be transgressed, however, if the large bowel is transgressed then it is recommended to place the patient on broad spectrum antibiotics for one week. Every attempt should be made to avoid puncturing these structures especially the large bowel.

Another potential complication is immobilization of fiducials to a distal site. In theory, placement of a fiducial in a significant artery could result in distal immobilization. This has not occurred in our practice but warrants mention in this paper. If there is significant arterial flow through the needle upon removal of the stylet placement of a fiducial at this location is not recommended instead, remove the needle, assess the patient's condition and if stable proceed by selecting another location to place the fiducial.



449

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



### Points To Consider

Typically, during placement of fiducials in pancreatic lesions the imaging does not include administration of intravenous contrast. Therefore, the contrast study from the patient's previous imaging should be studied to ensure that no significant vessels will be transgressed with the placement of the needle and fiducials. If there are any doubts, a contrast CT study should be performed during placement. There are some situations in which structures must be transgressed to access the lesion for fiducial placement. In our practice, the preference is to cross "nothing" first, stomach second, liver third, small bowel fourth and large bowel as an extreme last resort. As stated above, if the large bowel is punctured the patient should be administered antibiotics.

### Conclusion

The fiducial placement procedure is very similar and only slightly more elaborate than a standard image guided biopsy. Anyone who has experience with CT guided biopsies should be well aware of the methods employed and potential complications of the placement of needles in soft tissue organs such as the pancreas and liver. Perform the procedure utilizing the same methods used for an image guided biopsy, the main difference being that once the needle is placed in the lesion, fiducials are implanted rather than taking tissue out. The complications and challenges are almost identical. The key to success is to adequately inform the patient, perform the procedure with caution using the standard approach for needle biopsies, be prepared for potential complications and be familiarized with the fiducial placement principle.

## Cleaning and Sterilization

### Sterility

Implantable screw radiographic markers are supplied non-sterile and must be sterilized prior to use.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015





451 Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



# Patient Data & Image Administration
## Table of Contents

**Patient Data Administration** ..... 1
- Add New Patient Data ..... 1
- Discontinue Patient Data ..... 4
- Review Patient Treatment ..... 5
- Discontinue Treatment Plan ..... 8
- Archive Patient Database ..... 9
  - Errors ..... 13
- Restore Patient Database ..... 14

**Patient Image Administration** ..... 17
- Medical Image Review and Import Tool ..... 17
- Adding New Images ..... 18
- Review and Load Images to the Database ..... 19
  - Couch Position ..... 20
  - Patient Image ..... 21
  - Phantom Image ..... 23
  - Load Images from Tape ..... 23
  - Delete Image Before Import to Patient Database ..... 23
- Export Data from the CyberKnife User Control Console ..... 24
  - CT Image Study ..... 24
  - Other Studies ..... 25
- Deleting Images ..... 25
- Reloading Images for Incomplete Loaded Images ..... 26



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118 452

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015





453 Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



# PATIENT DATA AND IMAGE ADMINISTRATION

## PATIENT DATA ADMINISTRATION

This section describes how to do the following:

1. Add new patient data
2. Discontinue the use of patient data
3. Review patient data

### Add New Patient Data

**NOTE:** New patients are automatically added to the patient database when the patient's first medical image is loaded. Manual creation of a patient is optional and usually unnecessary.

**CyberKnife® System Menu -> Patients -> Add New Patient ->Patient**

**To add new patient data:**

**Step 1.** Click the **PATIENTS** button from the CyberKnife System menu, the Patients window appears (*Figure 1 Patient List, page 2*).



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



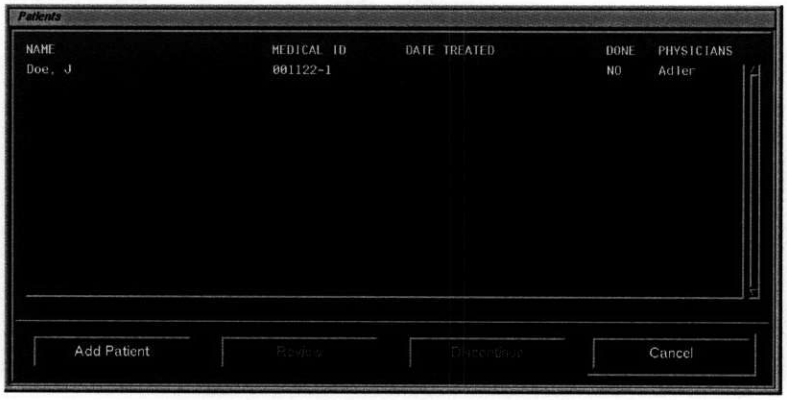



**Figure 1 Patient List**

**Step 2.** Click **ADD PATIENT** in the patients window. The Add New Patient window (*Figure 2 Add New Patient, page 2*) appears.

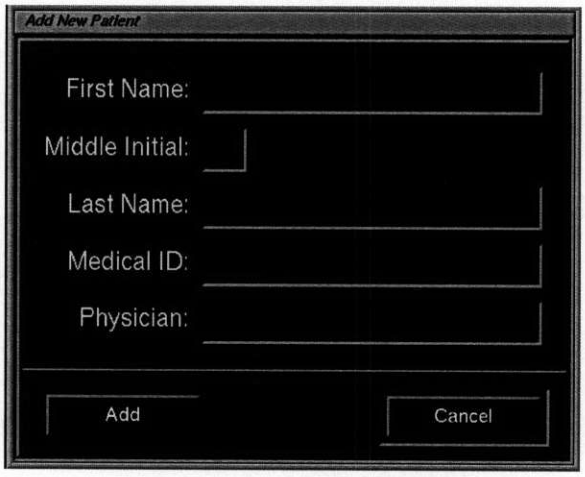



**Figure 2 Add New Patient**

**Step 3.** Move the cursor to the text fields and fill in the appropriate information. The patient's **Medical ID** must match that used for the CT.

To move back to any previously entered field, press <Enter> several times until the desired field is highlighted with the yellow box. Data entered with leading, embedded, or trailing blanks is stripped by the CyberKnife software and stored in the system without the extra blank spaces. For example: Type: 12 34 56 in the **Medical ID** field. When stripped and stored, **Medical ID** becomes 123456.

**Step 4.** After you type the text and check for accuracy, click **ADD**. The message "Updating database. Please wait" is displayed in a Status Message window (*Figure 3 Updating Database Wait Message, page 3*).



455

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015

**Figure 3 Updating Database Wait Message**

**Step 5.** When the information is stored in the database, the message, "A new entry has been added to the database." is displayed (*Figure 4 New Patient Added Status Message, page 3*). To continue, click **OK** in the message window and the Add New Patient window reappears.

**Figure 4 New Patient Added Status Message**

**Step 6.** Repeat the steps to add more patients.

**Step 7.** To return to the CyberKnife System menu, click **CANCEL**.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



# Discontinue Patient Data

Patient data can be discontinued or deleted when the patient does not need more treatment. Discontinued patient data is handled differently depending on the status of the patient. If a patient was never treated with the CyberKnife System, the patient data is completely deleted from the database. If a patient was treated, the patient data is marked as *discontinued* in the database, which means no one can work on this patient anymore, but the data is not deleted from the database. To reclaim the disk space of this discontinued patient data, you must archive it to tape (*see section, Archive Patient Database, page 9*).

**CyberKnife System Menu -> Patients -> Confirmation Message**

**To discontinue patient data:**

**Step 1.** Click **PATIENTS** from the CyberKnife System menu. The Patients window appears.

**Step 2.** Select the patient's name from the list and the **DISCONTINUE** button becomes active.

**Step 3.** Click **DISCONTINUE**. The Confirmation Message (*Figure 5 Discontinue Patient Confirmation Message, page 4*) appears. The Confirmation Message asks you to confirm discontinuance of the patient data.

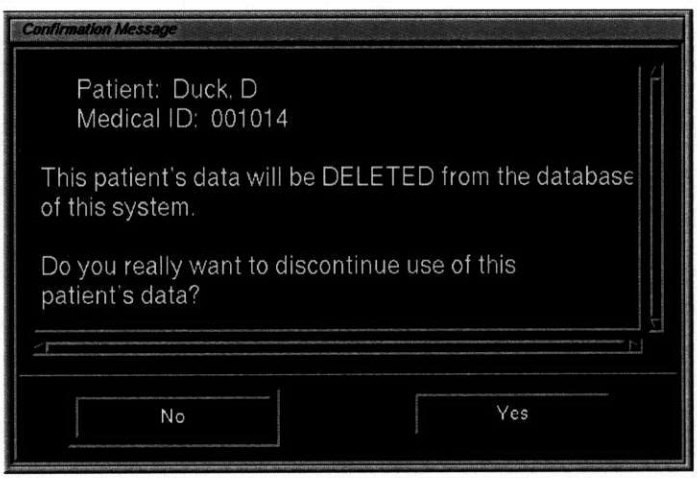



**Figure 5 Discontinue Patient Confirmation Message**

**Step 4.** Click **YES** to discontinue the patient data. The confirmation message disappears and the message "Updating database. Please wait." appears.

**CAUTION:** Once the patient is discontinued, the patient cannot be used again.

**Step 5.** Click **OK** in the Status Message, when the message "Database update successful. Patient data can no longer be used." appears and the Patient window returns.



457

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



# Review Patient Treatment

The CyberKnife System allows you to review the patient's treatment history of each site, plan and plan fractions.

**CyberKnife System Menu -> Patients -> Review Treatment Sites -> Review Treatment Plans -> Review Plan Usage**

**To review patient treatment:**

**Step 1.** Click the **PATIENTS** button from the CyberKnife System menu. The Patients window appears.

**Step 2.** Select the desired patient's name from the patients list. The **REVIEW** button becomes activated.

**Step 3.** Click the **REVIEW** button. If data is available, the Review Treatment Sites window appears (*Figure 6 Review Treatment Sites, page 5*). If no data is available, a status message (*Figure 7 No Treatment Data Status Message, page 5*) appears informing you that the selected patient has no data. Click **OK** to return to the Patients window.

The Review Treatment Sites window displays a list of the patient's sites. The name of the site, indication of the treatment status, date last treated, amount of radiation delivered and the prescribed dose appear in the window.

**Figure 6 Review Treatment Sites**

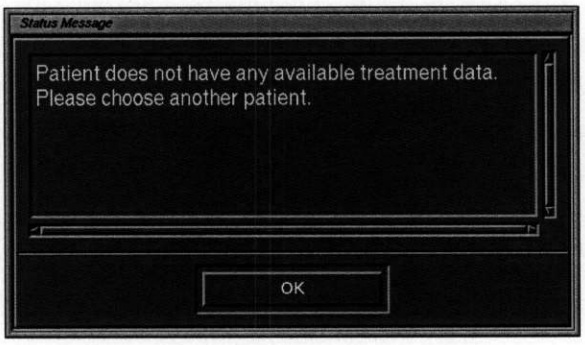



**Figure 7 No Treatment Data Status Message**



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



### To review the treatment plan history

Select the site name in the Review Treatment Sites window. The Review Treatment Sites window disappears and the Review Treatment Plans window (*Figure 8 Review Treatment Plans, page 6*) appears. Click **CANCEL** to return the Patients window.

The Review Treatment Plans window displays a list of the patient's plans. The name of the plan, plan treatment status, date last used and prescription radiation dose are given. If the plan is not complete, you can discontinue the plan in the Review Plan Usage window (*Figure 9 Review Plan Usage, page 7*).

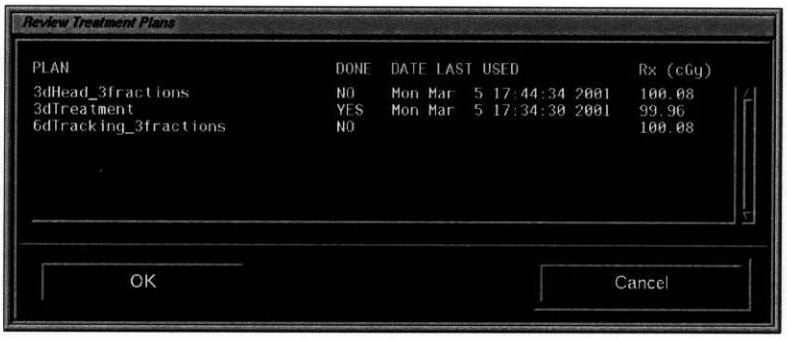



**Figure 8 Review Treatment Plans**

### To review plan fraction history

Select the treatment plan name in Review Treatment Plans. The Review Plan Usage window appears. Click **CANCEL** to redisplay the Review Treatment Sites window.

The Review Plan Usage window shows the treatment history of the specified plan. The text areas in this display show plan information. The **DISCONTINUE PLAN** button is active if the plan has not gone through the full course of treatment. The **DISCONTINUE PLAN** button allows you to discontinue use of the selected plan.

Each text area of the Review Plan Usage window is explained below.

- **Plan Selected**: Name of the treatment plan.
- **Rx (cGy)**: Total prescribed dose of this plan in cGy.
- **Number of Fractions**: The number of fractions for this plan.
- **Dose Per Fraction**: Dose for a fraction in cGy.
- **Plan Dose (cGy) Delivered**: Total radiation delivered using this plan in cGy.
- **Plan Dose (cGy) Remaining**: Total remaining radiation to be delivered for this plan in cGy.
- **Fractions Remaining Full**: The number of remaining full fractions.
- **Fractions Remaining Makeup**: The number of remaining makeup fractions (*see module, Treatment, section, Makeup Fractions*).



459

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



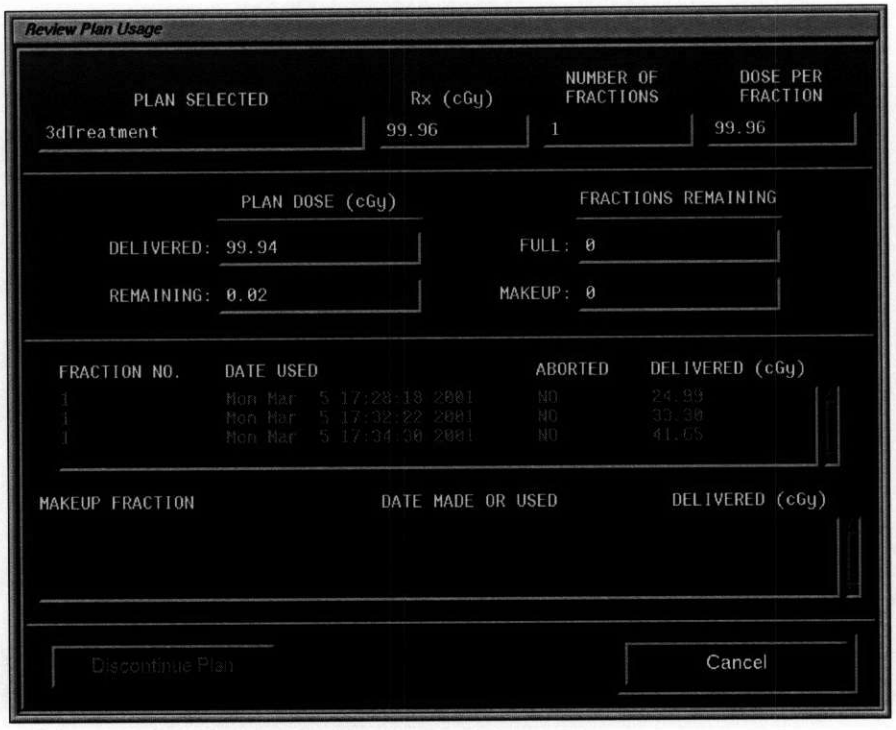



**Figure 9 Review Plan Usage**

The following is a list of information shown in the plan's Fraction History:

- **Fraction No.**: The fraction number.
- **Date Used**: The date and time this fraction was delivered.
- **Aborted**: The status of the fraction. If it has been aborted, YES is displayed; if not, NO is displayed.
- **Delivered**: Dose delivered for this fraction.

The following is a list of information shown in the plan's Makeup Fraction History:

- **Makeup Fraction**: The name of the makeup plan.
- **Date Made or Used**: The date and time this makeup fraction was created, if the dose delivered is zero. If the makeup fraction were used, the dose delivered would be greater than zero and the date and time would indicate when the makeup was last used.
- **Delivered**: Dose delivered for this makeup fraction.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



# Discontinue Treatment Plan

At the review plan usage window, you can discontinue use of a plan that has not finished the full course of treatment.

**CyberKnife System Menu -> Patients -> Review Treatment Sites -> Review Treatment Plans -> Review Plan Usage**

**To discontinue the treatment plan:**

**Step 1.** Follow the sequence to get to the Review Plan Usage window (*Figure 9 Review Plan Usage, page 7*).

**Step 2.** Click **DISCONTINUE PLAN** the confirmation message (*Figure 10 Discontinue Plan Confirmation Message, page 8*) appears. It displays the Plan, Site, Patient name, Medical ID information and the message "Do you really want to discontinue the use of this plan?"

**Step 3.** Click **YES** to discontinue the plan.

**CAUTION:** Once you discontinue the plan, the plan cannot be used again.

**Step 4.** Click **NO** to cancel discontinuation. The Review Plan Usage window is redisplayed and the confirmation message disappears.

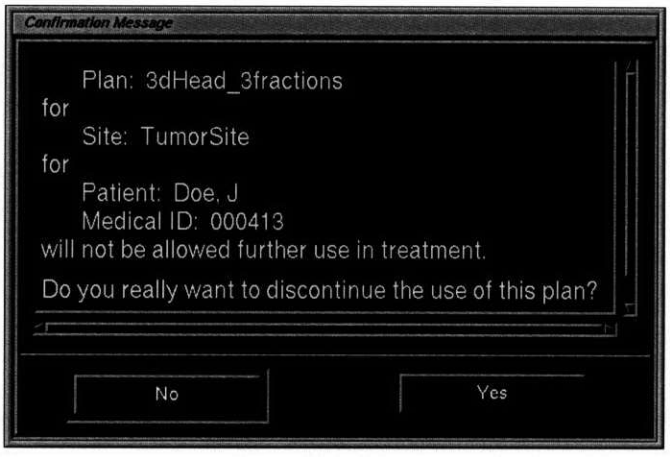



**Figure 10 Discontinue Plan Confirmation Message**



461

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



# Archive Patient Database

You can archive selected patient database to a 12 GB 4mm digital audio tape (DAT). If the database exceeds 12 GB, use several tapes. The patient database includes image sets, digitally reconstructed radiographs, treatment plans and treatment history data. Archiving unused data frees disk space by transferring a single patient's data to the archive tape. The archived data can be restored (*see section, Restore Patient Database, page 14*).

**CyberKnife System Menu -> Administration -> Archive -> Patients -> Patient Verification -> Archive Status Message**

**To archive the patient's database:**

**Step 1.** Pull down the **Administration** menu bar from the CyberKnife System menu (*Figure 11 CyberKnife System Menu, Administrative Submenu, page 9*).

**Step 2.** Click **ARCHIVE** from the menu bar. The Loading Process window is displayed with the message "Loading process. Please wait."

**Figure 11 CyberKnife System Menu, Administrative Submenu**

**Step 3.** When the archiving process is ready, the Patients window (*Figure 12 Archive Patients, page 10*) appears. Click **CANCEL** to return to the CyberKnife System menu.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118 462

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



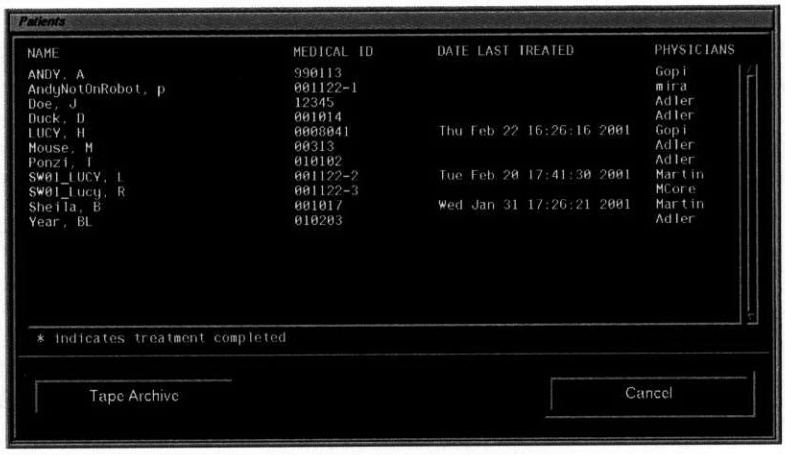



**Figure 12 Archive Patients**

**Step 4.** The Patients window shows a list of patients whose data can be archived. An "*" by a patient's name indicates that the patient record has been discontinued.

**Step 5.** Select the patient to be archived. The selected names will be highlighted.

**Step 6.** Click **TAPE ARCHIVE**. The Patient Verification window (*Figure 13 Archive Patient Verification, page 10*) appears.

**Figure 13 Archive Patient Verification**

**Step 7.** Review the patient information.

**Step 8.** If it is correct and you want to archive the patient's database, select the **PATIENT NAME CONFIRMATION** button. This action activates the **MEDICAL ID** button and deactivates the **Patient Name**.

**Step 9.** Confirm that the **Medical ID** is correct. When selected, the **MEDICAL ID** button becomes inactive and the **CONTINUE** button becomes active.

**Step 10.** Click **CONTINUE** to archive. The Archive Status Message appears. Clicking **CANCEL** discontinues the archive process. The Patients window appears.

**NOTE:** Cancel is always active.



463

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



**Write to the tape**

**Step 1.** When the Archive Status message (*Figure 14 Archive Patient Tape Status Message, page 11*) appears, a message instructs you to insert a blank 12 GB 4mm DAT into the tape drive.

**NOTE:** Any data on the tape will be overwritten.

**Step 2.** Make sure the write protect feature of the tape is in the off position. Consult the tape manufacturer's instructions for turning off the write protect feature.

**Figure 14 Archive Patient Tape Status Message**

**Step 3.** After the tape is in the tape drive, select CONTINUE. The Archive Message (*Figure 15 Checking Tape Archive Status Message, page 11*) appears. CANCEL discontinues the archiving. The Patient Verification window returns.

When the Archive Message appears, the archiving has started. The archiving process checks if the tape is in the tape drive and if there is any data on it, including other patients' archived data.

**Figure 15 Checking Tape Archive Status Message**

**CAUTION:** Make sure you want to discard any data already on the tape. Once a decision is made to write over existing data, you cannot recover that data

When the tape has been checked, the Tape Status message appears (*Figure 16 Initial Archive Tape Status, page 12 and Figure 17 Continue Archive Tape Status Message, page 12*). The archiving process is now writing to the tape.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118 464

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015

**Figure 16 Initial Archive Tape Status**

**Figure 17 Continue Archive Tape Status Message**

**Step 4.** A message in the Archive Status message window informs you that archiving is complete (*Figure 18 Archive Completion Message, page 13*). The selected patient's database is removed from the main disk of the console computer.



465

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



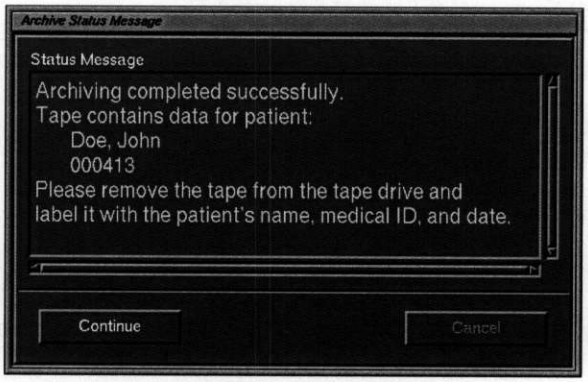



**Figure 18 Archive Completion Message**

**Step 5.** Click **CONTINUE** to return to the Archive Patients window.

**Step 6.** After successful archiving, remove the tape from the tape drive. Set the write protect tab and clearly label the tape. Do not subject tapes to extremes of temperature and humidity and keep tapes away from strong electromagnetic fields. For long-term storage, you should re-copy magnetic tapes every year to year-and-a-half to prevent data loss through deterioration.

**NOTE:** If problems occur while transferring data to tape, clean the tape drive head with a standard cleaning tape. To avoid problems due to a dirty tape drive head, clean the tape drive once a month.

## Errors

If there are any discrepancies during the archive process, the Archive Error Message (*Figure 19 Archive Error Message, page 13*) appears. Self-explanatory messages are displayed in the Archive Error Message to help you correct the problem and **CONTINUE** or **CANCEL** the archive.

**Figure 19 Archive Error Message**



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



# Restore Patient Database

Restores archived patient data to the CyberKnife System Main database from tape.

**CyberKnife System Menu -> Administration -> Restore -> Patients -> Patient Verification -> Restore Status**

**To restore the patient's database:**

**Step 1.** Pull down the Administration menu from the CyberKnife System menu (*Figure 11 CyberKnife System Menu, Administrative Submenu, page 9*).

**Step 2.** Click **RESTORE**. The Loading Process window displays the message "Loading process. Please wait."

**Step 3.** When the restoring process is ready, the Archived Patients window (*Figure 20 Restore Archived Patients, page 14*) appears.

**Step 4.** **CANCEL** displays the CyberKnife System menu.

The Archived Patients window lists patients whose data can be restored. An "*" by a patient's name indicates that the patient record has been discontinued.

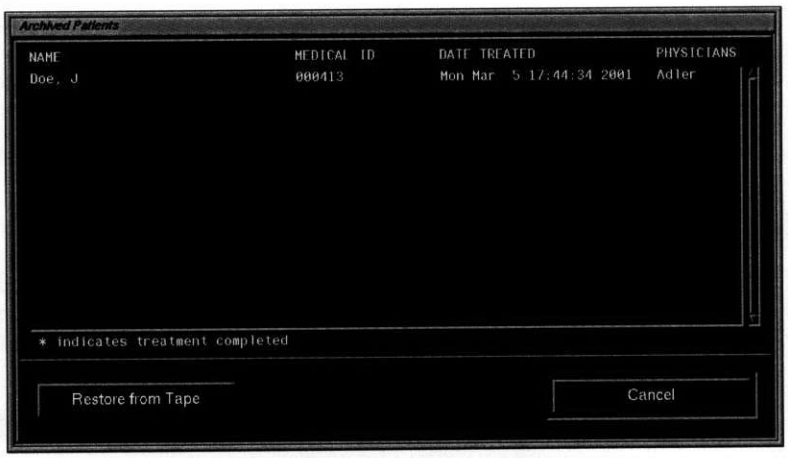



**Figure 20 Restore Archived Patients**



467

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



**To accept patient data for restoring:**

1. Select the desired patient's name in the Archived Patients list.
2. Click **RESTORE FROM TAPE**. The Patient Verification window (*Figure 20 Restore Archived Patients, page 14*) appears.

**Figure 21 Restore Patient Verification**

3. Review the patient information. The **PATIENT NAME** button is active.
4. Confirm that the **Patient Name** is correct. The **MEDICAL ID** button becomes active and the **PATIENT NAME** button becomes inactive.
5. Confirm that the **Medical ID** is correct. The **MEDICAL ID** button becomes inactive and the **CONTINUE** button becomes active.
6. Click **CONTINUE** to continue with the restoration procedure. The Restore Status window (*Figure 22 Restore Status Message, page 15*) appears.
7. Click **CANCEL** to discontinue. The Patients window appears.

**NOTE:** The **CANCEL** button is always active.

**Figure 22 Restore Status Message**



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



**To restore patient's database:**

**Step 1.** When the Restore Status window appears (*Figure 22 Restore Status Message, page 15*), a message instructs you to insert an archived patient tape into the tape drive. Make sure the write protect feature of the tape is off. Consult the tape manufacturer's instruction for turning off the write protect feature.

**Step 2.** Click **CONTINUE** to restore the patient's database to the console computer's main hard disk.

**Step 3.** Click **CANCEL** to discontinue restoring. The Patient Verification window returns.

**Step 4.** When restoration is complete, the "Restore completed successfully" message appears.

**Step 5.** Click **CONTINUE** to return to the Archived Patients window.

**Errors**

If the restoration process has discrepancies, the Restore Error message appears (*Figure 19 Archive Error Message, page 13*). Self-explanatory messages in this window help you correct the problem and continue or completely cancel the archive.

**NOTE:** After restoring the patient data, remove the tape from the tape drive and remove the patient labeling from the tape. The tape is reusable.



469

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



# PATIENT IMAGE ADMINISTRATION

This section shows you how to add new patient and phantom images, remove an image and reload an existing patient's image.

The CyberKnife System recognizes two input image sources in DICOM standard format. The first one is a digital audio tape (DAT) and the other is a DICOM network communication.

If the user site has a network system, a customized network version must be installed. Contact Accuray to discuss specifications. The recommended format of image that will be transferred via network is DICOM standard format.

## Medical Image Review and Import Tool

Click **IMAGES** from the CyberKnife Systems menu (*Figure 11 CyberKnife System Menu, Administrative Submenu, page 9*). The Medical Image Review and Import Tool (*Figure 23 MIRIT Main Screen, page 17*) will open. If a medical image has been exported to the CyberKnife System since the last time MIRIT was opened, the timer (*Figure 24 Import Images to CyberKnife, page 18*) will appear, while the imported images are sorted by patient and modality.

**NOTE:** If two or more image studies for the same patient with the same modality are going to be imported, you must import one image study to the database first. Then exit MIRIT and restart Images to load each study one at a time.

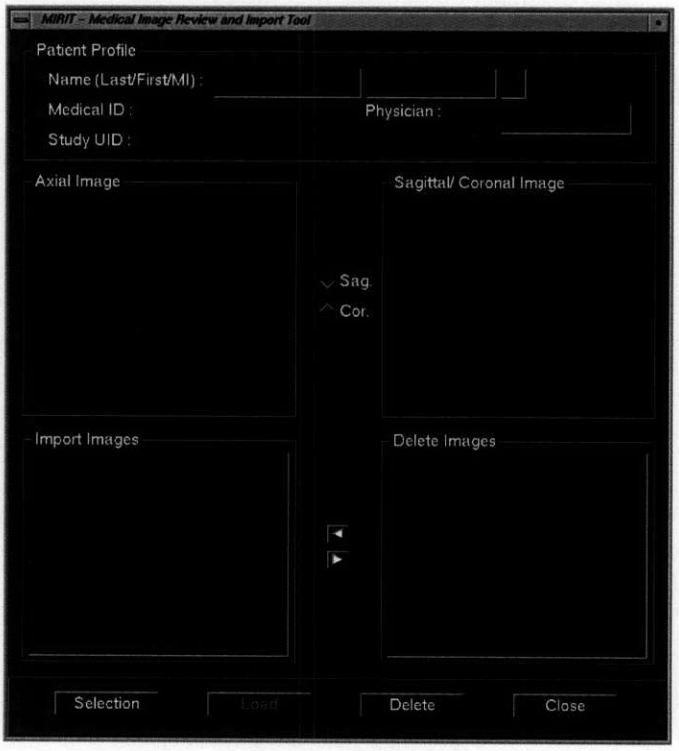



**Figure 23 MIRIT Main Screen**



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

470

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015

**Figure 24 Import Images to CyberKnife**

## Adding New Images

Use MIRIT to add Medical Images to the patient database. You can add images as either a patient or a phantom. Each phantom image in the database must be associated with a specific patient image. A patient, on the other hand, does not need an associated phantom image.

**NOTE:** The patient image must be entered first. A phantom image must be associated with a patient.

Click **SELECTION**. The Patient Selection Dialog (*Figure 25 Load Image Selection, page 18*) will appear. This interface has four options:

1. **OK** load an image into the user interface.
2. **DELETE** highlight an image and delete the image from the CyberKnife System.
3. **SPLIT** highlight an image with multiple series and split them into multiple studies.
4. **LOAD TAPE** load an image transferred to the system via tape media.
5. **CANCEL** cancel the selection.

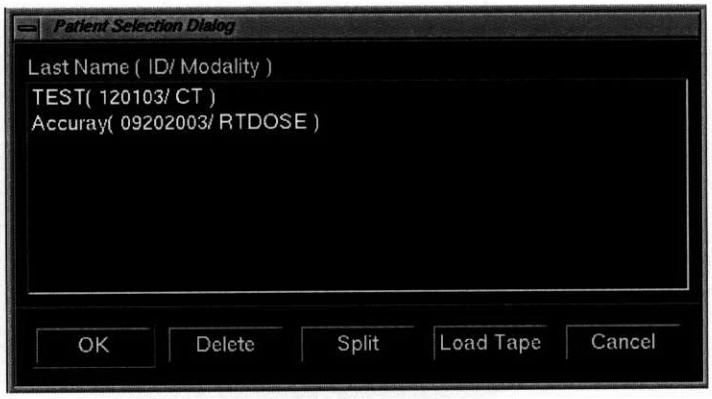



**Figure 25 Load Image Selection**

**NOTE:** If an image study has multiple series, the default import operation will combine these multiple series as one case (study) in the patient database. Using **SPLIT** allows you the option to import multiple seeries as multiple cases (studies) in the patient database.



471

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



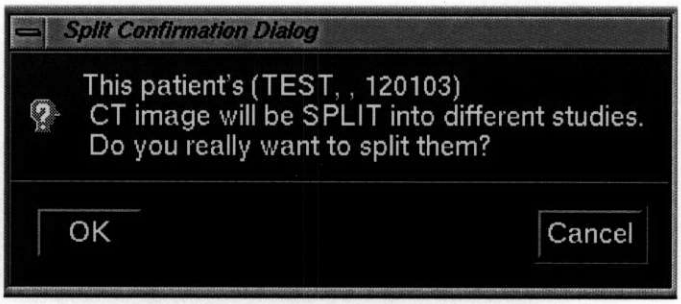



**Figure 26 Split Confirmation Dialog**

Typically, multiple series from the time the study is combined can be split into multiple studies if they represent non-contiguous anatomy.

## Review and Load Images to the Database

After the patient image is loaded, you can review the image. Images are sorted to preselect images to import and delete before importing into the database. Images are deleted if they are repeated positions or if they are scout images. Lists of images to import and images to delete are on the bottom of the display. The lists sort the image by the z-position of the slice. You can scan through the images to determine what to delete and what to import. Highlight the scan to move and use the arrow buttons to delete or retain image. The display has two image windows to help you review the image study.

The image window on the left has the axial slice data. A sagittal or coronal reconstruction of the patient image appears in the window on the right. You can toggle between sagittal and coronal with the buttons between the two image windows. In each window, you can change the view plane by dragging the cursor up or down in the window. You can select the axial slice to display by clicking the cursor in the reconstructed image, dragging the cursor left or right through the reconstructed image or highlighting the slice in the Image Import or Image Delete list.

If this is the first image imported for the patient, you can edit the patient name. You can modify the physician name anytime an image is loaded. Each patient must have a first name, last name and physician.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



## Couch Position

The average couch position separation is used to determine the distance between slices for planning and DRR generation.

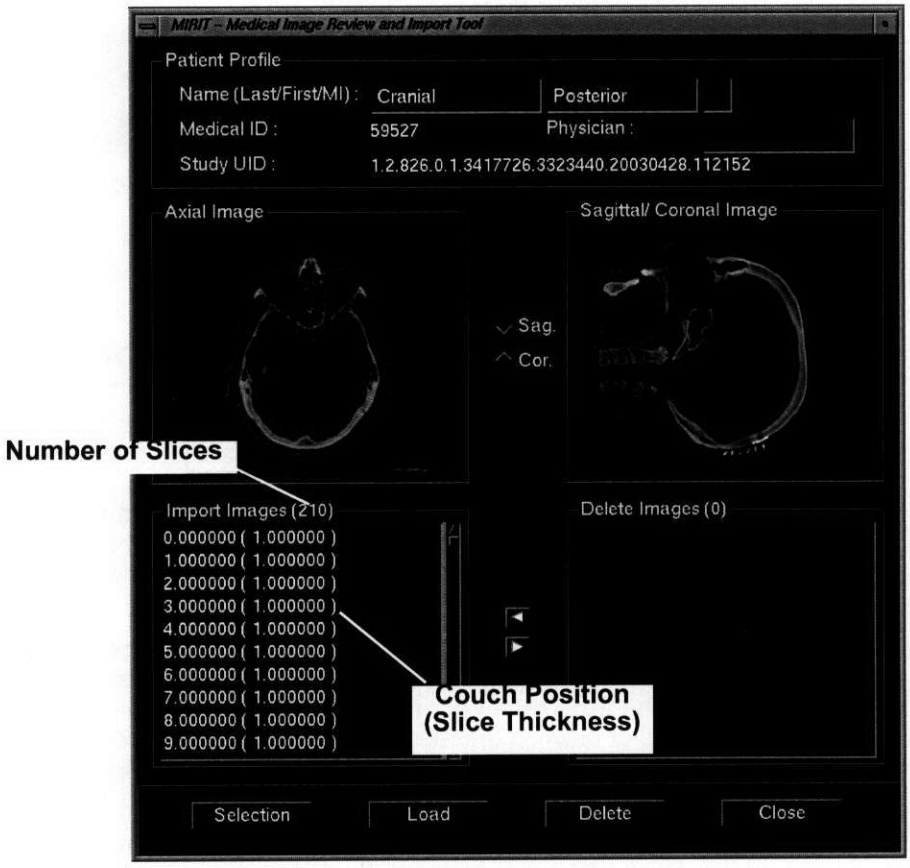



**Figure 27 Image Review**



473

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



Once you are satisfied that the Image Study is correct, click on **LOAD** Button to load the image. The confirmation (*Figure 28 Image Import Confirmation, page 21*) will appear. Select whether the image should be loaded as a phantom or a patient. Click **OK** to load or **CANCEL**.

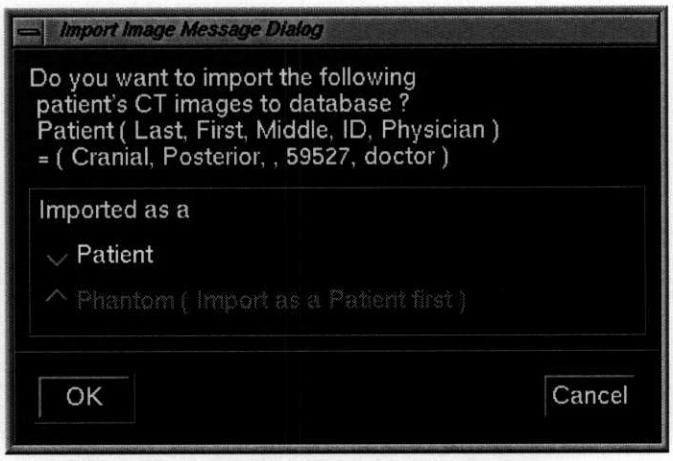



**Figure 28 Image Import Confirmation**

## Patient Image

The system will attempt to load the image to the patient database. A confirmation (*Figure 30 Successful Image Load, page 22*) or an error message (*Figure 31 Image Import Error Message, page 22*) will appear. Images will fail to load due to the following errors.

- Unacceptable patient or physician name
- Variable slice thickness, pixel size
- Study has skipped slices
- Essential DICOM header information is missing, such as patient position, rescale intercept/ slope for CT and PET
- A CT Study has a tilt angle other than zero
- Image with the same Study UID already loaded
- New scanner for CyberKnife System
- Repeated couch position
- Number of slices is over 300
- Slice thickness is not in the range, i.e, max (6 mm) and min (0.5 mm)
- Scout image

**NOTE:** The corresponding DICOM RT Structure Set is imported.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



**NOTE:** If no image series have the same study UID, you must split those series in order to import both to the patient database.

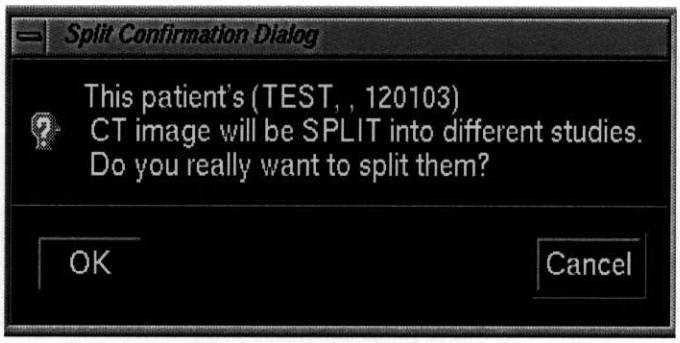



**Figure 29 Split Confirmation**

**NOTE:** Image studies are automatically named. The name is based on a time stamp of when the image was loaded to the CyberKnife patient database. The convention for names of an image study is: caseYYYY.MM.DD.HH.MM.SS, where YYYY is the year, MM is the month, DD is the day, HH is the hour, MM is the minute and SS is seconds.

**Figure 30 Successful Image Load**

**Figure 31 Image Import Error Message**



475

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



## Phantom Image

A phantom image must be associated with a previously loaded patient image. Therefore, when the image to load is a phantom, you will have to select an associated patient image from the list in the case selection dialog (*Figure 32 Case Selection for Phantom Image Load, page 23*) before the phantom image is loaded to the database. The image load will then proceed in the same way as patient image load.

**Figure 32 Case Selection for Phantom Image Load**

## Load Images from Tape

If you have transferred the image via tape rather than a local area network. Click **LOAD TAPE**. The computer will transfer the images on tape to the temporary database and sort them by Medical ID and modality. The exported image will then appear (*Figure 25 Load Image Selection, page 18*). Continue to load the image as described in *section, Review and Load Images to the Database, page 19*.

## Delete Image Before Import to Patient Database

If you cannot or do not want load an image study listed (*Figure 25 Load Image Selection, page 18*), highlight the study and click **DELETE**.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



# Export Data from the CyberKnife User Control Console

**NOTE:** CyRIS™ InView™ must be turned on in order for DICOM data to be transmitted to it.

One disadvantage of importing data directly from the scanner to CyRIS InView is that the image editing tools are not as sophisticated as on the CyberKnife User's Control Console (UCC). It may be easier for you to import the medical images to the UCC and then push those images to the CyRIS InView workstation.

## CT Image Study

If you have already imported a CT image study into the CyberKnife patient database, you can export the CT image by opening the Treatment Planning System and loading the CT image.

**Step 1.** Click **PLAN->EXPORT DICOM DATA**. *Figure 33 Export DICOM Data from the UCC, page 24* will appear.

**Step 2.** Select the CT Image Study to export.

**Step 3.** Choose to Export to Host.

**Step 4.** Select CyRIS InView as the host to export to.

**Step 5.** Click **OK**.

The UCC will export the CT image to CyRIS InView.

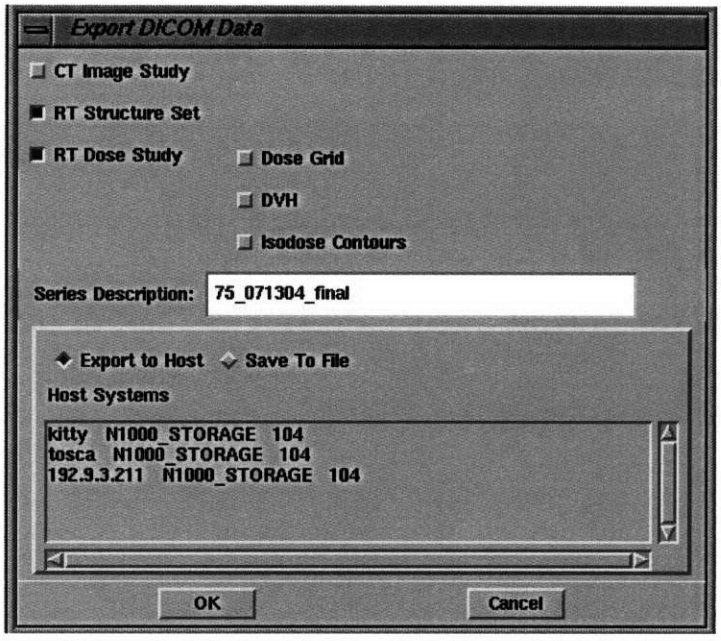



**Figure 33 Export DICOM Data from the UCC**



477

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



## Other Studies

To export a medical image that is not a CT study is a little more difficult, because you cannot use the treatment planning system to perform this operation. Instead you need to use the command-line controls.

**Step 1.** On the UCC, log in as cks and open a shell using the right mouse-click in the dark blue background.

**Step 2.** Go to the patient database directory by typing pats

```
>> pats
```

**Step 3.** Go to the desired medical image directory.

```
>> cd <patient_name>_<med_id>/ct/patient/<image_name>/
<image_modality>
```

The *image modality* can be CT, MR, XA, or PT.

**Step 4.** Type the command to send to the image. For example, if the AE_TITLE of CyRIS InView is *TPS*, the command is:

```
>> /accuray/tools/dicom/send_image -a N1000_STORAGE -c
<TPS_PW_ae_title> <TPS_PW_ip_address> 104 n*
```

*CKS_PW_ip_address* is the TP address of CyRIS InView and TPS_PW_ae_title is the AE_TITLE of the DICOM server on the CyRIS InView and that n is the first number in the listed image instance UID's and that the * is a character that tells the computer to push all images that begin with the alphanumeric *n*.

# Deleting Images

To delete a case from the patient database, click **DELETE** from the MIRIT main screen. The delete image dialog (*Figure 34 Select Case to Delete, page 26*) will appear. Select the patient case you want to delete. A list of image studies will appear. Highlight the case to delete and click **OK**. The Delete Confirmation window will appear (*Figure 35 Delete Case Confirmation, page 26*) to prompt you to confirm the deletion. Click **OK** and everything listed under this case will be deleted. If the case is deleted, a window will appear that informs you of the successful deletion. If the case could not be deleted, an error message will appear. Image studies cannot be deleted if the CT study was used to create a deliverable treatment plan or to generate DRRs.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



**NOTE:** Multiple modalities, such as CT, MR and RTSS, with the same study UID could exist as part of the same case. Thus, when you delete a case, it is possible that you will delete CT and MR images as well as RTSS instances.

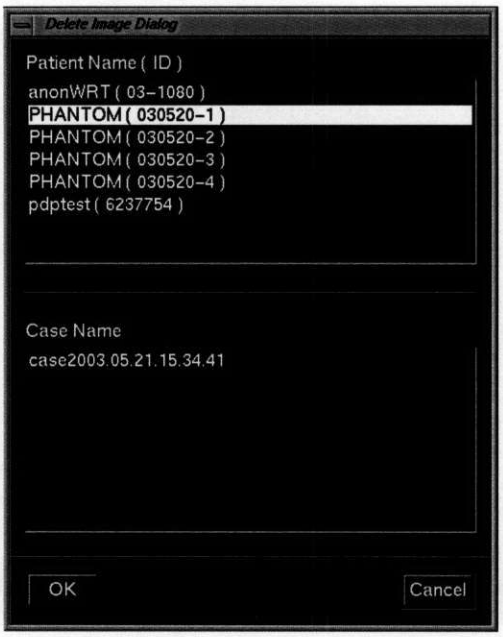



**Figure 34 Select Case to Delete**

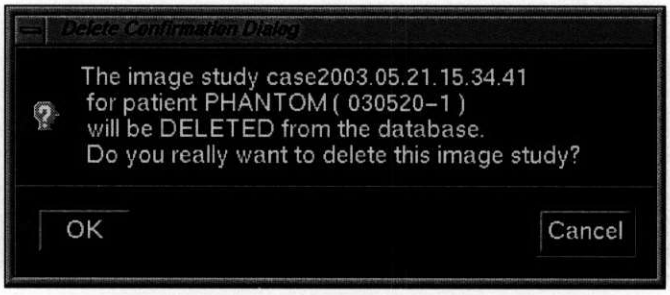



**Figure 35 Delete Case Confirmation**

## Reloading Images for Incomplete Loaded Images

To reload an image, you must first delete the image (see *section, Deleting Images, page 25*). Then you can reload the image using the method described in *section, Adding New Images, page 18*.

**NOTE:** Case name will be different because the image case name is based on a time stamp of when the image was loaded to the CyberKnife patient database.



479

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



# System Administration
## Table of Contents

Add New User ..... 1
Delete User ..... 6
Change User Status ..... 7
User Preference, Changing Password ..... 8
Database Backup ..... 10
Restore Database ..... 13
Print Screen ..... 17
Remote Diagnostics ..... 18
Computer Shutdown ..... 19



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118 480

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015







Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



# SYSTEM ADMINISTRATION

This module gives information for performing CyberKnife® System computer administration tasks, such as adding or deleting a user, changing user status, database backup, restoring the database, print screen and computer shutdown. In addition, this section describes how users can change their passwords.

## ADD NEW USER

The designated CyberKnife computer administrator enters the names and access permissions for users of the CyberKnife System and assigns and changes the access level of the user. The access level limits the access to various console computer functions of the system. The levels of access are as follows:

**Level 1**
Limited to activating the **PATIENTS**, **CTS**, **EQUIP POWER**, **PRESCRIPTION** and **TREATMENT** buttons of the CyberKnife System menu.

**Level 2**
Access to all buttons except **DRRS**, **PHYSICS and** the Administration menu Computer Submenu User buttons on the CyberKnife System menu.

**Level 3**
Full access to all functions of the CyberKnife System menu.

### CyberKnife System Menu -> CyberKnife Users -> New User -> Password and Access Level Verification -> Status Messages

**Step 1.** Click the **ADMINISTRATION** item in the menu bar on the CyberKnife System menu. (*Figure 1 CyberKnife System Menu with Computer Submenu Visible, page 2*) A submenu appears.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118 482

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



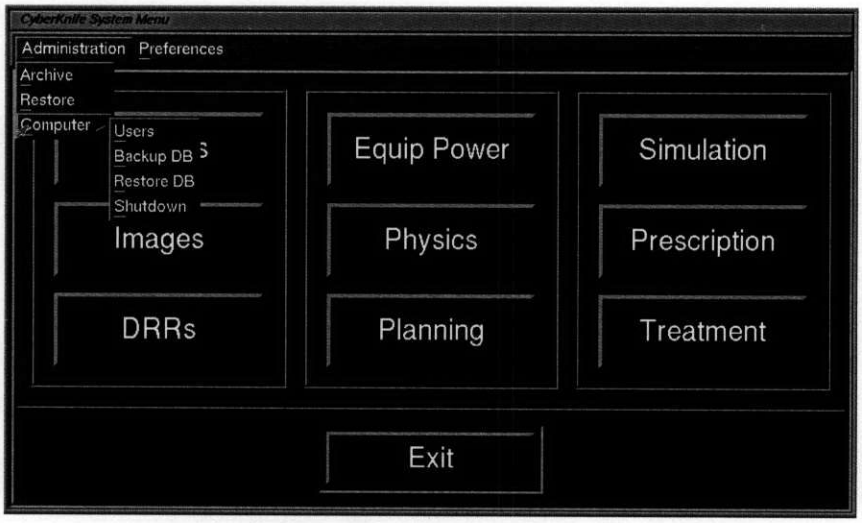



**Figure 1 CyberKnife System Menu with Computer Submenu Visible**

**Step 2.** Click the **COMPUTER** item. Another submenu appears.

**Step 3.** Click the **USERS** item. The CyberKnife System menu disappears and the CyberKnife Users window (*Figure 2 CyberKnife User's Menu, page 2*) appears. A list of users is displayed in this window.

**Figure 2 CyberKnife User's Menu**

**Step 4.** Click the **ADD USER** button and the New User window (*Figure 3 New User Screen, page 3*) appears. Clicking **CANCEL** on the Add User window returns you to the CyberKnife System menu. Click in the New User text area to activate the text area. The 'I' shaped text pointer appears in the text area.



483

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



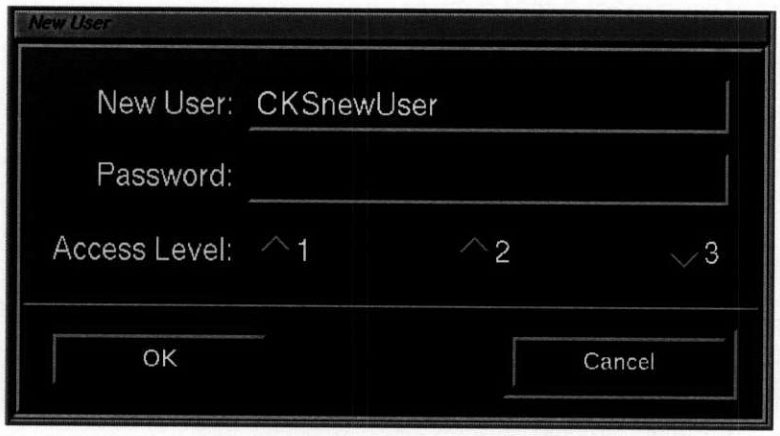



**Figure 3 New User Screen**

**Step 5.** Type in the name of the user. Do not use blanks or start a name with a numeric character. Press <Enter>.

**Step 6.** Type in the password. The cursor moves when a character is typed, but no character is displayed in the Password box. This is a form of password protection. When done, press <Enter>. The pointer moves to the **ACCESS LEVEL** buttons. Select the desired access level.

The access levels are categorized in the following way:

**Access Level 1: Operator**

- Treatment
- Add patient
- Load CT/ MIRIT
- Prescription
- Preferences->Password

**Access Level 2: Administrator**

- Treatment
- Add patient
- Patient archive
- Patient restore
- Database backup
- Database restore
- Administration -> computer -> shutdown
- Preferences->Password



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118 484

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



**Access Level 3: Super User**

- Treatment
- Simulation
- Linac calibration
- Treatment planning
- Add patient
- Load CT/MIRIT
- DRR generation
- Prescription
- Physics
- Patient archive
- Patient restore
- Administration ->computer -> users
- Database backup
- Database restore
- Administration ->computer -> shutdown
- Preferences -> passwd

**Step 7.** Click **OK**. The Password and Access Level Verification window (*Figure 4 Password and Access Verification Screen, page 4*) appears. Clicking **CANCEL** on the New User window redisplays the CyberKnife System menu.

**Figure 4 Password and Access Verification Screen**

**Step 8.** Move the pointer into Verify Password text area. Type in the password. Visually check the access level. If the information is not accurate, click **CANCEL** to return to the New User window.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



**Step 9.** Click **OK**. The Status Message (*Figure 5 New User Status Message, page 5*) informs you that the new user data is being entered into the CyberKnife System database. Clicking **OK** on the Status Message redisplays the CyberKnife Users window. The new user name and access level are displayed in the User list area.

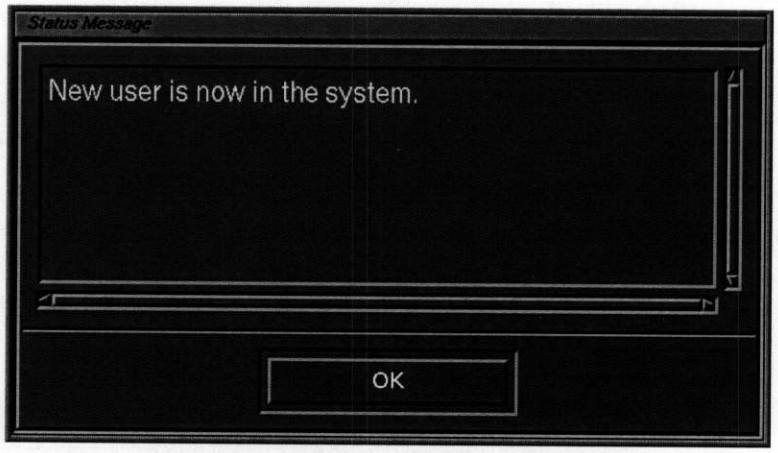



**Figure 5 New User Status Message**

### Errors

Any errors appear in the Error Message. Follow the instructions and click **CONTINUE** to return to the appropriate window for corrections.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

486

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



# DELETE USER

Data for users who can no longer have access to the CyberKnife System should be deleted from the CyberKnife database. Only a user with Level 3 access can delete a user from the system.

**CyberKnife System Menu -> CyberKnife Users -> Verify Selection -> Access Level -> Status Messages**

**Step 1.** From the CyberKnife Users window, select the name of the user to delete.

**Step 2.** Click the **DELETE USER** button and the Confirmation Message (*Figure 6 Delete User Confirmation Message, page 6*) appears. The system prompts you to verify that the correct item will be deleted.

**Step 3.** Click **YES** to delete the selected user and the Status Message appears with a message confirming the deletion of the user. Click **OK** to return to the CyberKnife Users window. If you click **NO** in the Verify Selection window, no action is taken and the CyberKnife Users window reappears.

**Figure 6 Delete User Confirmation Message**

### Errors

If any errors are displayed in the Error Message. Follow the instructions and click **CONTINUE** to return to the appropriate window for corrections.



487

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



# CHANGE USER STATUS

A user's password and access level can be changed as needed. Any user with Level 3 access can perform this activity.

**CyberKnife System Menu -> CyberKnife Users -> Change User's Password and Access Level -> Password and Access Level Verification -> Status Messages**

**Step 1.** From the CyberKnife Users window, click the name of the user. This selects the item for changes to password or access level.

**Step 2.** Click the **CHANGE** button. The CyberKnife Users window disappears and the Change User's Password and Access LeveL window (*Figure 7 Change User's Password and Access Level, page 7*) appears. This window displays the user's name and access level.

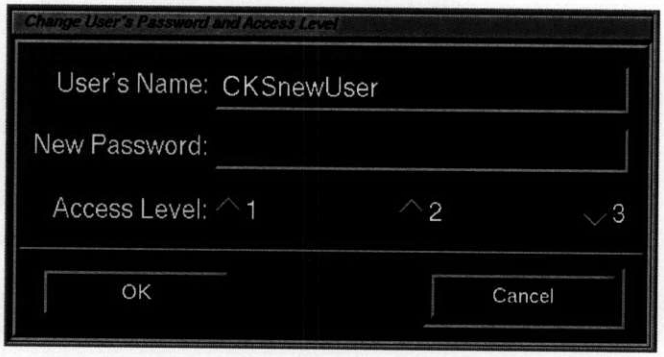



**Figure 7 Change User's Password and Access Level**

**Step 3.** Move the cursor into the New Password text area and type in the password. Click the desired access level button. This selects the new access level.

**Step 4.** Click **OK** and the Password and Access Level Verification window (*Figure 4 Password and Access Verification Screen, page 4*) appears. Type the new password in the Verify Password text area. Visually verify the access level. If the information is not correct, click **CANCEL** to return to the Change User's Password and Access Level window.

**Step 5.** If the data is correct, click OK and the STATUS MESSAGE appears. This window informs you that the changes have been incorporated into the CyberKnife database. Clicking **OK** on the Status Message redisplays the CyberKnife System Menu.

### Errors

Any errors are displayed in the Error Message. Follow the instructions and click **CONTINUE** to return to the appropriate window for corrections.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



# USER PREFERENCE, CHANGING PASSWORD

This subsection allows any user to change their password.

**CyberKnife System Menu -> Password -> Status Message**

**Step 1.** Click the **PREFERENCE** button in the menu bar on the CyberKnife System menu. The **PASSWORD** button appears.

**Step 2.** Click the **PASSWORD** button and the Password window (*Figure 8 Change Password Window, page 8*) appears.

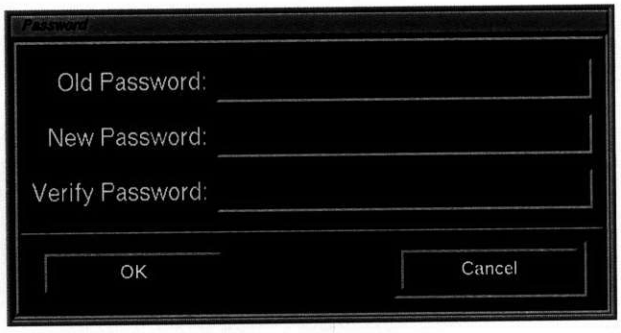



**Figure 8 Change Password Window**

**Step 3.** Type in the old password in the Old Password text area. Notice that no characters appear on the screen when the password is entered, but that the cursor moves. The characters are present but hidden for security. Use the <Delete> and <Backspace> keys to make corrections in the text. When the password is entered, press <Enter>. The 'I' shaped text pointer moves to the New Password text area. To return to the CyberKnife System menu at any time from the Password window, click **CANCEL**. No changes will be made to the CyberKnife System database.

**Step 4.** Type in the new password. When finished, press <Enter>. The text pointer moves to the Verify Password text area.

**Step 5.** Type in the new password. When finished, click **OK**. The Password window disappears and the Status Message (*Figure 9 Password Changed Status Message, page 9*) appears with a message that the new password is accepted.

**Step 6.** Click **OK** on the Status Message to redisplay the CyberKnife System menu.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

489

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



### Errors

Any errors are displayed in the Error Message. Follow the instructions and click **CONTINUE** to return to the appropriate window for corrections.

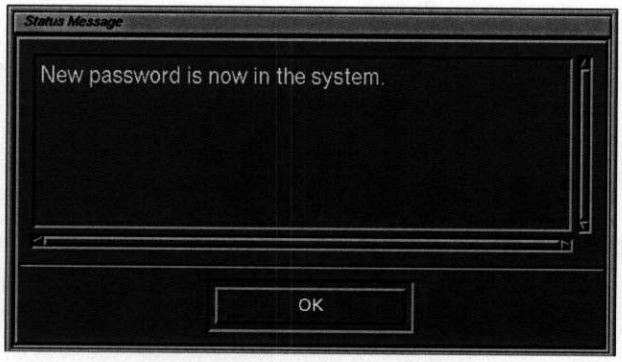



**Figure 9 Password Changed Status Message**



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



# DATABASE BACKUP

This procedure allows you to backup the CyberKnife System database and all configuration data files to 12 GByte DAT tapes.

**NOTE:** You should make a periodic backup to protect your data in case of disk corruption.

**Step 1.** Click the Administration menu in the menu bar of the CyberKnife System menu. The Administration submenu appears.

**Step 2.** Click the Computer menu to bring up the submenu.

**Step 3.** Click **BACKUP DB**. The CyberKnife System Database Backup window (*Figure 10 CyberKnife System Database Backup Screen, page 12*) appears.

**Step 4.** Follow the instructions displayed in the CyberKnife System Database Backup window. The following message is shown:

Backup CyberKnife System database

==========

Calculating size of your database...

You have xxx Megabytes of data. It will take about xx minutes and need x tapes (12 Gigabyte).

Insert new tape into tape drive and Press <Enter> key to continue or type in 'q' to abort this backup.

where **xxx** = the number of megabytes of data

**xx** = the approximate number of minutes to backup the database

**x** = the number of tapes needed to backup the database





Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



**Step 5.** If a new tape is placed into the tape drive, the system begins to backup the database to tape.

**Step 6.** If a used tape is placed into the tape drive, one of the following messages may be displayed:

a. Tape is write-protected. Set it to unsafe mode and insert the tape back into the drive.

b. Tape drive has Patient Archive data tape. Do you want to overwrite this tape? [y=yes, n=no, q=quit]

c. Tape drive has Unknown data tape. Do you want to overwrite this tape? [y=yes, n=no, q =quit]

d. Tape drive has Database backup tape. Do you want to overwrite this tape? [y=yes, n=no, q=quit]

When you see message 6a, remove the tape from the drive and set the write-protect tab to unlocked position.

When you see messages 6b, 6c, or 6d, make sure the data is not needed before you overwrite the tape. For the questions with the options of yes (y), no (n), or quit (q):

- If you specify **Y**, the backup software overwrites the tape and continues to backup.
- If you specify **N**, the backup process asks you to insert new tape into the tape drive and press <Enter>.
- If you specify **Q**, the system returns to the main menu on the CyberKnife System Database Backup window.

**Step 7.** When the backup is completed successfully, follow the instructions in the window. The following is the message displayed:

Backup completed successfully.
Remove the tape from the drive and make sure to put a label on the tape.
Press <Enter> key to return to CyberKnife System menu.

The CyberKnife System menu appears and the database backup disappears.

**NOTE:** f problems occur while transferring data to tape, clean the tape drive head with a standard cleaning tape. To avoid problems due to dirty tape drive heads, clean the tape drive once a month.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118 

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



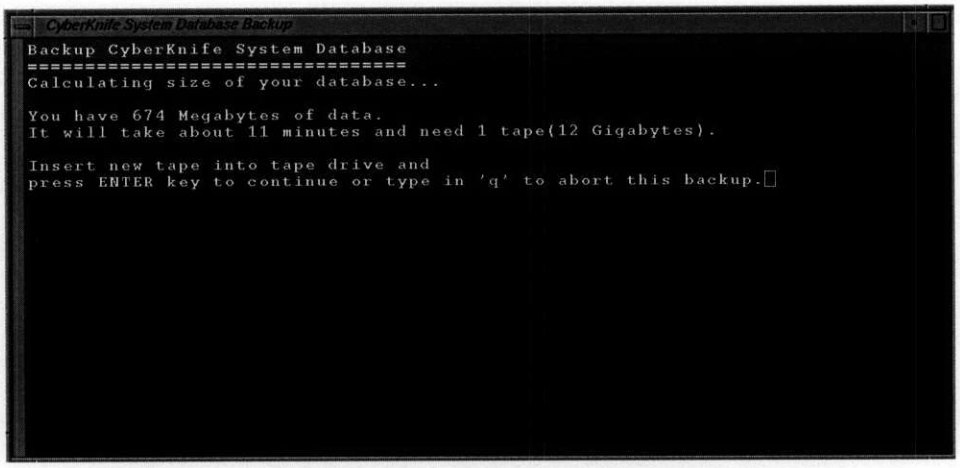



**Figure 10 CyberKnife System Database Backup Screen**



493

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



# RESTORE DATABASE

This procedure allows you to restore the CyberKnife System database and the configuration data files from the backup tape. This procedure replaces your database and configuration data files with the backup you made previously.

**CAUTION:** When you start this process, make sure you really want to do this. Once it starts, it removes the current database and configuration data files and replaces them with your backup. It is impossible to recover the removed database! Consult your System Administrator/Database Administrator before doing this.

**Step 1.** Click the **ADMINISTRATION** selection in the menu bar on the CyberKnife System menu to activate the submenu.

**Step 2.** Click **COMPUTER** and another submenu appears.

**Step 3.** Click **RESTORE DB**. The CyberKnife System Database Restore window (*Figure 11 CyberKnife Restore System Database Screen, page 13*) appears.

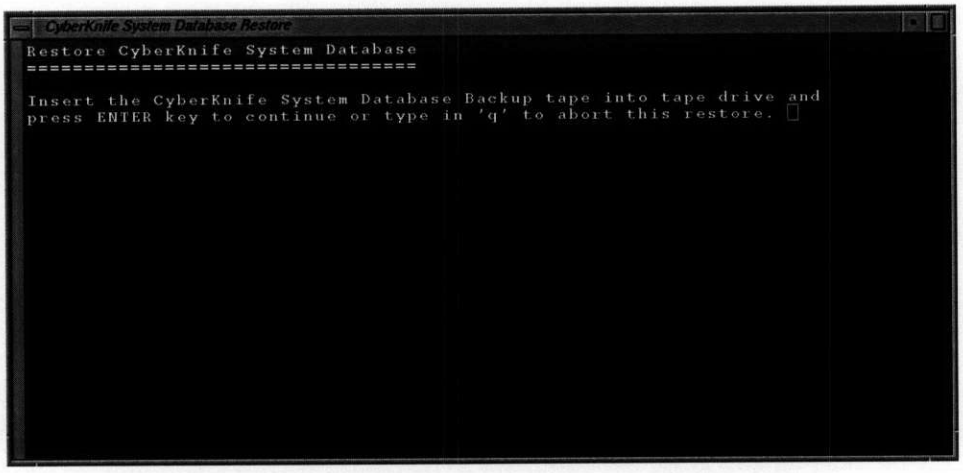



**Figure 11 CyberKnife Restore System Database Screen**

**Step 4.** Follow the instructions shown in the CyberKnife System Database Restore window. The following message appears:

Restore CyberKnife System database

==========

Insert the CyberKnife System Database Backup tape into tape drive and press the <Enter> key to continue or type in 'q' to abort this restore.

**NOTE:** To abort the restore process, type 'q' and press <Enter> to return to the CyberKnife System menu.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



**Step 5.** The restore process verifies the data on the tape. It displays the result of verification and one of the following messages are shown:

a. This tape contains no data.

b. Tape not found in the tape drive.

c. Tape drive has Patient Archive data.

d. Tape drive has Unknown data tape. Insert the CyberKnife System Database Backup tape into tape drive and press the <Enter> key to continue or type in 'q' to abort this restore.

e. Tape drive has Database backup tape. Do you want to restore this tape? [y=yes, n=no, q=quit]





Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



When the restore process checks the database backup tape, message 6e appears.

- Type in 'y' and press <Enter> to continue restoring the database.
- If you specify 'n' and press <Enter>, put in another tape.
- If you specify 'q' and press <Enter>, follow the instructions on the screen. The following messages appear.

Restore aborted.
Press <Enter> key to return to CyberKnife System Menu.

If any other messages are displayed, correct the problem and insert the database backup tape into the tape drive and follow the instructions on the screen. Before restoring information from the tape, the following warning messages are displayed on the screen.

***WARNING: You can not stop Restoring process from this point.
***WARNING: This process will erase all CyberKnife System Database

and

***WARNING: restore it from this tape.
***WARNING: Once this process starts, you can not stop this process.
***WARNING: After restoring is completed, CyberKnife System will be shutdown automatically.
Are you sure to continue? [y=yes, n=no]
Type in 'y' to continue with the tape in the drive, or 'n' to abort this process.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118 

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



Once the restoring process has begun, the following messages are displayed:

Note:==========
When your CyberKnife System Database can not be contained on one tape, you will see the following messages on this screen when the first tape is fully read:
Reached end of medium on input.
If you want to go on, type device/file name when ready:
When you see this message, insert the next tape into the tape drive, type in "/dev/tape" and press <Enter> key at the prompt.
==========

Restoring CyberKnife System Database...

When you are instructed to put in the next tape, remove the tape from the tape drive and put the next tape into the drive. Using the keyboard, type in /dev/tape and press <Enter>.

The following message appears at the end of a successful restoration:

Restore completed successfully.
Press <Enter> key to return to CyberKnife System Menu.

When you press <Enter>, the CyberKnife System deactivates all buttons from the CyberKnife System menu except **EXIT**. The system needs to be restarted. Click **EXIT** and continue to log off the CyberKnife software.

Log in again to view the restored database.





Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



# PRINT SCREEN

**CAUTION:** Do not press the **PRINT SCREEN** key while treating a patient. The screen capture process needs extensive computer resources; the normal treatment process may be interrupted.

There are two ways to print displays from screens. The easiest way is by clicking the **PRINT SCREEN** key, which prints the full screen and sends it to your default printer as a postscript file. The other way is to take a snapshot of a selected area of your screen and send it to your default printer. Consult your System Administrator to setup your default printer.

**Step 1.** Right-click over the background screen to reveal a hidden menu. Select the **SAVE IMAGE** button (*Figure 12 CyberKnife Hidden Buttons, page 17*). The **SNAPSHOT** button appears at the bottom left of the screen (*Figure 13 Snapshot Button, page 17*).

**Figure 12 CyberKnife Hidden Buttons**

**Step 2.** Position the pointer over the **SNAPSHOT** button and press the <Shift> key or middle mouse button. A special pointer appears in the shape of a camera.

**Figure 13 Snapshot Button**

**Step 3.** While still holding the **SHIFT** key or middle mouse button, move the camera pointer over to the starting point of the area to be captured, generally a corner. Click and hold the left mouse button. The pointer changes to a corner shape. Once the left mouse button is held, the <Shift> key or middle mouse button can be released.

**Step 4.** Left click, hold and drag a box around the area to be captured. When you've outlined the area, release the mouse.

**Step 5.** Click **PRINT IMAGE** to print the snapshot of the selected area.

**Step 6.** Click **EXIT** to exit the Snapshot.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118 498

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



# Remote Diagnostics

**CAUTION:** Do not select any of the transfer options while treating a patient. The data collection process may interrupt the normal treatment process.

Accuray provides four options to transfer system information using the Transfer Options menu. The purpose of collecting and transferring system information, is to help an Accuray Service Engineer better understand a particular problem.

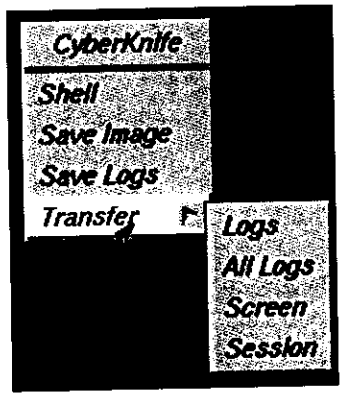



**Figure 14 CyberKnife System Transfer Options**

**Logs** used to transfer a subset of the CyberKnife System logs. The subset includes the log files that are most likely to reveal the system problem.

**All Logs** used to transfer all CyberKnife System logs.

**Screen** used to transfer the active visible interface. This gives an Accuray Service Engineer a view into a particular local problem.

**Session** used to transfer all information needed for an Accuray Service Engineer to reproduce the current imaging environment. Files that are transferred include the patient DRR's and the last pair of live images captured.





Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



# COMPUTER SHUTDOWN

Use these steps to shut down the user console computer for computer maintenance. You must use an account with Access Level 2 or 3 to shut down the console computer.

**Step 1.** Click the **ADMINISTRATION** selection menu bar on the CyberKnife System menu. The Administration submenu appears.

**Step 2.** Click the **COMPUTER** selection. Another submenu appears.

**Step 3.** Click the **SHUTDOWN** selection. The Confirmation Message (*Figure 15 Computer Shutdown Warning Message, page 19*) appears. Follow the instructions shown in this window. The window presents the following messages.

You are about to shut down the computer.
It will be safe to turn off the Computer after:
All CyberKnife screens disappear and
The Computer System Maintenance Menu appears.
CyberKnife System power will automatically be turned off.
Do you really want to shut down the user console computer?"

**Step 4.** To shut down the computer, click **YES**.

**Step 5.** Wait until the Computer System Maintenance Menu appears.

**Step 6.** When you see the Computer System Maintenance Menu, it is safe to turn the power off.

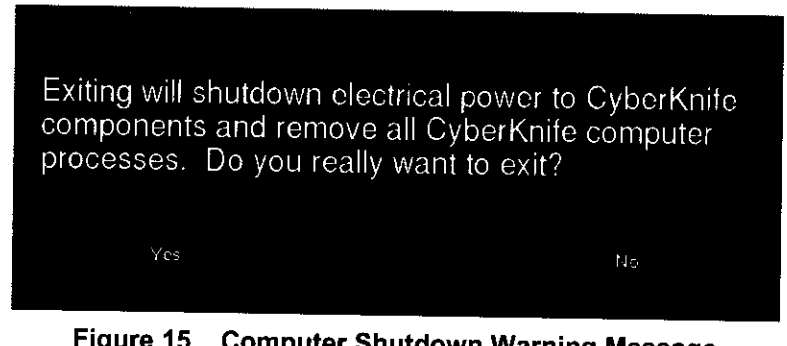



**Figure 15 Computer Shutdown Warning Message**



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118 500

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015





Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

501

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



# Patient Archive and Restore System
## Table of Contents


Introduction ..... 1
User Login ..... 1
Main Patient Archive and Restore System Screen ..... 2
General Use of the Patient Archive and Restore System ..... 3
Disk Space View ..... 3
Title Bar ..... 4
Status Bar ..... 4
Folder List ..... 5
Patient List View ..... 6
Action Bar ..... 6
Action Tabs ..... 7
View ..... 7
Archive ..... 9
Archive to Online Storage ..... 10
Copy To DVD ..... 11
Restore ..... 13
Restore From Online Storage ..... 13
Restore From DVD ..... 15
Maintenance ..... 17
Online Patient Record Deletion ..... 17
Patient Record Identification ..... 18




Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118 502

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015





503

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



# PATIENT ARCHIVE AND RESTORE SYSTEM

## INTRODUCTION

This module explains the operational procedures for the CyberKnife® Patient Archive and Restore System. The Patient Archive and Restore System consists of a PC with a DVD burn device located on the CyberKnife LAN, that allows users to perform patient record archive and restore operations.

The Patient Archive and Restore System supports archiving to the PC hard drive and to DVD. Both DVD+R and DVD+R Dual Layer disks are supported.

To start using the Patient Archive and Restore System, double-click the CyberKnife program icon to launch the application. When the application is launched the Login screen is displayed.

### User Login

The user login interface provides two fields to capture a user's id and password.

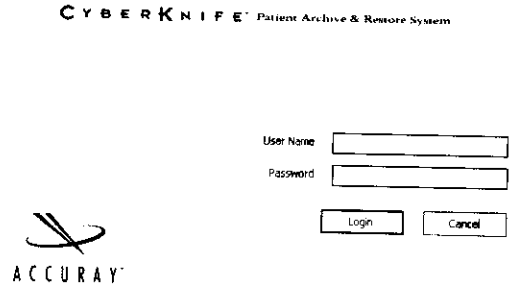



**Figure 1 Login screen**

**Step 1.** Type in your User Name.

**Step 2.** Type in your Password, click the **LOGIN** button.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



# Main Patient Archive and Restore System Screen

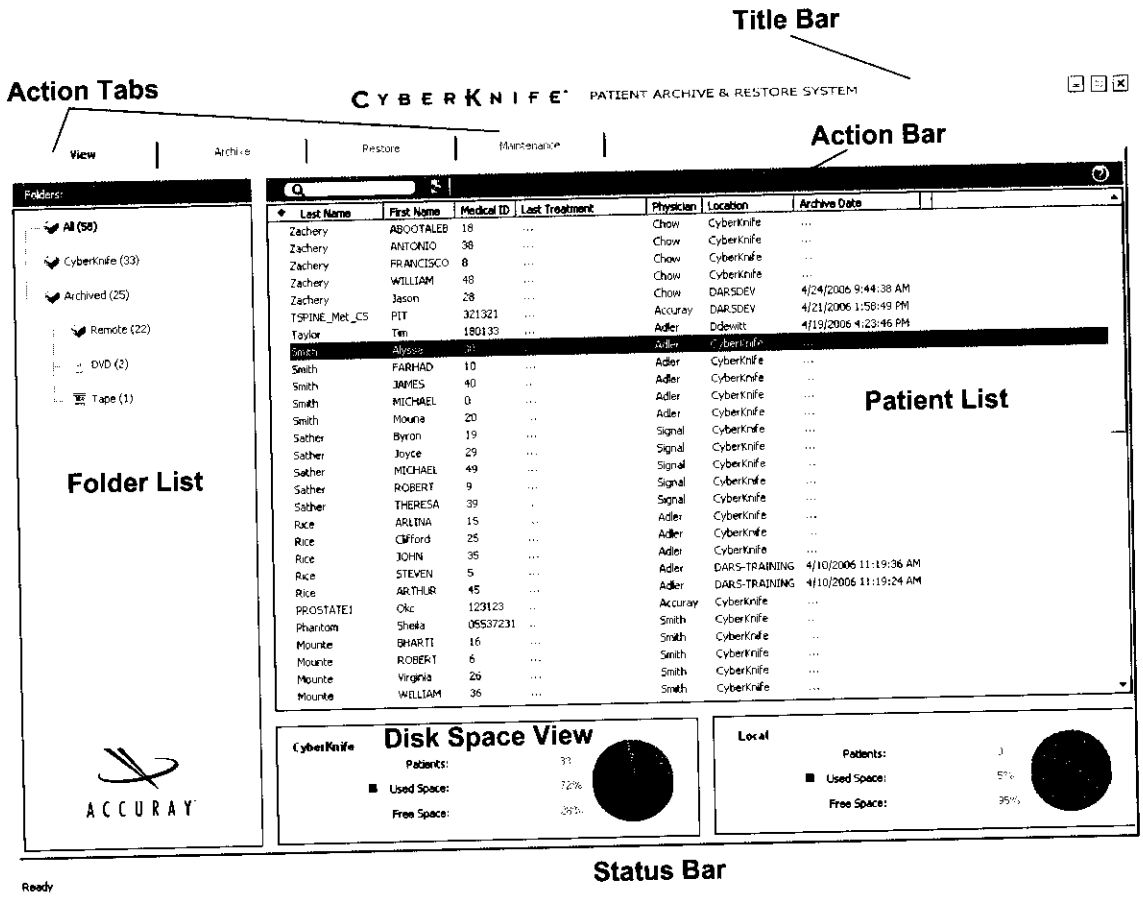



**Figure 2 Main Patient Archive and Restore System screen**

After logging in, the Main Interface is displayed. It consists of the following:

- Title Bar
- Action Tabs
  - View
  - Archive
  - Restore
  - Maintenance
- Action Bar
- Folder List
- Patient List
- Disk Space View
- Status Bar



505 Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



# General Use of the Patient Archive and Restore System

Once the user logs in the All folder is selected, and the system displays a list of all patients and the current location of their patient record. The list includes the following data:

- Last Name
- First Name
- Medical ID
- Last Treatment
- Physician
- Location of the patient record
- Archive Date

Several options are available on the system:

1. Sort the patient list by selecting the header of any of the displayed data.
2. Find a patient using the search tool on the action bar.
3. Filter the patient list by selecting a folder.
4. Archive, restore or perform maintenance on patient records.

## Disk Space View

The system provides a visual indication of the amount of space being utilized on the main CyberKnife database and on the local hard drive.

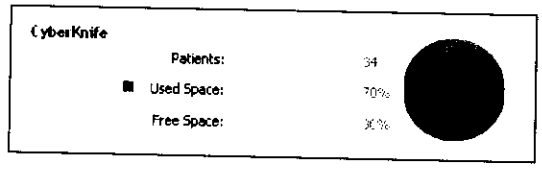



**Figure 3 Disk Space View**

**NOTE:** If the CyberKnife or the local disk space used exceeds 90%, a warning appears.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



## Title Bar

The title bar displays the product name, and provides **MINIMIZE**, **MAXIMIZE**, and **EXIT** buttons. The **MINIMIZE** button hides the main page from the user, the **MAXIMIZE** button expands the application until the desktop is filled. The **EXIT** button initiates application exit.

**Figure 4 Title Bar**

**NOTE:** If the **EXIT** button is selected during an active archive or restore session, the system displays a warning message that exiting the application will cancel the active session. Users must either confirm or cancel the exit request. If the exit request is confirmed, the system cancels the active session and closes the application. If the exit request is cancelled, the system returns to complete the active session.

## Status Bar

Provides a section to display text feedback, a scrolling progression bar used to indicate activity, and a screen drag button.

**Figure 5 Status Bar**



507

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



# Folder List

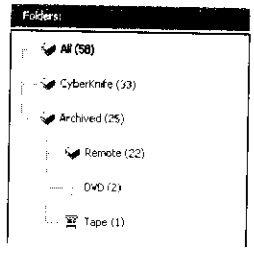



**Figure 6 Folder List**

Provides selectable folders that represent locations of CyberKnife patient records. The number in ( ) next to the folder name indicates the total number of patient records stored in that folder. There are seven selectable folders:

- **All**

  Combination of patient records included in both the Archived and the CyberKnife folders.
- **CyberKnife**

  Patient records stored on the CyberKnife database.
- **Archived**

  Combination of patient records archived to Local, Remote, DVD, and Tape.
  - **Local**

    Archived patient records stored on local hard drive.
  - **Remote**

    Archived patient records stored on other Patient Archive and Restore System hard drives.
  - **DVD**

    Archived patient records stored on DVD's.
  - **Tape**

    Archived patient records stored on Tape.



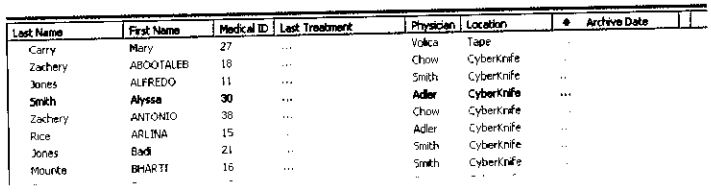
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118 508

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



# Patient List View

Displays the patient records associated with a selected folder. For each patient the system displays: last name, first name, medical id, physician, last treatment date, record location, and the archive date. You can sort the patient list by clicking on the column header of the field to be sorted by.



| Last Name | First Name | Medical ID | Last Treatment | Physician | Location | Archive Date |
|---|---|---|---|---|---|---|
| Carry | Mary | 27 | ... | Volica | Tape | |
| Zachery | ABOOTALEB | 18 | ... | Chow | CyberKnife | |
| Jones | ALFREDO | 11 | ... | Smith | CyberKnife | |
| Smith | Alyssa | 30 | ... | Adler | CyberKnife | ... |
| Zachery | ANTONIO | 38 | ... | Chow | CyberKnife | |
| Rice | ARLINA | 15 | | Adler | CyberKnife | |
| Jones | Badi | 21 | | Smith | CyberKnife | |
| Mounte | BHARTI | 16 | ... | Smith | CyberKnife | |

**Figure 7 Patient List View**

# Action Bar

Provides capabilities that can be used for patients displayed in the patient list. The following actions are available on all views:

### Search Text Field

Allows a user to reduce the patient list to entries that contain text entered. For example if a user enters "X", the patient list is reduced to those entries starting with "X" in any of the fields.

### Help Menu

The Help menu contains an About menu item that displays information about the application.

**NOTE:** Actions specific to individual functions will be described in each function section of this manual.

**Figure 8 Action Bar**



509

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



# Action Tabs

## View

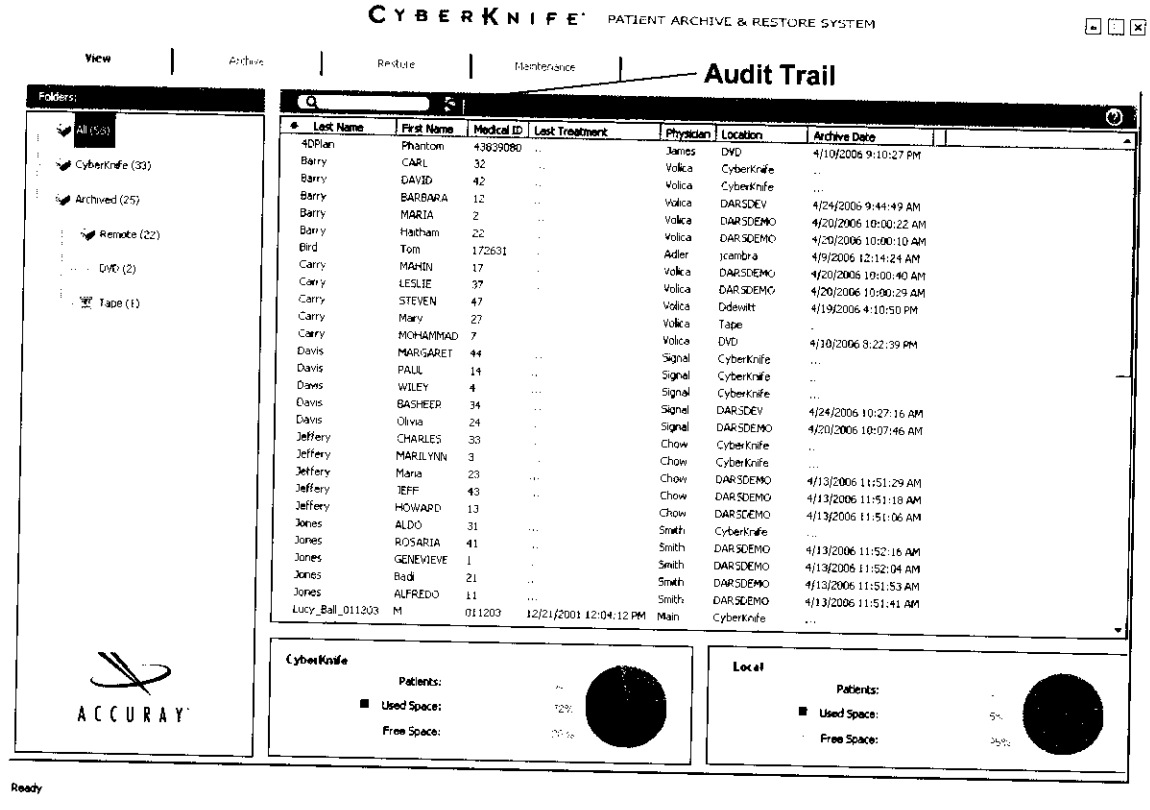



**Figure 9 View Screen**

When the View tab is selected, in addition to viewing the complete list of patients and the current location of their patient records, the user can view an audit trail of all Archive and Restore actions performed on a patient record. To view an audit trail select the **VIEW AUDIT TRAIL** icon on the Action bar. The Audit Trail view replaces the disk space (*Figure 10 Audit Trail View, page 8*), and the **VIEW AUDIT TRAIL** icon changes to the **HIDE AUDIT TRAIL** icon. Once the Audit Trail view appears, select a patient from the patient list. All Archive and Restore actions performed on the selected patient's record are displayed in the Audit Trail view.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



| | | | | | | |
|---|---|---|---|---|---|---|
| Jones | ALDO | 31 | ... | Smith | jcambra | 4/12/2006 11:13:57 AM |
| Lucy_Ball_011203 | M | 011203 | 12/21/2001 12:04:12 PM | Main | jcambra | 4/9/2006 2:41:21 AM |
| LUNG_left_NSC_C5 | Phx | 112233 | ... | Accuray | CyberKnife | ... |

| | Medical ID | Date | Action | User | Machine |
|---|---|---|---|---|---|
| 1 | 42 | 4/10/2006 7:24:41 PM | Archived to Local Drive | a | 10.20.22.84 |
| 2 | 42 | 4/10/2006 7:24:41 PM | Archived to Local Drive | a | 10.20.22.84 |
| 3 | 42 | 4/10/2006 7:24:41 PM | Archived to Local Drive | a | 10.20.22.84 |
| 4 | 42 | 4/10/2006 7:24:41 PM | Archived to Local Drive | a | 10.20.22.84 |
| 5 | 42 | 4/10/2006 7:24:41 PM | Archived to Local Drive | a | 10.20.22.84 |
| 6 | 42 | 4/10/2006 7:24:41 PM | Archived to Local Drive | a | 10.20.22.84 |

**Figure 10 Audit Trail View**

For each action listed the following information is provided:

- Medical ID
- Date & Timestamp of action
- Action performed
- User who performed action
- IP address of the machine where the action was performed.

When another patient is selected, the audit trail list clears, and the selected patient's audit entries appear. Hide the audit trail by selecting the **HIDE AUDIT TRAIL** icon. The disk space view becomes visible.



511 Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



# Archive

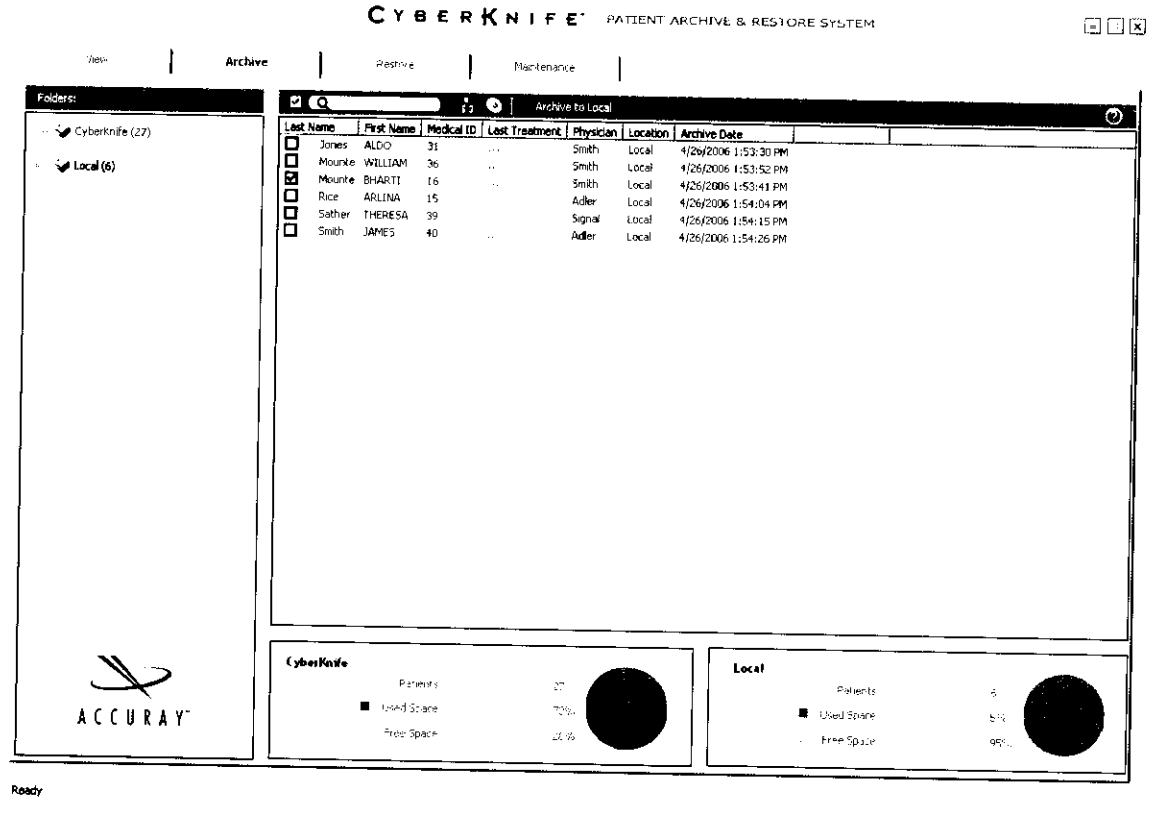



**Figure 11 Archive Screen**

The Archive tab provides a way to archive a patient record from the CyberKnife onto online storage, and a way to copy an archived patient record from online storage to DVD.

When the Archive tab is selected two icons are displayed in the Action bar which are Active or Inactive depending on which folder is selected. For instance, when the CyberKnife folder is selected, the **ARCHIVE TO LOCAL DRIVE** icon is active. When the Local folder is selected, the **COPY TO DVD** icon is active. In addition a **SELECT ALL** icon appears to the left of the search text field.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

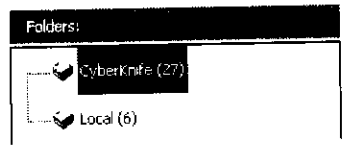
Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



## Archive to Online Storage

To archive a patient from the CyberKnife onto online storage:

**Step 1.** Select the CyberKnife folder.

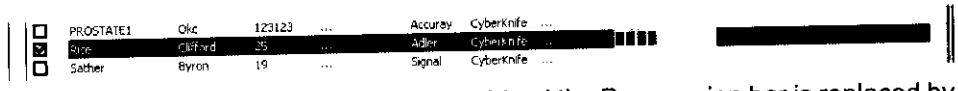



The Patient List view is updated to show patients whose records are located in the CyberKnife database.

**Step 2.** Select one or more patients and then select the **ARCHIVE TO LOCAL** icon located on the Action bar.

A patient can be selected by either double clicking the patient record, selecting the patient checkbox or selecting the **SELECT ALL** icon located on the Action bar. Deselect a patient by double clicking the selected patient, selecting a checked patient check box, or deselecting the **SELECT ALL** icon.

During the archive a Progression bar appears in the patient list view next to the patient whose record is being archived, and is updated as the patient files are copied from the CyberKnife to the local disk. The state of the operation is displayed in the Status bar.




Once the patient record has been successfully archived the Progression bar is replaced by a check mark. If more than one patient was selected for online archive, the system advances to archive the next patient record, displaying the Progression bar next to that patient's name. This continues until all selected patient records are archived. An archive can be canceled by selecting the **STOP** icon located on the Action bar. If the system fails to archive a patient record, the patient entry in the patient list view is highlighted red, and the Progression bar is replaced with an "X" mark. Following the online patient archive session a Report Summary dialog appears.

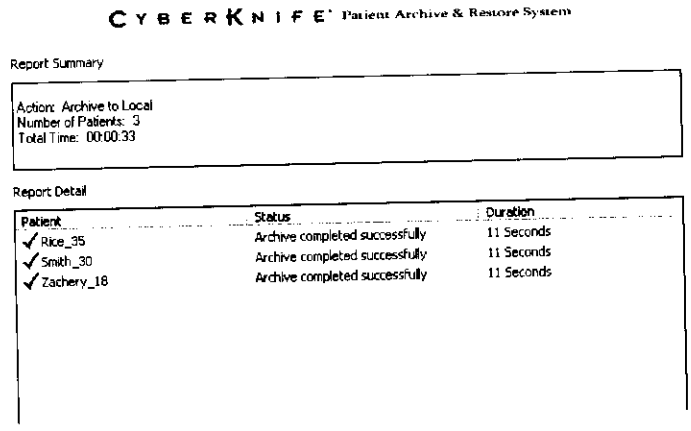



**Figure 12 Report Summary**

**Notification:** It is recommended that each archived patient record be copied onto DVD.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

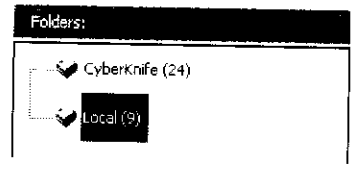
Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



## Copy To DVD

To copy an archived patient record to DVD from online storage:

**Step 1.** Select the Local folder.



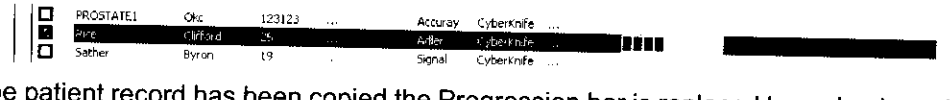

The Patient List view is updated to show patients whose records are located on the hard drive.

**Step 2.** Load a DVD into the DVD writer on the computer.

**NOTE:** Only one patient can be archived to a single DVD.

**Step 3.** Select one or more patients and then select the **COPY TO DVD** icon located on the Action bar.

During the copy a Progression bar appears in the patient list view, and is updated as the patient files are copied from local disk to the DVD. The state of the operation is displayed in the Status bar, and the Activity Progression bar is activated.




Once the patient record has been copied the Progression bar is replaced by a check mark. If more than one patient is selected to be copied to DVD, when the first patient record is completed the system will prompt the user to remove the DVD and insert another DVD. The system then advances to copy the next patient record to the DVD. This continues until all selected patient records are copied. Copy can be canceled by selecting the **STOP** icon located on the Action bar.

If the system fails to copy a patient record to DVD, the patient entry in the patient list view is highlighted red, and the Progression bar is replaced with an "X" mark. Following the offline patient archive session a Report Summary dialog appears.

It is recommended that the DVD be labeled with information to identify the patient who's record is copied there. If the user is unsure of the information stored on a DVD, use the Identify DVD feature described in *Maintenance, page 17*.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118 514

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



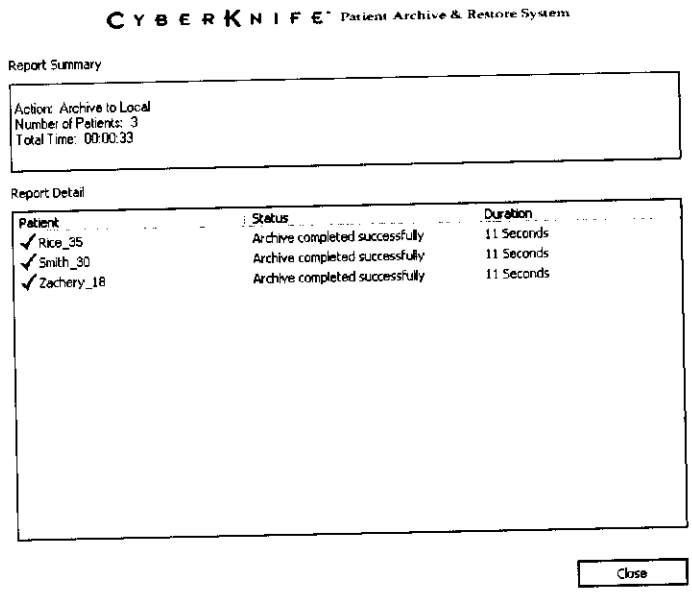



**Figure 13 Report Summary**

**NOTE:** Once an archived record has been copied to DVD, that record is now available on both the local hard drive and the DVD. A patient record can be copied to multiple DVD's. To remove the patient record from the local hard drive, refer to *Maintenance, page 17*.

**WARNING: Improper handling of DVD can cause data lost and/or corruption. Here are some general handling guidelines:**

**1. Hold the DVD on the outer edge or through the center hole to avoid fingerprints on the bottom of the DVD.**
**2. Avoid flexing the DVD when removing them from a player, recorder or a storage case.**
**3. Do not put excessive pressure on the center hub when inserting the DVD in its case.**
**4. Pick the DVD straight up from a flat surface; do not slide the DVD.**

**WARNING: Improper storage of DVD can result in data lost and/or corruption. Here are some general storage guidelines:**

**1. Optical discs should be kept in storage cases for protection against contaminants, light, or accidental scratches.**
**2. Storage cases should stand on their edges so that the disc hangs from its center hub.**
**3. The ideal storage environment should be cool, dry, and dark. 4° C (39° F) < Ideal storage range < 20° C (68° F).**





Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



# Restore

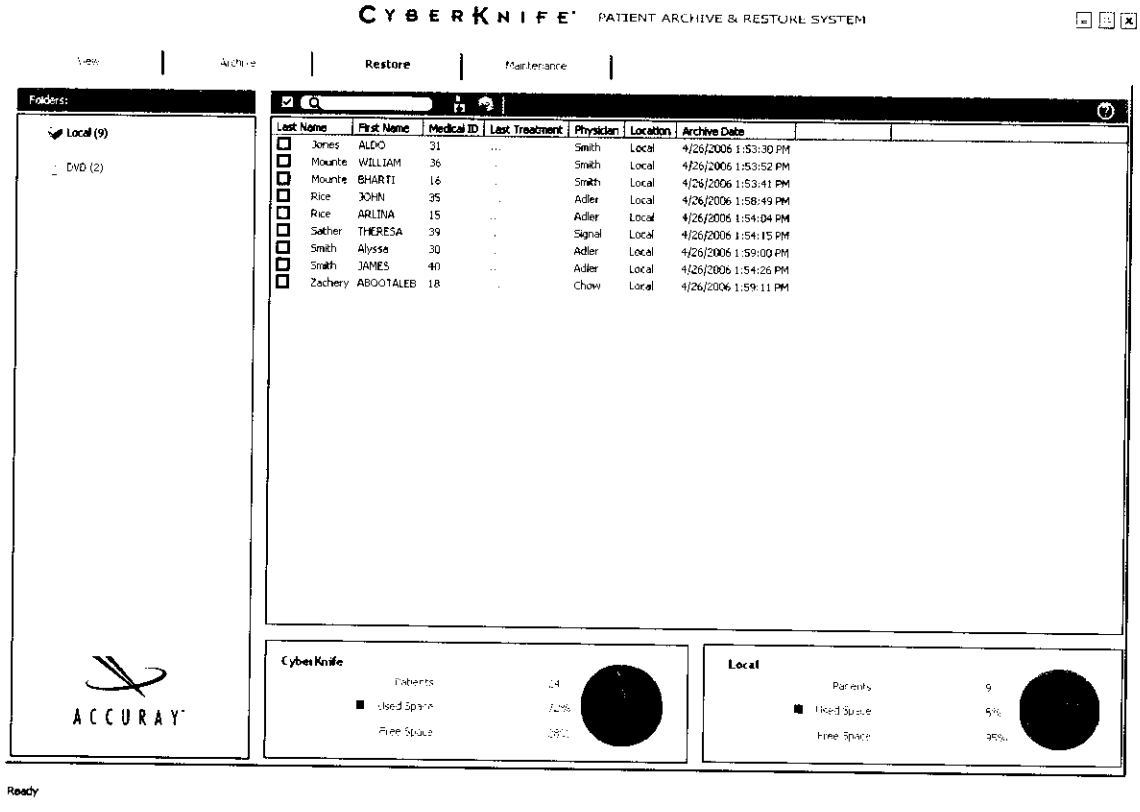



**Figure 14 Restore Screen**

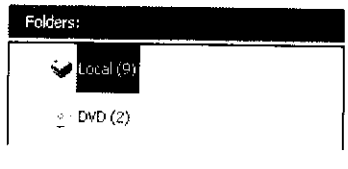
The restore tab provides a way to restore a patient record from either online storage or from DVD to the CyberKnife.

When the Restore tab is selected, two icons are displayed in the Action bar which are Active or Inactive depending on which folder is selected. For example, when the Local folder is selected, the **RESTORE FROM LOCAL** icon is active. When the DVD folder is selected, the **RESTORE FROM DVD** icon is active. In addition, a **SELECT ALL** icon appears to the left of the Search text field.

## Restore From Online Storage

To restore a patient to the CyberKnife from online storage:

**Step 1.** Select the Local folder.






Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118 516

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015

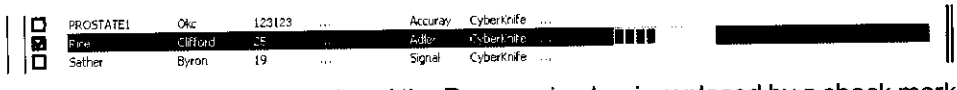


The Patient List view is updated to show patients located on the local hard drive.

**Step 2.** Select one or more patients and then select the **RESTORE FROM LOCAL** icon located on the Action bar.

A patient can be selected by either double-clicking the patient record, selecting the patient checkbox or selecting the **SELECT ALL** icon located on the Action bar. Deselect a patient by double clicking the selected patient, selecting a checked patient check box, or deselecting the **SELECT ALL** icon.

During restore a Progression bar appears in the patient list view, and is updated as the patient files are restored to the CyberKnife. The state of the operation is displayed in the Status bar.




Once the patient record has been restored the Progression bar is replaced by a check mark. If more than one patient was selected to restore, the system advances to restore the next patient record, displaying the Progression bar next to that patient's name. This continues until all selected patient records are restored. Cancel a restore by selecting the **STOP** icon located on the Action bar. If the system fails to restore a patient record, the patient entry in the patient list view is highlighted red, and the Progression bar is replaced with an X mark. Following the online patient record restore session a Report Summary dialog appears.

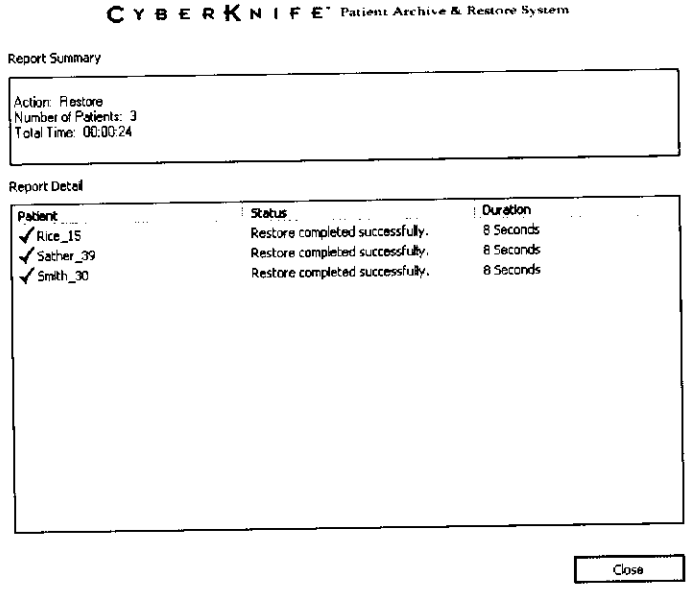



**Figure 15 Report Summary**



517

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



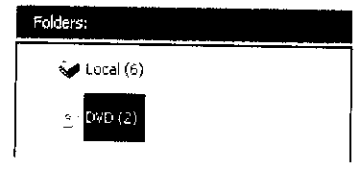
## Restore From DVD

To restore a patient record to the CyberKnife from DVD:

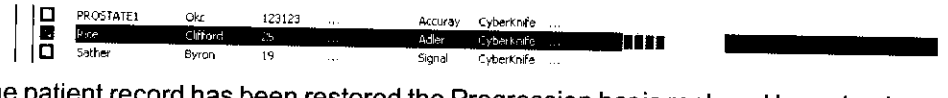
**Step 1.** Load a DVD into the DVD writer located on the computer.

**Step 2.** Select the DVD folder. The Patient List view is updated to show patients located on DVD.

**Step 3.** Select one or more patients and then select the **RESTORE FROM DVD** icon located on the Action bar.




During the restore a Progression bar appears in the patient list view, and is updated as the patient files are restored to the CyberKnife from DVD. The state of the operation is displayed in the Status bar.




Once the patient record has been restored the Progression bar is replaced by a check mark. If more than one patient is selected to be restored from DVD, when the first patient record is completed the system will prompt the user to remove the DVD and insert the next DVD to be restored. The system then advances to restore the next patient record from the inserted DVD. This continues until all selected patient records are restored. Cancel a restore by selecting the **STOP** icon located on the Action bar. If the system fails to restore a patient record, the patient entry in the patient list view is highlighted red, and the Progression bar is replaced with an "X" mark. Following the restore session a summary dialog appears.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



CYBERKNIFE Patient Archive & Restore System

Report Summary

Action: Restore
Number of Patients: 3
Total Time: 00:00:24

Report Detail

| Patient | Status | Duration |
|---|---|---|
| ✓ Rice_15 | Restore completed successfully. | 8 Seconds |
| ✓ Sather_39 | Restore completed successfully. | 8 Seconds |
| ✓ Smith_30 | Restore completed successfully. | 8 Seconds |

Close

**Figure 16 Report Summary "Restore from DVD"**

If the user is unsure of the information stored on a DVD, use the Identify DVD feature described in *Maintenance, page 17*.



519 Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



# Maintenance

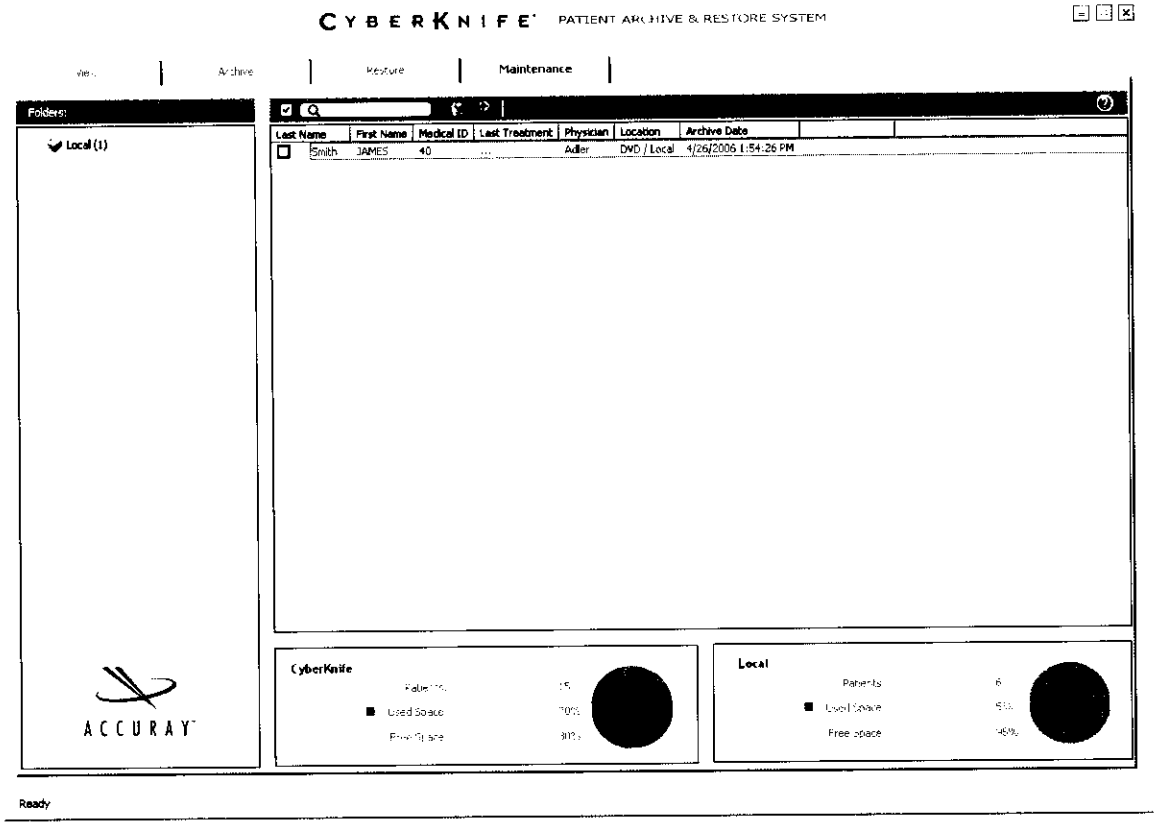



**Figure 17 Maintenance Screen**

The maintenance tab provides a way to remove local archived patient records that have been copied to DVD, and a way to identify an archived patient record located on DVD.

When the Maintenance tab is selected three icons are displayed in the Action bar; including a **SELECT ALL** icon, a **DELETE PATIENT RECORD** icon and an **IDENTIFY DVD** icon.

## Online Patient Record Deletion

To delete archived patient records from local hard drive:

**Step 1.** Select the Local folder. Archived patients located on the local hard drive that have been copied to DVD are listed.

**Step 2.** Select one or more patients and then select the **DELETE** icon located on the Action bar.

A patient can be selected by either double clicking the patient record, selecting the checkbox or selecting the **SELECT ALL** icon located on the Action bar. Deselect a patient by double clicking a selected patient, selecting a checked patient check box, or deselecting the **SELECT ALL** icon.



520

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



During the deletion a prompt appears requesting confirmation of the deletion. Either terminate the deletion session, skip to the next selected patient, or continue with the patient deletion. Following the deletion session a summary dialog appears.

## Patient Record Identification

To identify an archived patient record located on DVD:

**Step 1.** Select the **IDENTIFY DVD** icon located on the Action bar. If a DVD is not present, a prompt for a DVD appears.

**Step 2.** Insert a DVD, or cancel the identification request.

If a patient record is located, a dialog appears with the record information. Fields displayed in the dialog include:

- Last Name
- First Name
- Medical ID
- Physician
- Last Treatment Date
- Record Location
- Archive Date
- Record Size in Bytes
- Archive Record ID
- Offline Patient Archive Date
- Disk Number.

In addition there is a text section that informs the user if the patient record on the DVD can be restored to the CyberKnife.





Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



# CyRIS™ MultiPlan™
## Table of Contents


**Introduction to CyRIS MultiPlan** ..... 1
**Getting Started** ..... 2
- User Interface Display Organization ..... 2
  - Workflow for the CyRIS MultiPlan ..... 2
  - Screen Layout ..... 3
  - 2D Display Layout ..... 4
    - Split Screen View ..... 5
    - Checkerboard View ..... 6
    - Overlay View ..... 7
- Global Tools ..... 8
  - Pointer ..... 9
  - Zoom, Pan, & Reset ..... 9
  - Window/Level Mode ..... 10
  - Ruler Mode ..... 11
  - Screen Capture ..... 12
  - Export DICOM ..... 13
  - Print ..... 13
  - Plan/Patient Information ..... 15
  - Return to the Startup Wizard ..... 15
- Keyboard Controls ..... 16
- Plan Templates ..... 16
  - Contents Saved in Plan Templates ..... 16
  - Manage Plan Templates ..... 18
    - Create a Plan Template ..... 19
    - Copy a Plan Template ..... 20
    - Delete a Plan Template ..... 20
    - Edit a Plan Template ..... 21
- Set Preferences ..... 22
- Maintenance ..... 25
- Help ..... 26
- Launch the Planning Program ..... 27

**Load Plans and Data** ..... 28
- Startup Wizard ..... 28
  - Select a Patient and a Plan ..... 28
  - Select the Fixed Image ..... 29




Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

522

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



Select the Moving Image and Volumes of Interest ..... 30
Select the Plan Template ..... 31
Restart the Startup Wizard ..... 32
Reasons to Use the Load Task Rather than the Startup Wizard ..... 32
**Load Task ..... 33**
Begin a New Plan ..... 33
Select the Fixed Medical Image ..... 34
Select the Moving Image ..... 34
Select Anatomical Contours ..... 34
Load the Selected Image Data ..... 35
**Load an Existing Plan ..... 35**
**Recover the Last Plan ..... 36**
**Delete a Plan ..... 36**
**Refresh Patient List ..... 36**
**Fuse Two Image Series ..... 37**
**Seed-Point Alignment ..... 37**
Set Seed Points ..... 38
3D and 2D Layouts ..... 38
Choose Seed Points ..... 39
The 3D Filter ..... 39
Load a Preregistered Image ..... 39
**Image to Image Registration ..... 39**
Intensity-based Registration ..... 39
Seed-Point Registration ..... 41
**Manual Registration ..... 41**
**Align ..... 43**
**Set Treatment Parameters ..... 43**
**Identify Fiducials ..... 45**
**Position the Machine Center ..... 46**
**Contour ..... 48**
**Volumes of Interest ..... 48**
VOI Structure ..... 48
VOI Properties ..... 48
Display Settings ..... 50
**Drawing Tools ..... 51**
Interpolation of Volumes of Interest ..... 58
Pen ..... 59
Line ..... 59
Ellipse ..... 59



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



Rescale ..... 59
Magic Wand ..... 60
3D Magic Wand ..... 60
Bumper ..... 60
Smart Curve Fitting Option ..... 61
**Plan ..... 62**
**Setup ..... 62**
Density Model ..... 63
Beam Intersection ..... 63
Dose volume ..... 63
Dose Isocontours ..... 64
**Isocentric Planning ..... 64**
The Isocenter Menu ..... 65
Creating an Isocenter ..... 65
Resizing an Isocenter ..... 65
Moving an Isocenter ..... 65
Changing an Isocenter's Properties ..... 66
Conformal ..... 66
Dose (cGy) ..... 66
Color ..... 66
Use Path 1,2,3 ..... 66
Deleting an Isocenter ..... 66
Layouts ..... 66
**Conformal Planning ..... 67**
Collimator Size Table ..... 67
Min. and Max. MU ..... 68
Optimization Method ..... 68
Targeting Slider ..... 68
Dose Constraints Panel ..... 69
Volume of Interest Constraint ..... 69
Point Constraint ..... 70
Number of Constraints ..... 71
Generate Beams ..... 71
Pause ..... 71
Reset ..... 72
Dose Volume Histogram views ..... 72
Beam statistics ..... 72
**Plan Evaluation ..... 73**
Dose Prescription ..... 74
Final Review ..... 74



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118 524

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



Dose Volume Histograms ..... 74
Dose Statistics Table ..... 75
Layouts ..... 75
The 3D view ..... 75
**Visualization ..... 76**
**Multi-Slice View ..... 76**
**3D Visualization ..... 77**
Window/Level Filter ..... 77
Color Filter ..... 78
Dose and Anatomy Overlays ..... 79
**Save and Push Data ..... 80**
**Save Plan ..... 80**
**Push DICOM Formatted Data ..... 81**
Select Host ..... 82
Volumes of Interest ..... 82
Dose Distribution Data ..... 83
Image Data ..... 83
**Advanced Plan Evaluation ..... 84**
**Reference Plan ..... 84**
**Plan Summation ..... 85**
**Robot Animation ..... 86**
**Phantom Overlay ..... 88**
**Load Task ..... 88**
**Fuse Task ..... 91**
**Align Task ..... 93**
**Plan Evaluation Step ..... 94**
**Physics ..... 95**
**Dose Table ..... 95**
**Ball-Cube Test ..... 96**
**Dose Calculation Algorithm ..... 96**
Dose Mask ..... 97
Dose Resolution ..... 97
Inhomogeneity and Contour Correction ..... 97
Isodose Curves ..... 97
Point Dose ..... 98
**Coordinate Frames of Reference ..... 98**



525 Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



**Glossary** ..... **100**
Terms ..... 100
Acronyms and Abbreviations ..... 101
**Warnings and Errors** ..... **103**



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015





Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



# CyRIS™ MultiPlan™

## Introduction to CyRIS MultiPlan

This guide explains the operational procedures for CyRIS MultiPlan. CyRIS MultiPlan is a full purpose treatment planning system. It gives physicians, medical physicists, and dosimetrists the ability to plan safe and deliverable CyberKnife® System treatments. It is specifically designed to optimize the flexible nature of the robotic treatment delivery system.

In planning a treatment, you typically follow these steps:

**Step 1.** Push required medical images (including at least one CT series) to the primary workstation for the CyberKnife System and load those images into the central patient database.

**Step 2.** Start the MultiPlan workstation (which automatically starts the application).

**Step 3.** Load the patient images.

**Step 4.** If needed, fuse multiple images (i.e. CT and MRI or PET images).

**Step 5.** Set the delivery system parameters and align the CT study with the imaging system.

**Step 6.** Identify and delineate target and critical volumes.

**Step 7.** Generate plans for the prescribed treatment.

**Step 8.** Evaluate, modify, and compare plans.

**Step 9.** Save plans. Saved plans are stored in treatment files associated with a patient.

**Step 10.** Animate the CyberKnife System treatment.

**WARNING: Do not attempt to modify a treatment file. Improperly changed data could result in death or injury of the patient.**



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



# GETTING STARTED

## User Interface Display Organization

The user interface has two organizational strategies. Data presented to you is organized based on the treatment planning workflow and based on pre-defined areas of the screen.

### Workflow for the CyRIS MultiPlan

The user interface is organized into functional groups. It uses three tiers of functional groups.

The top tier is the Task. Tasks are the major functions that you perform on CyRIS MultiPlan. The CyRIS MultiPlan has six planning tasks. These tasks are usually necessary when creating a treatment plan.

**Load**. Select and load patient data.

**Fuse**. If you chooses two medical images, this task allows you to fuse the images so they are aligned to the same physical space.

**Align**. Set the treatment modes, identifies fiducials, and aligns the nominal patient position within the detectors of the imaging system.

**Contour**. Contours anatomical volumes of interest.

**Plan**. Generate and modify isocentric and non-isocentric plans. Evaluate the dose distribution for the plan.

**Visualization**. View an array of the 2D image slices or merge and filter volume renderings of the patient anatomy.

**CyRIS MultiPlan** has three ancillary tasks. These tasks provide advanced plan evaluation tools, system quality assurance tools, preference settings, and on-line help.

**Plan QA**. Compare two potential plans for the same treatment. You can sum two or more plans for the same patient. Display the dose distribution for the plan as treated to a phantom during a film test. Animate robot delivery of the treatment plan.

**Settings**. This task includes a tool to center the dose distribution for a ball-cube plan. The interface displays the list of beams and their geometric patterns for the current plan. Set color preference for the isodose curves, VOI's, and screen overlays. Set the behavior of the zoom and pan controls.

**Help**. Access this manual on-line. Read about CyRIS MultiPlan and Accuray, Inc.

Tasks are divided into steps. Each time you change step the layout of the CyRIS MultiPlan will change. This change includes different controls as well as different presentations of the medical images.

The third tier has the functions that you can accomplish in a given step.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



## Screen Layout

The layout of the user interface is divided into seven areas on the screen. *Figure 1 User Interface Layout, page 3* illustrates the user interface layout. The seven areas on the screen are:

1. **Identification**. The top left identifies the software as part of the CyRIS product line. The top right has minimize and exit controls.
2. **Task/Step Control**. The top menu bar lists the tasks. Below it is a list of the steps contained in the selected task.
3. **Global Controls**. Along the right side of the display are the global controls that permit you to access functions that may be desired during any of the steps in the planning workflow.
4. **Control View**. The middle left of the display has the controls available for the currently selected step. Each step will have a different set of controls.
5. **Display View**. The large display center includes the display of the medical images and other large graphical and text controls. Each step will have a different display layout. For some steps, you will be able to select the display layout.
6. **Patient Identification**. The bottom left displays patient and plan information, including patient name and medical ID, plan name, date and time the plan was saved, and the prescription percentage and dose.
7. **Status**. The bottom center and right displays status. The position of the image focus and value of the image gray scale number appear on the right. On the left is general information, including a time-elapsed bar.

**Figure 1 User Interface Layout**



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



## 2D Display Layout

A typical 2D display (with two loaded images) is shown in *Figure 2 Split-Screen Axial 2D View, page 5*. Axial, sagittal, and coronal views are displayed in CyRIS MultiPlan. The appearance of the image within this display will be slightly modified when you use a global tool to change the mode of operation.

The bottom left indicates the plane. In this example, an axial slice is displayed. The display is an icon of a human head. A mouse-click over the icon will change it. It will cycle through three icon types: a human head, a human body, and the name of the view. This mouse-click will affect the display in all three planes. In the center of each side is a direction indicator. These indicators position the patient's left, right, superior, inferior, anterior, and posterior sides.

The top left includes a selector that allows you to choose which image to view. You can view the fixed image (A), the moving image (B) or one of three multiple image modes: a split view (A/B), a checkerboard view (A+B), or an overlay view (A&B). Click on the indicator to cycle through the choices. This feature is available only when two images have been registered. If only one image is loaded, no indicator appears. If two images have been loaded, but they have not been registered, the indicator appears surrounded by a dashed box. It is insensitive and only the A image can be displayed. These views act on only the view displayed, so you can have a different image viewed in the Axial, Coronal, and Sagittal views. In the Delineate screen (*see section, Drawing Tools, page 51*), changing the image for the delineation plane to the split, checkerboard, or overlay view only affects the large window. The small multi-slice view of twelve images will display the fixed A image.

The bottom right indicates the slice. To step one slice, click on either the forward or backward arrow. Click inside or drag along the slider to move more slices.

The notched focus lines give the intercepts of viewed perpendicular planes. You can change the plane of these views by sliding these notches or by double-clicking at the desired point of intersection for these views.



531 Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



## Split Screen View

For the split screen view (*Figure 2 Split-Screen Axial 2D View, page 5*), the slider oblique line will appear. You can rotate this line about its axis of rotation to change the modality used to display different areas of the view. The point of rotation is the intersection of the focus lines. Click and drag the mouse to move these lines.

**Figure 2 Split-Screen Axial 2D View**



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



## Checkerboard View

The checkerboard view shown in *Figure 3 Checkerboard 2D Axial View, page 6* allows you to view the patient anatomy in a quilt-like pattern of fixed and moving image. The size of the checkerboard is controlled by the slider at the top right. The value of the sliders is the edge length of each patch in screen pixels. Therefore the larger the number, the larger the patches in the display. The maximum and minimum grid sizes are 4 and 256 pixels.

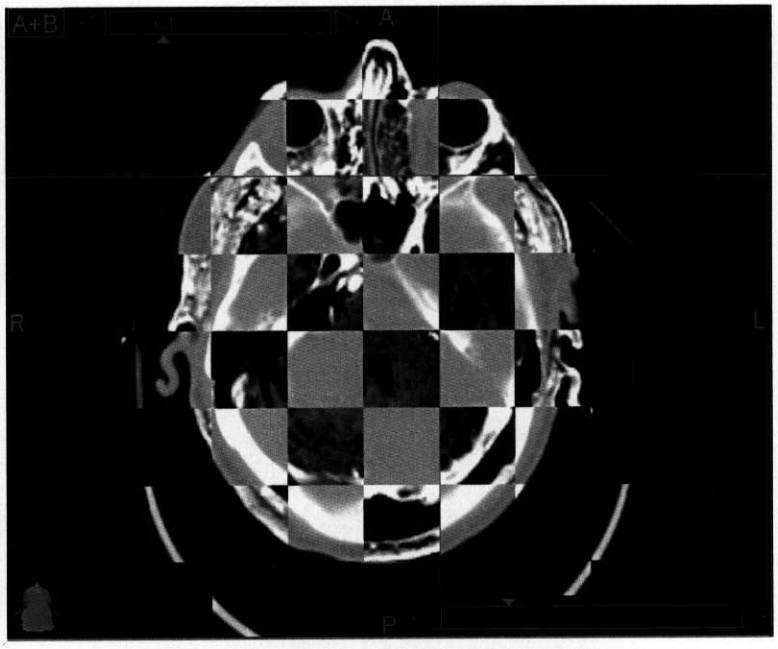



**Figure 3 Checkerboard 2D Axial View**



533

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



## Overlay View

The overlay view (*Figure 4 Overlay Axial 2D View, page 7*) displays the fixed and moving images at different opacity levels. You can set the color of the moving image in the overlay view from the Secondary Overlay pull-down window in the Preferences step. (*see, Figure 17 Preferences, page 23*).

**Figure 4 Overlay Axial 2D View**



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



# Global Tools

The right side of the User Interface (*Figure 5 Global Tools, page 8*) has a string of buttons that are always available to you. The top buttons are called **Tool Buttons** and they set tools that change the way the mouse interacts with the image Display View. These tools need to be freed by clicking the Pointer tool. The bottom buttons are Command Buttons. They open a popup window (Screen Capture, Save and Push and Print), except for the Reset function which has its effect without changing the method of interaction with the Display View.

The Save and Push function is described in *section, Save and Push Data, page 80*.

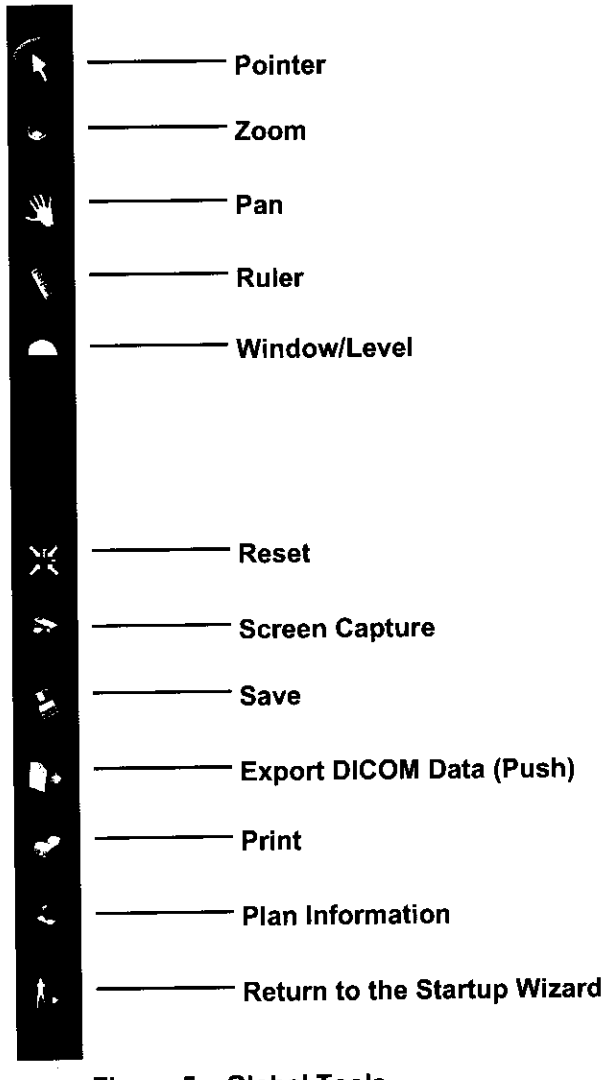



**Figure 5 Global Tools**



535

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



## Pointer

This mode is the default tool for the system. In this mode you can drag the focus lines for the different planar views, display the current status of the image, or change the focus lines by double-clicking in one view.

## Zoom , Pan , & Reset

Select the **MAGNIFYING GLASS** button to enter the zoom mode. The cursor in the 2D display will become a magnifying glass.

In the zoom mode, you step in the zoom level by a single mouse click in any 2D window and step out the zoom level by a single mouse right-click in any 2D window.

You can also frame the zoom by placing the cursor at the top left of the desired field of view, depressing the left mouse button and dragging the mouse to the bottom right of the desired field of view. A box bordered by a dashed line will indicate the resulting field of view.

You can zoom in the field of view by depressing the scroll-mouse and scrolling forward. You can zoom out of the field of view by scrolling backward.

Select the **hand icon** to enter Pan mode and the cursor will become a hand. Simply click the mouse and drag the image to the desired location. The pan image mode re-frames the view in all 2D displays.

The zoom and pan functions can be set so that the 2D views function independently or in unison. Choose the option in the Settings task (*see section, Set Preferences, page 22*).

Select the button with the **square icon** and **four arrows** to reset the display so that it is in its standard zoom and pan position.

The zoom and pan tools also work in the 3D view (*see section, 3D Visualization, page 77*).



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118 536

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



## Window/Level Mode

The button with the circle (white top, black bottom) icon sets the Window/Level mode. In this mode, the cursor is the same circle as the icon.

Click the mouse and drag left to reduce the window value. Drag right to increase the window value. Drag up to reduce the level. Drag down to increase the level.

If you have loaded more than one image, select the desired image at the top left of the 2D display view and adjust the window and level for either the fixed or moving image. In the split or checkerboard modes (A/B or A+B), the system automatically detects the image to adjust based on the cursor position. In the overlay mode (A&B), the left mouse button controls adjustment of the window and level in the fixed image and the right mouse button controls adjustment in the moving image.

You can also use histograms (*Figure 6 Window/Level Histogram, page 10*) to adjust the window and level of the display. The histogram is a representation of the distribution of the gray scale values. This representation allows you to hone in on the regions that have peaks along the histogram. For instance, to visualize bony anatomy on a CT image, narrow the display to the region around the peak centered near a CT number of 1400. To visualize soft tissue, narrow the display to the region around the peak centered near a CT number of 1000.

Select the tab to control the image for which you wish to view the histogram and adjust the window and level. You can use the histogram to adjust the Window and Level in any mode. You do not need to go to Window/Level mode to adjust those values, if you use the histogram to perform the adjustments.

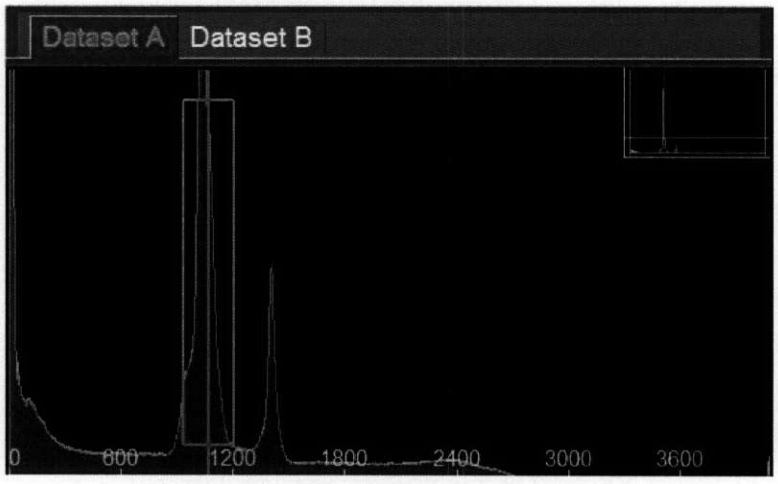



**Figure 6 Window/Level Histogram**



537

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



## Ruler Mode

Select the button with the **ruler icon** to enter the ruler mode. The cursor becomes a small diagonally oriented ruler with crosshair at the upper left. Depress and drag with the mouse to draw a line that measures a distance. When the ruler is drawing the crosshair on the cursor becomes an arrow.

*Figure 7 Rulers, page 11* shows a sample set of measurements created with the ruler. On the top right are buttons that allow you to **delete** the active measurement or to **clear all** the measurements. You can also adjust the active measure by grabbing either end and dragging it to a different spot on the screen.

The measurements are overlays on the 2D view. If you change slice, the measurements will remain unchanged. If you exit ruler mode the measurements will disappear. They will, however, return if you reenter ruler mode unless you had previously cleared them.

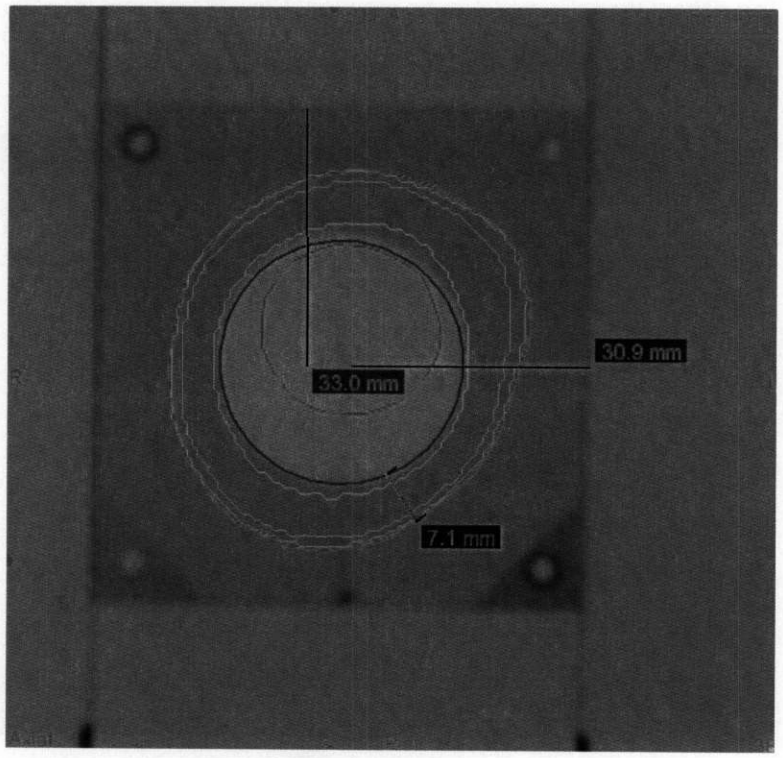



**Figure 7 Rulers**



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



## Screen Capture

The camera icon opens the screen capture function. A browser will appear that allows you to name the image and set the location of it (*Figure 8 Capture Image Dialog, page 12*). The default location is *c:\accuray\Image*. The default name is today's date and a counter. For instance, 20040317_002 is the second picture snapped on March 17, 2004. The image is always captured in JPG format.

**NOTE:** Because the image can only be saved in one image format, the Save as Type is not an active input. You cannot set a value in this field.

This function captures the whole screen. You can edit the image using a standard image editor, such as Paint.

The patient identification can be masked. Click the patient identification area, before the screen capture function is opened, and an Accuray logo will mask the patient name and medical id (*Figure 9 Logo Overlaying Patient Identification , page 12*).

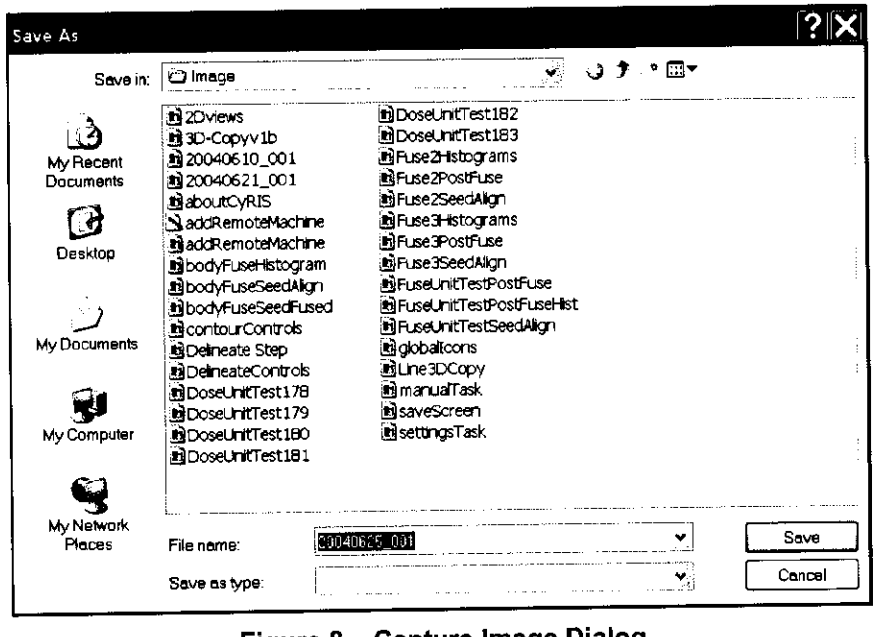



**Figure 8 Capture Image Dialog**

**Figure 9 Logo Overlaying Patient Identification**



539

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



## Export DICOM

This global function is detailed in *section, Push DICOM Formatted Data, page 81.*

## Print

The **printer** button gives you access to the print dialog. Selecting this option opens *Figure 10 Print Plan and Beam Data, page 14.*

You can print four types of reports.

1. Plan Overview
2. Path List
3. Beam List
4. DVH Tables

The data is sent to the printer as well as saved in the sub folders of the directory:

*c:\accuray\Reports*

These reports are only available for plans saved on the Multiplan system. To print plans in MultiPlan that were created on the SGI On-Target Treatment Planning System, load the plan in MultiPlan and save it under a new name.

**Plan Overview** summarizes the global properties of a saved plan. Data is divided into patient information, plan information, fiducial description, treatment information, treatment dose information, node information, and target volume description. Each plan overview has signature blocks for a physician and a physicist.

**Path List Report** lists each beam in a path. The list has a line to check off beam delivery. The list gives the node an id, the number of monitor units, reference dose, indicates if the beam is blocked, and identifies the Linac position in robot coordinates.

**Beam List Report** lists the beams and geometric parameters associated with them. This list can be used to perform hand calculations to verify that the reference dose for each beam is consistent with the number of Monitor Units for that beam. The radius from the central beam axis is user selectable. You can choose to display the radius projected to the point along the central axis by one of the following:

- at a distance of 800 mm from the X-ray source in the Linac (Radius 800),

  or

- at the Source Axis Distance of the plan reference point (Radius SAD).

The data for the beam list report can be saved to a file and then imported into a user-defined spreadsheet. The spreadsheet can be used to include an independent verification of the dose calculation.

The beam list report will be disabled if the number of beams is zero or if the MU for each beam is zero.

**DVH Tables Report** tabulates the values (at increments of 1% of the maximum dose) for the dose volume histogram. If this report is printed to a file, you can use the data to analyze the DVH and compare it directly to other plans. As with the Beam List, you can save the DVH Tables Report to a file and then import the saved DVH table data to a spreadsheet and use that spreadsheet to evaluate the data.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



The print interface allows you to print the beam tables used by the dose calculation algorithm. The options allow you to print the dose output factor table (DM), the tissue maximum ratio (TMR) for any collimator, or the off-axis ration (OAR) for any collimator. Collimator size is selected using the cascade button to the right of the TMR and OAR options. You can select the collimators individually or select all the collimators at one time. The last option is to select all collimators and print the data at the same time. This data is primarily used when commissioning the system. You can use it to validate that the content and format of the beam tables are stored correctly.

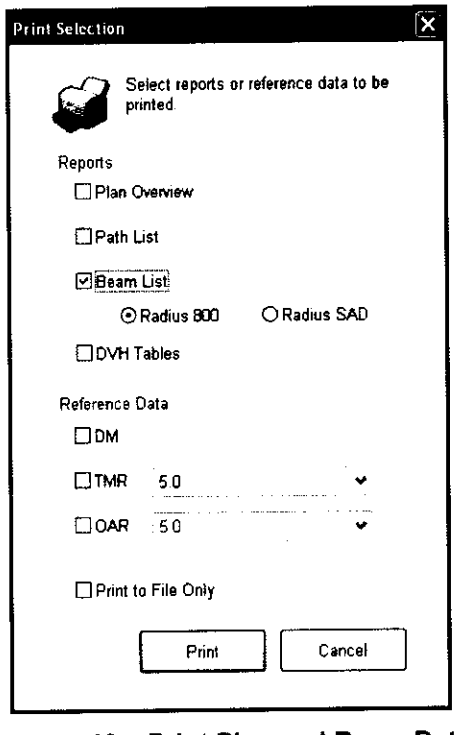



**Figure 10 Print Plan and Beam Data**



541

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



## Plan/Patient Information

Plan summary information is displayed at the bottom left of the display. If you would like to see more detail about the currently displayed plan, select the plan/patient icon on the bottom of the global switch array to open the Patient Information dialog (*Figure 11 Patient Information, page 15*).

This dialog gives detailed information on the primary (Fixed, A) image study and secondary (Moving, B) image study, including the name and modality of the study. Plan information is also detailed. This information includes the plan name, the date and time a plan was saved, the plan status, the delivery configuration, the prescription dose, the number of stages, the total MU and the total number of beams.

Information that is not available will be left blank in this display.

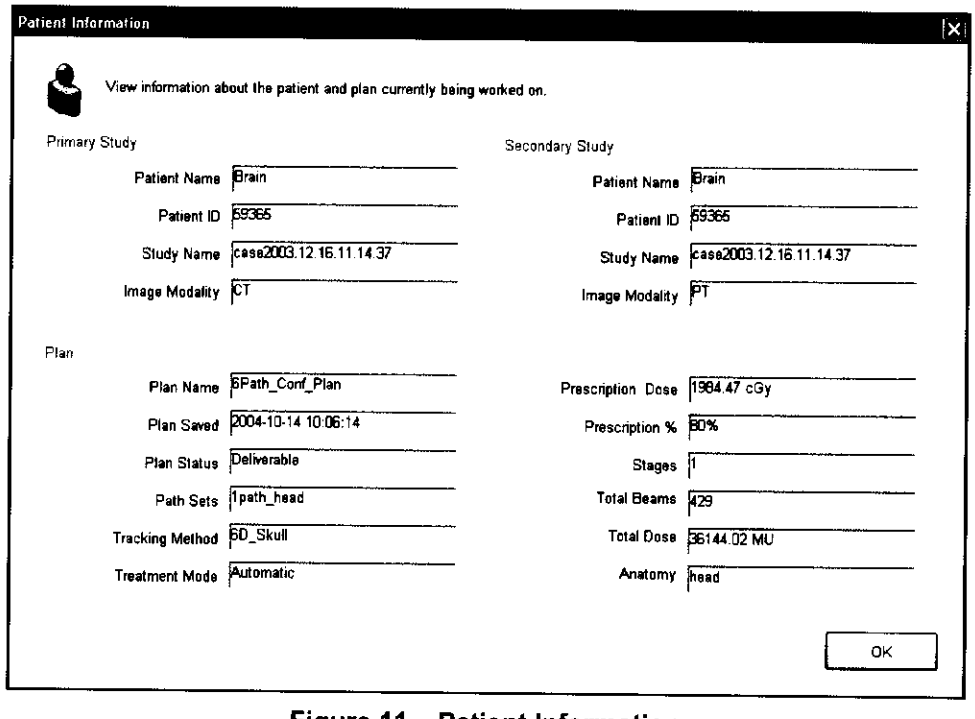



**Figure 11 Patient Information**

## Return to the Startup Wizard

To start a new plan or load an existing plan using the Startup Wizard if you are already in CyRIS MultiPlan, select the bottom, full-body icon in the column of global controls at the right side of the user interface. Once selected, you will be prompted to save the current version plan and then redirected to the first step of the Startup Wizard.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



# Keyboard Controls

Multiplan provides the keyboard shortcuts tabulated in *Table 1: Keyboard Controls, page 16.*

**Table 1: Keyboard Controls**

| Shortcut | Keys | Comments |
|---|---|---|
| Previous slice | S, [left arrow], [up arrow] | |
| Next slice | D, [right arrow], [down arrow] | |
| Previous page | A, [Page up] | Step 5 slices up. |
| Next page | F, [Page down] | Step 5 slices down. |
| First slice | W, [Home] | |
| Last slice | E, [End] | |
| **Shortcuts available only in the Delineate Step** | | |
| Copy contour | C | Same as [Copy] button in the control window. |
| Paste contour | V | Same as [Paste] button in the control window. |
| Delete contour | X | Same as [Delete] button in the control window. |

# Plan Templates

This section describes the contents of plan templates and how to create, edit, and delete plan templates.

## Contents Saved in Plan Templates

Each plan template is a stored set of default parameters for a specific type of treatment. Templates are created based on the current planning configurations in the CyRIS MultiPlan session. Each template can have the following contents. The only required content is the Template Description.

**Template Description (required content)**

- Author
- Password Protection
- Template Name
- Body Region



543 Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



**Template Plan Parameters**

- Number of Stages
- Treatment Anatomy
- Path Set
- Tracking Method
- Maximum Beam On Duration
- Optimization Algorithm
- Minimum MU per Beam
- Maximum MU per Beam
- Prescription Dose
- Prescription Isodose Percentage
- Fixed Image Modality
- Fixed Image Window (hidden data)
- Fixed Image Level (hidden data)
- Moving Image Modality
- Moving Image Window (hidden data)
- Moving Image Level (hidden data)

**Template VOI Parameters (for each VOI)**

- Opacity
- VOI Name
- VOI Type
- VOI Color
- VOI Line Width (hidden data)
- VOI Minimum Dose Limit
- VOI Maximum Dose Limit
- VOI Minimum Dose Weight
- VOI Maximum Dose Weight
- Skip Factor

**Isodose Curve Template (for each Isodose Line)**

- Isodose Percentage
- Isodose Color
- Isodose Line Width
- Isodose Display Flag

**WARNING: When a template is loaded it presets many planning conditions, including the fractionation and the dose limits for plan optimization. Verify that each element preset is the desired value for the particular patient whose treatment you are planning.**



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118 544

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



## Manage Plan Templates

CyRIS MultiPlan provides capabilities to create, edit, and delete plan templates. Plan templates have an author and they can optionally be protected with a password. The UI for managing plan templates is located in the Plan Template step (*Figure 12 Plan Template Step, page 19*) of the Settings task.

**NOTE:** The Plan Template step can be used to manage template contents. It cannot be used to select a template. Template selection can only be done from the last step of the Startup Wizard.

The control window (shown on the left of the screen) of the Plan Template step contains:

1. a list control that allows you to select any template defined on the MultiPlan workstation;
2. command buttons to create, delete, copy, and edit the current displayed template;
3. a template properties section that displays the following properties: name, the anatomical region, the author, and the status of password protection.

The plan template view (in the center of the window) displays the contents of the currently selected template in three sections: planning parameters, isocurve settings and VOI settings. You can edit the template contents in this view.

**NOTE:** If a template is password protected, you must enter the password to be able to edit.



545 Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015

**Figure 12 Plan Template Step**

## Create a Plan Template

You can create a new plan template with all the parameters populated from the currently selected plan, or with all the parameters empty.

To create a template, click the **NEW** button on the plan template step control window. You will be prompted to create the new template based on the current plan (*Figure 13 Create a new plan template, page 20*). If you select **YES**, a new template will be created with all the settings of the currently loaded plan. If you select **NO**, a new empty template is created.

When a new template is created, a computer generated name will be assigned to the template. You can change the name in the Name field of the Template Properties section.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



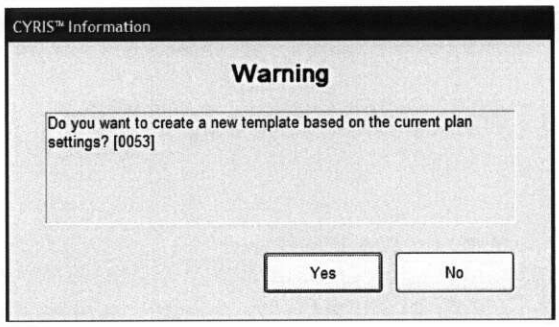



**Figure 13 Create a new plan template**

## Copy a Plan Template

You can copy an existing template to a new template. Before you copy a template to a new one, you need to select the template you wish to copy from the template list. Then, select the **SAVE AS** button on the step control window. You will be prompted to input a name for the new template (*Figure 14 Save Plan Template, page 20*). The name of a template cannot be empty or the same as any other existing templates. After you input a name for the new template and click the **OK** button, a new template will be inserted into the template list and become the current selection.

If the source template has password protection, you can still copy it to a new template without typing the password. The password will not be copied to the new template.

**Figure 14 Save Plan Template**

## Delete a Plan Template

To delete a plan template, select the template from the Plan Template pull-down list, then select the **DELETE** button. If the template is password protected a dialog will appear that requires you to type in the password (*Figure 15 Plan Template Password Confirmation, page 21*). If the password entered is correct, the template will be deleted.

If the template is not password protected, the template will be deleted.



547 Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



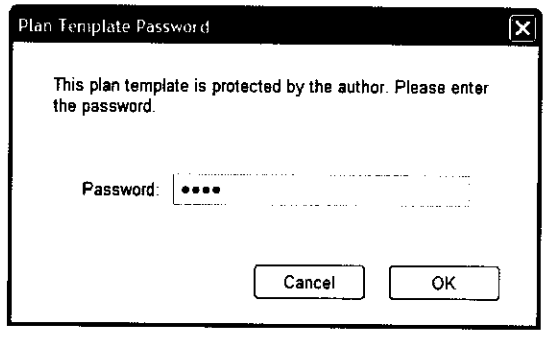



**Figure 15 Plan Template Password Confirmation**

## Edit a Plan Template

If you want to edit or update an existing template, select the template from the plan template pull-down list.

- If the plan is not password protected, the fields can be edited.
- If the plan is password protected, click the **EDIT** button and a dialog box appears. (*Figure 15 Plan Template Password Confirmation, page 21*). Enter the password and click **OK** to unlock the template for editing.

You can check the Password Protection option to add password protection or uncheck it to remove password protection. You can also replace an existing password by clicking the **CHANGE PASSWORD** button under the checkbox.

Edit template fields as needed. Edits will immediately update the template contents. Changes are not applied to any plan previously saved plan using this template. To change the settings saved with a plan, you must update the plan itself.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015

**Figure 16 Template Properties Window**

## Set Preferences

You can set display preference and defaults in the Settings task of CyRIS MultiPlan. The display of the Preferences step is shown in *Figure 17 Preferences, page 23*. The display has six groups of parameters – five of which allow you to set defaults.



549

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



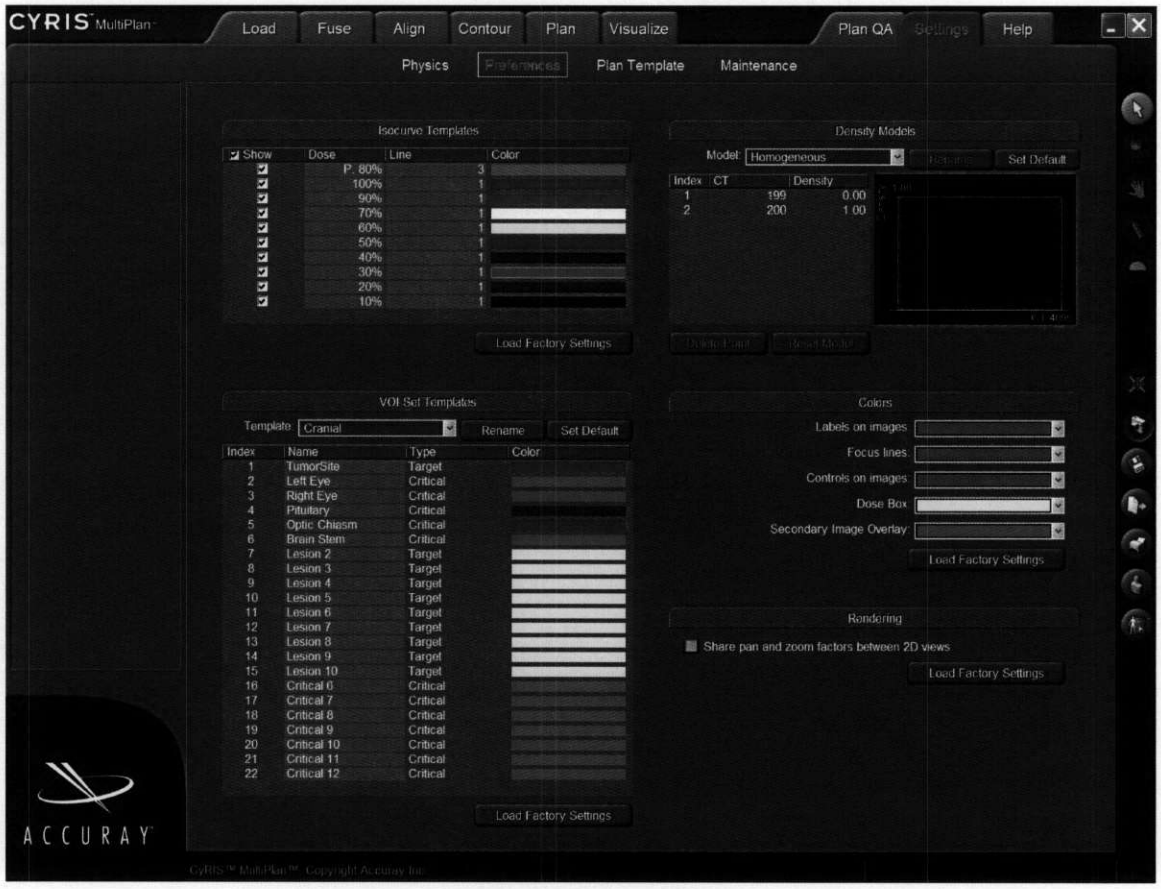



**Figure 17 Preferences**

The top left allows you to set the current or update the default Isocurve Template. You can set the percent of the maximum dose for each curve, the line width, the color, and whether or not to show any or all of the dose curves.

The bottom left allows you to set a VOI template set from a list of five saved VOI Set Templates. When you select a template, the properties will change for all VOI that do not have a defined contour. If a VOI has been previously delineated, that VOI will retain its current properties (including the VOI name). For each standard template, you can set the name, type, and color of up to 22 Volumes. The **RENAME** button allows you to select a default name for each VOI template.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



The top right provides you an interface to create a density model for dose calculations. The system has three default models: a homogeneous model, a linear model, and a lung anatomy model. These models cannot be changed. You can create and name up to seven more models for a total of ten models. The models are piece-wise linear curves. You can enter as many points as you wish. The maximum CT number allowed is 65535. The system has no maximum density. You can enter the inflection points in any order. The system will automatically sort them by CT number. The density curve will appear to the right of the point list.

**NOTE:** Suppose you generate and save a plan that uses a specific dose model. Then, you change the curve associated with that model. When you reload that plan it will reuse the curve saved with the plan. The name of the density curve in the Plan Setup (*see section, Density Model, page 63*) step will be bracketed to indicate that the parameters differ from the default density curve with the same name.

The middle right allows you to set the Color Template for the patient image views. You can set the color for labels, focus lines, controls, and the dose box boundary.

The bottom right allows you to set the implementation of the zoom and pan functions. If checked, all 2D views will have the same zoom level and focus point. You can also clean up the report directory. Anytime a file is printed a soft copy is saved and time-stamped in the directory *c:\accuray\tmp\reports*. Select Cleanup report folders to delete these files from the workstation.



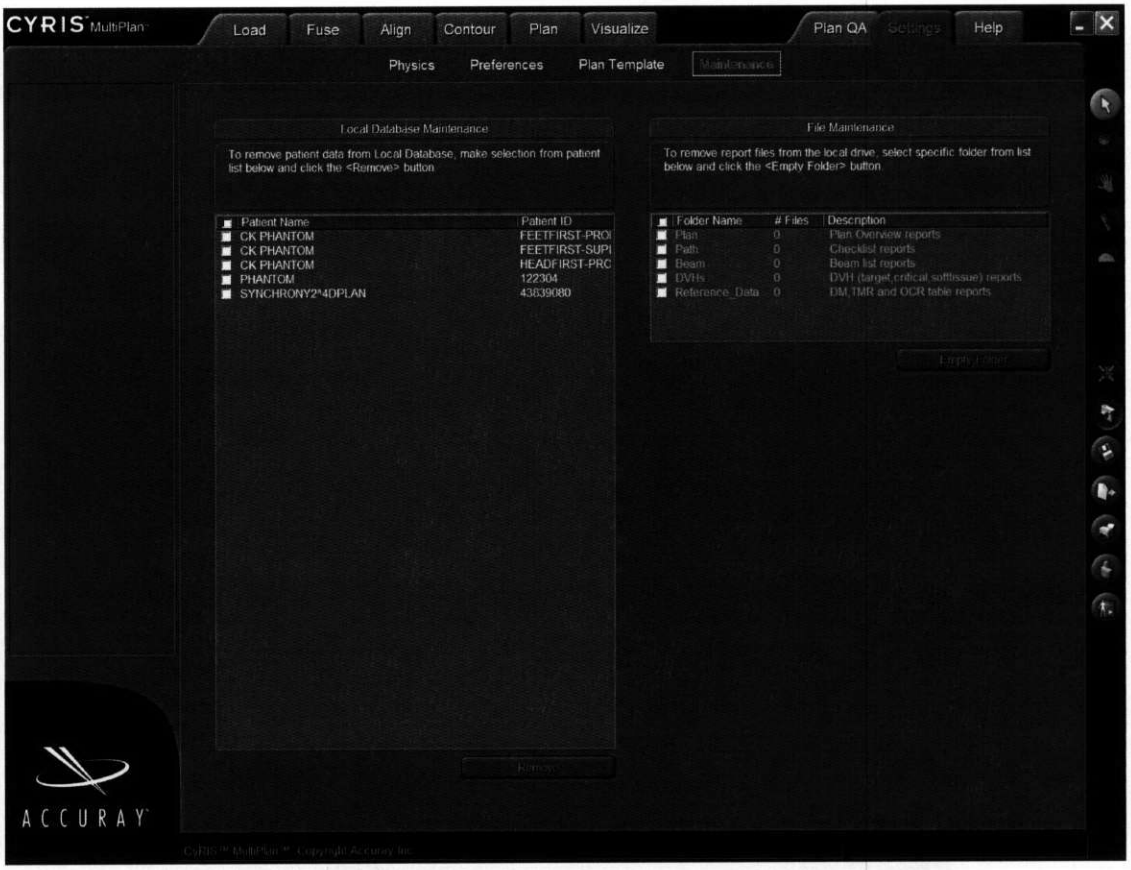
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

551

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



# Maintenance




The maintenance step allows you to delete images from the workstation if the image is stored locally on MultiPlan. To delete an image select the patient or patients whose images you no longer need and select **REMOVE**.

**NOTE:** Patient images are stored on the primary workstation for the CyberKnife System. The data you delete here is duplicate data.

Whenever you print, a file of that data is stored on MultiPlan. To delete folders that contain previously printed information, choose the folder and select **EMPTY**. The following folders can be deleted:

**Plan**: Plan overview files.

**Path**: Path checklists.

**Beam**: Beam data printed out for patient plans.

**DVH**: Tabulated text files for the DVH curves.

**Reference_Data**: Beam verification printouts.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



# Help

The help task has two steps.

**Step 1.** Gives you access to an on-line version of this Manual (*see, Figure 18 User's Manual, page 26*). The manual is in PDF format. The bookmarks give a tree-structure on the left that you can use to search for manual sections. Because of the limitation of Adobe Acrobat Reader, an instance of a stand-alone Acrobat Reader will conflict with the Manual screen of CyRIS MultiPlan. Please do not use Adobe Acrobat Reader when CyRIS MultiPlan is running.

**Step 2.** Informs you About CyRIS MultiPlan (*see, Figure 19 About CyRIS MultiPlan, page 27*).

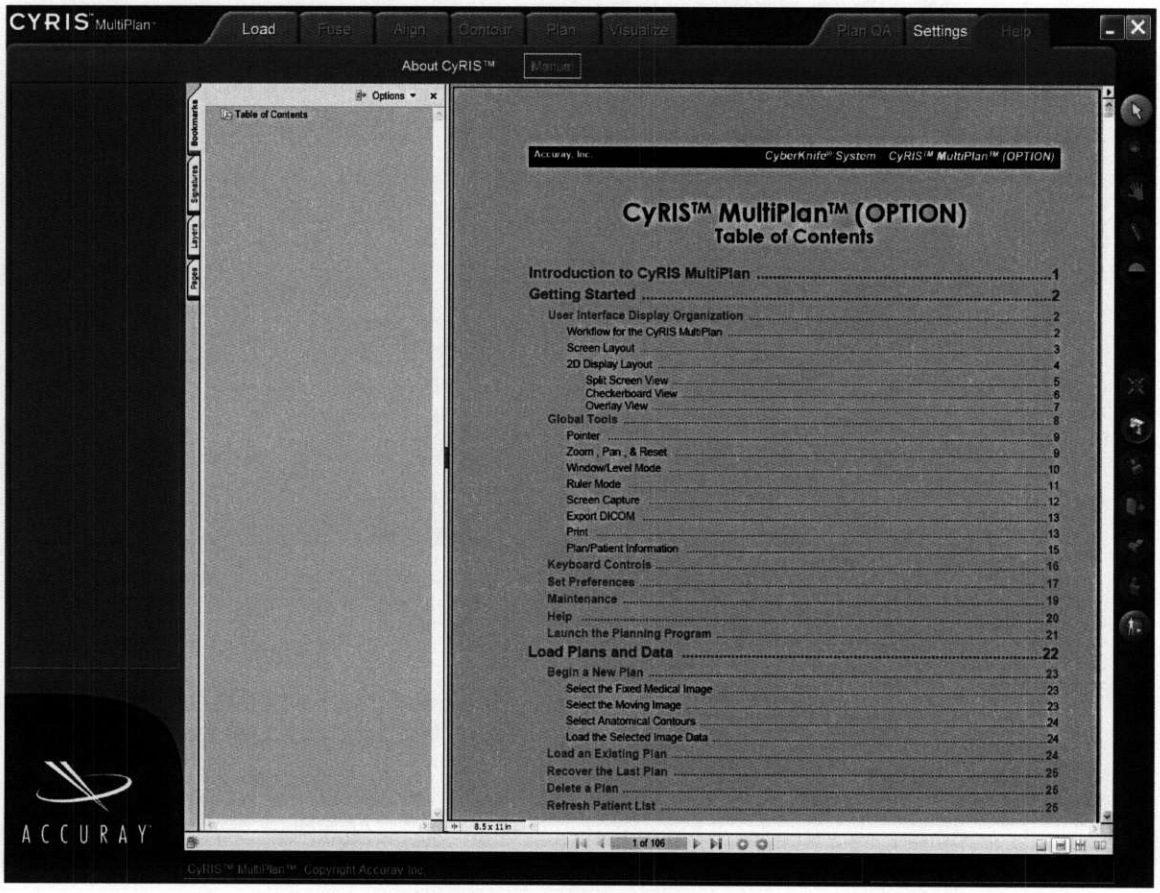



**Figure 18 User's Manual**



553

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



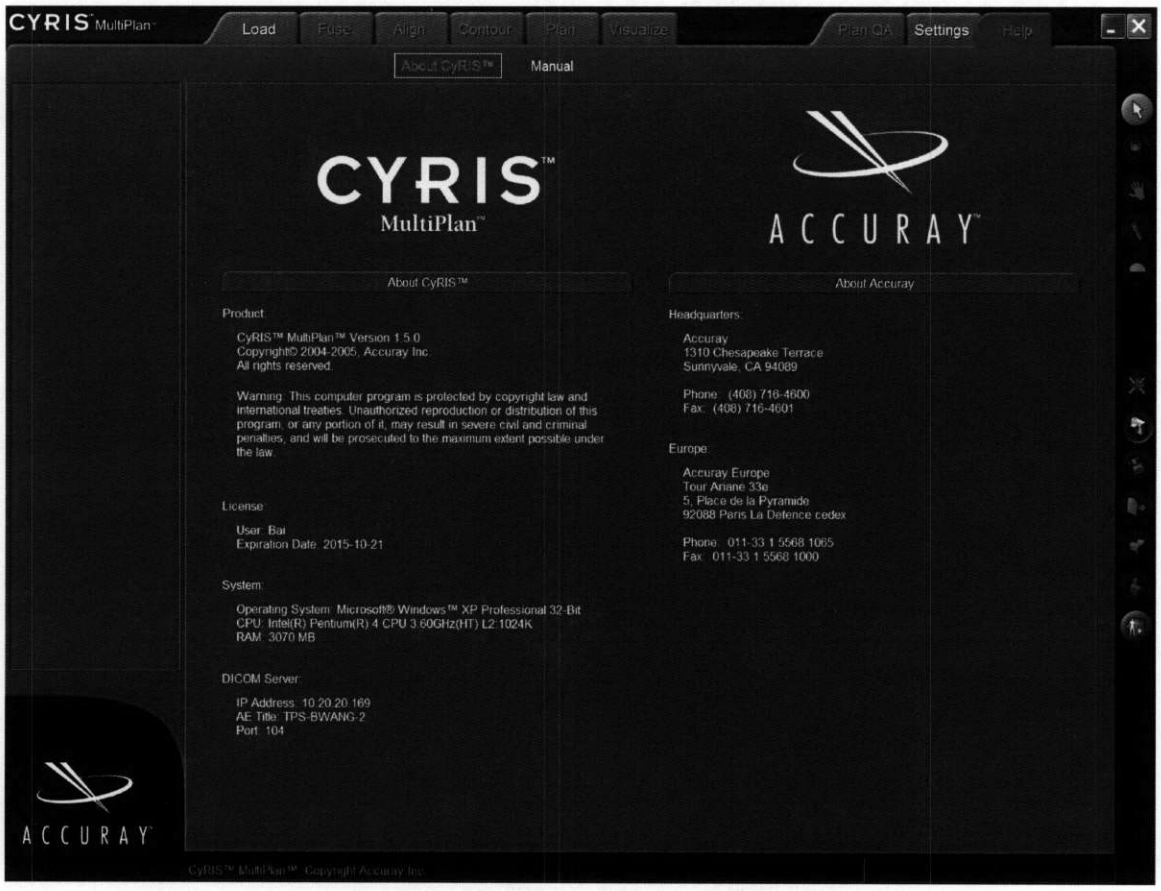



**Figure 19 About CyRIS MultiPlan**

## Launch the Planning Program

CyRIS MultiPlan will have one or more users that can access the executable for this software. The user logs onto the system by inputting the appropriate USERNAME and PASSWORD for one of these users.

The software will automatically be launched when the user uses an appropriately configured user name. The application can also be launched from the MultiPlan icon on the desktop or in the Start Menu.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



# LOAD PLANS AND DATA

There are two methods to start a new plan or load an existing plan. A startup wizard will guide you through the selection of plans, images, and templates. The Load Task provides more options for loading and managing plans.

## Startup Wizard

There are two methods for starting a treatment plan on CyRIS MultiPlan: the Startup Wizard and the Load Task. The wizard is a simple workflow that helps you get started with a new plan or continue working on an existing plan.

The wizard user interface is divided into three sections.

1. The top right is a label that indicates the selected patient name and medical ID.
2. Below that is the wizard selection area.
3. At the bottom is the step control.

Generally, the left side of the user interface moves you to the previous step and the right side moves you to the next step. The center right has buttons that complete the wizard while maintaining the current selections.

### Select a Patient and a Plan

The left side of the first wizard displays a patient list (*Figure 20 Select Patient and Plan, page 29*). When you select a patient name from the list, the right side of the wizard will be enabled. The first entry on the right side is [New Plan]. Any previously saved plans for the selected patient will display below [New Plan].

The **QUIT WIZARD** button at the bottom left of the wizard is always enabled. select **QUIT WIZARD** to close the wizard and return to the Load Task.

When you select [New Plan] the **NEXT** button is enabled. Select **NEXT** to proceed to the next step of the wizard. When you select an existing plan from the plan list, the **FINISH** button is enabled. Select **FINISH** to load the selected plan.



555 Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015

**Figure 20 Select Patient and Plan**

## Select the Fixed Image

The next step in the wizard is the Select Primary Exam step. The selected patient's name is displayed on the upper right of the wizard. Located on the left side is a list of all CT exams for the selected patient. Select an exam to be the fixed image. 2D views of the selected exam will appear on the right. A green progress bar gives the status of images as they are loaded. You can browse through this stack of 2D views. The selected images are displayed at the bottom left. You can change the selected series by either selecting a new series or by clicking on the **REMOVE** button and selecting a new series.

Select **NEXT** to proceed to the next step of the wizard. Select **FINISH** to load the CT series and proceed to the Align task of MultiPlan. Select **PREVIOUS** to go back and select a different patient.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118 556

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015

**Figure 21 Select Fixed Image**

## Select the Moving Image and Volumes of Interest

The next step in the wizard allows you to select the moving image and volumes of interest (*Figure 22 Select Moving Image, page 31*). The selected patient's name is displayed. The selected patient's name is displayed on the upper right of the wizard. On the left are two lists. The first is a list of modality types. When a modality is selected, the lower list displays all exams for the selected modality type. Select an exam. 2D views of the selected exam will appear on the right. A green progress bar gives the status of images as they are loaded. You can browse through this stack of 2D images.

Volumes of Interest can be selected in this step. They are indicated by the RTSSET modality. No images will appear on the right when the RTSSET modality is selected to load.

The bottom of the selection area has the fixed image on the left. The moving image and volumes of interest are to the right.

Select the **NEXT** button to proceed to the next step of the wizard. Select **FINISH** to proceed to the Fusion Task of CyRIS MultiPlan if a moving image was selected or the Align task if you will not use a moving image to aid in delineation. The **PREVIOUS** button takes you back to the Select Fixed Image step.



557

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015

**Figure 22 Select Moving Image**

## Select the Plan Template

The last step in the Startup Wizard is to select a plan template (*Figure 23 Select a Plan Template, page 32*). Templates are organized by anatomic region. Available regions are head and neck, chest, abdomen, and other. Templates are created by the user ( *Manage Plan Templates, page 18*).

**NOTE:** If you click the **START-UP WIZARD** button while you are working on a plan, all the plan data will be lost if it is not saved prior to pressing the Start-up Wizard. You are prompted about losing your data.

Select the anatomical region from the figure at the left. As you mouse over regions, they change color from dark blue to light blue. When an anatomical region is selected, it becomes green. The list at the right displays the previously created templates for that anatomic area. Each template has the author listed. If you select a template, the names of the VOI's saved with that template are listed as Target and Critical VOI's below the figure and the template list.

If a template is selected, the left button **DONE**, is active. Select this option to proceed to the selected template loaded. If a template is not selected, the **FINISH** button is active. Select this option to proceed without loading a template. The **PREVIOUS** button takes you back to the Select Moving Image step.

**NOTE:** If you load VOI saved as a DICOM RT Structure Set (RTSSET) series and a template, the names for the RTSSET will take precedence over the template names.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118 558

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



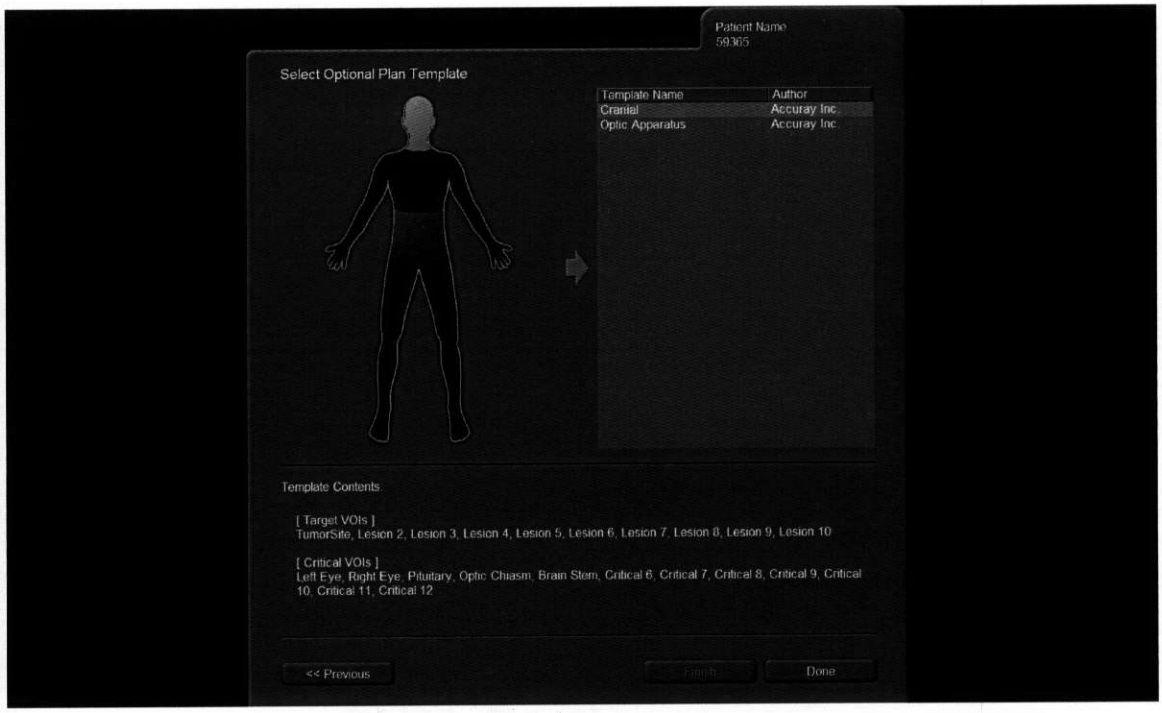



**Figure 23 Select a Plan Template**

## Restart the Startup Wizard

To start a new plan or load an existing plan using the Startup Wizard when you are already in CyRIS MultiPlan, select the bottom, full-body icon in the column of global controls at the right side of the user interface (*Figure 24 Return to the Startup Wizard, page 32*).

**Figure 24 Return to the Startup Wizard**

## Reasons to Use the Load Task Rather than the Startup Wizard

The Startup Wizard is the preferred method for starting a treatment plan. For special situations, however, the Load task is necessary. The Load task is preferable to:

- Delete a plan.
- Overwrite the moving image with a different moving image from a previously saved plan.
- Load a moving image that is assigned to a different patient Medical ID than the fixed CT image.
- Use the phantom overlay procedure. See section, Phantom Overlay, page 88.
- Load an image stored using the .N1kCT or .N1kMR volume representation. (This image format is no longer generated. It was replaced with the CyberKnife version 3.2.2.)



559

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



# Load Task

The user interface for this task is shown in *Figure 25 Start the Load Step, page 33*. This task allows you to load previously saved plans, start a new plan by loading DICOM formatted patient data, including volumes of interest pushed as DICOM RT structure sets, recover the last plan worked on, or delete a previously saved plan.

**NOTE:** If you have not loaded patient data, the only tasks available are Load, Setting, and Help. All other tasks are inaccessible.

When Start the Load Step first appears, only the patient list is filled. When you select a patient, the plan list and image study list are filled. You have the option of selecting an existing plan or starting a new plan. To start a new plan choose "Click here to start a new plan" at the top of the plan list.

**Figure 25 Start the Load Step**

## Begin a New Plan

A new plan can be created if the option "Click here to start a new plan" is selected from the plan list. After that has been done, you can load a fixed image, a moving image (if desired), and a DICOM RT structure set (if desired).



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



## Select the Fixed Medical Image

**NOTE:** The fixed medical image must be a CT image.

Select the desired study from the study list and the desired CT series from the series list. The selected series will appear in the image view on the right. View all the slices using the mouse-scroll button.

Select the check box before the series identifier. A check mark and the A indicator will appear with the series. The center image of the study will appear in the left medical image view with identification data (patient medical id, study name, and series modality) as shown in *Figure 25 Start the Load Step, page 33.*

## Select the Moving Image

As with the fixed image, you select the moving image by first selecting the patient, study, and series. (The moving image can be stored with a different patient medical id. A warning will appear, however, when you load the studies.) When the series has been selected, it will appear in the right 2D View. You can view all the slice data using the mouse-scroll.

Select the check box before the series identifier. A check mark and the B indicator will appear with the series. The center image of the study will appear in the middle medical image view with identification data, as shown in *Figure 25 Start the Load Step, page 33.*

**NOTE:** If the moving image is a CT series, then the fixed image should always be selected first. The system assumes the first selected CT series is the fixed image. If the moving image is PET, MR, or XA, it may be selected first. If you select a 'B' CT image first. Deselect it. Select the primary CT image and then reselect the moving CT image.

## Select Anatomical Contours

CyRIS MultiPlan and InView can save and push anatomical contours as DICOM RT structure sets. The system can also receive DICOM RT structure sets from other planning and contouring stations.

As with the fixed and moving image series, select the check box before the series identifier. A check mark and the V indicator will appear with the series. Its description or Series UID indicator will appear below the fixed CT image.

You can edit the contours after they have been loaded. Do this in the Delineate step of the Contour task.

**NOTE:** A DICOM RT Structure Set of anatomical contour data can only be loaded into CyRIS MultiPlan if it is a part of the same study as the fixed medical image.

**WARNING: Be certain to verify that all imported contours align with the fixed CT image.**



561

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



### Load the Selected Image Data

If you have made a mistake selecting the data you wish to load, deselect the unwanted series by unselecting the check mark before that series.

If the data is consistent, the **LOAD DATA** button in the Control View is active. Choose that Load Data to load the data and permit access to the Fuse task (if you have multiple images) and the Align task.

## Load an Existing Plan

After selection of a patient, the plan list appears. Select a plan from the list. The **LOAD DATA** and **DELETE PLAN** buttons become active. The left 2D view displays the patient information including the plan name.

Before loading the plan, you can change the moving image or add a DICOM RT structure set to replace the existing contours. You cannot, however, change the primary image.

To change the moving image, you must select the existing plan first, and then select the moving image you want to use.

Select the **LOAD DATA** button to load the plan.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118 562

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



## Recover the Last Plan

If the system exited unexpectedly or you inadvertently exited planning without saving the result, you can recover much of your work using the Recover Plan option. This option is only available if neither a plan nor an image series has been selected.

The recovered plan will generally not recover everything that you have done. The system automatically records the state of the active plan every five minutes. The amount of lost work is typically five minutes or less.

## Delete a Plan

After selection of a patient, the plan list appears. Select a plan from the list. The **LOAD DATA** and **DELETE PLAN** buttons become active. You can delete a plan as long as treatment for that plan has not begun. You can also not delete a plan that another user is currently working on.

## Refresh Patient List

If you or another user has changed the patient database while you have been planning, press **REFRESH PATIENT** List to update the patient list.



563

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



# FUSE TWO IMAGE SERIES

Once two images (a fixed and moving image) are loaded, the Fuse Task is enabled in the user interface of CyRIS MultiPlan. To enter, click on the Fuse tab. The screen layout will change, and you will now be in the first step of the Fuse task, Seed Point alignment (*see, Figure 26 Seed Point Selection with 3D Views, page 38*).

**WARNING: Be certain that the two images you will register are images of the same patient.**

## Seed-Point Alignment

The image fusion component of the CyRIS MultiPlan works by finding the transformation that maximizes the mutual information of the two loaded images. Once this transformation has been determined, the images may then be fused onto a common space. In order to function correctly, an approximation of the correct transformation must first be supplied. Do this by selecting three seed points in each image that correspond to the same anatomical landmarks. Select the landmarks in the same order on each image.

The seed points only need to represent approximately the same positions in each image; you do not need to spend a great deal of time and care selecting these points. If the refinement in the Register step is successful, the final accuracy of the fusion is not affected by the initial choice of seed points. However, if the seed points differ too greatly in the two images, this may lead to a failure of the refinement in the Register step. In *Figure 26 Seed Point Selection with 3D Views, page 38*, a CT and MR image are shown, with the seed points chosen to be the left and right eyes, and a point located on the forehead.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015

**Figure 26 Seed Point Selection with 3D Views**

## Set Seed Points

When three seed points have been selected in the fixed and moving images, the Register step is enabled.

**NOTE:** The transformation represented by the seed points becomes ill-defined as the points approach becoming collinear. For this reason, it is recommended that you choose seed points that are clearly non-collinear. (For example, the configuration shown in *Figure 26 Seed Point Selection with 3D Views, page 38* is acceptable.)

### 3D and 2D Layouts

Two layouts are available for seed point selection. The default layout has 3D volume renderings of the fixed and moving image in the top left and right of the Display View. Typically, this layout is preferable when using cranial images, because adequate seed points can be chosen on the skin surface. However, for extracranial images, it is often very difficult to select seed points with the 3D views. In these cases, a layout using 2D are preferred method seed point selection. Two 2D pairs are available: axial and sagittal images, and axial and coronal images. To change layouts, click on the desired layout in the Control View. Any seed points already selected will be retained and transferred to the new views.



565

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



### Choose Seed Points

Select a seed point by double clicking when the cursor is at the desired location. When the 2D layout is selected, a seed point will be created at the desired position and displayed on both the axial and coronal image slices. When the 3D layout is selected, a seed point will be created at the surface point closest to the cursor position. To delete the last seed point in the fixed/moving image, click the appropriate Delete last button on the control panel. To delete all the seed points in the fixed/moving image, click the appropriate Delete all button on the control panel.

### The 3D Filter

The windows in the bottom left and right of the view contain the 3D filter controls for the fixed and moving images respectively. These controls work similarly to the window/level controls on the histogram discussed in *section, Window/Level Mode , page 10.* However, instead of operating on the brightness of the image, they operate on the opacity of the image. Hence anything in the image having intensity less than that of the left hand side of the rectangle is transparent in the volume rendering. Anything with intensity greater than that of the right hand side is fully opaque. By manipulation of the 3D filter, different structures in the image may be hidden or highlighted.

## Load a Preregistered Image

In some cases the fixed and moving images are already in a common space. This is most likely to occur if the moving image is the saved result of a previous fusion (*see section, Image Data, page 83*).

Check the Already Registered box to disable seed point selection and use the other steps without completing the Register task.

If the Define Seed Points step is entered after the Register step is partially or fully completed, the Already Registeresd box will be checked. Uncheck the box to enable seed point selection. Then, perform the Register step again if desired.

# Image to Image Registration

The Register step uses maximization of mutual information to refine the transformation relating the moving image to the fixed image. Select **Register** to enter the Register step. *Figure 27 Register Step, page 40* appears.

## Intensity-based Registration

The Display View for the Register step has a single 3D and three 2D "split views".



566

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



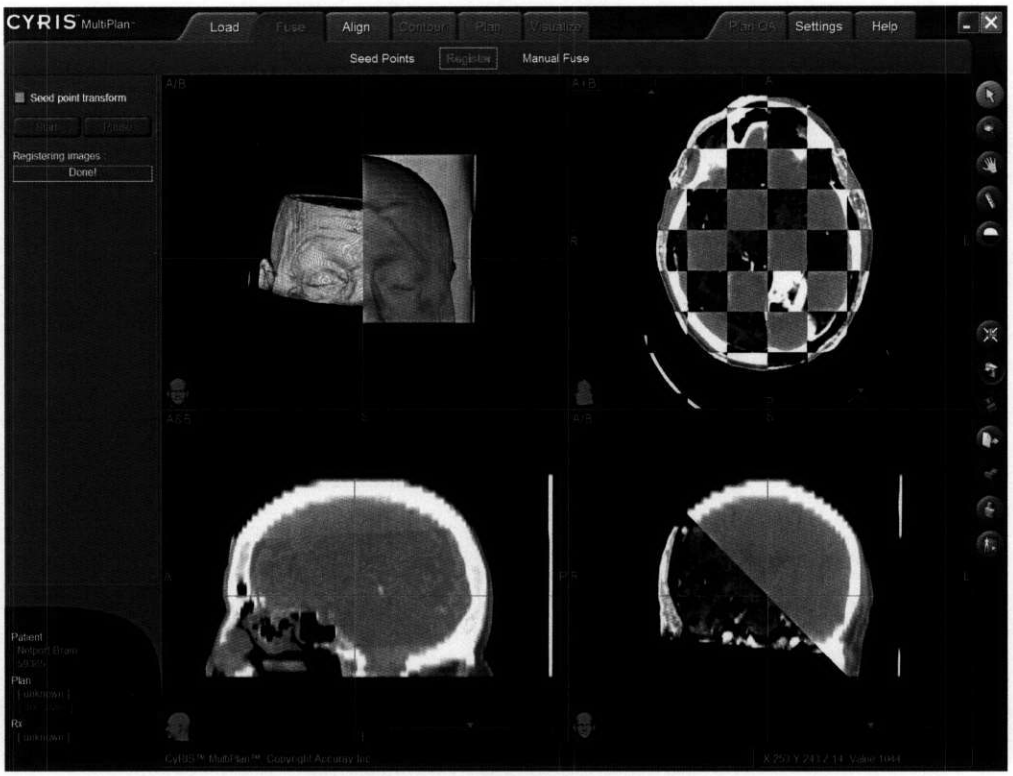



**Figure 27 Register Step**

The fixed and moving images are displayed, fused according to the transformation that was calculated using the seed points. This fusion will generally look approximately correct, but not perfect. Click the **START** button to begin the refinement process. After a short pause, the progress bar will start expanding towards the right, and the images in the views will make small movements relative to each other as the fusion is refined.

During the refinement process, you may manipulate the split views to evaluate the quality of the fusion. Move the image partition in any of the 2D views by clicking the mouse at the intersection of the two green lines and dragging to the desired position. Rotate the image partition by clicking the mouse on the partition and dragging to rotate it. The position of the partition in the 3D view is automatically updated when the partition is moved or rotated in the 2D views.

Click the **PAUSE** button to suspend the refinement process, and use **CONTINUE** to resume it. When the progress bar reaches the right hand edge of the scale, the word Done! appears in the progress bar. **CONTINUE** and **PAUSE** are both disabled and the refinement has been completed.

If you are satisfied with the quality of the fusion before the refinement process has been completed, you may at any time proceed to another task; the refinement will be stopped, and the currently displayed fusion will be retained.

In some cases (for example, if the seed points do not correspond closely enough), the refinement process may fail. This will generally be immediately apparent: instead of the two images moving into closer alignment, they will move completely out of alignment during refinement. If this happens, the recommended corrective action is to return to the seed point selection screen, uncheck the Already Registered box, choose seed points more carefully, and perform the Register step again.



567 Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



**WARNING: The intensity-based algorithm finds the optimal registration between the two images based on a specific mathematical model. The user, however, is responsible for assuring that the final registration is clinically acceptable for target and critical volume delineation. Use the overlay, split screen, and checkerboard display modes to visually check that the algorithm has adequately registered the two images.**

## Seed-Point Registration

Check the **Seed point registration** box to use the transform based solely on the seed points to define the final fusion. It is generally not recommended that you do this; one example, however, in which it may be necessary, is the case in which fusion refinement cannot be done successfully on the two loaded images. In these cases, if seed points are chosen with sufficient care, an acceptable fusion can be achieved in this manner. When the **Seed point registration** box is checked, the controls for refinement are disabled; while refinement is in progress, the **Seed point registration** box is disabled.

**NOTE:** If you check the "Seed point registration" box after you have completed a refinement, you will lose the refined fusion result!

# Manual Registration

If the automatic registration is not acceptable, you can use the manual registration is not fully acceptable, you can use the tools in the Manual Registration step (*Figure 28 Manual Fuse Step, page 42*) to update the transformation between the fixed and moving images.

You can translate or rotate the moving image in any of the three planar views. Drag the cursor to make gross changes to the transformation. The faint circle in the view defines the boundary of the translation and rotation portions of the screen. Inside the circle, cursor movements translate the moving image; outside the circle, cursor movements rotate the moving image.

Fine motion is controlled with the arrows at the bottom right of each planar view. The straight arrows translate the image one pixel (in screen coordinates) in the indicated direction. The arced arrows rotate the image one pixel in the indicated sense. Since the resolution of the transformation is based on screen pixel resolution, you can get finer movements by zooming in on the image.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118 568

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



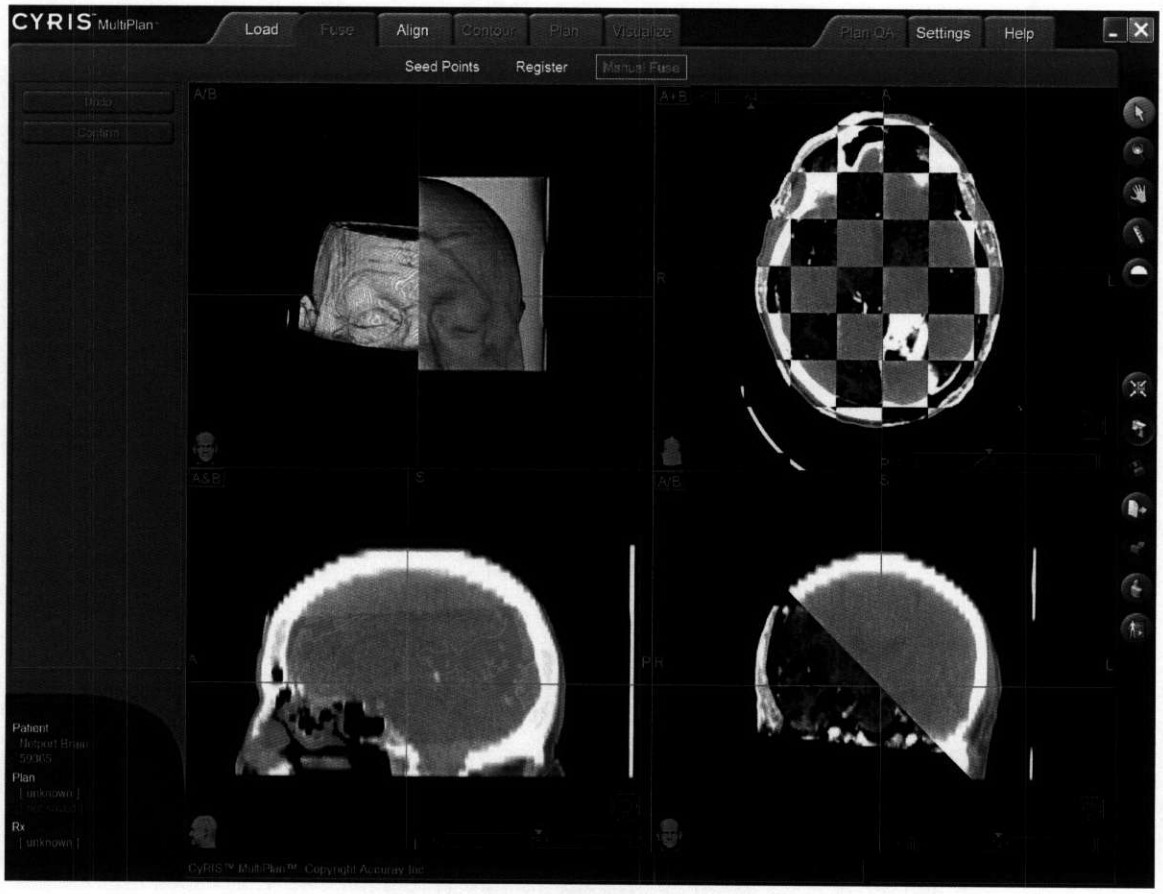



**Figure 28 Manual Fuse Step**

You can either **UNDO** or **CONFIRM** the transformation from the appropriate buttons in the Control View. If you leave the step without confirming the transformation, *Figure 29 Confirm Manual Registration, page 42* will appear. This prompts you to either accept or reject the manual transformation.

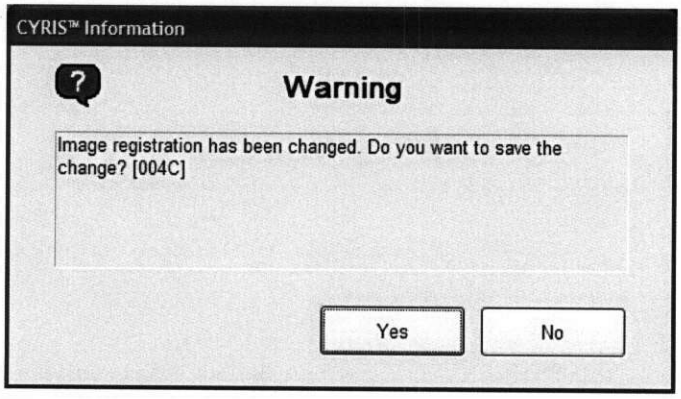



**Figure 29 Confirm Manual Registration**



569

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



# ALIGN

The ALIGN task allows you to set parameters that describe how the patient will be treated. The task is divided into three steps. The first allows you to set the basic Treatment Parameters. The second allows you to locate and identify fiducials. The last allows you to set the machine center with respect to the CT study.

## Set Treatment Parameters

The user interface for the Treatment Parameters step is shown in *Figure 30 Set Treatment Parameters, page 44*. All the work that you will do will be in the control view.

The top setting is the Number of Stages. You can type in a number or increment or decrement the number of stages using the '+' or '-' buttons. The entire patient treatment will be divided into the number of stages selected. Each stage of the treatment will be planned to deliver the same dose as the other stages.

Two cascade buttons provide you means to select the Treatment Anatomy and Template Path Set. The top button tells the planning and delivery system what the general anatomical area being treated is. Each anatomy has one or more unique template path sets. Use the second button to set the template path set for this treatment.

**WARNING: Never use node sets for one anatomical site to treat another anatomical site. Using the wrong node creates a risk of collision with the patient, because the couch model may not accurately represent the patient position.**

Below the two cascade buttons is the Tracking Method option. The available tracking methods are dependent on the configuration of your system.

You can then select the Treatment Mode. Two options are possible, Automatic and Manual. In Automatic mode, the computer controls the timing for diagnostic images and the firing of individual beams. This mode is the default for most treatments. In Manual mode, the operator signals the system to take diagnostic images and fire individual beams. Manual mode is generally used only when respiration effects are minimized using breath holding.

The next option predominantly supports manual mode operation. This option allows you to set the maximum duration that a single beam is on. The value should be set at 1.5 times the length of time you expect the patient to hold his or her breath during treatment. The value can also be used if you have a specific limit of beam-on time you wish to use between diagnostic x-rays. Set the maximum beam-on time to 1.5 times the beam-on limit.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



The last option SST Mode is only available when you choose SST (Skeletal Structure Tracking) as the tracking method. When you choose SST, you must indicate the anatomical regions being treated. Options include CSPINE (cervical spine), TSPINE (thoracic spine), or LSPINE (lumbar spine).

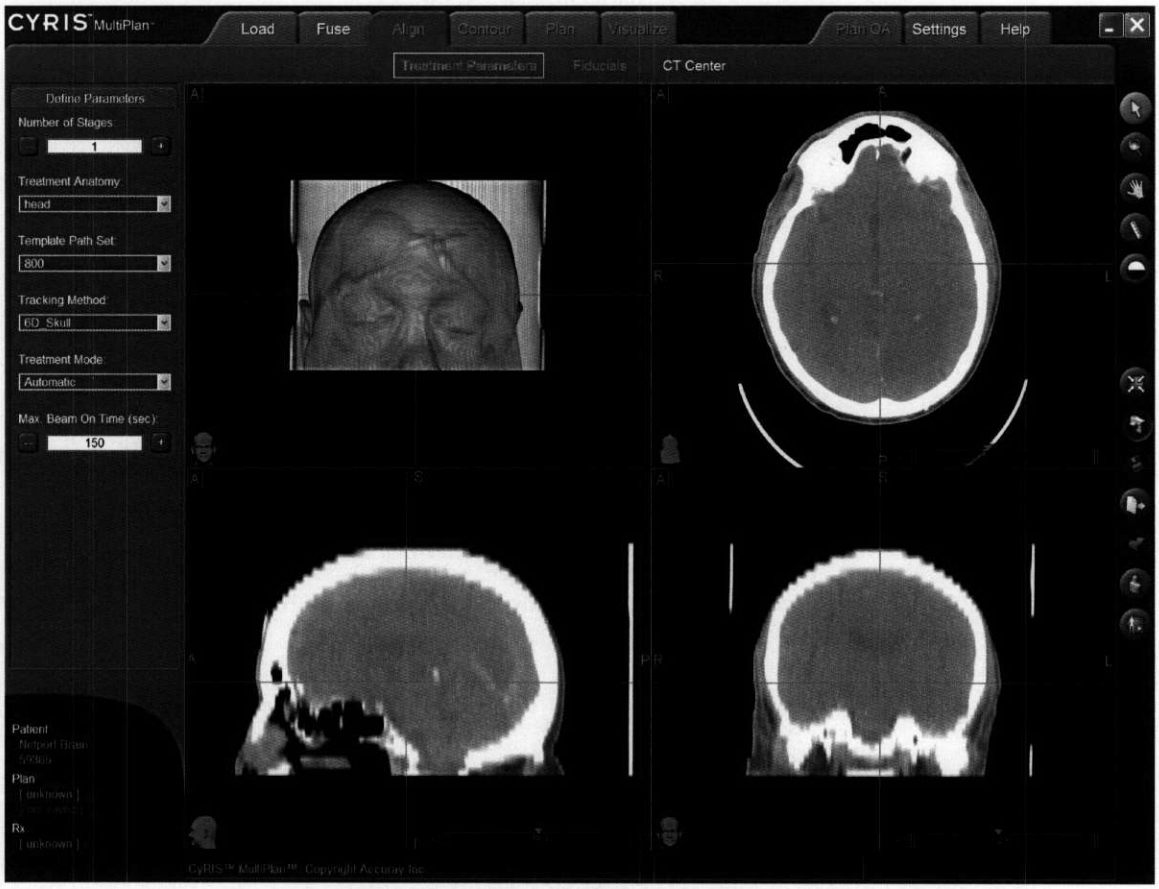



**Figure 30 Set Treatment Parameters**



571

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



# Identify Fiducials

**WARNING: Delivery accuracy depends on correct identification of fiducial locations. Be careful to correctly identify the locations of the fiducials.**

If you select fiducial tracking in the Treatment Parameters step, you will need to identify at least one fiducial before proceeding. The Fiducial location step is shown in *Figure 31 Fiducial Identification, page 46*. The display view consists of a 3D view and three planar views (axial, coronal, and sagittal).

First select the type of fiducial. The types available are dependent on the configuration of your system.

Place a checkmark in the Auto Center check box to use the Auto Center mode. When Auto Center is checked, the system determines the center of the fiducial by locating the center of gray-scale intensity in a small volume around the marked fiducial location. When Auto Center is unchecked, the center of the fiducial is the marked fiducial location.

**NOTE:** When the Auto Center mode is checked, be sure to mark the fiducial close to the center rather than at the end of the fiducial. This ensures that when the system searches for the center of gray-scale intensity the entire fiducial will fall within the search region.

**Step 1.** Adjust the 3 planar views so that the fiducial being marked is centered in each of the axial, sagittal and coronal views. This can be accomplished using the slice sliders.

**Step 2.** Visually locate the center of the fiducial, usually on the planar view that includes the majority of the fiducial. This can be confirmed using the ruler tool.

**Step 3.** Click on the center of the fiducial to mark it.

The fiducial will appear as a magenta marker in the 2D views. The coordinates of the marker will be added to the list of fiducials.

If you want to change the location of an identified fiducial, highlight it and select **Delete**. Then, relocate the fiducial. You can relocate the fiducial in the 2D or 3D views by dragging the markers. You can also delete the last fiducial in the list or all the fiducials with the appropriate button.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



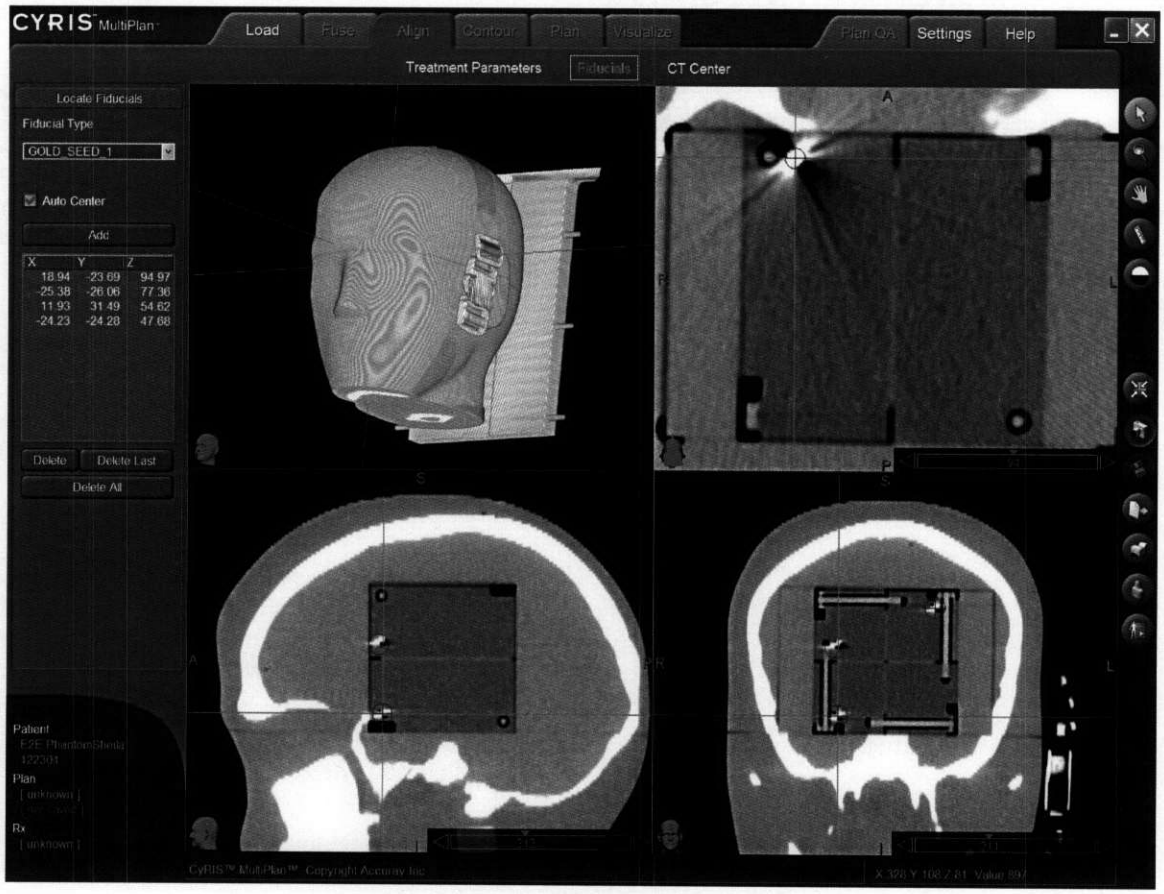



**Figure 31 Fiducial Identification**

## Position the Machine Center

During treatment it is important that the machine center is set with respect to the CT study in such a way that the imaging system can function correctly.

The CT Center step is shown in *Figure 32 Confirm CT Center, page 47*. The Display View includes 5 windows. The top two are digital reconstructed radiographs (DRR) of the patient, given the current machine center. The algorithm used to generate these DRR's differs from the algorithm used by the delivery system. This algorithm allows for instant updates of the DRR's. The quality of the image, however, is not as good as you will see with the delivery system.

The bottom 3 windows are the axial, coronal, and sagittal 2D views of the patient. The focus of these three 2D views is the current CT center. As you move the CT center the Current CT Center Point coordinates will appear in the Control View. If coordinates have been confirmed they will appear in the Confirmed CT Center Point table.

For skull tracking, you generally want to align the CT study so that the silhouette of the patient has a 10-15 mm gap in each view at the superior and anterior sides of the patient. For fiducial tracking, you want to be certain that all the required fiducials for a given plan are within the Field of View of the camera.



573

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



When you are satisfied with the CT offset, select **CONFIRM** from the Control View. After selecting Confirm the values in the Confirmed CT Center Point table will change so that they are the same as in the Current CT Center Point table.

**NOTE:** You must confirm the CT Center before you can proceed to the Contour and Plan tasks. If you need to change the CT Center, you have to reconfirm the new CT Center or the plan will retain the original CT center.

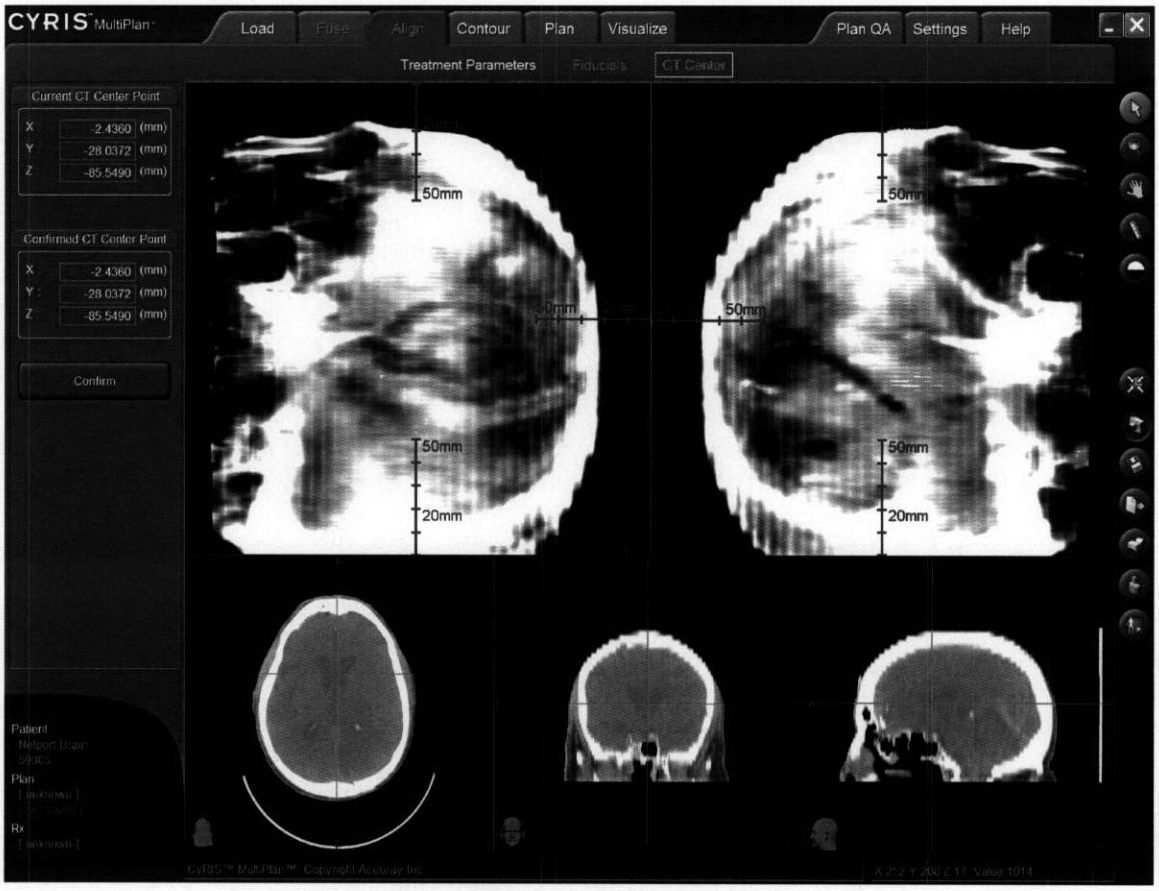



**Figure 32 Confirm CT Center**



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



# CONTOUR

You can create and modify anatomical volumes of interest in the Contour task. This task has two steps: Delineate and Properties. The Properties step allows you to change specific tags and display settings associated with each Volume of Interest. The Delineate step has the drawing tools you use to draw and edit Volumes of Interest.

## Volumes of Interest

A Volume of Interest (VOI) is a user defined region overlain on the medical images. In general, each VOI should represent a distinct anatomical feature. You can draw up to 22 VOI.

### VOI Structure

Each VOI consists of one or more Contour Sets. Contour Sets allow you to have substantial flexibility when defining the geometry of a VOI. One application for multiple contour sets might be a VOI that can be defined by two disjoined contours in one or more slice. For instance, the superior portion of the femur might be drawn as two contours in each axial slice. Though the contours are the same VOI because they are connected in the inferior slices, they are part of different contour sets in superior slices. A VOI may also be comprised of a solid contour set and a cavity contour set. This capability allows you to create hollow Volumes of Interest. This possibility is especially useful for inverse planning.

Each Contour Set is comprised of contours drawn on one of the primary orientations (axial, coronal, or sagittal) for the patient. Each Contour Set can have only one contour per slice.

### VOI Properties

*Figure 33 Properties Step, page 49* shows the Properties step of the Contour task. The list on the right of the Display View indicates the properties associated with each VOI. Each VOI has a name that you can set, as well as a type. Two types are available: Target and Critical.

The properties list also provides the volume of each VOI. The volume is a calculated for each volume of interest. Volumes are calculated by counting the pixels in the CT study that are enclosed or partially enclosed by the contours of the volume of interest. Therefore, the accuracy of the volume measure is the resolution and slice thickness of the CT study.

These properties and other VOI properties can be set from the properties dialogue (*Figure 34 VOI Properties Dialogue, page 49*) accessed from the Delineate step. This dialogue also allows you to name the VOI, set its type and color. In addition, you can set the plane of delineation for the VOI. The default plane is the axial plane. You can also choose coronal and sagittal planes. Each Contour Set for a Volume of Interest must be drawn in the same plane. You can also select if a VOI is a boundary VOI. In this instance, the VOI will be treated like a surface in three dimensional space. Boundary VOI's can have only 1 Contour Set.



575

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



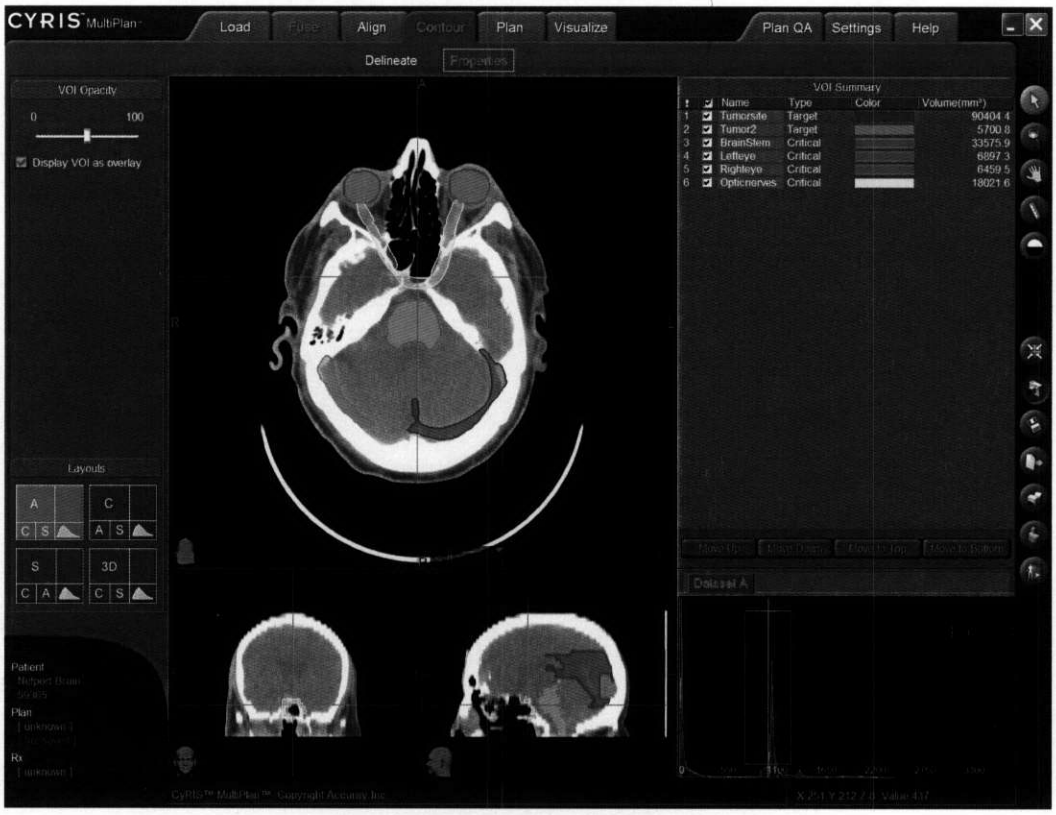



**Figure 33 Properties Step**

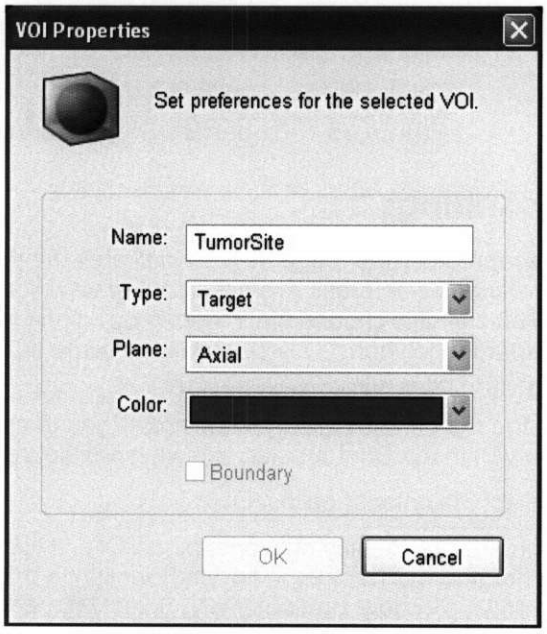



**Figure 34 VOI Properties Dialogue**



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



The layout switcher in the control view allows you to set either a 2D View (*Figure 33 Properties Step, page 49*) or a 3D View (*Figure 35 Properties Step with Volume Rendered Image, page 50*) as the large image at the top left of the display view.

Use the 3D View configuration to use the volume rendered anatomy to find a starting point for 2D contouring. This capability can be especially useful for locating the nidus of an AVM a 3D rotation angiographic image. To do this, filter the 3D angiograph so that the circulatory system is visible. Then click on the nidus in the 3D view. The center of the 2D views will appear at the boundary of nidus selected in the 3D view.

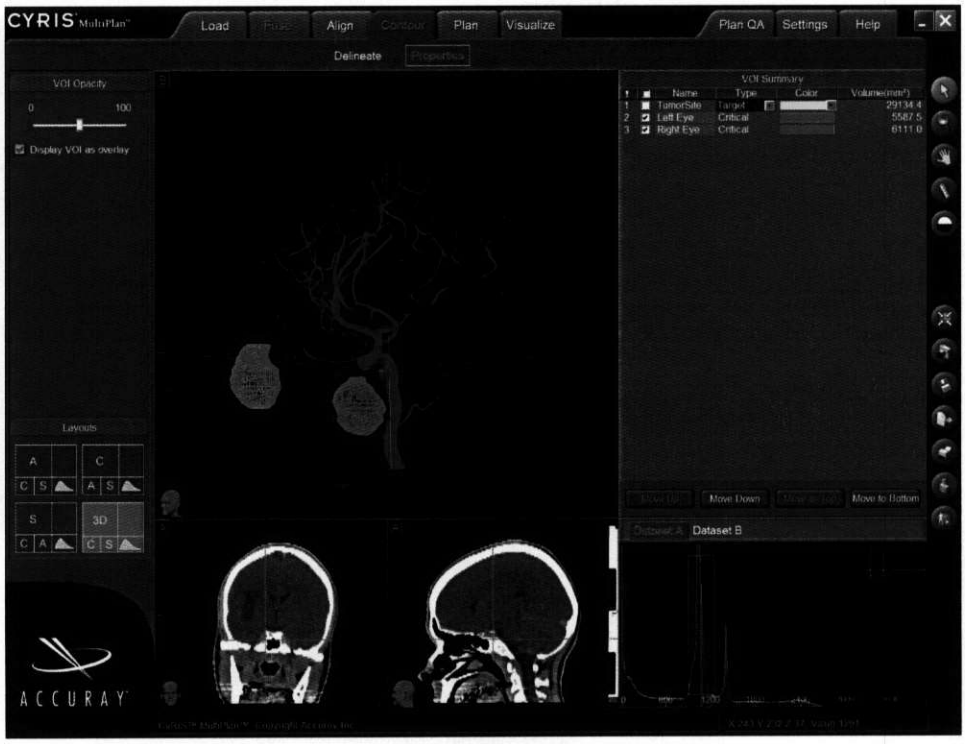



**Figure 35 Properties Step with Volume Rendered Image**

## Display Settings

*Figure 33 Properties Step, page 49* also indicates the display settings that you can use to portray the drawn volumes of interest. From the control view you can determine whether to fill or not fill the contours. You can also choose the transparency of the filled contours. Move the slider to the left for a fully transparent polygon. (This setting is the same as including no fill for the polygons.) Move the slider to the right for a fully opaque polygon.

The list on the right of the Display View allows you to choose to display or not display each VOI. (The active VOI in the Contour step is always visible, regardless of the setting chosen here.)

You can select the color of each VOI.

You can prioritize the display of overlapping VOI's. If two volumes overlap, the higher VOI in the list has the higher priority. To change priority, highlight a VOI and select **MOVE UP** or **MOVE DOWN** to step the priority up or down, respectively. Select **MOVE TO TOP** or **MOVE TO BOTTOM** if you want to give a VOI either the highest or lowest priority.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



# Drawing Tools

*Figure 36 Contour Step, page 52* presents the Delineate step of the Contour task. This task provides you access to the drawing tools you can use to create and modify Volumes of Interest.

In this figure, no VOI has been selected for you to draw. All the VOI are displayed in the selected display color. At the top of the Control View, select the VOI to work on from the cascade list of possible Volumes of Interest. The default VOI names, types, and colors are selected from the Preferences step. After selection of a VOI the Control View functions become active as shown in *Figure 37 Contour Step With VOI Selected, page 53.*

You have the option to choose how other VOI's and isodose curves are displayed when drawing a specific VOI. The Display All VOI and Display Isocontours options allow for full color display of all VOI and the isodose distribution when drawing a VOI. Visualizing isodose curves is especially helpful when creating tuning structures to tailor results during conformal inverse planning. When the Display All VOI is disabled, the other VOI appear gray. When the Display Isocontours is disabled, the isodose curves will not appear at all. Disabling visualization of these overlays allows you to draw based solely on the information in the medical image.

Select **Properties** to open the dialog of *Figure 34 VOI Properties Dialogue, page 49*. As noted earlier, you can rename the VOI from this dialog.

You can also change the display color of the VOI. A cascade list of default colors will appear. The last option in this list opens a custom color creator that has a color grid you can use to choose any color.

As noted earlier, you can also choose the VOI type (critical or target), set it as a boundary VOI, and choose the drawing plane for the VOI.

Initially each VOI has one contour set. That contour set is a solid. Contour sets are identified by number and type. The first contour set is 'Contour Set 0' and is always a solid contour. Subsequent contour sets can be either solids or cavities. A solid is the default for a contour set. Select **New** to begin to define a new contour set for a VOI. You can also Delete a contour set. If all the contour sets of a VOI are deleted, the VOI becomes undefined.

By default, every Contour Set is contoured in Auto Interpolation mode. You can opt to turn off automatic interpolation with the check box. This mode is explained in *section, Interpolation of Volumes of Interest, page 58.*



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118 578

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



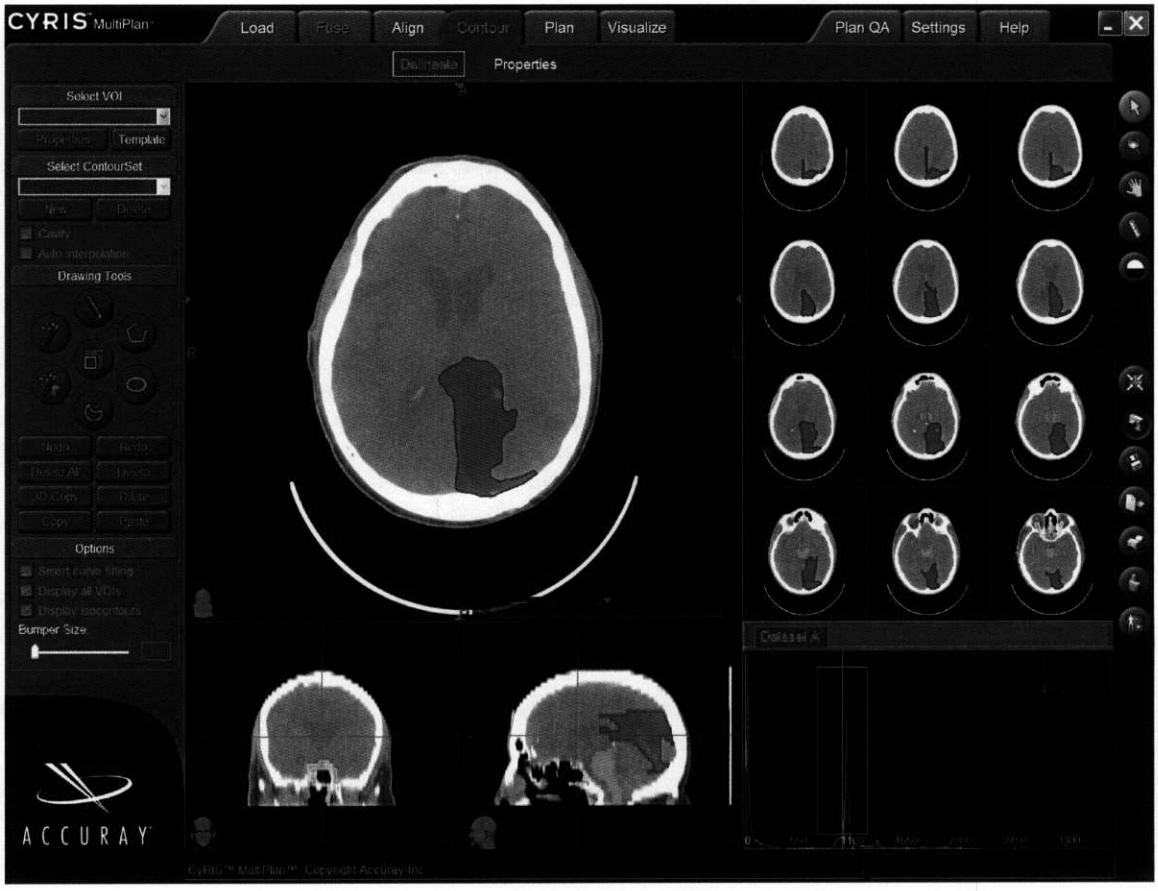



**Figure 36 Contour Step**



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

579

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



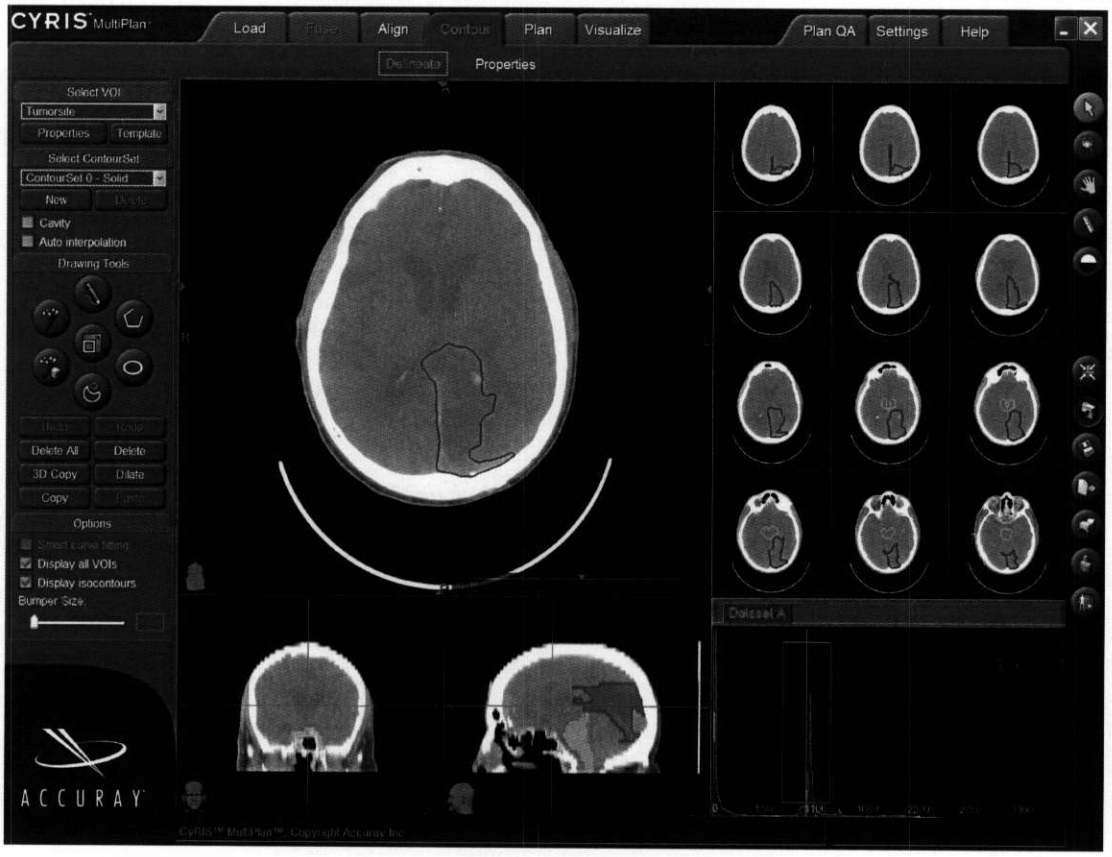



**Figure 37 Contour Step With VOI Selected**

The Edit Commands below the drawing palette allow you to Undo the last drawing action you took. You can back through everything you have drawn since you entered the Delineate step. You can Redo drawing steps you have backed through, but did not intend to undo.

You can Copy a contour and Paste it onto another slice as the same or as a different VOI.

Use the 3D Copy tool to copy all the drawn and interpolated contours of a contour set into another contour set. When you select this option, the popup shown in *Figure 38 3D Copy of a Contour Set, page 55* appears. You have three options for the destination of the copied contour set. The first option copies the contour set into a contour set for the same VOI. The second option copies the contour set into a contour set for a different VOI. The third option copies the contour set into a shell contour for a different VOI. If the third option is chosen, the new VOI will have two Contour Sets. The inner contour will be a cavity. The outer contour will be a solid.

You also have the option to immediately proceed to the Dilate option and to choose whether the copied contour set will be a solid or a cavity. If the Dilate option is selected, *Figure 39 Dilate or Erode a VOI, page 56* opens immediately after *Figure 38 3D Copy of a Contour Set, page 55* closes.

Use the bottom cascade buttons to choose the Target VOI and the Target Contour Set. Although the default Source VOI and Source Contour Set is currently the selected VOI, you can select a different source with the left cascade buttons.

After the VOI Contour Set has been copied, the selected VOI and Contour Set is the target for the 3D Copy.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



A contour can be dilated or eroded with the Dilate option. Choose this option and *Figure 39 Dilate or Erode a VOI, page 56* appears. The algorithm for this option uses a rolling ellipsoid to provide true 3D dilation and erosion. You can choose Isotropic (in which case the ellipsoid degenerates into a sphere) or Anisotropic dilation. If Isotropic is chosen, enter the amount you wish to dilate or erode the region in mm. If anisotropic, enter the amount in each cardinal patient direction (anterior, posterior, right, left, inferior, and superior). You can erode, dilate, or leave unchanged the VOI in any direction using this command.

**NOTE:** The maximum allowable offset for dilation and erosion is 15 mm. Larger offsets are overly memory intensive and time consuming. If you wish to dilate or erode more than 15 mm, it is much faster to do so in two steps. For instance, to dilate 30 mm in one step will take four times as long as dilating 15 mm twice. Discrepancies in the dilation or erosion will be on the order of the pixel size of the image.

Apply the values from *Figure 39 Dilate or Erode a VOI, page 56* to a VOI shaped like the yellow ellipsoid in *Figure 40 VOI Dilated and Eroded, page 57*. The resulting VOI (in one plane) is the green ellipsoid. It is eroded in lateral direction and dilated in the anterior/posterior direction.

You can Delete an individual contour or Delete All the contours of the selected Contour Set. If all the contours of a Contour Set are deleted, the Contour Set becomes undefined.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



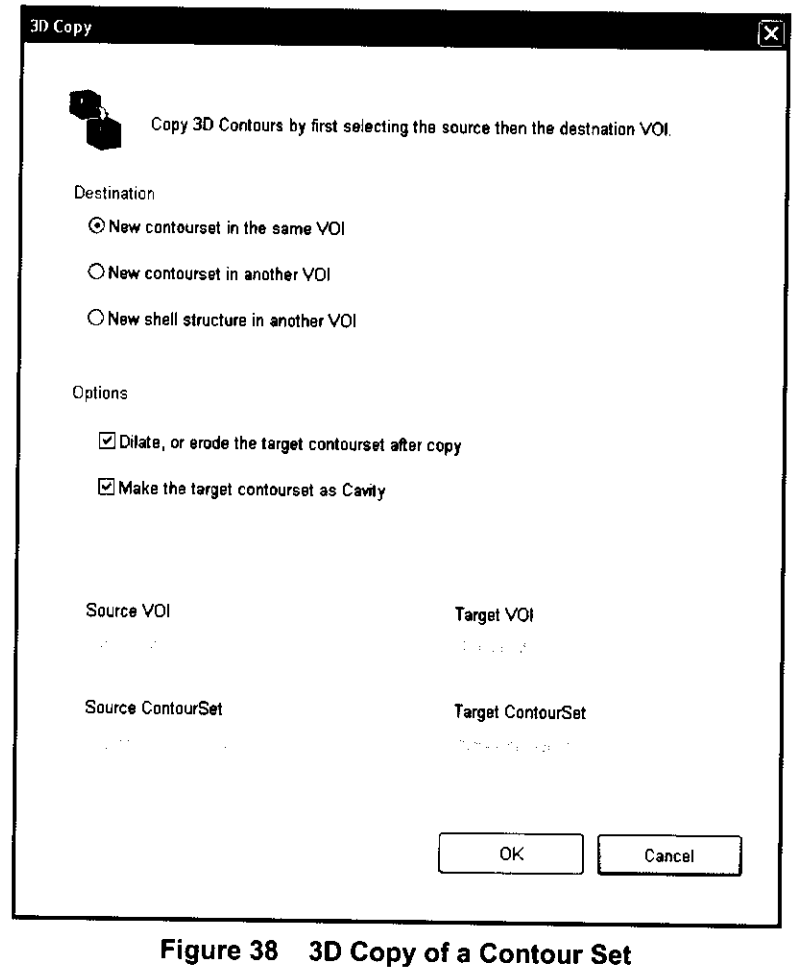



**Figure 38 3D Copy of a Contour Set**



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



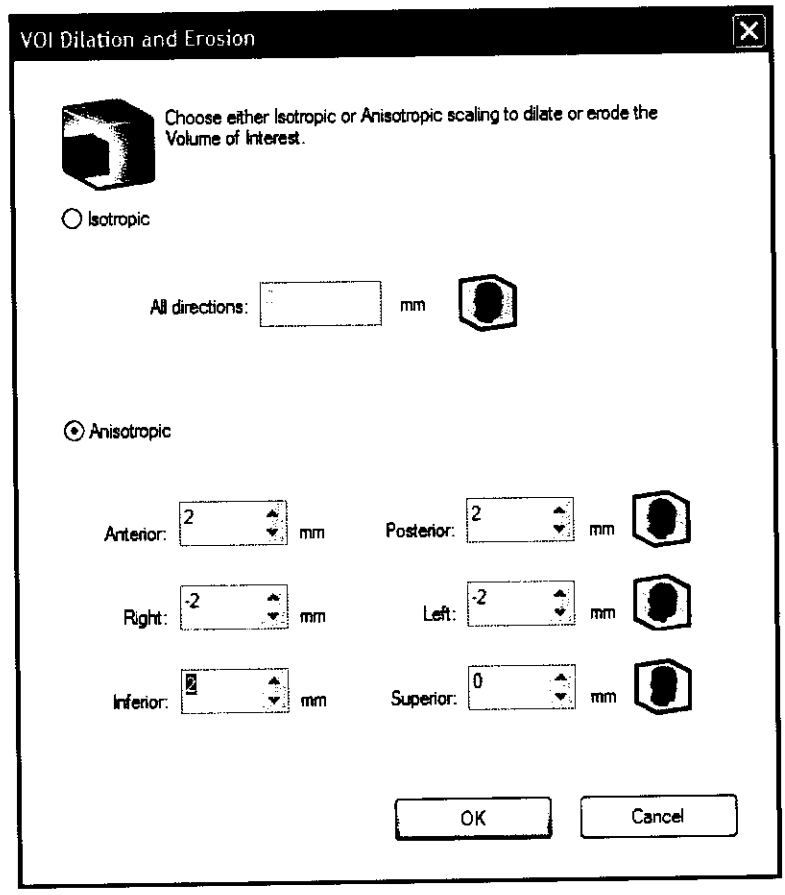



**Figure 39 Dilate or Erode a VOI**



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



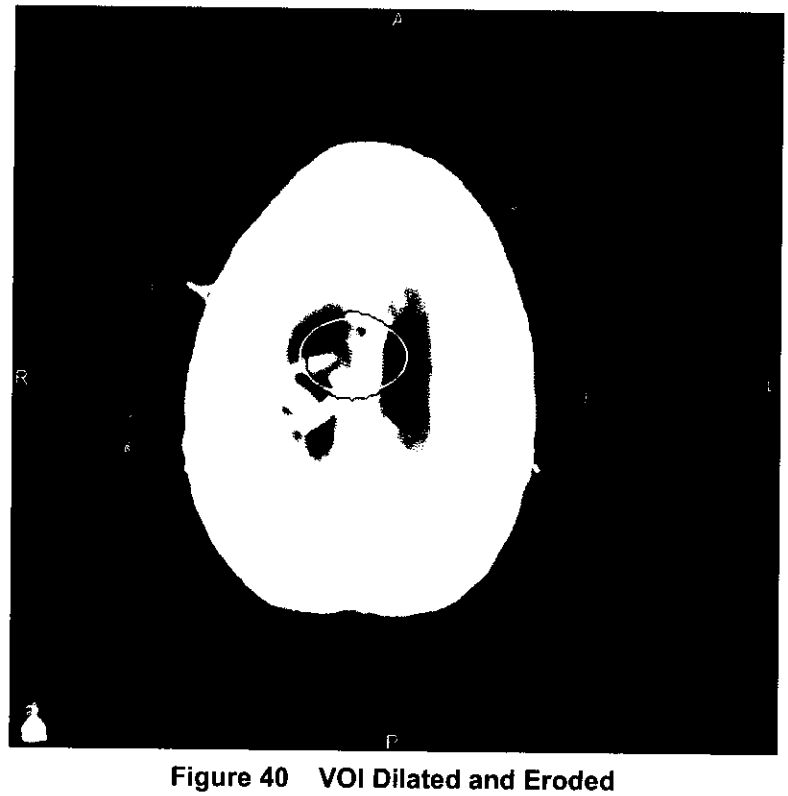



**Figure 40 VOI Dilated and Eroded**

Set the drawing tools from the palette of icons under the Drawing Tools label. The tool arrangement on the palette, clockwise from the top, is Pen, Point, Ellipse, Bumper, 3D Magic Wand, and Magic Wand modes. The middle button is the Rescale mode.

In addition to displaying VOI and isocontours while drawing, the Options at the bottom of the Control View include the ability to set manual drawing in Smart Curve mode. This mode allows you to use the image intensity to 'snap' a contour to a contrast boundary in the anatomy. *Section, Smart Curve Fitting Option, page 61* describes this option in more detail.

The Display View has a large image at the top left. This image is a 2D view of the drawing plane. Immediately below that are the 2D perpendicular views. To the left of the large view are twelve smaller views of the drawing plane. These views are the six slices preceding the axial view and the six slices following the axial view. In Pointer Mode, if you click the slice number in one of the smaller slices, the focus will change so that the slice becomes the large axial view. Typically, you should draw on the large view. It is possible, however, to draw on any of the smaller views. You can change the displayed modality of the large view or the perpendicular views. The viewed images are fixed image (A), moving image (B), and split image (A/B). The smaller drawing windows have the same mode as the larger window, except that the split image display displays the fixed (A) images in the small windows.

At the lower right of the Display View are the image histograms you can use to set the Window and Level of the 2D images (*see section, Window/Level Mode , page 10*).



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118 584

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



## Interpolation of Volumes of Interest

As noted above, each contour set can use automatic interpolation to speed up generation of that contour set. You can also choose to turn off this feature for each contour set.

In automatic interpolation mode, you draw a contour on one slice and draw a second contour on another slice. The intermediate contours are automatically determined using linear interpolation. If a contour is drawn on an interpolated slice or an interpolated contour is modified, the other interpolated contours will be updated.

The system distinguishes between drawn and interpolated contours. Drawn contours are solid lines. (For instance, examine the left eye in *Figure 41 Drawn Contour, page 58.*) Interpolated contours are dashed lines. (For instance, examine the right eye in *Figure 42 Interpolated Contour, page 59.*)

Extrapolated contours are shown as dotted lines and have the same shape as the nearest drawn contour. The dots have a larger separation than interpolated lines. These extrapolated contours are not a part of the contour set. They are shown to give you a visual reference for the shape and location of the closest drawn contour.

For non-active, gray volumes, extrapolated curves are not shown, because they are not considered part of the VOI. Interpolated curves are shown as solid lines because they are part of the VOI.

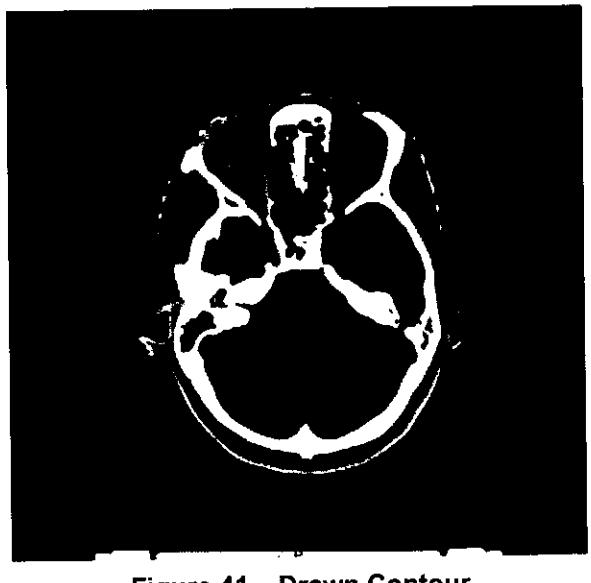


**Figure 41 Drawn Contour**



585

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015

**Figure 42 Interpolated Contour**

## Pen

Select Pen and the cursor will change to a pencil shape when over the 2D views. Depress the mouse and drag it around the contour to be drawn. The contour will automatically be closed and intersecting regions will be eliminated.

## Line

Select Line and the cursor will become a crosshair when over the 2D views. Start the contour by clicking the mouse. Add vertices by clicking the mouse at points along the boundary of the region being contoured. Delete the contour by right clicking. End the contour by double-clicking; the contour will automatically be closed and intersecting regions will be eliminated.

## Ellipse

Select Ellipse and the cursor will be elliptically shaped when over the 2D views. Contour the region by clicking the mouse at one edge of the ellipse and then dragging across to the opposite edge.

## Rescale

Select Rescale and a square will envelope the selected Volume of Interest.

Eight rescale vertices are on the square, one at each corner and one in the middle of each side. When the mouse is over one of these vertices, the cursor becomes a line with arrows at each end. Depress the mouse at a vertex and drag the vertex to rescale the contour.

Two yellow control points are inside the square. The **Move** control point is at the center of the square. The **Rescale** control point is in the middle of the horizontal line between the center point and the right side of the square.

If the mouse is over the **Move** control point, the mouse cursor will change to a cross with arrows at the end of each line. Move the contour by depressing the mouse and dragging it in the 2D view.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



If the mouse is over the **Rescale** control point, the mouse cursor will change to a horizontal double arrow line. Depress the mouse left button at the control point and drag the point to rescale the contour in all directions. The contour will grow (if you drag the point away from the center), or shrink (if you drag the point close to the center). The rescale is proportional with respect to the center point.

When the cursor is in any other location, it becomes a small arrowhead and you cannot do anything.

## Magic Wand

The Magic Wand is a tool that allows you to automatically generate a contour on an image slice. Select Magic Wand and the cursor takes on the shape of a wand in the 2D view.

Adjust the Window & Level for the image so that the region of interest you wish to delineate has a large amount of contrast in relation to the surrounding anatomy. The contrast of the image should be such the object you plan to contour is a closed region. Otherwise, the delineated contour is likely to leak outside the object. Click the mouse toward the center of the region you wish to contour and it will be automatically contoured.

For some volumes, the boundary contrast may lead to the automatically drawn contour bleeding outside the volume. Use the Minimum Leakage Allowed slider at the bottom of the Control View to prevent leakage. The slider sets the length of boundary segments. This helps the magic wand bypass possible regions of leakage. It, however, yields more coarsely defined VOI.

## 3D Magic Wand

The 3D Magic Wand is similar to the Magic Wand. The only difference is that it will attempt to contour the VOI across the entire image volume instead of just within a single 2D slice. The main difficulty with the 3D Magic Wand is that over numerous slices, the contour can bleed into adjoining anatomy if the contrast within the image becomes less clear.

Use the Minimum Leakage Allowed slider at the bottom of the Control View to prevent leakage. The slider sets the length of boundary segments. This helps the 3D magic wand bypass possible regions of leakage. It, however, yields more coarsely defined VOI.

## Bumper

The Bumper is a tool for modifying an existing drawn, extrapolated, or interpolated Volume of Interest. When you choose to use the Bumper tool, the cursor appears as a circle in the 2D views.

Depress the left mouse button and drag the cursor around the contour to push the boundary the direction you wish to move it. The curvature of the "bump" is dependent on the size of the circle relative to the zoom level of the image. Zoom into the image to get more precise shape control.

In addition to adjusting the VOI boundary, you can erase or cut out parts of a contour. Simply use the contour to cleave off a portion of the VOI. The system will automatically delete the smaller piece cut with the Bumper. If the portion you wish to delete is larger than the portion you wish to keep, cut the contour multiple times to ensure you do not delete the portion you want to retain.

If you modify an interpolated or extrapolated curve, that curve will become drawn and the contour will be displayed with a solid line.

The Bumper tool can also be used to initiate a VOI. If no contour has been defined in a VOI, selecting Bumper tool and clicking on the image will create a circular contour, which has the same size as the current Bumper size, at the position of the mouse click.

Change the diameter of the bumper with the Bumper Size slider at the bottom of the Control View.





Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



## Smart Curve Fitting Option

The Pen, Line, Ellipse, and Bumper drawing tools have available the Smart Curve Fitting option. This option is similar to the Magic Wand drawing tool, except that you start by drawing a contour, rather than by simply selecting a point. Smart contouring is a little more robust than using the Magic Wand. It, however, requires more effort by you.

Select Smart Curve Fitting to use this option.

Before you select the desired drawing tool, adjust the Window and Level of the image to maximize the contrast between the volume you want to draw and the surrounding anatomy.

In Pen, Line or Ellipse mode draw close to the volume you want to contour. The curve will reshape to fit the boundary based on the contrast within the display. The curve fitting algorithm is most robust if the starting contour is fully inside the region you want to draw.

In Bumper mode, you modify the curve so that it is near the boundary and it will reshape based on the contrast within the display. If you are modifying an interpolated curve, reshape that contour by double-clicking it.

The ALT key also serves as an alternative to the current Smart Curve Fitting state. In any drawing section, If the ALT key is held just before the mouse button is about to released, the current Smart Curve Fitting state will be altered, and applied to the result contour.

**NOTE:** The automated drawing tools use the displayed image modality to determine boundaries. You set the modality by clicking the indicator at the top left of the 2D image display. This setting is unique for each view, so modifying one view does not affect the other views. This limitation includes the small axial views, which always display the reference image (A).

**WARNING: The magic wand, 3D magic wand, and smart curve tools use the current settings of window, level and image intensity to define boundaries. These contours may not always accurately match the volume boundary. Therefore, you should always visually inspect each contour to assure that it defines the intended volume.**



588

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



# PLAN

The Plan task contains the functionality necessary for creating, refining, and reviewing treatment plans. MultiPlan supports isocentric, conformal, and mixed isocentric/conformal planning.

## Setup

The purpose of the Setup step is to allow you to set certain parameters which will be used in the planning process. This step is shown in *Figure 43 Plan Setup, page 62*.

**Figure 43 Plan Setup**



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

589

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



## Density Model

The Density Model selection bar allows you to change the way in which effective depth is calculated from the CT intensity in the image. There are several predefined models: Homogeneous, Lung Standard, and Body Standard. You may also configure and save your own density models as described in *section, Set Preferences, page 22*.

For new plans, the default density mode, which can be modified in the Preference screen, is used and selected as the active item in the density model list. For any previously saved plan, the density model of the plan is selected as the active item of the density model. If the density model from the existing plan is not found in the current system, a new item will be added in the end of the density model list. The name of this model is a combination of a prefix([plan]), and the original model name. The original model name can be the same as one of the system density models. Since the model contents are different, the prefix is added to differentiate it from others.

Changing the density model has no effect on beam objects that have already been created for a plan that has been saved and reloaded. Beams created after the change in density model selection will use the new model.

## Beam Intersection

By unchecking the box next to one of the structures, you instruct MultiPlan to assign a zero dose to all beams intersecting that structure. By leaving the box checked, MultiPlan may assign a dose to beams intersecting that structure when seeking a solution.

If a solution has already been created, unchecking the box will change the dose of any non-zero intersecting beam to zero, potentially changing the solution. In this case, it may be necessary to reoptimize the inverse plan to improve the solution.

## Dose volume

The yellow box on the 2D and 3D views defines the volume within which dose is calculated during the planning process. You may alter this box in the 2D images: move the mouse over one of the control points on the corners and edges of the box – the cursor changes to a double arrow. Hold the left mouse button down and move the mouse, then release the mouse button to reposition the control points. This will cause a corresponding change in the dose calculation box. You can also drag and drop any edge of the box to move the box without resizing it. The Plan Setup and Plan Evaluate steps are the only steps in which the dose volume may be modified.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



## Dose Isocontours

The colored vertical bar in the top right corner of the 2D images shows the dose isocontours currently selected, along with their dose percentages and corresponding colors. You may change the dose isocontours at any time in any 2D image that contains this vertical bar. If no isocontour line is enabled, text (ConfigISO) will appear instead. Move the mouse over the bar (or the ConfigISO text) and click the left mouse button – the bar changes into a table of isocontour settings. You may edit any field in the table by clicking the left mouse button over that field; the color selection will give a pull-down menu, and the percentage and line thickness fields give text edit windows. The first percentage value, with the "P." preceding it, represents the currently selected prescription dose percentage: you may change this at any time, and there will be a corresponding update in the conformality and coverage indices for the current plan. Changing the percentage value of any other isocontour affects only the display and not the plan statistics. By selecting or deselecting the box to the left of an isocontour, you direct MultiPlan to show or hide that contour. You may select or deselect all contours by checking the box to the left of "Color" in the header bar. After you finish editing the isocontour settings, close the isocontour window by clicking on any region outside the isocontour window.

# Isocentric Planning

The Isocentric step, shown in *Figure 44 Isocentric Planning, page 64*, allows isocentric plans to be created and modified. In MultiPlan, in addition to creating traditional isocentric plans consisting of sets of beams, each beam in a set having equal weight and being directed at a single target point, it is possible to create beam sets targeted at the same point, but having weights later assigned by the conformal planning step.

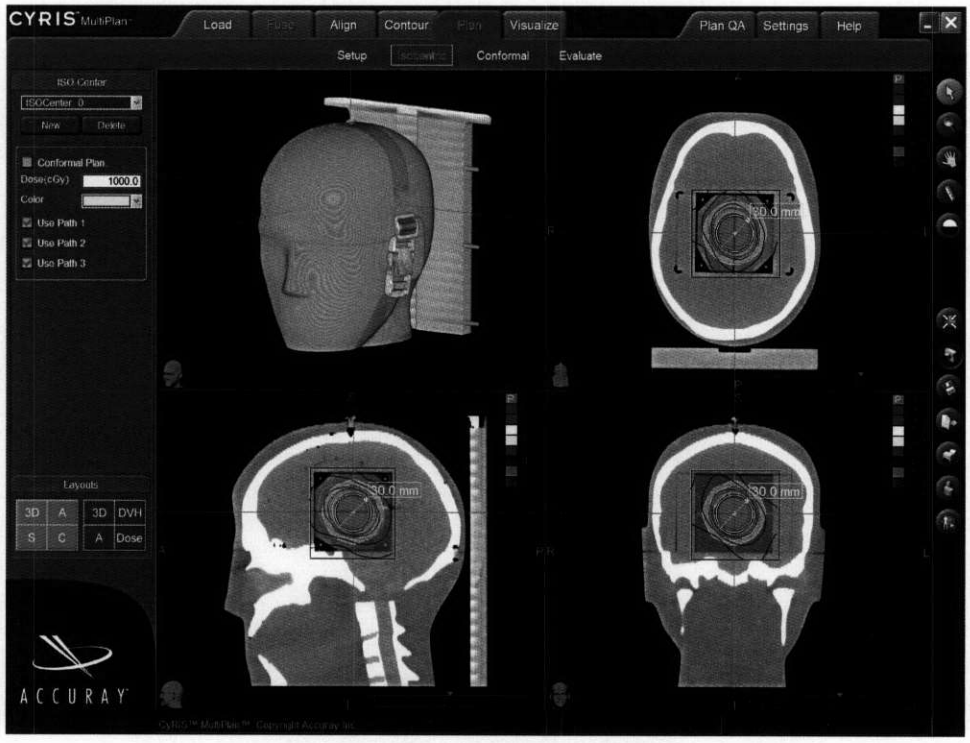



**Figure 44 Isocentric Planning**



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

591

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



## The Isocenter Menu

Under the Isocenter heading, there is a pull-down menu consisting of all the currently existing isocenters. If there are none present, the text window will be blank. When isocenters are present, you may select the one you wish to modify by choosing it from the isocenter menu. The selected isocenter will then become active: it will be shown in color on the 2D images, and its properties will be shown in the table on the left of the screen.

## Creating an Isocenter

Move the green crosshairs in the 2D images by moving the mouse over the green lines, then clicking and holding the left mouse so that the lines are dragged to the desired position. Once the intersection of the lines is at the desired location in space, click the **NEW** button at the top left of the screen. You will see a yellow circle appear at the chosen location, along with a legend describing the collimator size used for the beams making up this isocenter. There will also be a flashing light at the bottom of the screen to inform you that a thread is busy creating the beam objects and their dose masks. After a few seconds, the light stops flashing and dose isocontours appear on the image. The isocenter object is now created: you will see it in the Isocenter selector at the top left.

The default collimator size is 30 mm.

## Resizing an Isocenter

Move the cursor towards the edge of the isocenter in any of the 2D images. When you are sufficiently close to the edge of the circle, the cursor will change to a diagonal two-way arrow. Click and hold the left mouse button, move the mouse to the desired location of the edge, and release the mouse button. As the mouse is moved, the size of the circle and the collimator size legend change in increments according to the set of available collimator sizes. The circle cannot be made smaller or larger than the size defined by the smallest and largest available collimators, respectively. Once the mouse is released, if the collimator size has been changed, you will see the "thread busy" light at the bottom flash for several seconds as the beam set is recreated and the dose updated.

## Moving an Isocenter

Move the cursor towards the center of the isocenter in any of the 2D images. When you are sufficiently close to the center of the circle, the cursor will change to a four-way arrow. Click and hold the left mouse button, move the mouse to the desired location, and release the mouse button. The isocenter will be moved to the selected location: you will see the "thread busy" light at the bottom flash for several seconds as the old beams are deleted, new beams are created, and the dose contours are updated.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



## Changing an Isocenter's Properties

Select the isocenter whose properties you wish to change by choosing it from the Isocenter menu. The properties for the selected isocenter are shown in the white box on the left of the screen.

### Conformal

By checking the Conformal box, you declare that the beam geometry (i.e. the target and collimator size of the beam set) will be created in the Isocentric Plan step, but the weights of the beams will be assigned later during conformal planning. Thus checking Conformal will zero the weights of the beams corresponding to the active isocenter, and remove any dose contours associated with the isocenter.

### Dose (cGy)

Typing a value in centiGray into this text window instructs MultiPlan to set the beam weights for this isocenter so that the dose at its center matches the given value. Existing dose from other isocenters and conformal planning is taken into account for this calculation. If the existing dose at the center is already higher than the selected value, all the beam weights are set to zero for the active isocenter. This setting cannot be used in conjunction with the Conformal selection. When "Conformal is checked, the Dose dialog is disabled.

### Color

This pull-down menu sets the color that will be used to display the isocenter, both as a circle on the 2D views and as a 3D object on the 3D view. It is purely a display setting and has no effect on planning.

### Use Path 1,2,3

Selecting and deselecting these boxes instructs MultiPlan to use or omit paths while creating beams for the active isocenter. Each node on the selected paths contributes a single beam to the isocenter.

## Deleting an Isocenter

Select the isocenter you wish to delete from the Isocenter menu. Left click on the **DELETE** button. The "thread busy" light will flash for a few seconds as the beam set for this isocenter is deleted, and the dose contours are updated. The deleted isocenter will disappear from the list.

**NOTE:** After you delete an isocenter, you should not add, delete or modify an isocenter until the "thread busy" light stops flashing.

## Layouts

There are two layouts available for the Isocentric Plan step: one which contains a 3D view and three 2D views in the three cardinal planes, and one containing a 3D view, a 2D axial view, and a Dose Volume Histogram with a table of dose statistics. You may switch between the layouts at any time by clicking the left mouse button over the desired layout.





Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



# Conformal Planning

In the Conformal Plan step, MultiPlan uses an iterative optimizer to produce conformal plans giving a balance of homogeneity and conformality. In order to start a conformal plan, at least one region designated as a target must be defined. The user interface for conformal planning is shown in *Figure 45 Conformal Planning, page 67*.

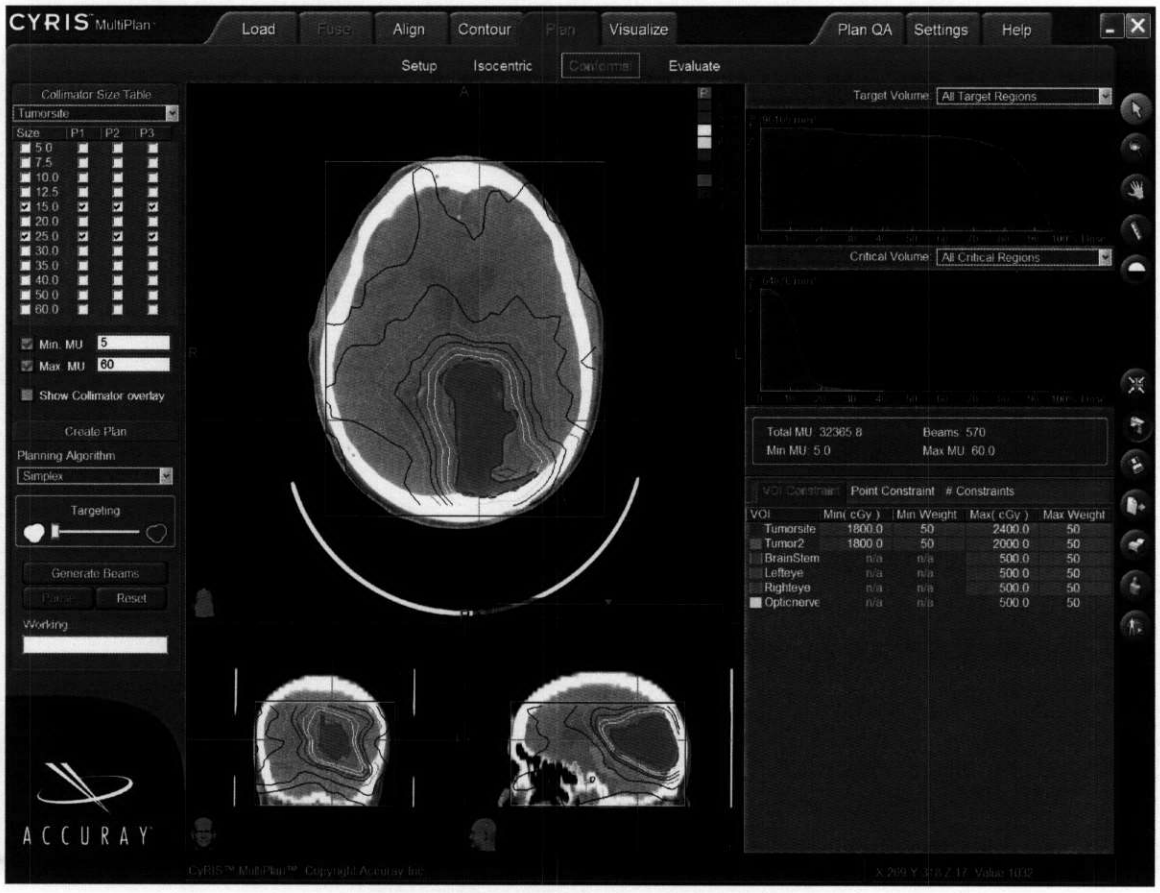



**Figure 45 Conformal Planning**

## Collimator Size Table

This table defines which collimator size and paths to use for each target. Select the desired target using the pull-down list control above the table. For the selected target, check the desired collimator size (left hand column). You will see that all three paths are enabled by default for this target. You may select or deselect individual paths by checking or unchecking the boxes under the columns "P1", "P2", and "P3". Alternatively, by checking a box in one of the Path columns, you may enable beams using that collimator size for the given path only. Targets that do not have any collimators selected are not used for beam targeting; the beam set is hence evenly divided amongst the selected targets and collimators. Before a conformal plan can be started, you must have at least one collimator selected for at least one target.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



## Min. and Max. MU

These two sets of controls set the minimum non-zero and maximum MU allowed for beams targeted at the currently selected target. By default, these settings are disabled, meaning that the beams may be assigned any MU value during conformal planning. To activate the setting, check the box to the left of the Min. or Max. MU text field. Type the desired value into the window to the right of the text. Tightly constraining the MU range can prevent hot spots and reduce the number of non-zero beams, but sometimes this is at the expense of homogeneity and/or conformality of dose.

**NOTE:** If the minimum non-zero MU is not set, a default minimum non-zero MU is used. This value is set in the datafiles and is determined by the minimum dose that the Linear Accelerator can accurately deliver.

## Optimization Method

The pull-down menu provides access to two algorithms for optimizing the dose distribution based on user-defined constraints. The two options are Iterative and Simplex.

The Iterative algorithm optimizes deviations above maximum dose constraints and below minimum dose constraints. The optimization begins with a defined set of beam geometries. As the optimization proceeds beams with little dose are retargeted to cold spots in the tumor. This method will achieve a more homogeneous solution. Plans generated with this algorithm often require more monitor units than the Simplex algorithm.

The Simplex algorithm minimizes the number of monitor units subject to the constraints. Weights set to 100 are exact constraints. Multiple exact constraints and/or a low value of maximum dose may lead to problems that have no viable solution. Setting the weight to a value less than 100 will improve the chances of finding a solution. Modifying the constraints or the constraint weights requires you to restart optimization from the beginning. The Simplex method tends to generate plans using fewer monitor units.

**NOTE:** One way to take advantage of both optimizers is to begin the optimization with the Simplex method and then after finding the first solution use the iterative algorithm. This will enable you to refine the plan (using the Iterative algorithm) beginning with a minimal MU solution.

## Targeting Slider

Using the targeting slider enables you to define how many of the beams will be aimed at points internal to the target, and how many aimed at its boundary. When the slider is fully to the left, by the solid contour, all beams are aimed at points randomly chosen within the target. With the slider fully to the right, near the hollow contour, all beams are aimed at the periphery of the target. Choosing an intermediate slider position instructs MultiPlan to split the beam set proportionately between the interior and the periphery. In many cases, better homogeneity and conformality can be achieved by targeting at the periphery; however, when the collimator size is small compared to the largest dimension of the lesion, it may be necessary to aim beams at the interior to avoid a "cold spot" towards the middle of the target.



595 Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



# Dose Constraints Panel

The Dose Constraints Panel includes two types of constraints, Volume of Interest (VOI) Constraint and Point constraint. These constraints are controlled by two tabs from the Dose Constraints table. The third tab lists the Number of VOI Constraints and allows you to adjust that value by setting a skip factor.

## Volume of Interest Constraint

In this table (*Figure 46 VOI Constraint, page 69*), each row corresponds to a target or critical structure for which contours have been defined. For targets, there is a column for minimum and maximum dose in centiGray; for critical structures, only the maximum dose column is enabled. Each VOI has a corresponding weight between zero and 100. To enter constraints, click on the cell of the table you want to edit, and type the value into the text window for that cell.

If you choose the **Iterative Optimizer**, it is allowable (and often recommended) to make the target minimum and maximum dose the same in order to maximize homogeneity. The weights have relative and not absolute meaning. For example, setting weights of all structures to 10 would give you an identical plan to that where all structures had weights set to 100. To start a conformal plan, at least one of the targets must have a minimum dose value that is non-zero.

If you choose the **Simplex Optimizer**, it is recommended that you set the constraints slightly narrower than your clinical goal and use a high weighting. A weight of 100 forces the optimizer to find the exact solution.

VOI Constraint | Point Constraint | # Constraints

| VOI | Min( cGy ) | Min Weight | Max( cGy ) | Max Weight |
|---|---|---|---|---|
| TumorSite | 2400.0 | 50 | 3000.0 | 50 |
| Left Eye | n/a | n/a | 1000.0 | 50 |
| Right Eye | n/a | n/a | 1000.0 | 50 |
| Brain Sten | n/a | n/a | 1500.0 | 50 |

**Figure 46 VOI Constraint**



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



## Point Constraint

Select the Point Constraint tab at the top of the Dose Constraint Panel to access point constraints. The buttons at the bottom of the list (*Figure 47 Point Constraint Table, page 70*) allow you to **ADD** a new point constraint, **DELETE** the highlighted point constraint, or **DELETE ALL** of the point constraints.

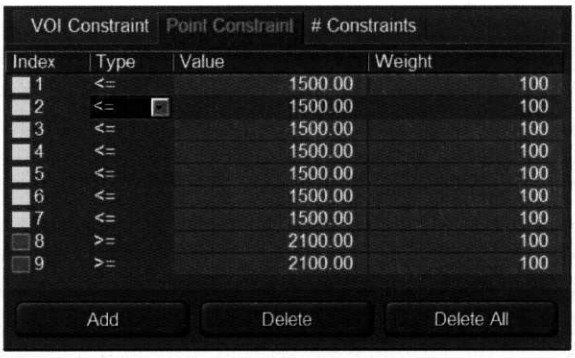



**Figure 47 Point Constraint Table**

The constraints are listed above these buttons. To add a constraint, change the focus in the 3 planar views. Then, select **Add** constraint. After the constraint is added, set whether you want a minimum (≥) or maximum (≤) constraint, the dose value, and the weight. When a constraint is added, the default will have the same values as the previous constraints. The point constraint will appear as a dot, labeled on each planar view.(*Figure 48 Conformal Planning Point Constraint, page 70*)

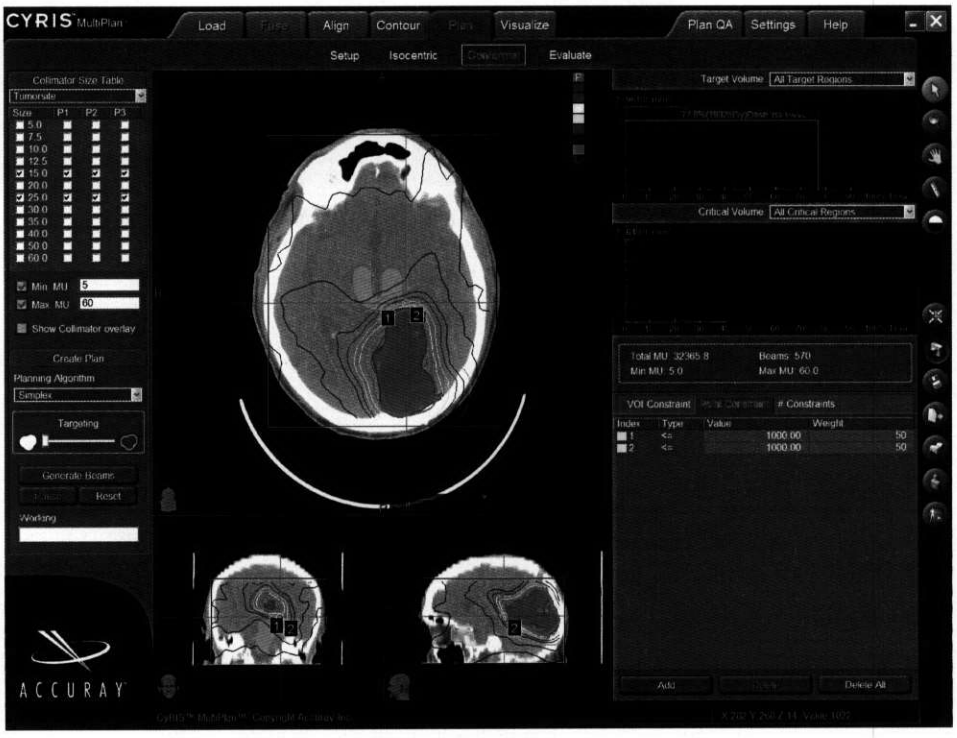



**Figure 48 Conformal Planning Point Constraint**



597

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



### Number of Constraints

The third tab opens the Number of Constraints Table. (*Figure 49 Number of Constraints, page 71*) This tab lists the VOI's and gives the number of points or voxels constrained for each VOI. The second column (Skip) in this tab gives you the ability to set a skip factor. The default skip factor is 1. With this skip factor every voxel comprising the fine dose calculation volume is constrained. You can enter an integer value in this column. For any number n, (n-1) voxels are not constrained for every voxel that is constrained. For example, if you enter the value 8, seven voxels are skipped for every voxel that is constrained.

You can reduce the total number of constrained points by increasing the skip factor for one or more VOI.

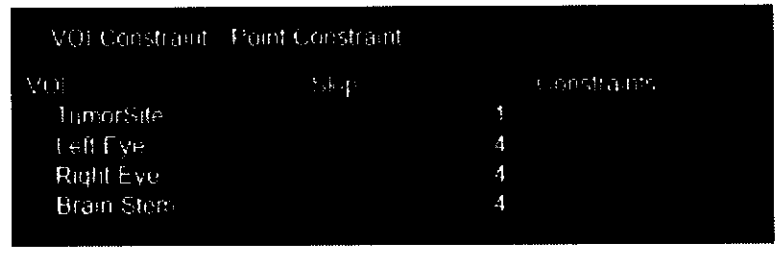



**Figure 49 Number of Constraints**

## Generate Beams

Generate Beams starts or continues the conformal planning process. The button is enabled once the collimator selection and dose constraint prerequisites have been met. When you click **GENERATE BEAMS** for the first time, several progress dialogs are displayed on the bottom bar of the screen as the beam set is generated and the beam dose masks are created. After this process is completed, the Working window will show progress of the current iteration step. One traversal of the progress bar in the Working window represents a single iteration of the optimizer. After each optimization step or at five second intervals (whichever is longer), the dose volume histograms and dose isocontours are recomputed and updated. You will generally notice that the dose distribution is quite poor after the first optimization step, but rapidly improving after subsequent iterations. When the optimizer reaches the best solution it can find at the current resolution, it reduces the increments by which the beam weights are changed. Hence the changes in the dose distribution become smaller over time. If you allow MultiPlan to continue planning, the optimization process will eventually reach completion (denoted by the Generate Beams button being re-enabled and the Pause button disabled). However, in some cases it may take several hours to get to this point: it is often preferable to pause the planning process, change plan settings, and continue planning (if the iterative refinements have become small and the plan is grossly unacceptable), or accept the plan as-is (if the refinements are small and the current plan is deemed sufficient).

## Pause

The **PAUSE** button is enabled only when conformal planning is in progress. Clicking **PAUSE** suspends conformal planning, once the current iteration has been completed. In many cases, in order to produce an acceptable plan it is necessary to change plan settings during the planning process. This is easily done in MultiPlan: the dose constraints, region weights, min/max MU, and targeting slider may all be changed while planning is paused. When conformal planning is resumed, the optimizer will start from the current solution and use the new settings for future iterations. However, changing the collimator size selection during planning will delete all existing beams and recreate a new set of beams based on the new collimator size settings.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118 598

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



## Reset

The **RESET** button deletes all conformal beams and removes all dose associated with them. On clicking the **RESET** button, you will see a progress bar at the bottom of the screen as the beam objects are deleted and the dose contours updated. Isocenters are unaffected by this deletion; in order to delete isocentric beams, you should use the **Delete** feature in the Isocentric Plan step.

## Dose Volume Histogram views

In the top right quadrant of the screen are two Dose Volume Histograms (DVH's). The top DVH is for target structures, and the bottom DVH is for critical structures. At any time, including while planning is in progress, you may use the pull-down list control for each view to select the desired structure for which you wish to view the DVH, or view an aggregate DVH of all structures of that type (target or critical). Left clicking the mouse over the graph will show you statistics giving the dose in centiGray corresponding to a given percentage dose, and the amount of coverage of the selected region at that dose percentage. These views are updated after each iteration of the conformal planning step or every five seconds, whichever is longer.

## Beam statistics

Directly underneath the DVH views is a box containing beam statistics. This shows the minimum non-zero MU of all currently existing beams, the maximum MU, the total MU, and the number of non-zero beams. Isocentric beams are included in these calculations. These statistics are updated when entering the Conformal Plan step, and at the end of each planning iteration.





Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



# Plan Evaluation

**WARNING: Be sure to carefully examine the entire dose distribution throughout the patient to assure that the patient receives an acceptable level of dose.**

The purpose of the Plan Evaluate step is to allow you to visualize a plan that has been created and is deemed to be broadly acceptable, in order to determine whether the plan should be delivered or needs further fine-tuning. *Figure 50 Plan Evaluation, page 73* shows this step.

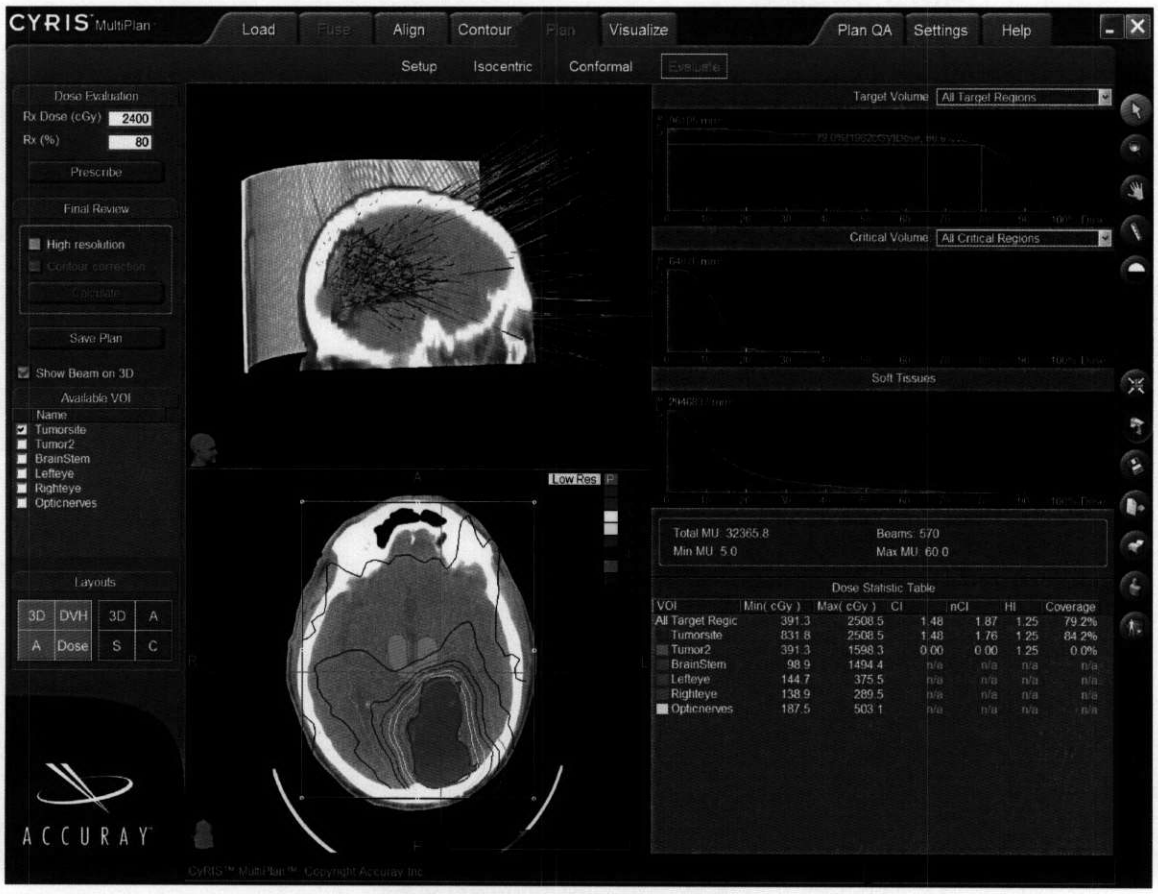



**Figure 50 Plan Evaluation**



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

600

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



## Dose Prescription

The current prescription dose is shown, at the upper left of the screen, both as a percentage of maximum dose, and as a value in centiGray calculated by applying the prescription percentage to the current maximum dose. Either or both of these settings may be changed by typing the new values into the corresponding text window. The changes will not take effect until the **PRESCRIBE** button is clicked. When **PESCRIBE** is clicked, the beam weights will be uniformly scaled so that the maximum dose is correct given the currently chosen prescription percentage and value. The dose statistics in the bottom right panel are then recomputed, and the prescription dose isocontour is redrawn if the prescription percentage has been changed.

## Final Review

Performing a high resolution dose calculation allows a more accurate evaluation of the dose to both target and critical structures. The dose grid used for optimization has 32 voxels in each direction; the high resolution dose grid has 64. High resolution dose calculation is a necessary step before a deliverable plan can be saved. Checking the **HIGH RESOLUTION** box enables the **CALCULATE** button. Before **CALCULATE** is clicked, you may optionally select the **CONTOUR CORRECTION** box also. Contour correction provides a dose calculation in which tissue inhomogeneity and variation of the surface intersection across the cross-section of the beams is partially taken into account, resulting in a more accurate, but slower, calculation. Select **CALCULATE** to bring up a dialog that warns you that high resolution dose calculation can be slow. On confirming within the dialog, you will see a bar at the bottom of the screen giving you the current progress. Once the progress bar has reached the end, the dose isocontours and statistics will be recalculated in high resolution, and the yellow Low res legend will disappear from the 2D views and be replaced by High res in green. Most actions which change the dose distribution (e.g. continuing conformal planning, editing isocenters, or changing the dose volume) will invalidate the high resolution dose volume and replace it with the low resolution one. However, changing the prescription dose or percentage involves only scaling, and hence preserves the high resolution dose volume.

## Dose Volume Histograms

On the upper right side of the Display View are three Dose Volume Histogram (DVH) graphs. The top graph has the target DVH. You can look at the DVH for individual targets or the sum result over all targets. Use the pull-down list control to choose the target you wish to evaluate. The middle graph has critical region DVH. You can look at the DVH for individual critical regions or for the sum of all the targets. Use the pull-down list control to choose the critical region you wish to evaluate. The bottom graph gives the DVH for the soft tissue within the calculation volume.

Use the left mouse button to get precise volume-dose pairs. The dose is displayed in cGy and as a percentage of the maximum dose. The volume is displayed as percentage of the total volume of the VOI. The total volume is at the top left of the graph.

The upper two DVH views are similar to those in the Conformal Plan step. If the high resolution dose volume has been created, the DVH's are computed using data from this volume; otherwise, the low resolution dose volume is used.

**WARNING: Volumes used to determine the dose volume histogram include only the portion of a VOI that is enclosed by the dose calculation grid. Therefore, if a volume is only partially enclosed by that grid, the apparent total volume of the VOI for DVH calculation will be less than the volume calculated in the Properties step (*section, VOI Properties, page 48*).**



601

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



## Dose Statistics Table

Below the DVH graphs is a table of dose statistics associated with each VOI. The statistics calculated are the maximum and minimum doses for each VOI. The target volumes have calculations for the parameters listed below.

Conformality Index (CI) – The conformality index is the ratio of the tissue volume receiving the prescription isodose or more to the tumor volume receiving the prescription isodose or more.

New Conformality Index (nCI) – The new conformality is the CI multiplied by the ratio of the total tumor volume to the tumor volume receiving the prescription isodose or more.

Homogeneity Index (HI) – The homogeneity index is the ratio of the maximum dose to the prescription dose. For the current configuration of the CyRIS MultiPlan, the maximum dose is always the 100% isodose.

Coverage – The coverage is volume of the tumor receiving greater than or equal to the prescription dose divided by the total volume of the tumor times 100.

## Layouts

There are two layouts available in the Plan Evaluate step. The first gives a 3D volume and 2D axial view with a DVH and dose statistics panel. The second gives a 3D volume and three 2D views corresponding to the three cardinal planes. You may switch layouts at any time by clicking on the corresponding layout icon towards the left of the screen.

## The 3D view

The 3D view in the top left panel of the screen can be a powerful visualization tool both for plan evaluation and patient conferencing. To configure the opacity filters used to produce the 3D view, see the Visualize, 3D Filter step. If two images are loaded and have been fused, you may switch between Image A, Image B, and mixed A/B by clicking on the icon in the top left corner of the image pane. To use the virtual cutting plane, activate the Pointer tool on the right hand tool bar, left click in the image pane, and use the middle mouse scroll button to move the cutting plane forward and back. The plane is always perpendicular to the viewing direction, so the anatomical orientation of the cutting plane can be changed by rotating the image. The prescription dose isocontour, along with the regions that have been selected in the Visualize, 3D Filter step, are rendered in the 3D volume. You can turn beam on/off in 3D view by check/uncheck the Show Beam checkbox. You can also select which VOI to show in 3D view in Available VOI table.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



# VISUALIZATION

The Visualization task has two steps that alternate means to view the plan and the dose distribution.

## Multi-Slice View

The Multi-Slice View user interface is shown in *Figure 51 Multi-Slice View, page 76*. You can look at multiple planar slices in this view. These slices will include dose distributions and VOI. You can view one of six layouts that range from 1 slice filling the entire screen to a 6 x 5 array of consecutive slices. Choose the view size with the Layout switch at the bottom of the Control View. Choose the viewing plane with the pull-down list control at the top of the Control View. You can view axial, coronal, or sagittal views. Find the slices of the volume that you wish to view using the vertical slider on the right side of the Display View.

If two images are loaded and registered, a new group of controls will show up to allow you to change the image source of all the multi-slice views. For example, in the image below, the 2nd image (Dataset B) is selected.

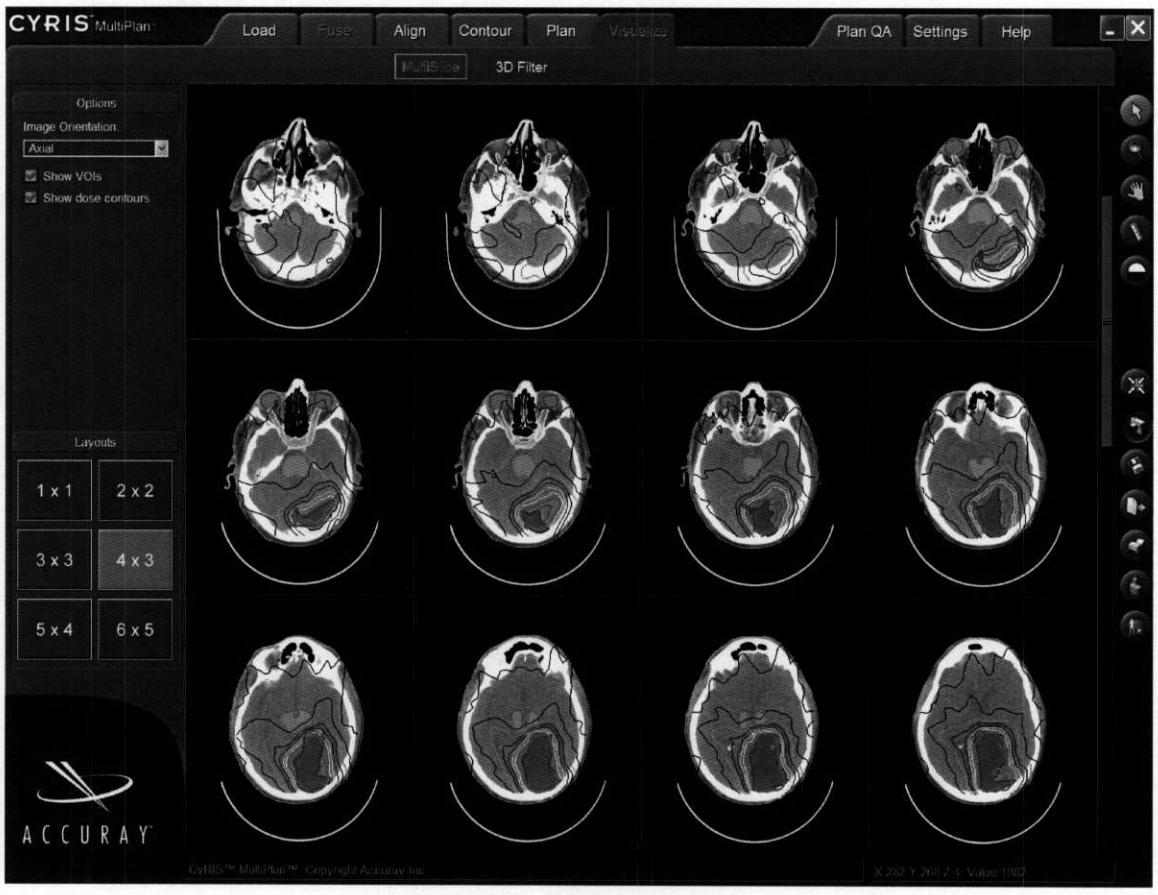



**Figure 51 Multi-Slice View**



603

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



# 3D Visualization

You can also visualize the VOI and dose distribution on 3D volumes.

*Figure 52 3D Filter with One Image Series, page 77* has the 3D Filter step of the Review task. The layout shown is for a plan with a single medical image. Use the list of VOI to select which VOI to display in the 3D view. The displayed isodose cloud is the first of the ten displayed isodose curves. The first displayed isodose curve is identified as the prescription curve. Turn on/off the curves and set the color and percentage using the color key on the top right of the 3D view.

*Figure 53 Window/Level 3D Image Filter, page 78* shows the 3D Filter layout for a plan with two fused medical images. The Display View differs for the two cases, because with two image sets you can see three volume renderings: the fixed image, a mixed fusion of the fixed and moving image, and the moving image. *Figure 54 Color 3D Filter, page 79* also has two image histograms, because two image sets are being sampled. The Control View with two image studies adds the control buttons to generate the mixed image. You can either Merge Data A to B (fixed to moving image) or Merge Data B to A (moving to fixed image).

When a plan has two images, the 3D view in the Review step will use the mixed image.

## Window/Level Filter

With the Enable Color 3D Filter mode inactive, you can adjust the presentation of the 3D image by changing the Window and Level settings, as described in *section, Window/Level Mode , page 10*. The setting shown brings out the vascular structure of the patient.

**Figure 52 3D Filter with One Image Series**



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

604

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



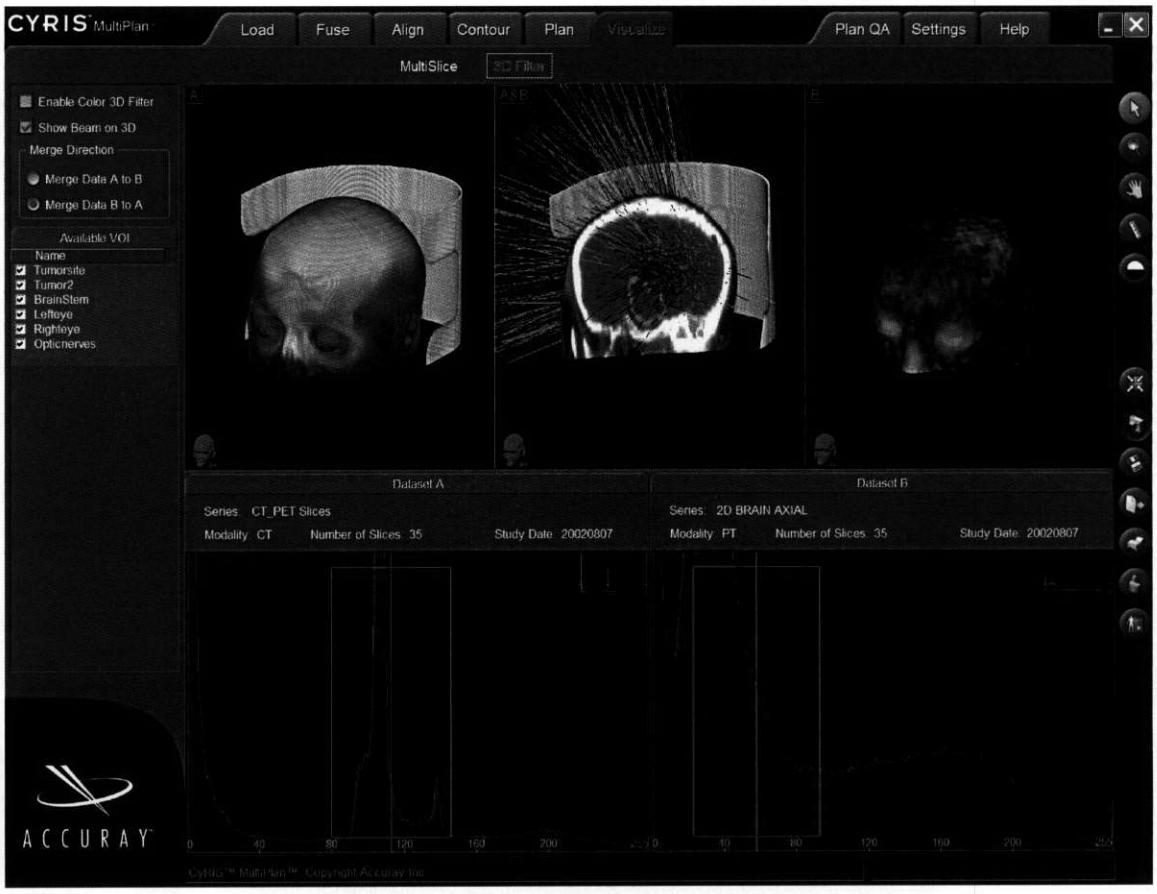



**Figure 53 Window/Level 3D Image Filter**

## Color Filter

You can display the 3D volume images in color. For instance, it may be preferable to present vascular structures in red. Select 3D color filter mode and the layout shown in *Figure 54 Color 3D Filter, page 79* will appear.

The image histograms have color filter controls rather than a Window and Level setting. The color filter is implemented by drawing two lines on the histogram.

Click and drag the left mouse button to draw the opacity function. The opacity is a magenta line on the graph. The opacity increases as the y-value increases, so values near the bottom of the scale are transparent, and values near the top of the scale are opaque.

Use the color grid to choose a color for the image. Click and drag the right mouse button to draw a color function. The color intensity increases as the y-value increases. The color function is a yellow line on the graph.



605

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015

**Figure 54 Color 3D Filter**

After creating a color filter that satisfies you, save it to a directory using the **SAVE FILTER** button. The left button is for image A and the right button is for image B. You can load the filter using the **LOAD FILTER** button. The left button is for image A and the right button is for image B. The default directory for saving filters is *C:\accuray\filters*.

## Dose and Anatomy Overlays

- The 3D view can display up to seven Volumes of Interest and a single isodose cloud. The isodose cloud displayed is the first active dose in the isodose contour list. The default is therefore the prescription isodose value. Select the VOI from the list in the Control View.
- Rotate the 3D view and change the cutting plane of the image to better view the displayed dose cloud and the VOI. The 3D view can be rotated by clicking and dragging the mouse in the 3D view. In the inner part of the screen, you can roll the patient anatomy. If you move the mouse toward the boundary of the 3D view, the cursor will change to two arcs. In this mode, you can pitch or yaw the 3D image.
- Forward scroll and backward scroll with the mouse scroll-mouse to change the cutting plane through the image. Forward scroll cuts deeper through the image. Backward scroll cuts more shallowly through the image. In this way you can see the VOI as well as the dose distribution and evaluate how well they conform.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



# SAVE AND PUSH DATA

You can save plans and reopen them with the MultiPlan workstation or push data to other workstations. This section describes the procedures for saving data and pushing data.

## Save Plan

From the Global Tools, select the **SAVE** button. (The **SAVE** button has an icon of a floppy disk.) *Figure 55 Save Plan, page 80* will appear. If the active plan has been previously saved the default name will be the name of the existing plan. Otherwise, the default plan name will be blank. If a plan is not deliverable, the Deliverable Plan option will be grayed out. If the plan is deliverable, the Deliverable Plan option will be enabled and the default is to save the plan as a deliverable plan. If a plan is saved as a deliverable plan, the contents of the plan will be passed to the CyberKnife delivery system and be available for prescription.

A plan is deliverable, if the CT Offset has been confirmed, the high resolution dose has been calculated in the Plan Evaluate step, and no inconsistencies have been found. Inconsistencies include:

A fiducial tracking plan without identified fiducials.

A primary CT study that is tagged with a different medical ID than the patient medical ID.

The dose displayed is inconsistent with the dose recorded in the treatment paths.

The latter inconsistency will only be detected while you are saving a plan. Therefore, a warning noting this inconsistency may appear when you attempt to save a plan.

Deliverable plans can be prescribed for treatment by the delivery system. If you prescribe a plan, then overwrite that prescribed plan, the prescription is nullified. You will need to prescribe the plan again in order to treat it. You cannot overwrite a plan for which any dose has been delivered.

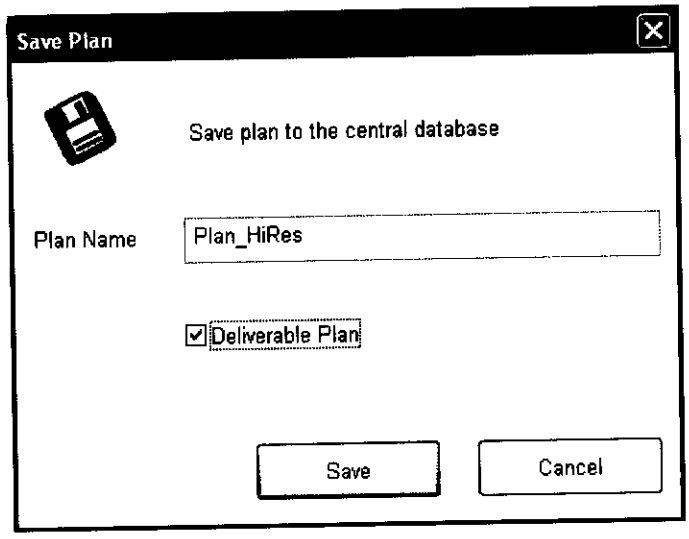



**Figure 55 Save Plan**



607

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



# Push DICOM Formatted Data

From the Global Tools, select the **PUSH** button. (The **PUSH** button has an icon of a piece of paper with an arrow pointing right.) *Figure 56 Push DICOM Data, page 81* will appear. This function allows you to send volumes of interest, the dose distribution, and the image data to other workstations such as InView, Multiplan or SGI TPS.

Use the text field to set the description (in the DICOM header) for each DICOM series you will send.

**NOTE:** The companion CyRIS InView™ workstation uses the description as the displayed name for image, volume, and dose information. Therefore, it is advantageous to choose a unique name when you export this data.

**NOTE:** To conform to RTOG (Radiation Therapy Oncology Group) data requirements, you need to download the **ITC DICOMpiler Software**. At the time of the release of this manual, that software is available from the link *http://itc.wustl.edu/DICOMpiler/index.htm* Process the DICOM RT instances with this software before submitting them to RTOG.

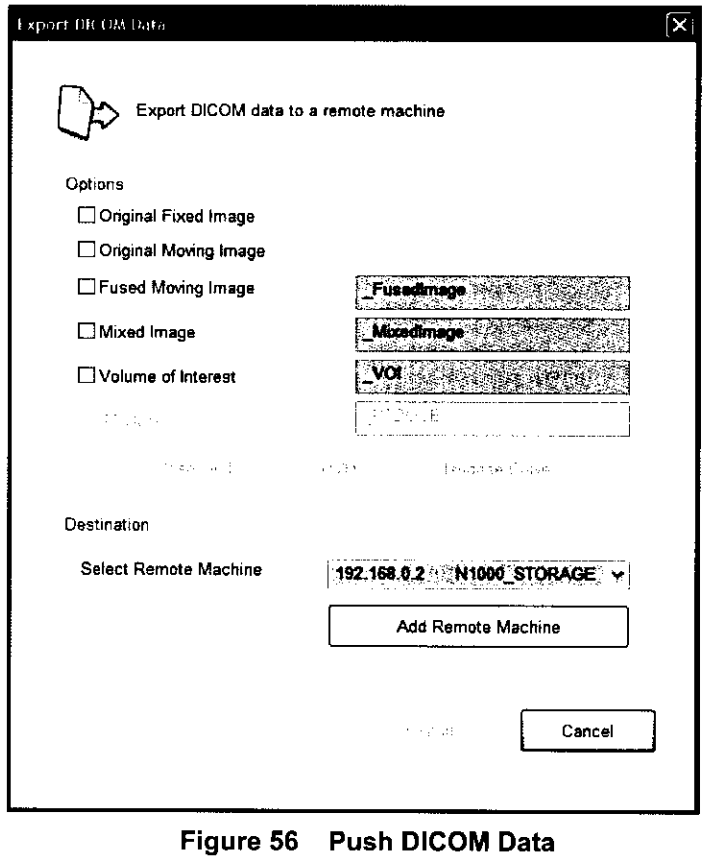



**Figure 56 Push DICOM Data**



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

608

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



## Select Host

The Select Remote Machine menu in *Figure 55 Save Plan, page 80* allows you to select from a list of workstations that receive DICOM data from the MultiPlan system.

You can add a machine to the list of machines to push DICOM data, if necessary. Select Add Remote Machine from the dialog in *Figure 56 Push DICOM Data, page 81* and *Figure 57 Add Remote Machine, page 82* appears. Type in the AE Title, IP Address and DICOM port for the machine to which you intend to push data.

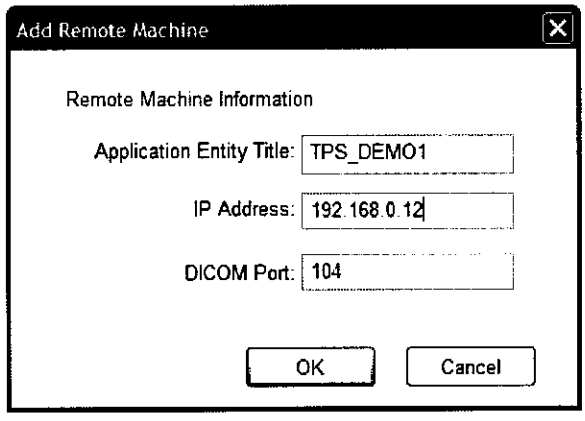



**Figure 57 Add Remote Machine**

## Volumes of Interest

You can push the contoured volumes of interest as a DICOM RT Structure Set instance. The instance will be a series associated with the primary CT study.

Each Volume of Interest will have the name and color you set. The study also indicates if the contour is a solid or a cavity. The contours will be tagged as drawn or interpolated and include all the points that contain the boundary of the contour.

**NOTE:** CyRIS InView and the Treatment Planning System for the Silicon Graphics can only accept Volumes of Interest with one contour per slice and all contours must be drawn in the Axial plane. Therefore contours exported to those systems that do not meet those limited criteria will not be fully loaded into those applications.



609 Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



## Dose Distribution Data

You can push the dose distribution as a DICOM RT Dose instance. The instance will be a series affixed as part of the primary CT study. You can choose among three types of dose data to export: a multi-frame dose grid, DVH plots, and isodose contours. Use the **SELECTION** buttons near the bottom of *Figure 56 Push DICOM Data, page 81*.

Each point in the dose grid is saved at either a resolution of 1 centiGray or 1/10$^{th}$ of 1 centiGray. The resolution will depend on the maximum dose in the plan. Dose points are saved at each pixel in the CT study that is a part of the fine dose calculation grid.

Dose contours are generated from the fine dose calculation grid. The exported contours are the displayed isodose curves at the time of image export.

Each VOI includes a Dose Volume Histogram (DVH). The DVH is only calculated within the fine dose grid. This data is exported with the DICOM RT Dose instance as an array of 100 bins on a histogram. The bins range from 0% of the maximum dose to 100% of the maximum dose.

## Image Data

You can push four types of image data.

Push a DICOM image series of the registered image. This image will have the same frame of view as the fixed CT image series. The gray scale values, however, will be calculated from the moving image.

The registered image series will have the same modality as the moving image, except for XA images. For XA data, the registered image is set as a derived MR image series, because the DICOM Library on the CyberKnife System UCC assumes that XA images are scanned as Coronal slices and the registered image series is transferred as axial slice data.

Push a DICOM image series of a mixed image that is a fusion of the CT image and the moving image. The contents of this image are created in the 3D Filter step described in *section, Window/ Level Filter, page 77*. Only a gray scale image can be saved and pushed. If 3D Filter has been used, it will be converted to a gray scale image before being exported to the DICOM image series.

The mixed image series will have the same modality as the moving image, except for XA images. You can only push the mixed image series if the mixed image has been created in the 3D Filter step of the Visualization task.

Push the imported fixed CT image series or the moving image. CyRIS MultiPlan merely sends the imported data to another machine. It does not alter it in any way.

Data is saved and stored locally in DICOM Part 10 format. The DICOM data export tool, however, does not handle Part 10 format so it only pushes the DICOM stream data to a remote host without DICOM File Meta Information within it.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118 610

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



# ADVANCED PLAN EVALUATION

The Plan QA task has three steps that will provide you with means to evaluate the plan in a more detailed manner. The Reference Plan step gives the opportunity to compare, side by side, two plans. You can also sum two or more plans in this step. The Animation step allows you to visualize the motion of the robot motion during treatment. The Load Overlay step allows you to view the dose distribution of a given plan when treated to a phantom with a film cube. This step helps you evaluate a film-cube test created from a specific patient plan.

## Reference Plan

*Figure 58 Reference Plan, page 84* shows the Reference Plan step. This step allows you to compare an active and a previously saved reference plan. When this task is entered you will see two columns of display windows. The left window is the active plan. The right window is the reference plan.

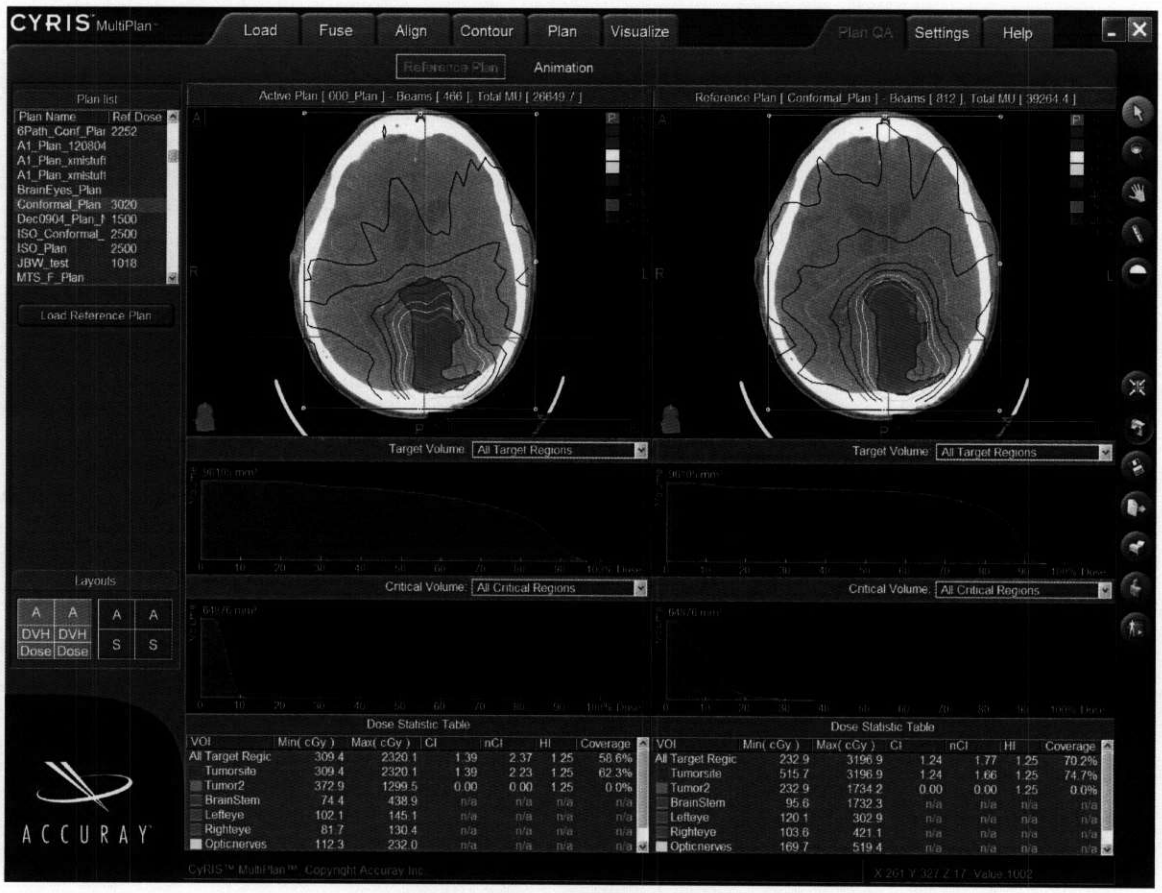



**Figure 58 Reference Plan**



611

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



Use the Control View to select the reference plan to load. A list of plans associated with the current patient is displayed at the top of the Control View. Highlight the plan you want to compare the active plan to and select **LOAD REFERENCE PLAN**. When a reference plan is loaded, its dose distribution is calculated and displayed in the right side. Two layouts are available to compare the plans. One includes the axial view, DVH, and dose statistics for the two plans. The other includes Axial and Sagittal Views of the two plans.

You can resize the dose calculation box for either the active or the reference plan. If you do this the system will recalculate the dose distribution, dose statistics, and DVH.

**NOTE:** You can only select a reference plan that is based on the same primary CT image (A) as the active plan.

**NOTE:** When a reference plan is loaded, only the VOI defined in the active plan are evaluated. The system does not load the VOI from the reference plan.

## Plan Summation

Plan summation is a function within the Reference Plan task. Plan summation allows you to evaluate the effect of multiple plans on critical structure dose as well as the target dose.

To sum plans you must select at least two plans. To select more than one plan use the <Shift> or <Ctrl> key while selecting. If you use the <Shift> a list of consecutive plans will be highlighted. If you use the <Ctrl> key you toggle selection of plans regardless of how many plans are selected. Without the keyboard keys selected, the plan list is in single select mode and only a single reference plan will be loaded. When you choose two or more plans to load, the system will sum and display those plans. If they treat lesions that are widely separated, you can resize the dose calculation box.

**NOTE:** The active plan is not incorporated in the summation of multiple plans. If you want that plan included in the evaluation, you must first save the plan and then include the saved plan when you select the plans to sum.

**NOTE:** When plans are summed, only the VOI defined in the active plan are evaluated. The system does not load the VOI from the summed plan.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



# Robot Animation

A fully integrated robot simulation program is provided with the Treatment Planning System as a tool to preview the motion of the manipulator. The program accurately models the kinematics of the robot as well as the geometry of the room, including all the equipment in the treatment room. This shows you the exact motion of the robot and helps you check for potential collision hazards.

*Figure 59 Robot Animation, page 87* shows the Animation step of the Plan QA task. The display view has the controls, the 3D animation and axial and coronal views of the patient.

Select the path to animate from the **PATH** cascade button. You can select either an individual path or you can opt to run through the entire treatment. The forward arrow provides continuous forward motion; the backward arrow provides continuous reverse motion; the lined forward and backward arrows step through the nodes in a forward and reverse direction; and the lined double arrows take the simulation to beginning or the end of the path. The double line pauses the animation.

The animation moves the robot through the selected path. During the animation colliding structures are indicated by the structure turning red. The two colliding components are noted in the text field. You can also see the closest obstacle pair and the distance separating them in the control view. The distance is indicated in text and with a slider. If the color of the slider is green, the collision error is minimal. If the color is yellow, the separation is less than double the buffer distance. If the color of the slider is red, the distance is less than the allowed buffer during delivery.

**NOTE:** Only saved, deliverable plans can be animated. In order to animate a plan: ensure it is deliverable, save the plan, and reload the plan. These steps ensure that path files are available for animation.



613

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



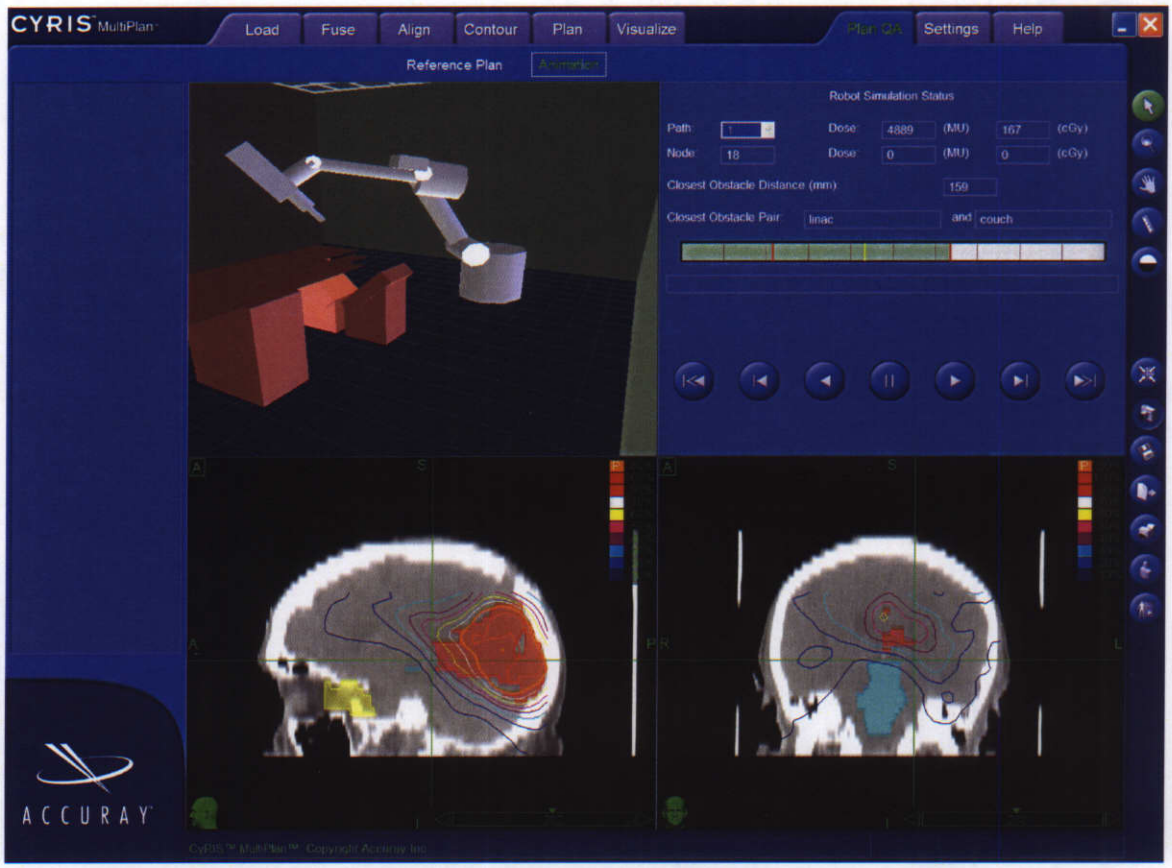



**Figure 59 Robot Animation**



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

614

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



# PHANTOM OVERLAY

The Phantom Overlay procedure allows you to deliver a treatment to a phantom. For example, the orientation of treatment and the number of monitor units for each beam is the same for the phantom as for the patient.

**NOTE:** When the plan is loaded using the Phantom Overlay procedure, the dose distributon may not align with the phantoms measuring tool. In this case, use the Fuse task to align the images.

**WARNING: Do not load a Phantom Overlay plan for patient treatment.**

## Load Task

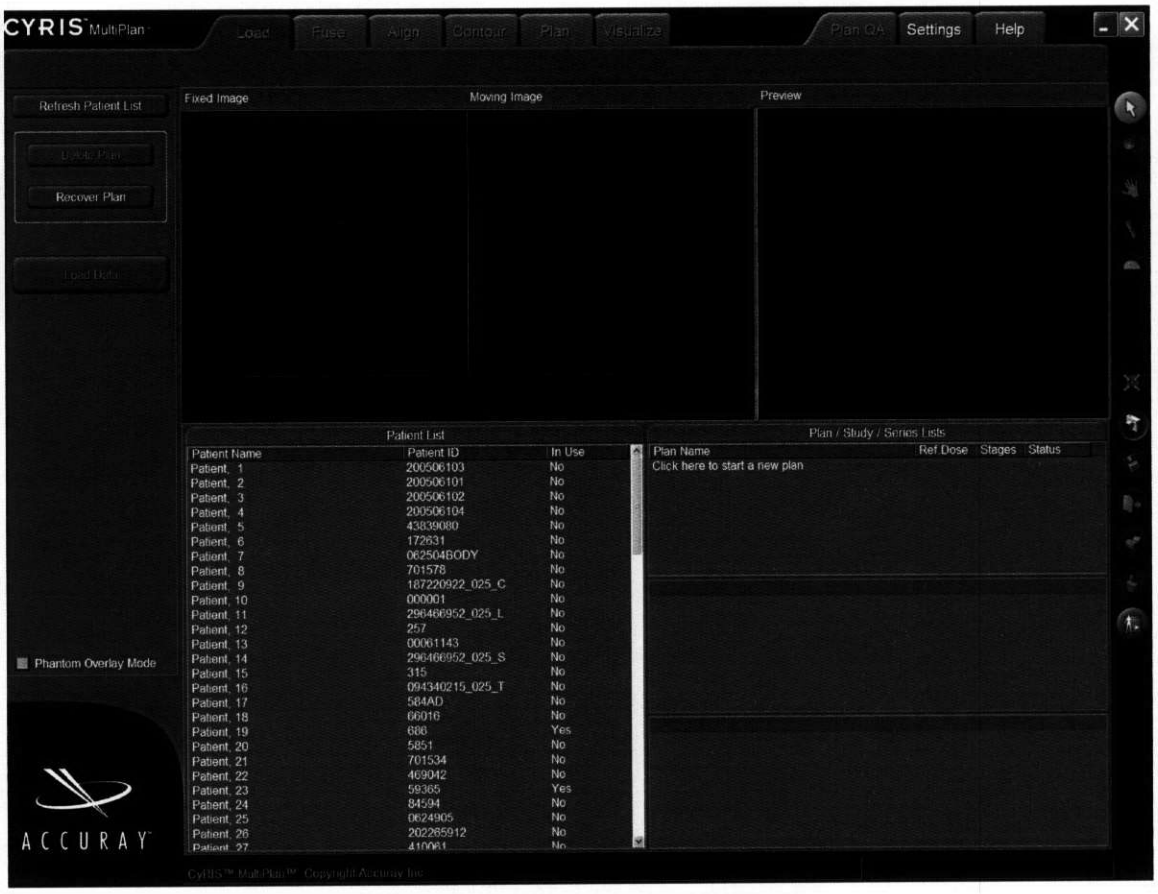



**Figure 60 Standard Load Screen**



615

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015

**Figure 61 Load Phantom Study**

The phantom overlay procedure starts in the Load task tab. The Load screen has a Phantom Overlay mode check box at the bottom of the control view (*Figure 60 Standard Load Screen, page 88*). When the checkbox is checked, the load screen is reorganized (*Figure 61 Load Phantom Study, page 89)*. This view allows you to select the desired phantom image from the displayed patient, study and series lists, select the phantom patient, and select the phantom study.

**NOTE:** If you select the wrong phantom study, you need to uncheck and then recheck the **PHANTOM OVERLAY MODE** checkbox to reselect the phantom study.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

616

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015

**Figure 62 Load Plan to Overlay on Phantom**

After you have selected the phantom image, the Load Task lists will reconfigure (*Figure 62 Load Plan to Overlay on Phantom, page 90*). The new configuration allows you to select the plan to overlay.

**Step 1.** Select the patient.

**Step 2.** Select the plan.

**Step 3.** Select **LOAD DATA** (the plan is loaded and overlayed on the Phantom Study).

The entire plan will not be loaded. Only the beam data and treatment parameters will be loaded. Volumes of Interest and Fusion information are not included. After loading all data, the system changes to the Fuse Task.



617

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



# Fuse Task

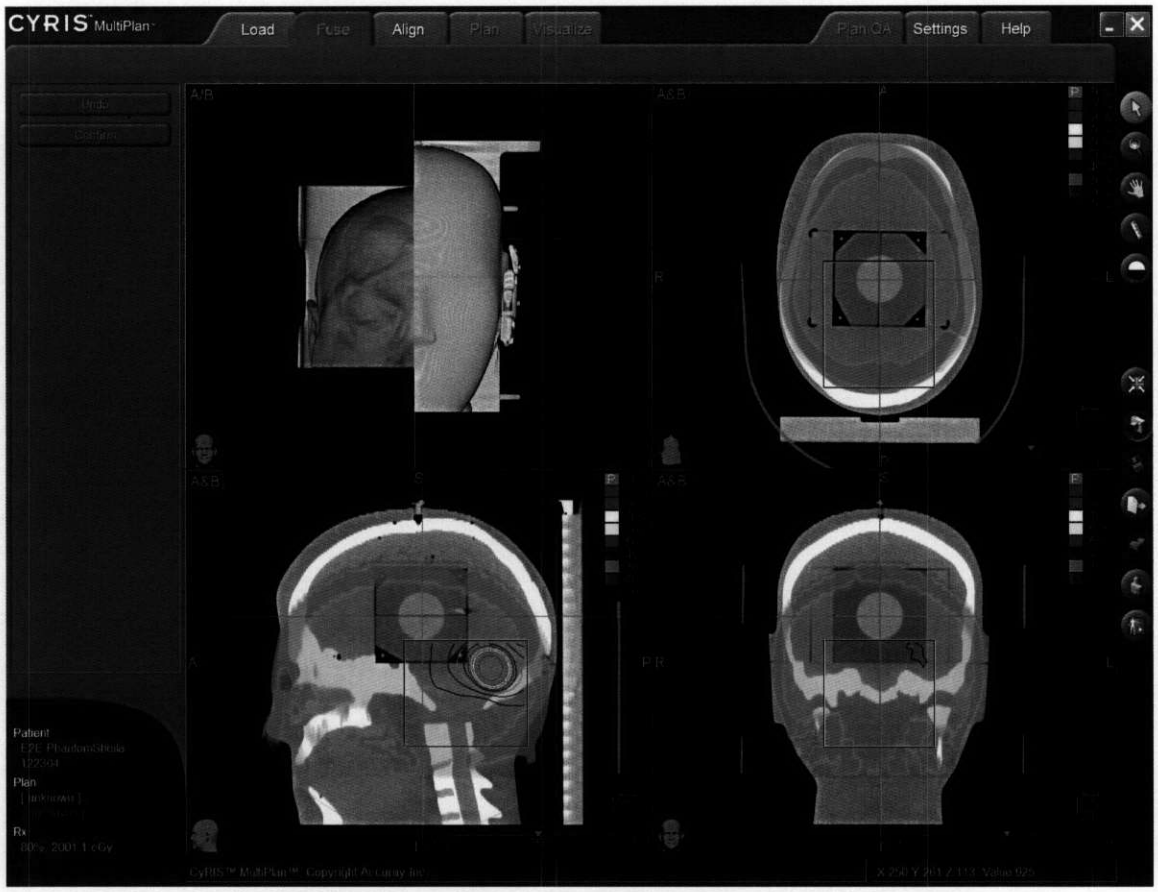



**Figure 63 Dose Misaligned**

The Fuse Task allows you to reposition the dose distribution within the field of view of the Phantom study. Movement of the dose distribution does not change the number of monitor units or change the orientation of the treatment beams. It does, however, modify the position of the CT Center saved with the plan.

When the Fuse Task first appears, the dose distribution will appear misaligned (*Figure 63 Dose Misaligned, page 91*). Use the mouse in the 3 2D views to translate the dose distribution so that it aligns with the measurement region. In the example shown in *Figure 64 Aligned Dose Distribution, page 92*, the measurement region is the ball cube. Select **CONFIRM** to accept the updated position. You can also select **UNDO** to return to the original alignment (*Figure 63 Dose Misaligned, page 91*). The following is the best method to move the dose distribution over a specific spot on the phantom

**Step 1.** Put the cursor on the center of the dose distribution in one of the 2D views

**Step 2.** Move the cursor to the desired location.

**Step 3.** Click **CONFIRM** after every shift.

This will align the dose on the spot you want in two dimensions.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118 618

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



**Step 4.** To align the third dimension, use steps 1-3 on a different 2D view, move the dose over and click **CONFIRM**.

**NOTE:** Typically, you only need to move the distribution twice to align it to the right location.

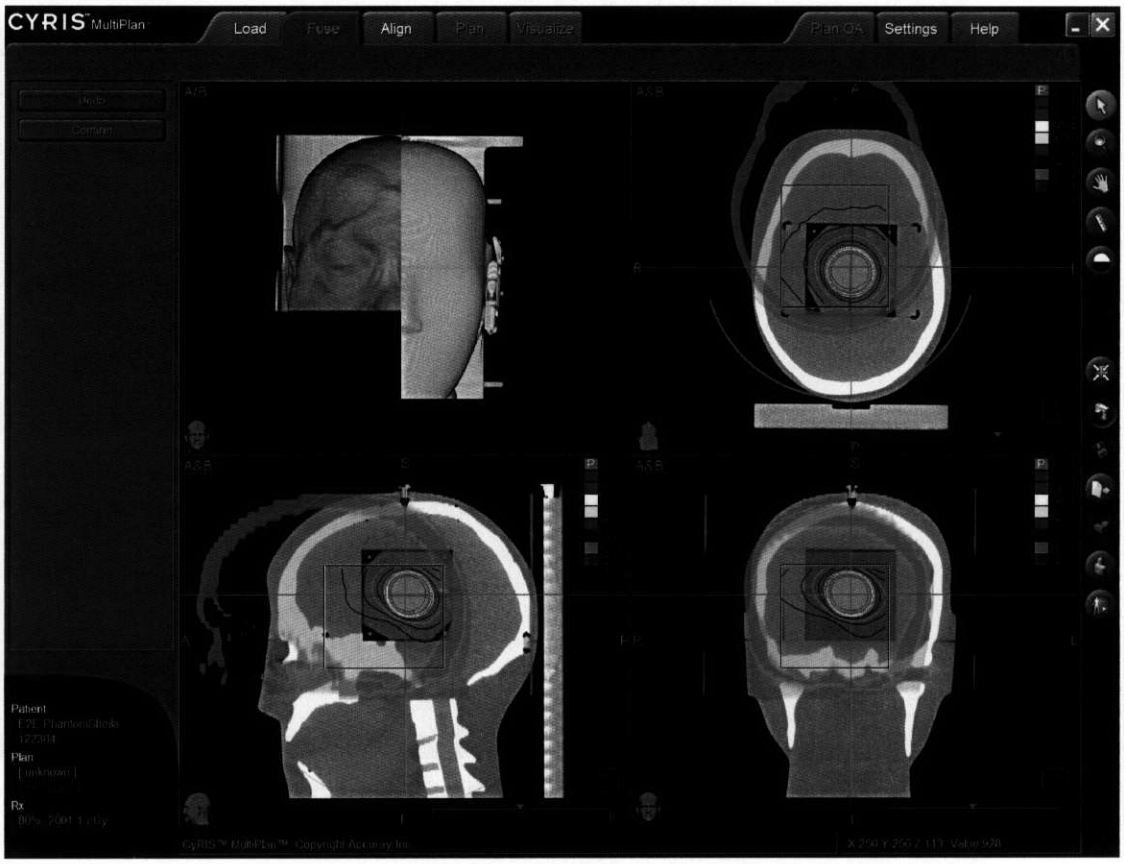



**Figure 64 Aligned Dose Distribution**

After the dose distribution is aligned, proceed to the Treatment Parameters Step of the Align Task.



b|9

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



# Align Task

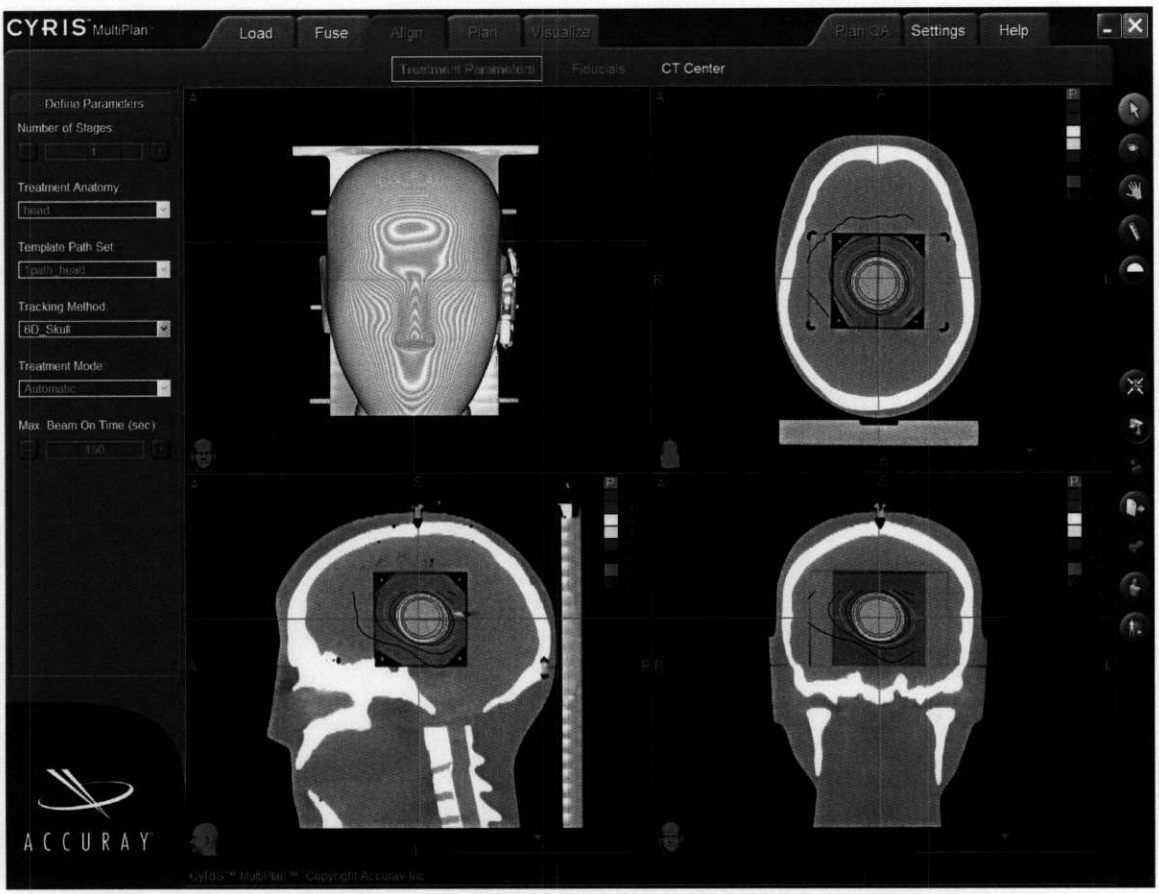



**Figure 65 Set Treatment Parameters for the Phantom Overlay Procedure**

The Treatment Parameters Step in the Phantom Overlay Procedure differs from the standard Treatment Parameters Step in that the only setting you can choose is the Tracking Method. See *Figure 65 Set Treatment Parameters for the Phantom Overlay Procedure, page 93*. You cannot change the fractionation or the node set. This allows you to test a cranial case using fiducial tracking.

**NOTE:** If the plan cannot be tracked using skull tracking use fiducial tracking.

If you choose the Fiducial Tracking Method, you will need to identify fiducials in the phantom. You do this in the same way as in the Standard MultiPlan procedure. One difference of the Phantom Overlay Procedure is that the default CT Center is not changed after identifying these fiducials.

The final step in the Align Task is the Confirm CT Center step.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



# Plan Evaluation Step

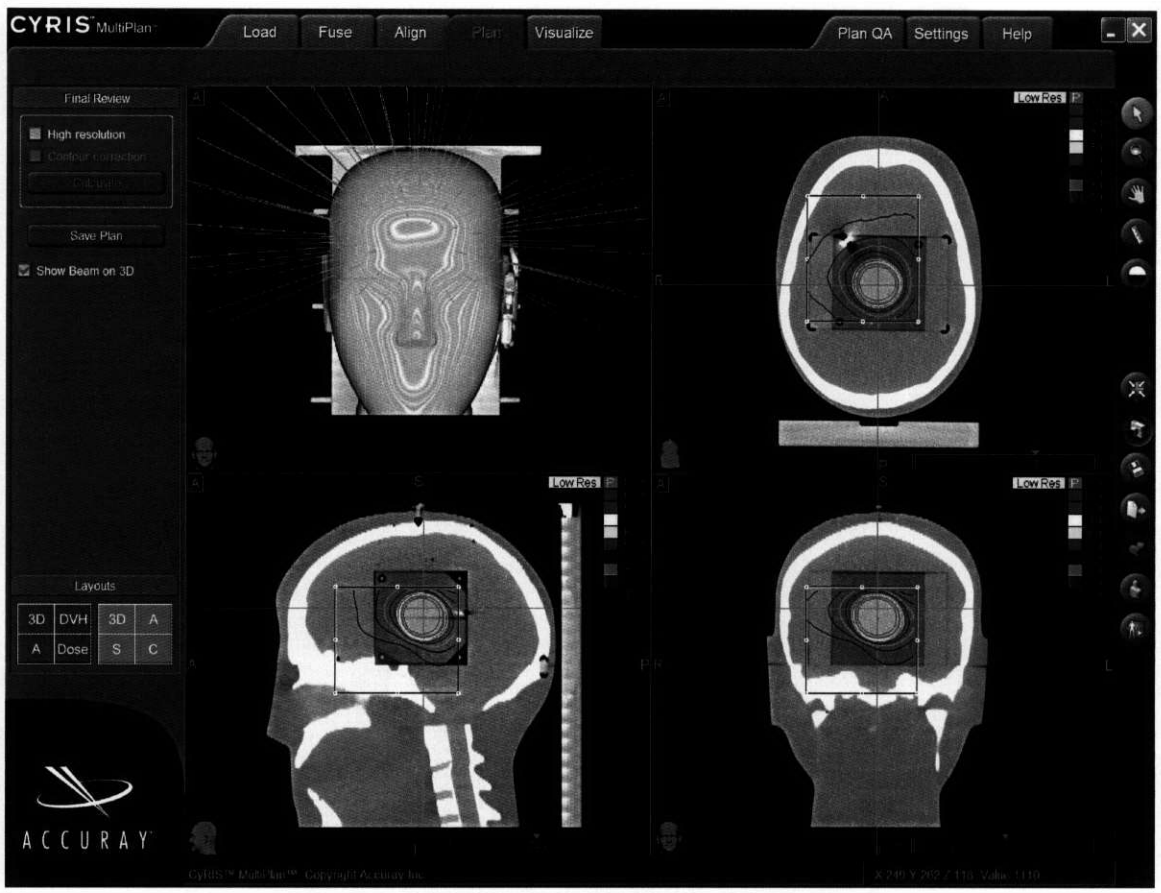



**Figure 66 Phantom Overlay Plan Evaluation**

The only step in the Plan task available to the user is the Evaluation Step, shown in *Figure 66 Phantom Overlay Plan Evaluation, page 94*. This step is changed from the version on the standard MultiPlan procedure. The only functions you can perform are to Calculate the dose, toggle display of the beams, and save the plan. The default layout in the Display View shows three planar views and the 3D View.

To save the plan, select the high resolution dose calculation and select Save Plan. Save the plan as a deliverable plan. When the plan is saved, the name you give it will have added to it a prefix "phm_" to indicate that you have saved a plan using the Phantom Overlay Procedure.

**NOTE:** The phantom Accuray provides with the CyberKnife System exposes two orthogonal planes of the dose volume. To measure the distribution throughout the whole volume, you will need to obtain an additional phantom.

**NOTE:** Once a Phantom Overlay plan is saved it is "read only" and cannot be edited or renamed.



621

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



# PHYSICS

The Physics step provides tools to perform hand calculations and conduct system quality assurance tasks. This step is shown in *Figure 67 Physics Step, page 95*.

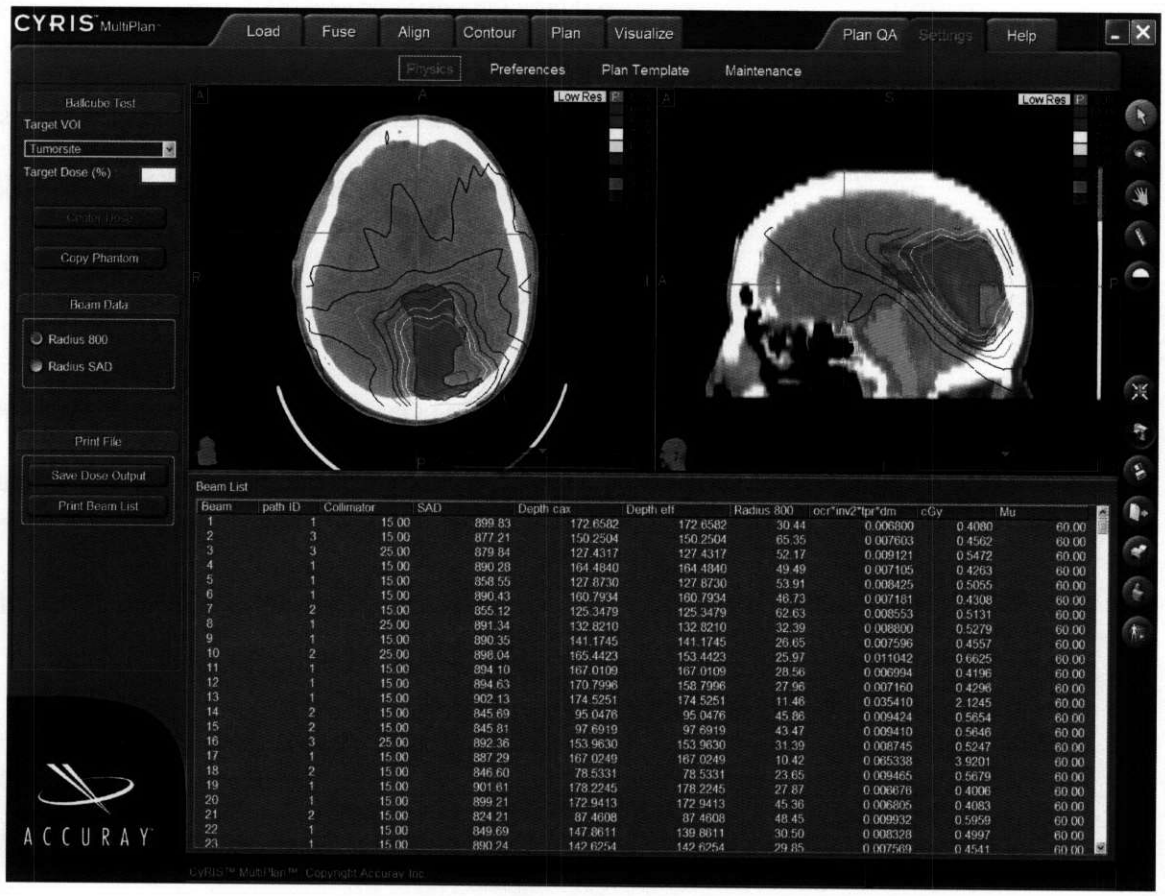



**Figure 67 Physics Step**

## Dose Table

To validate the dose calculation, you may wish to perform an independent check of the dose calculation on individual beams. The chart provides geometric and dose parameters for a beam and a reference point in the dose calculation grid. The reference point is the point of maximum dose. The chart provides the SAD, beam depth, radius, the dose at the reference point, and the number of monitor units for each beam. You can use this data and the beam data stored in the datafiles to independently verify that the dose at that point is consistent with the number of monitor units. You can display the radius either at the level of the reference point (Radius SAD), or project it back so that the perpendicular radius is relative to a point 800 mm along the central axis from the radiation source in the LINAC (Radius 800).

Select the Print Beam List to print out the data and store it to a file in the directory c:\accuray\reports\beams



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



## Ball-Cube Test

The ball-cube test is a quality assurance tool that allows you to create a dose distribution at the center of the film-cube with a spherical target. Use this test to verify the pointing accuracy of the CyberKnife. To conduct this test you should perform the following steps.

**Step 1.** Load a CT study of the ball-cube phantom.

**Step 2.** Proceed to the Treatment Parameters step of the Align task. Set the desired path set and target method for the ball-cube test. Set one stage.

**Step 3.** If fiducial tracking has been chosen, proceed to the Fiducial task and identify the fiducials.

**Step 4.** Proceed to the CT Center task and verify that the patient position is acceptable.

**Step 5.** Proceed to the Delineate step of the Contour task. Contour the ball target. Contour a dose drop-off region around the ball target.

**Step 6.** Proceed to the Setup step of the Plan task. Set the dose calculation grid and select an inhomogeneity model.

**Step 7.** Proceed to the Isocentric planning step and create an isocenter. Choose to use inverse planning to set the dose for the isocenter.

**Step 8.** Proceed to the Conformal planning step and create a conformal plan.

**Step 9.** Proceed to the Physics step of the Settings task. Select to Center Dose on the ball cube target.

**Step 10.** You can save and deliver this plan in order to verify the geometric accuracy of the CyberKnife System.

## Dose Calculation Algorithm

The standard algorithm uses a ray-tracing function based on stored beam percent depth dose data (PDD) and off-axis ratios (OAR). The PDD values are separated into two tables, an output factor that depends only on the collimator, DM, and a tissue maximum ratio (TMR). *CyberKnife Beam Commissioning Manual*, Accuray Part No. 018963, provides a method for generating the data that comprise these tables.

At each point, the contribution from each beam is given by the equation:

$$d = (SAD/800)^{-2} * DM * TMR * OAR * MU,$$

where SAD is the source axis distance, along the central axis of the beam, to the point of the dose calculation, and MU is the number of monitor units for the beam.

The value for DM is found from the collimator size of the beam. The value for TMR is dependent on the field size and the depth of the point. Values are linearly interpolated from calculated points for the PDD. The value for OAR depends on the field size, beam depth, and radial distance between the point of interest and the beam central axis. Values for the OAR are also interpolated linearly, based on stored measured points. Interpolations are done based on perturbations of field size, depth, and radial distance from the central axis. The number of stored beam data points, the number of beams, and the beam geometry affect the amount of error associated with this dose calculation. Generally, more beams in a plan will yield smaller interpolation errors, because each beam's error should be random.



623

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



## Dose Mask

The dose is calculated from a dose mask created for each beam at the resolution of the dose calculation grid. The dose mask is a cone that is 1.75 times the field size at a given SAD. This mask stores, in each element, the ratio (d/MU) from the dose algorithm above. That is the dose at each point due if the beam has a 1 MU.

The dose distribution is calculated by multiplying the scale factor by the number of monitor units and then updating the dose grid. At low resolution the dose mask is stored for each beam. At high resolution the dose grid is not stored. It is created for each beam and the total dose is summed in a loop.

## Dose Resolution

Dose is calculated on a dose grid. During planning, a low resolution dose grid is used. In low resolution mode each dimension has up to 32 voxel elements. The grid resolution is an even multiple of the voxel size of the primary CT image. Therefore the resolution, in the lateral directions, will be the pixel dimensions or an integer multiple of the pixel size and the axial resolution will be the slice thickness or an integer multiple of the slice thickness.

During evaluation, you have the option of a higher resolution grid. This grid will use up to 64 voxel elements in each direction. The same rules as the low resolution grid apply.

For DVH calculation the volumes of the VOI are calculated on the same resolution as the CT image. If the dose grid is at a lower resolution, the dose is interpolated between grid points to map the DVH.

## Inhomogeneity and Contour Correction

You can set a model for the effective dose depth as a function of the CT number, as described in *sections, Set Preferences, page 22 and Density Model, page 63.* This model affects the method in the value selected in the TMR lookup table. You can set the model and create up to 100 total density models.

You can enable contour correction for the dose calculation in the Evaluation step (*section, Final Review, page 74*). If you choose contour correction, 8 vectors are created for each beam. Each vector includes an effective depth and a dose mask element, corrected for the effective depth. The correction assumes the TMR value is affected by the depth change; whereas, the OAR table uses the central axis depth. When applying contour correction the nearest vector to a given point is used to determine the effective dose.

## Isodose Curves

The dose distribution on the 2D views is displayed as isodose curves. You can display up to ten isodose curves. You set which the curves to display from the list at the top of the Control View.

The check box at the left allows you to choose the number of curves to display.

The top isodose curve is, by default, the prescription isodose. That this is the prescription isodose is indicated by the "P" in front of the percentage value. This percentage is used to calculate the dose statistics for target volumes.

Use the color bar to change the color of any curve. Like the VOI color settings, a cascade button with default colors is available by clicking on a color bar. The last option in the cascaded list is a custom color grid that you can use to choose any color for the isodose curve.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118 624

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



Choose the percent isodose to display from the text field next to the color bar. Only integer percentage values of the maximum plan dose are allowed.

The right option allows you to set the line thickness for any isodose curve. You can set the thickness to be any integer value between 1 and 5.

### Point Dose

You can also evaluate the dose on any 2D view by clicking the mouse over any point. You can drag the mouse to find the dose along a line. The dose will be displayed in cGy and as a percentage of the maximum dose value. This dose value is more accurate than the isodose curves, because the error induced by pixilation through the dose grid is eliminated.

## Coordinate Frames of Reference

MultiPlan uses a single frame of reference. The CyRIS MultiPlan **CT coordinate frame** is the same as a head first supine CT scan of the patient. The origin of the image is the top left pixel in the x and y directions and the zero couch position (in the superior-inferior direction). The x axis is positive patient right to left; the y axis is positive patient anterior to posterior; and, the z axis is positive patient interior to superior. In *Figure 68 Coordinate Frames, page 99*, the MultiPlan CT coordinate frame is indicated by the subscript, mp.

Plans created by MultiPlan are saved in path files that use the **manipulator coordinate frame.** This frame has its origin at the patient coordinate frame origin. Its x and y axes depend on where the manipulator is located with respect to the patient. If the manipulator is at the patient's right-superior, x is positive to the patient's left-inferior and is roughly 45 degrees from the patient's inferior; y is positive to the patient's left-superior and is roughly 45 degrees from the patient's left. If the manipulator is at the patient's left-superior, x is positive to the patient's right-inferior and is roughly 45 degrees from the patient's right; y is positive to the patient's left-inferior and is roughly 45 degrees from the patient's inferior. The z-axis is positive to the patient's anterior regardless of where the manipulator is. The units are millimeters. The exact rotation is calibrated during installation. In *Figure 68 Coordinate Frames, page 99*, the manipulator frame is indicated by the subscript, m.

The On-Target Treatment Planning System hosted on the Silicon Graphics workstation used two other coordinate frames discussed below.

The origin of the **patient coordinate frame** is automatically set within the CT image based on either the field of view for the imaging system or the centroid of the locus of fiducials. The axes are: x is positive to the patient's right; y is positive to the patient's anterior; z is positive to the patient's superior. The units are millimeters. In *Figure 68 Coordinate Frames, page 99*, the p subscript indicates the patient coordinate frame.

The **legacy CT coordinate frame** has its origin at the lower (operator's) left corner of the first CT section. All coordinates in the study are positive; x is horizontal in the axial plane and positive to the patient's left; y is vertical and positive to the patient's anterior; z is parallel to the normal to the axial plane and positive to the patient's superior. Two units are used for this coordinate reference, millimeters and slice number. In *Figure 68 Coordinate Frames, page 99*, the CT subscript indicates the legacy CT coordinate frame.



625

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



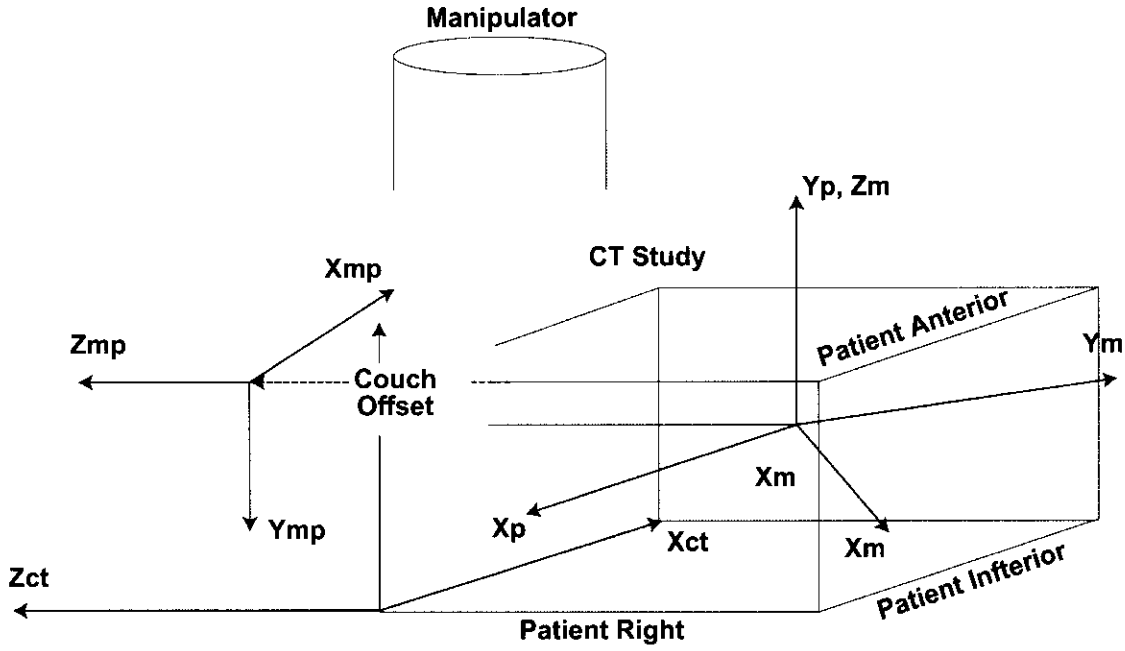



Figure 68 Coordinate Frames



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118 626

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



# GLOSSARY

## Terms

The following terms and their definitions are used in this guide:

**Active Plan** – The plan you are working on.

**Ball Cube Phantom** – A phantom used for target accuracy tests. This phantom has a ball in the middle that can house two orthogonal squares of film.

**Cavity** – A contour set that removes volume from a Volume of Interest.

**Constraint** – The desired maximum or minimum dose to a Volume of Interest.

**Contour Set** – A group of contours that are a part of the same VOI. A contour set can only have one contour on each slice.

**Control Database** – The database that controls what scanners have permission to send medical image data to CyRIS MultiPlan.

**DICOM Host** – A DICOM server to which CyRIS MultiPlan can send medical image data

**DICOM RT Dose** – A means of transferring dose distribution data.

**Export** – Create a DICOM series from image, dose or volume data.

**Fixed Image** – The CT image used to localize the patient during treatment. Also known as Image A.

**Focus Line** – A line in a 2D view that indicates the displayed perpendicular plane of the medical image.

**Function** – An operation you can perform on CyRIS MultiPlan.

**Machine Center** – A physical point in the treatment room that is the origin of the treatment room coordinate system to which the imaging and robot coordinate systems are calibrated.

**Moving Image** – A Medical Image used to assist delineation and evaluation of specific Volumes of Interest. Also known as Image B.

**N1K Image Data** – Image data stored in an obsolete volume data format. MultiPlan supports import of this data.

**Path Set** – A set of template paths for specific treatments.

**Phantom Image** – A CT image stored as a phantom that has a corresponding patient CT.

**Phantom Overlay** – A phantom CT image that overlays the patient CT Image.

**Phantom Overlay Plan** – The plan and dose distribution for a patient as it would be delivered to a phantom.

**Phantom Overlay Procedure** – A procedure that allows the user to move the dose distribution for a treatment plan without changing the beam orientations.

**Plan Template** – A collection of parameters used to pre-populate the user interface for CyRIS MultiPlan.

**Push** – Send medical image data to DICOM server.

**Reference Image** – The Fixed Image



627 Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



**Reference Plan** – A plan that is displayed for comparison. This plan cannot be modified and resaved.

**Refined Registration** – The result of registering two images using the maximization of the Mutual Information between the two images.

**Registered Image** – A moving image that has been transformed so that it aligns with the Fixed Image

**Seed Point** – A point placed on the patient anatomy to obtain a starting position for the Registration.

**Seed Point Registration** – Registering two medical images using only 3 seed points on each image.

**Startup Wizard** – An application that starts CyRIS™ MultiPlan™ by loading patient images or a patient plan.

**Step** – A group of functions organized into a single user interface layout.

**Task** – A group of steps.

**Template Paths** – A set of sequential positions that the robot assumes. The orientations for the template paths point the treatment beam at machine center.

**Weight** – The relative importance of the constraints on a Volume of Interest.

**Volume of Interest** – A target or critical structure.

## Acronyms and Abbreviations

The following acronyms and abbreviations are used in this guide:

**2D** – 2 Dimensional

**3D** – 3 Dimensional

**3DXA** – Rotational or 3-Dimensional X-Ray Angiography

**CI** – Conformality Index

**CT** — Computed Tomography

**DICOM** – Digital Image Communication for Medicine

**DICOM RTSS** – DICOM Radiotherapy Structure Set

**DVH** — Dose Volume Histogram

**HFS** — Head First Supine

**HI** – Homogeneity Index

**MIRIT** – Medical Image Review and Import Tool

**MR** — Magnetic Resonance

**nCI** – New Conformality Index

**OAR** – Off-axis ratio

**PET** – Photon Emission Tomography

**PT** – Photon Emission Tomography

**RT** – Radio Therapy



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



**RTSSET** – Radiotherapy Structure Set

**SAD** – Source Axis Distance

**TMR** – Tissue Maximum Ratio

**TPS** — Treatment Planning System

**UCC** – User Control Console

**UID** – Unique Identifier

**VOI** – Volume of Interest

**Voxel** — volume pixel

**WRT** — with respect to



629

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



# WARNINGS AND ERRORS

*Table 2: Warnings and Error Messages, page 103,* tabulates warning and error messages used in CyRIS MultiPlan. Warnings have codes that begin with a '0'; errors have codes that begin with an '8'. The table also includes workarounds to help resolve errors.

**Table 2: Warnings and Error Messages**

| Code | Error/Warning Message | Recommended Actions |
|---|---|---|
| | **WARNINGS** | |
| 0001 | Closing this application may cause loss of data. Do you want to close this application? | No action is needed. |
| 0010 | Your license will expire in %s days. Please contact Accuray Inc. to obtain a new license. | Contact Accuray to obtain a new license. |
| 0011 | This VOI is not empty. Changing the contour plane will erase all the existing contours. Do you want to proceed? | No action is needed. |
| 0012 | Deleting plan will cause all plan data to be lost! Do you want to proceed? | No action is needed. |
| 0013 | Deleting the current slice may cause the current series to become unloadable! Do you want to delete anyway? | No action is needed. |
| 0014 | Are you sure you want to delete the current series permanently? | No action is needed. |
| 0015 | Warning: If the merged series has variable slice thickness, it cannot be loaded! | No action is needed. |
| 0016 | This field only accepts integer values in the range of %s. The original value will be used! | Input an integer in the field. |
| 0017 | This field only accepts floating point values in the range of %s. The original value will be used! | Input a number in the field. |
| 0018 | The VOIs have not been saved since the last modification. Do you want to proceed without saving them? | Save VOIs, if desired. If not, no action is needed. |
| 0019 | Please quit this application before logging off or switching to another user! | Logoff if changing user. |
| 001A | The previously selected series belongs to a different patient. Do you want to clear the previous selection? | No action is needed. |
| 001B | The images have not been registered. 3D images will not be shown correctly. Please go back to Fuse task. | Fuse the two loaded medical images, if desired. If not, no action is needed. |
| 001C | The previous DICOM push process has not finished. Closing the application may result in the data not being fully transmitted. Do you want to quit the application? | Cancel CyRIS MultiPlan exit to prevent an incomplete data set being loaded onto CyberKnife System User Control Console. |



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118 630

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



**Table 2: Warnings and Error Messages**

| | | |
|---|---|---|
| 001D | The previously selected series belongs to a different patient. Do you want to continue? | No action is needed. |
| 001E | You do not need to split the currently selected slice! | No action is needed. |
| 001F | Only 7 VOI can be viewed on the 3D image! | Delete one selected VOI to display on the 3D view, before attempting to add a VOI for display on the 3D view. |
| 0020 | You need to deselect the previous selection to select a new dataset! | Deselect a selected image or RT dataset, before you attempt to select this dataset. |
| 0021 | The system will sort the image first; then, you can choose the slice to delete! | No action is needed. |
| 0022 | No VOI contour has been detected after erosion. The system has cancelled the operation, and the original VOI retained. If you wish to delete the VOI, please use the [Delete All] command instead | Choose to erode less of the VOI or delete the VOI. |
| 0023 | Are you sure you want to save %s? | Confirm users' selection of the local and remote push. |
| 0024 | Are you sure you want to discard current work and load new dataset? | Discard or save current work. |
| 0025 | There is no item in the list control. | No action required. |
| 0026 | The offset from the centroid of the target isodose volume to the centroid of the target VOI is %s, which is greater than the tolerance [%s]. Do you want to center the dose one more time? | Try to center the dose distribution again. If that fails regenerate either the ball-cube plan or the ball-cube VOI. |
| 0027 | The offset from the centroid of the target isodose volume to the centroid of the target VOI is %s, which is below the tolerance [%s]. Do you want to center the dose one more time? | Try to center the dose. |
| 0028 | Recovering the automatically saved plan will cause the current plan data to be lost! Do you want to proceed? | If you want to save the current plan, select No and save that plan. |
| 0029 | Do you want to pirate %s plan lock? Failed to acquire it for %s in SGI database! | You can either take the lock or open a different plan. |
| 002A | Failed to acquire the lock of %s image for %s in SGI database! | Call Accuray. |
| 002B | This process can be a lengthy. Are you sure you want to continue? | Continue if you want a high resolution dose calculation. |
| 002C | The plan saved is not DELIVERABLE! | No action required. |
| 002D | The Patient ID (%s) from the central database differs from the patient ID (%s) of CT image header! | The primary CT cannot be used to generate a deliverable plan. You need to reload the CT in such a way that it is associated with the patient medical ID. |



631 Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



**Table 2: Warnings and Error Messages**

| | | |
|---|---|---|
| 002E | The fiducial tracking plan needs AT LEAST ONE fiducial to be identified! | Identify a fiducial. |
| 002F | A DELIVERABLE plan MUST generate AT LEAST ONE treatment path with dose! | Check the plan to be sure that the plan has dose. Call Accuray, if it does. |
| 0030 | The total MU between the stored beam data and the path files is inconsistent! | Rescale the data so that rounding errros are minimized. Verify that all calibration data is present. |
| 0031 | Loading beam data is in progress...This process MUST be completed before you proceed | No action required. |
| 0032 | Cannot save a <READ_ONLY> plan. Load another plan or reload this plan to update its status. | Reload plan or load a different plan. Plan should not be locked. |
| 0033 | Loading a reference plan based on a different CT image set than the loaded CT %s! | The primary CT cannot be used to generate a deliverable plan. You need to reload the CT in such a way that it is associated with the patient medical ID. |
| 0034 | Are you sure you want to RESET the beam data generated for conformal plan? | No action required. |
| 0035 | This command will remove all previously saved reports on your local drive. \nAre you sure you want to Cleanup report folders? | Remove files if they are no longer needed. |
| 0036 | Failed to acquire the %s plan lock for %s! Do you want to load this plan in READ ONLY mode? | Load a different plan. If problem persists, call Accuray. |
| 0037 | Latest change to the CT Center has not been confirmed. Do you want to confirm it? | You can confirm or discard the new CT Center. |
| 0038 | The CT number of the following fiducial(s) is (are) low!\ n%s | No action required. It's a good idea, though, to verify that all fiducials are located at fiducials. |
| 0039 | Please select a fiducial type before defining fiducials! | Select the type of fiducial. |
| 003A | The input value is out of range. Please input a valid value in [%s]. | Change the input value. |
| 003B | Maximum number of fiducials (eight) has been reached. | Stop identify fiducials or delete a fiducial before identifying a new fiducial. |
| 003C | This patient has been discontinued. | No action required. |
| 003D | Changing VOISet template will override all empty VOIs in the current plan. Do you want to continue? | If drawn VOI not needed, continue. If it is needed, select No. |
| 003E | Are you sure you want to change the density model of the current plan? | Confirm if desired. |
| 003F | Do you want to cancel the current process? | Confirm if desired. |
| 0040 | Recovered %s plan in READ ONLY mode! | Wait for plan to be freed by user. |



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118 

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



**Table 2: Warnings and Error Messages**

| | | |
|---|---|---|
| 0041 | No moving image is loaded because %s of patient %s doesn't exist in central database! | Load moving image into CKS central database. Then, restart treatment planning. |
| 0042 | Are you sure you want to overwrite %s plan? | Confirm if desired. |
| 0043 | Changing the collimator size will delete the current conformal plan. Are you sure you want to continue? | Confirm if desired. |
| 0044 | All Beams have zero MU. Cannot generate beam data for report or display. | Generate a plan before creating a report for the plan. |
| 0045 | There are no beams generated ( total beams = 0 ). | Replan. |
| 0046 | The node coordinates of the beams are inconsistent with the treatment paths. | Delete all beams and restart plan generation process. |
| 0047 | The reference dose is inconsistent between the path and the beam set. | Delete all beams and restart plan generation process. |
| 0048 | Changing to Simplex planning will delete the current conformal plan. Are you sure you want to continue? | Confirm if desired. |
| 0049 | The Simplex algorithm failed to find a solution. The current beam set will be deleted. | Use weights less than 100 on the constraints. Increase the Maximum MU per beam. |
| 0052 | Plan template [%s] already exists. Do you want to replace it? | Confirm if desired. |
| 0053 | Do you want to create a new template based on the current plan settings? | Confirm if desired. |
| 0054 | This operation is supported only in phantom overlay mode. No change will be made. | No action required. |
| 0055 | There is no deformation control point volume. | No action required. |
| 0056 | Do you want to discard current work to switch Phantom Overlay Mode? | Confirm if desired. |
| 0057 | The dose has been successfully centered.The offset from the centroid of the target dose line to the centroid of the target VOI is %s.Do you want to refine the center with high resolution dose volume? | Confirm if desired. |
| 0058 | The new position is very close to an existing landmark. The system can not add it as a new landmark. However, you can choose to replace the existing landmark with the new position. Do you want to replace the existing landmark with the new position? | Confirm if desired. |
| 0059 | There are fiducials defined in dataset A. Do you want to import those fiducials to the landmark list of dataset A? | Confirm if desired. |





Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



**Table 2: Warnings and Error Messages**

| | | |
|---|---|---|
| 0060 | You will lose all fused and delineation information for selected patients.If you need to save these information, you must export patient information to a remote machine. Do you want to remove selected patients? | Confirm if desired. |
| 0061 | The template paths from the current plan are inconsistent with the ones from SGI datafiles. | You need to select a new path set and replan, if you plan to generate a deliverable plan. If you wish to review a previously treated plan, no action is required. |
| 0062 | The new anatomical region conflicts with the treatment anatomy of this template, the treatment anatomy and other planning parameters will be reset. Do you want to apply the new anatomical region? | Confirm if desired. |
| 0063 | Switching to the wizard may cause loss of data. Are you sure you want to switch to the wizard? | Confirm if desired. |
| 004A | Using the Pause feature will abort the Simplex algorithm and delete the current beam set. Are you sure you want to continue? | Confirm if desired. |
| 004B | Are you sure you want to delete all constraint points? | Confirm if desired. |
| 004C | The image registration transformation has been changed. Do you want to save the change? | Confirm if desired. |
| 004D | Please enter an string at least with %s characters. | Enter a string with enough length. |
| 004E | Please enter an string with alphanumeric characters. | Enter an alphanumeric string. |
| 004F | Changing the density model will cause the current plan to be deleted. Are you sure you want to continue? | Confirm if desired. |
| **MESSAGES** | | |
| 4001 | Loading has finished successfully. Do you want to proceed to the next available task? | Confirm if desired. |
| 4002 | The dose has been successfully centered. The offset from the centroid of the target isodose volume to the centroid of the target VOI is %s, which is below the tolerance [%s]. | No action required. |
| 4003 | Do you want to delete the current conformal beam set? | Confirm if desired. |
| 4004 | Print job is completed. | No action required. |
| 4005 | Finished Cleaning up all selected report folder(s | No action required. |
| 4006 | All selected patient(s) has been removed successfully from local database. | No action required. |
| **ERRORS** | | |
| 8000 | Unknown system error! | No advice is available. |



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118 634

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



**Table 2: Warnings and Error Messages**

| | | |
|---|---|---|
| 8001 | System does not have enough memory to load this data! | Close all non-CyRIS MultiPlan related applications. Close and restart the application.<br>If this fails, reboot the system.<br>If this fails, attempt to reduce the size of the medical images. |
| 8002 | The current operating system does not support this application. Please run this application on Windows XP Pro or higher version of windows system. | Contact Accuray service to arrange a Window's operating system upgrade. |
| 8003 | Please set your display resolution to 1600 x 1200 and 32 color bits. | Select the Control Panel from the Start Menu. Select Appearance and Themes. Select Display. Open the Settings tab.<br>Set the Screen resolution to 1600x1200 and the Color quality to Highest (32 bit). |
| 8004 | Failed to capture image! | Try to recapture image. |
| 8005 | Failed to save file [%s]! Please make sure the disk has enough space and is not write protected. | If saving data to a floppy disk, verify that the disk is writable. |
| 8006 | Graphics system failed! Error found in OpenGL [%s]. | Reboot the computer. |
| 8007 | The license file is missing. Please contact Accuray Inc. to obtain a new license. | Contact Accuray to obtain a new license. |
| 8008 | Invalid license. Please contact Accuray Inc. to obtain a new license. | Contact Accuray to obtain a new license. |
| 8009 | License has expired. Please contact Accuray Inc. to obtain a new license. | Contact Accuray to obtain a new license. |
| 800A | Another instance of this application is running! | Close CyRIS MultiPlan application. |
| 800B | The seed points you have defined are collinear. Please redefine one or more seed points. | Redefine one or more seed points so that all three are not collinear. |
| 800C | The seed points you have defined are too close to each other. Please redefine one or more seed points. | Redefine one or more seed points and separate them further. |
| 800D | Wrong filter file cannot be loaded! | Attempt to load a different filter file. |
| 8100 | Invalid database connection! | Restart MSSQL server. |
| 8101 | No connection to TPS_DICOM Database via ODBC [DNS:DICOMServer]! | Ensure MSSQL server is running and ODBC connection is good for "DNS:DICOMServer". |
| 8103 | Failed to start the DICOM Archive Server! Please make sure [archive_server.exe] is in the right folder. | Restart DICOM Server by clicking on c:\ accuray\bin\restartDICOMServer.cmd |
| 8104 | Could not find the local configuration files! | Ensure all necessary configuration files exist in c:\accuray\config\ |
| 8105 | Failed to save file [%s]! Please make sure the disk has enough space and is not write protected. | If the space and protection is okay, check the network connection. |
| 8106 | Failed to initialize local datafiles! | Check the network connection. |





Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



**Table 2: Warnings and Error Messages**

| | | |
|---|---|---|
| 8107 | Failed to create local data folder! | Check permissions in the c:\accuray folder. |
| 8108 | Failed to initialize DBMCommClient! | Check network connection. |
| 8109 | No connection to SGI Database via ACE [db_comm_server]! | Check network connection. |
| 810A | Failed to acquire the database lock! %s. Please wait for the patient database to be available. | Open a different patient or wait until that particular patient is locked. |
| 810B | Failed to release all locks on the SGI database held by %s! | No action required. |
| 810C | Failed to release %s plan lock from the SGI database held by %s! | No action required. |
| 810D | Failed to acquire the lock of %s CT image for %s in the SGI database! | Open a different patient or wait until that particular patient is locked. |
| 810E | Failed to add the %s plan to the central database! %s. | Check network connection. |
| 810F | Failed to add the %s plan to the central database! %s. | Check network connection. |
| 8110 | Failed to reset the system application! | No action required. |
| 8111 | Failed to acquire the lock of %s patient for %s in the SGI database! | Open a different patient or wait until that particular patient is locked. |
| 8112 | Failed to initialize robot data! | Check network connection. |
| 8113 | Invalid TMR table found in SGI data file! Please read log file for details. | Based on information from the datafiles, correct datafile format. |
| 8114 | Invalid DM table found in SGI data file! Please read log file for details. | Based on information from the datafiles, correct datafile format. |
| 8115 | Invalid OCR table found in SGI data file! Please read log file for details. | Based on information from the datafiles, correct datafile format. |
| 8116 | Failed to acquire the RSP lock of %s patient for %s in SGI database. | You cannot save or delete data for this patient, because you cannot acquire lock priveleges for this patient. You must wait until other users stop accessing this patient before you can work on this patient. |
| 8117 | Failed to remove patient <%s> from local database. | You should check the permissions on your system to see if you are allowed to delete data from the local database. |
| 8200 | Failed while reading image! | Resend DICOM data from scanner or workstation. If that fails, call Accuray. |
| 8201 | Failed while loading image! | Perform System Maintenance Task. If that fails, call Accuray. |
| 8202 | Image slice count error! The image may have fewer than 2 slices. | Rescan or send image so that it has at least two slices. |



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118 636

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



**Table 2: Warnings and Error Messages**

| | | |
|---|---|---|
| 8203 | The image does not contain valid slice spacing! | Delete slices that create erroneous slice spacing. |
| 8204 | The image does not have valid patient position! | Rescan patient as HFS. |
| 8205 | The image contains SAGITTAL slices, which are not supported by this application. | Delete sagittal slices, or rescan patient. |
| 8206 | The pixel format of the image is not supported by this application. | Rescan image or call Accuray. |
| 8207 | The slice thickness of this image set is not consistent! The system cannot load this image. | Rescan image or delete slices that cause unequal slice thickness. If that fails, call Accuray. |
| 8208 | The slice sizes of this image set are not consistent! The system cannot load this image. | Rescan image or delete slices that cause unequal slice thickness. If that fails, call Accuray. |
| 8209 | The pixel spacing for this image set is not consistent! The system cannot load this image. | Rescan the image or delete slices that cause unequal pixel spacing. If that fails, call Accuray. |
| 820A | Some slices of the image are missing. The system cannot load this image. | Resend or rescan image. If that fails, call Accuray. |
| 820B | The patient position of this image is not HFS! This application will not load this image. | Rescan image or resend image as a HFS image set. If that fails, call Accuray. |
| 820C | Failed to read image data. The image data may be incomplete or invalid. | Rescan or resend image. If that fails, call Accuray. |
| 820D | The system does not allow an image study with more than <n> slices to be loaded! | Delete enough slices to assure the study has no more than 300 slices. |
| 820E | The Slice thickness is not in the range (min, max) = <f>! | Rescan image with a valid range for the slice thickness or call Accuray. |
| 820F | Rescale Intercept or Slope has no value! | Rescan image or resend image with appropriate image header. |
| 8210 | Gantry/Detector Tilt is not ZERO! | Rescan image with zero gantry tilt. |
| 8211 | <s> patient position is not supported! | Rescan image in a valid patient position. |
| 8212 | The image is blank! Failed to load image. | Try to reload a different image. |
| 8280 | Failed to load plan! | Try to load a different plan. |
| 8281 | Failed to read plan data. The plan may include invalid or incomplete data. | Try to load a different plan. |
| 8282 | Failed to recover plan data! | Try to recover again. If that fails, call Accuray. |
| 8283 | Failed to generate high resolution dose. | Save plan. Restart MultiPlan. Load plan and try to generate high resolution dose again. |



637 Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



**Table 2: Warnings and Error Messages**

| | | |
|---|---|---|
| 8284 | Failed to apply contour correction. | Retry. If that fails, save plan. Restart MultiPlan. Load plan and try to apply contour correction again. |
| 8285 | No recoverable plan exists! | No action required. |
| 8286 | Failed to read %s reference plan data. The plan may include invalid or incomplete data! | Try to load a different plan. |
| 8287 | Failed to initialize reference plan(s)! | Try to load a different plan. |
| 8288 | Failed to initialize the plan object! | Try to load a different plan. |
| 8289 | Failed to load reference plan. | Try to load a different plan. |
| 828A | Failed to load RTP Plan file. | Try to load a different plan. |
| 828B | Failed to load RTP plan file as reference. | Try to load a different plan. |
| 828C | Failed to transfer %s plan data to local drive![%s] | Check network connection. Try to load a different plan. |
| 8300 | Failed to load the RTDose dose distribution! | Resend the RTDose from the CyberKnife System. If that fails, call Accuray. |
| 8301 | Failed to load the RTSS volumes of interest! | Resend RTSS Volumes. If that fails, call Accuray. |
| 8302 | Invalid RTSS data, or the RTSS structure does not contain any VOI! | Resend RTSS data with VOI. |
| 8303 | Failed to export the volumes of interest file! | Verify that archive_server is running. If it is, call Accuray. |
| 8304 | Failed to export the fused image file! | Verify that archive_server is running. If it is, call Accuray. |
| 8305 | Failed to export the mixed image file! | Verify that archive_server is running. If it is, call Accuray. |
| 8306 | Failed to export the merged image file! | Verify that archive_server is running. If it is, call Accuray. |
| 8307 | Failed to export the split image file! | Verify that archive_server is running. If it is, call Accuray. |
| 8308 | Failed to save the volumes of interest! | Verify that archive_server is running. If it is, call Accuray. |
| 8309 | Failed to push the original image [%s] to the remote computer %s! | Verify that archive_server and the DICOM server on the recipient host are running. If they are, call Accuray. |
| 830A | Failed to push the volumes of interest to computer %s! | Verify that archive_server and the DICOM server on the recipient host are running. If they are, call Accuray. |



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



**Table 2: Warnings and Error Messages**

| | | |
|---|---|---|
| 830B | Failed to push the fused moving image to computer %s! | Verify that archive_server and the DICOM server on the recipient host are running. If they are, call Accuray. |
| 830C | Failed to push the mixed image to computer %s! | Verify that archive_server and the DICOM server on the recipient host are running. If they are, call Accuray. |
| 830D | Failed to push the merged image to computer %s! | Verify that archive_server and the DICOM server on the recipient host are running. If they are, call Accuray. |
| 830E | Failed to push the split image to computer %s! | Verify that archive_server and the DICOM server on the recipient host are running. If they are, call Accuray. |
| 830F | Failed to add the remote machine! | Call Accuray. |
| 8310 | The fused volume data is invalid to export! | Verify the moving image properly registered in Fuse Task. |
| 8311 | Failed to export the dose volume file! | Check file and folder permissions. |
| 8312 | Failed to push the dose volume to computer %s! | Check file and folder permissions. |
| 8313 | Failed to push the original image [%s] in N1k Format to the remote computer %s! | Check network connection. |
| 8380 | Failed to connect to DICOM server! The server could be dead or there may not be a network connection to %s! | Verify that the recipient DICOM server is running. Resend DICOM data. If that fails, call Accuray. |
| 8381 | Interrupted DICOM network connection to %s! | Verify that the recipient DICOM server is running. Resend DICOM data. If that fails, call Accuray. |
| 8382 | DICOM server aborted this Association request to %s! | Verify that the recipient DICOM server is running. Resend DICOM data. If that fails, call Accuray. |
| 8383 | Request for this Association rejected by the DICOM Server because of the wrong calling AE title for %s! | Modify the calling AE title for the remote machine. Resend DICOM data. If that fails, call Accuray. |
| 8384 | Timeout (%s secs) for pushing DICOM files: SCU application is hanging because of a AEs error or the network may be too slow to %s! | Verify that the recipient DICOM server is running. Resend DICOM data. If that fails, call Accuray. |
| 8385 | Failed to run C_STORE application as SCU. It could be that send_image.exe is missing! %s | Call Accuray. |
| 8386 | Failed to either verify AEs or write to DICOM database %s! | Verify AE title and that the recipient DICOM server is running. Resend DICOM data. If that fails, call Accuray. |
| 8387 | Request for this Association rejected by the DICOM Server because of an illegal calling AE title for %s! The maximum string length of AE title is 16 characters. | Correct the AE title for the DICOM Server. |



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



**Table 2: Warnings and Error Messages**

| | | |
|---|---|---|
| 8400 | Failed to save the plan! | Check that the primary SGI is on. Check that the database manager is running on the SGI. Check network connection. |
| 8401 | Failed to delete the plan! %s. | Check that the primary SGI is on. Check that the database manager is running on the SGI. Check network connection. |
| 8402 | Failed to save the plan because of duplicate plan name! Please give the plan another name. | Rename the plan. |
| 8403 | Failed to read the plan list from the central database! | Check that the primary SGI is on. Check that the database manager is running on the SGI. Check network connection. |
| 8404 | Failed to overwrite the DELIVERABLE plan with the current NON-DELIVERABLE plan! Please do not name this plan %s. | Rename the plan. |
| 8405 | Failed to overwrite the RTP plan with the CYRIS plan! Please use another plan name. | Rename the plan. |
| 8406 | Failed to write the treatment path for a deliverable plan! | Verify that the node data is non-zero. Check the network connection. |
| 8407 | Failed to write the check file for a deliverable plan! | Check the network connection. Check the permissions on the SGI. |
| 8408 | Failed to write the plan data file for a deliverable plan! | Check the network connection. Check the permissions on the SGI. |
| 8409 | Failed to write the fiducial file for a deliverable plan! | Check the network connection. Check the permissions on the SGI. |
| 840A | Failed to delete the currently loaded plan %s! | Check the network connection. Check the permissions on the SGI. |
| 840B | Failed to delete the currently loaded series %s! | Check the network connection. Check the permissions on the SGI. |
| 8500 | No dose has been found, or dose volume is empty. Please go back to the Plan task to create a valid plan. | Generate a plan. |
| 8501 | No beams have been found. Please go back to the Plan task to create a valid plan. | Generate a plan. |
| 8502 | Failed to copy %s image set from patient to phantom directory in the central database. | Check permissions. Verify that a phantom study does not already exist. |
| 8600 | Failed to create a new contour set! The VOI already has the maximum number [%s] of contour sets. | Reformat contour set. |
| 8700 | Failed to create writable file <%s>. | No action required. |
| 8701 | Failed to open file <%s> at location <%s> for reading. | Check existence and permission of file. |
| 8702 | Failed to open writable file <%s> at location <%s>. | Check file and folder permissions. |
| 8703 | Failed to read file <%s> at location <%s>. | Check existence and permission of folder. |



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



**Table 2: Warnings and Error Messages**

| | | |
|---|---|---|
| 8704 | Failed to write to file <%s> at location <%s>. | Check file and folder permissions. |
| 8705 | Failed to load plan file <%s>.<%s> | Check network connection. Check existence and permission of file. |
| 8706 | Failed to create dose volume output file <%s>. | Check file and folder permissions. |
| 8770 | Invalid Plan XML file name <%s>. %s | No action required. |
| 8771 | <%s>. Failed to generate Checklist report. | Check the network connection. Check the permissions on the SGI. |
| 8772 | Cannot generate checklist report for an RTP plan. | Check printer connection. Check permissions in C:\\accuray folder. |
| 8773 | Cannot generate checklist report. Treatment file is not available(number of path files are zero). | Check printer connection. Check permissions in C:\\accuray folder. |
| 8774 | Cannot generate checklist report. Failed to read node information from path file <%s>. | Check printer connection. Check permissions in C:\\accuray folder. |
| 8800 | Failed to read server IP address from TPSMain.ini file.It is blank. | You need to reconfigure the TPSMain.ini file to point to an SGI server. |
| 8801 | Failed to start NFS client service. | Restart the application. If that fails, check the network connection. |
| 8802 | Failed to mount NFS server at IP address<%s>.Timeout error. 1) Make sure server is up and running. 2) Make sure IP address used in TPSMain.ini file is correct. | Restart the application. If that fails, check the network connection. If that fails, verify that the IP address in the TPSMain.ini file. |
| 8803 | Failed to establish NFS connection with server.Cannot continue. | Restart the application. If that fails, check the network connection. If that fails, verify that the IP address in the TPSMain.ini file. |
| 8870 | Invalid template name. | Change the name of the template and attempt to resave. |





Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



# CyRIS™ InView™
## Table of Contents


Introduction to CyRIS InView ..... 1
Getting Started ..... 2
Import Medical Images ..... 2
Configure Scanners ..... 2
Export Data from the CyberKnife System User Control Console ..... 2
CT Image Study ..... 2
Other Studies ..... 3
User Interface Display Organization ..... 5
Workflow for the CyRIS InView ..... 5
Screen Layout ..... 6
2D Display Layout ..... 7
Split Screen View ..... 8
Checkerboard View ..... 9
Overlay View ..... 10
Global Tools ..... 11
Pointer ..... 12
Zoom ..... 12
Window/Level Mode ..... 13
Ruler Mode ..... 14
Screen Capture ..... 15
Keyboard Controls ..... 16
Ancillary Tasks ..... 17
Preferences ..... 17
Maintenance ..... 18
Help ..... 20
Load Data ..... 22
Load Data ..... 22
Select the Fixed Medical Image ..... 23
Select the Moving Image ..... 24
Select Anatomical Contours ..... 24
Select a Dose Distribution ..... 24
Load the Selected Image Data ..... 25
Edit Image Data ..... 25
Fuse Two Image Series ..... 27
Seed-Point Alignment ..... 27




Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

642

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



Set Seed Points ..... 28
3D and 2D Layouts ..... 29
3D Filter ..... 29
Load a Preregistered Image ..... 29
Image to Image Registration ..... 29
Intensity-based Registration ..... 30
Seed-Point Registration ..... 31
Manual Registration ..... 31
Contour ..... 33
Volumes of Interest ..... 33
Properties Step ..... 33
Display Settings ..... 34
Delineate Step ..... 36
VOI Properties ..... 36
Contour Sets ..... 38
Drawing Tools ..... 39
Pen ..... 39
Line ..... 39
Ellipse ..... 39
Rescale ..... 39
Magic Wand ..... 39
3D Magic Wand ..... 40
Bumper ..... 40
Edit Commands ..... 40
Interpolation of Volumes of Interest ..... 44
Smart Curve Fitting Option ..... 46
Plan Review ..... 47
Receiving Dose Distributions ..... 47
Layouts ..... 48
Displayed Dose ..... 49
Isodose Curves ..... 50
Point Dose ..... 50
Global Metrics ..... 51
Dose Volume Histograms ..... 51
Dose Statistics Table ..... 52
3D Visualization ..... 53
Window/Level Filter ..... 53
Color Filter ..... 55
Dose and Anatomy Overlays ..... 56



643 Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



**Save and Push Data** ..... 57
- Configure Hosts ..... 59
- Volumes of Interest ..... 60
- Image Data ..... 60

**Glossary** ..... 61
- Terms ..... 61
- Acronyms and Abbreviations ..... 62

**Warnings and Errors** ..... 63



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118 644

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015





645 Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



# CyRIS™ InView™

## Introduction to CyRIS InView

This module explains the operational procedures for CyRIS InView. CyRIS InView is designed to provide a very specific set of planning features most frequently used by physicians that can be performed remotely from the CyberKnife® System Treatment Suite.

The CyRIS InView gives physicians and medical physicists the ability to:

- fuse two medical images
- contour Volumes of Interest
- import and review dose distributions created with the CyberKnife Treatment Planning System.

The user should generate and give final approval of treatment plans using the CyberKnife Treatment Planning System.

This guide details the procedures available to the user of CyRIS InView.

**WARNING: Do not attempt to modify a treatment file. Improperly changed data could result in death or injury of the patient.**



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



# GETTING STARTED

## Import Medical Images

Medical Images must be pushed to CyRIS InView. They can be pushed from either the source scanner or the CyberKnife System User Control Console (UCC).

### Configure Scanners

The scanner that will send data to CyRIS InView will need to be configured with the AE Title, IP address, and DICOM port for your InView workstation.

### Export Data from the CyberKnife System User Control Console

**NOTE:** CyRIS InView must be turned on in order for DICOM data to be transmitted to it.

It is recommended that the user import the medical images to the CyberKnife System first and then push those images to CyRIS InView workstation.

#### CT Image Study

For CyberKnife versions 5.2.2 and earlier, If you have already imported a CT image study into the CyberKnife System patient database, you can export the CT image by opening the Treatment Planning System and loading the CT image.

**Step 1.** Select **PLAN->EXPORT DICOM DATA**. *Figure 1 Export DICOM Data from the UCC, page 3* will appear.

**Step 2.** Select the CT IMAGE STUDY to export.

**Step 3.** Choose to Export to Host.

**Step 4.** Select CyRIS InView as the host to export to.

**Step 5.** Select **OK**.

The CyberKnife System will export the CT image to CyRIS InView.



647 Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



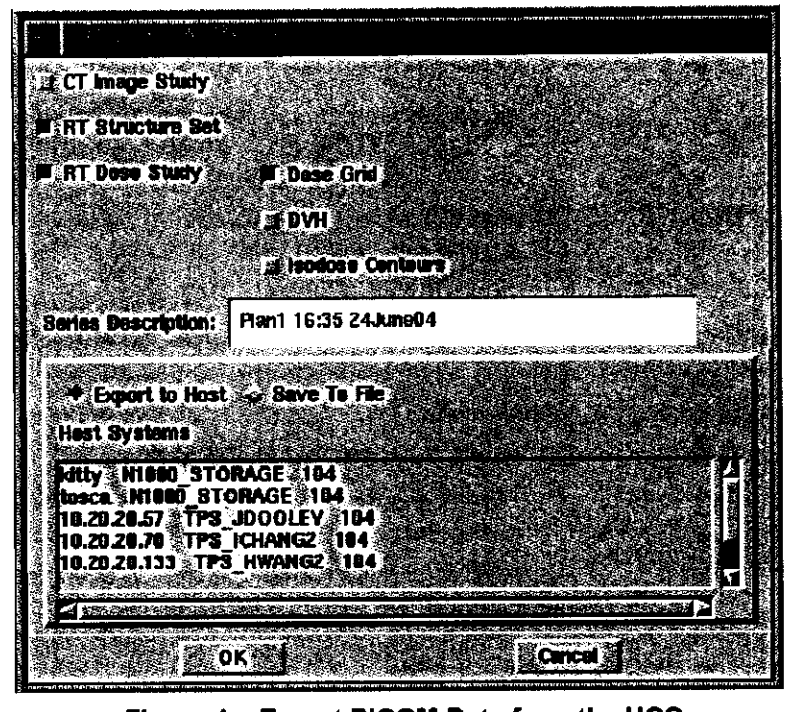



**Figure 1 Export DICOM Data from the UCC**

## Other Studies

Export Dicom image studies to InView from a unix shell. You will need to know the IP Address and the AE Title of the InView station where the images should be sent to. If needed, call Accuray Customer Support for assistance.

**For CyberKnife System versions 5.2.2 and earlier**, follow these steps. Note – it is important to type the commands exactly as shown here, including upper and lower case and spacing.

**Step 1.** Open a shell

**Step 2.** Go to the 'patients' directory

- At the prompt type **pats** <Enter>

**Step 3.** Go to the directory of the patient whose images you want to send

- At the prompt type **cd <patientname_id>/ct/patient** <Enter>

**Step 4.** List the contents of this directory

- At the prompt type **ls** <Enter>

**Step 5.** Go to the directory of the case number with the images you want to send

- At the prompt type **cd <case...>** <Enter>

**Step 6.** List the contents of this directory

- At the prompt type **ls** <Enter>

**Step 7.** Go to the directory of the modality with the images you want to send

- At the prompt type **cd <CT, MR, PT>** <Enter>



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118 648

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



**Step 8.** List the contents of this directory

- At the prompt type **ls** <enter>

**Step 9.** Send the images to the CyRIS InView Station

- At the prompt type **/accuray/tools/dicom/send_image –a N1000_STORAGE –c <AE Title of InView> <IP Address of InView> 104 *** <Enter>

**Step 10.** The system will provide messaging indicating that images are being sent. When you get a prompt you can exit the shell

- Type **exit** <Enter>

**For CyberKnife System versions 6.2.0 and higher**, follow these steps. Note – it is important to type the commands exactly as shown here, including upper and lower case, and spacing.

**Step 1.** Open a shell

**Step 2.** Open the Push DICOM image tool

- At the prompt type **cd /accuray/tools/dicom/pushDicomImage** <Enter>

**Step 3.** At the 'Select patient index number' prompt, enter the number that is displayed to the left of the patient's name whose images you want to send, <Enter>

- Note: you may need to scroll to find the patient name

**Step 4.** At the 'Select study case index number' prompt, enter the number that is displayed to the left of the study whose images you want to send <Enter>

**Step 5.** At the 'Select series index number' prompt, enter the number that is displayed to the left of the modality type (CT, MR, PT, XA) of the images you want to send <Enter>

**Step 6.** At the 'Select DICOM host index number' prompt, enter the number that is displayed to the left of the IP address and AE Title for the InView where you want the images sent <Enter>

**Step 7.** The system will provide messaging indicating that images are being sent. When you get a prompt you can exit the shell.

- Type **exit** <Enter>



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



# User Interface Display Organization

Data presented on the user interface is organized based on the treatment planning workflow and is available in pre-defined areas of the screen.

## Workflow for the CyRIS InView

The user interface is organized into functional groups. It uses three tiers of functional groups.

The top tier is the Task. Tasks are the major functions that you can perform on CyRIS InView. The CyRIS InView has six tasks.

- **Load**. Select the data to use.
- **Fuse**. If you choose two medical images, this task allows you to fuse the images so they are aligned in the same physical space.
- **Contour**. You can contour anatomical volumes of interest.
- **Review**. You can evaluate the dose distribution for a plan created using the CyberKnife Treatment Planning System and display anatomy and dose using 3D volumetric rendering of the medical images.
- **Settings**. You can set color preference for the isodose curves, VOI's, and screen overlays. You can also set the behavior of the zoom and pan controls, and remove patient information from the CyRIS InView local database.
- **Help**. Access this manual on-line. Read about CyRIS InView and Accuray, Inc.

Tasks are divided into steps. Each time you change a step the layout of CyRIS InView will change. This change includes different controls as well as different presentations of the medical images.

The third tier has the functions that you can accomplish in a given step.

**Figure 2 User Interface Tasks**



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118 650

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



## Screen Layout

The layout of the user interface is divided into seven areas on the screen. *Figure 3 User Interface Layout, page 6* illustrates the user interface layout. The seven areas on the screen are:

- **Identification**. The top left identifies the software as part of the CyRIS product line. The top right has minimize and exit controls.
- **Task/Step Control**. The top menu bar lists the tasks. Below it is a list of the steps contained in the selected task.
- **Global Controls**. Along the right side of the display are the global controls that permit you to access functions that may be desired during any of the steps in the planning workflow.
- **Control View**. The middle left of the display has the controls available for the currently selected step. Each step will have a different set of controls.
- **Display View**. The large display center includes the display of the medical images and other large graphical and text controls. Each step will have a different display layout. For some steps, you will be able to select the display layout.
- **Patient Identification**. The bottom left displays patient and image information, including patient name, medical id number, CT image series UID, and secondary image series UID.
- **Status**. The bottom center and right displays status. The position of the mouse and value of the image gray scale number appear on the right. On the left is general information, including a time-elapsed bar.

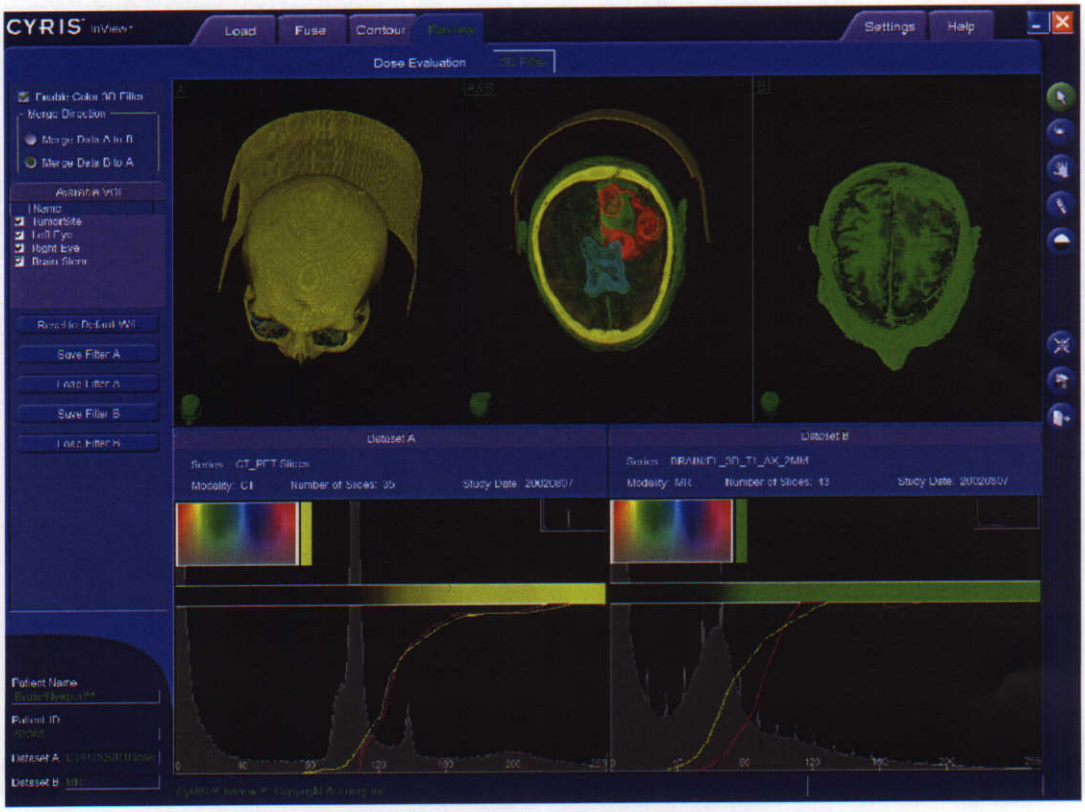



**Figure 3 User Interface Layout**



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

651

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



## 2D Display Layout

A typical 2D display (with two loaded images) is shown in *Figure 4 Split-Screen Axial 2D View., page 8.* Axial, sagittal, and coronal views are displayed in CyRIS InView. The appearance of the image within this display will be slightly modified when you use a global tool to change the mode of operation.

The bottom right indicates the plane (*Figure 3 User Interface Layout, page 6*). In this example, an axial slice is displayed. The display is an icon of a human head. A mouse-click over the icon will change it. It will cycle through three icon types: a human head, a human body, and the name of the view. This mouse-click will affect the display in all three planes. In the center of each side is a direction indicator. These indicators position the patient's left, right, superior, inferior, anterior, and posterior sides.

The top right includes a selector that allows you to choose which image to view. You can view the fixed image (A), the moving image (B), or a split view (A/B). Click on the indicator to cycle through the choices. This feature is available only when two images have been registered. If only one image is loaded, no indicator appears. If two images have been loaded, but they have not been registered, the indicator appears surrounded by a dashed box. It is insensitive and only the A image can be displayed. These views act on only the view displayed, so you can have a different image viewed in the Axial, Coronal, and Sagittal views. In the Delineate screen (*see section, Delineate Step, page 36*), changing the Axial View only affects the large window, the small multi-slice views always display the fixed A image.

The bottom left indicates the slice. To step one slice, click on either the forward or backward arrow. Click inside or drag along the slider to move more slices.

The notched focus lines give the intercepts of viewed perpendicular planes. You can change the plane of these views by sliding these notches or by double-clicking at the desired point of intersection for these views.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118 652

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



## Split Screen View

For the split screen view (*Figure 4 Split-Screen Axial 2D View., page 8*), the slider oblique line will appear. You can rotate this line about its axis of rotation to change the modality used to display different areas of the view. The point of rotation is the intersection of the focus lines. Click and drag the mouse to move these lines.

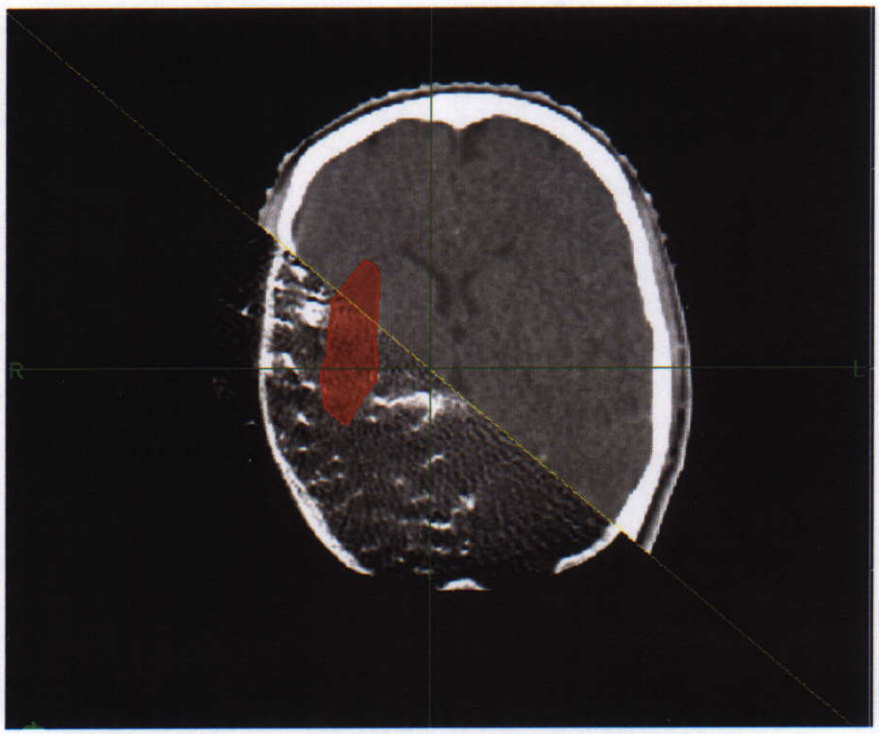



**Figure 4 Split-Screen Axial 2D View**



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



## Checkerboard View

The checkerboard view (*Figure 5 Checkerboard 2D Axial View., page 9*) allows you to view the patient anatomy in a quilt-like pattern of fixed and moving image. The size of the checkerboard is controlled by the slider at the top right. The value of the sliders is the edge length of each patch in screen pixels. Therefore the larger the number, the larger the patches in the display. The maximum and minimum grid sizes are 4 and 256 pixels.

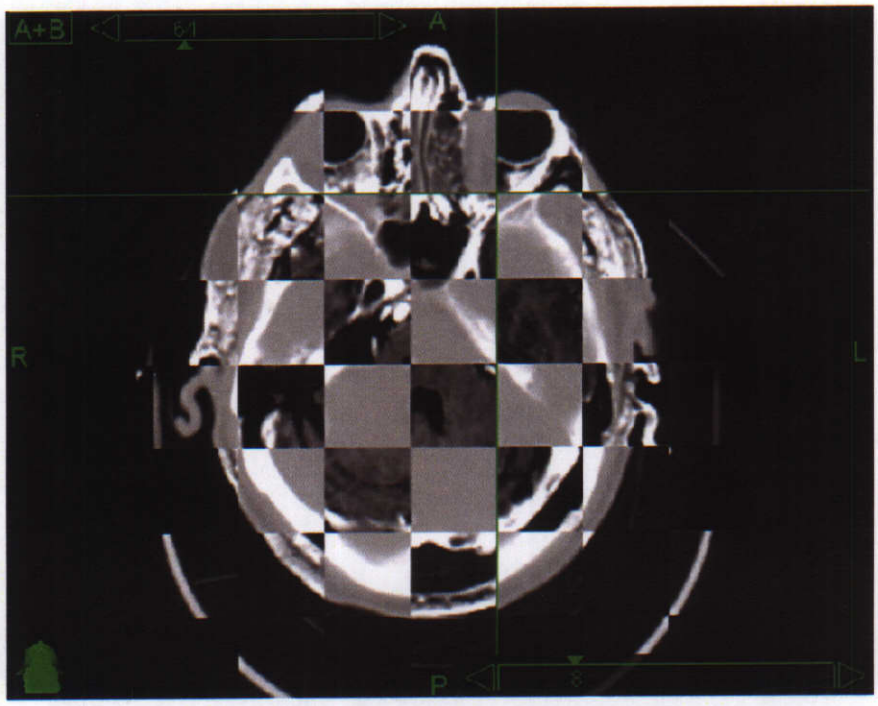



**Figure 5 Checkerboard 2D Axial View**



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



## Overlay View

The overlay view (*Figure 6 Overlay Axial 2D View., page 10*) displays the fixed and moving images at different opacity levels. You can set the color of the moving image in the overlay view from the Secondary Overlay pull-down window in the Preferences step (*Figure 12 Settings Task, page 17*).

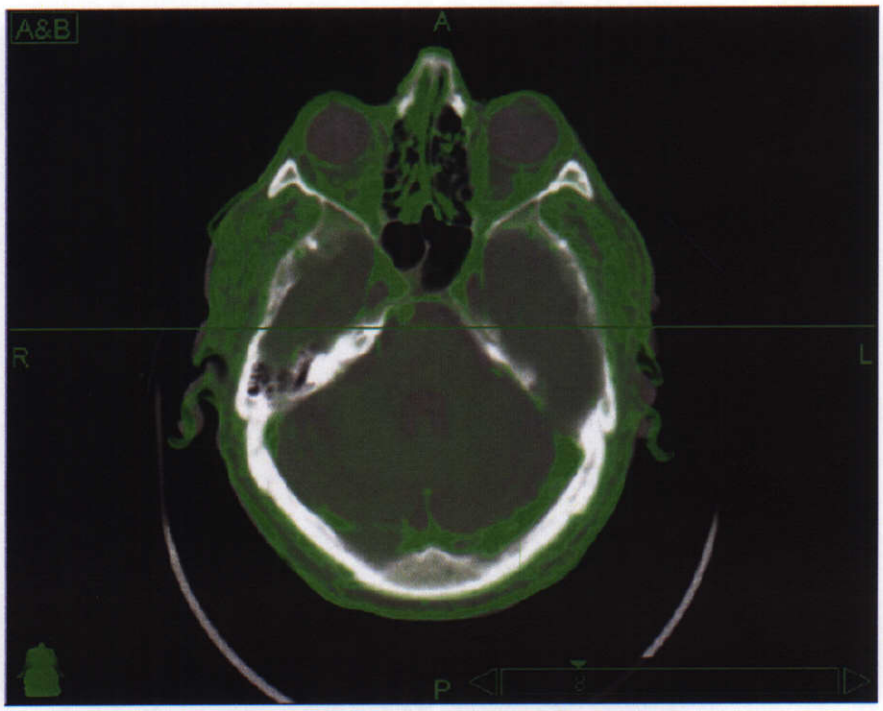



**Figure 6 Overlay Axial 2D View**



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

655

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



# Global Tools

The right side of the User Interface (*Figure 7 Global Tools, page 11*) has a string of buttons that are always available to you. The top buttons are called **Tool Buttons** and they set tools that change the way the mouse interacts with the image Display View. These tools need to be freed by clicking the Pointer tool. The bottom buttons are **Command Buttons**. They open a popup window (Screen Capture and Save and Push), except for the **Reset** function which has its effect without changing the method of interaction with the Display View.

The Save and Push function is described in *section, Save and Push Data, page 57*.

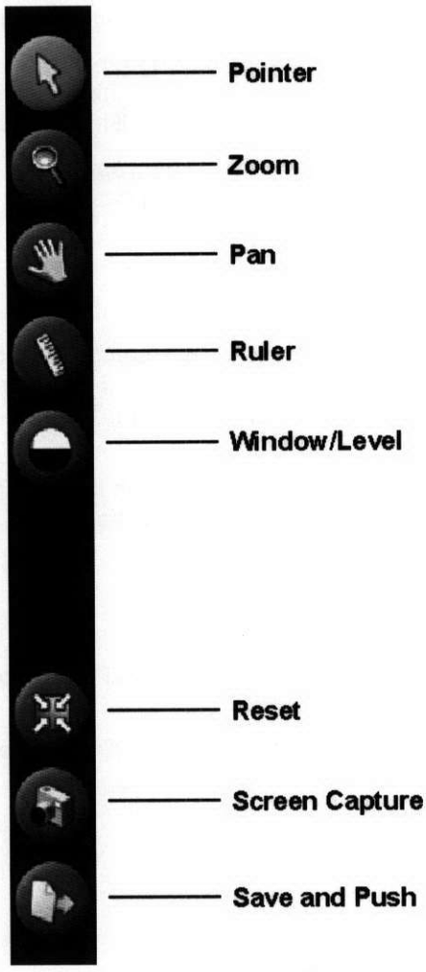



**Figure 7 Global Tools**



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

656

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



## Pointer

This is the default tool for the system. In this mode you can drag the focus lines for the different planar views, display the current status of the image, or change the focus lines by double-clicking in one view.

## Zoom

Select the **MAGNIFYING GLASS** button to enter the zoom mode. The cursor in the 2D display will become a magnifying glass.

In the zoom mode, you step in the zoom level by a single mouse click in any 2D window and step out the zoom level by a single mouse right-click in any 2D window.

You can also frame the zoom by placing the cursor at the top left of the desired field of view, depressing the left mouse button and dragging the mouse to the bottom right of the desired field of view. A box bordered by a dashed line will indicate the resulting field of view.

You can zoom in the field of view by depressing the scroll-mouse and scrolling forward. You can zoom out of the field of view by scrolling backward.

## Pan

In addition to setting the zoom, you can select the button with the **Pan icon** to pan the image within the field of view. Select the hand icon and the cursor will become a hand. Simply click the mouse and drag the image to the desired location. The pan image mode reframes the view in all 2D displays.

The zoom and pan functions can be set so that the 2D views function independently or in unison. Choose the option in the Settings task. (*see section, Preferences, page 17*)

## Reset

Select the button with the **Square icon** and four arrows to reset the display so that it is in its standard zoom and pan position.

The zoom and pan tools also work in the 3D view. (*see section, 3D Visualization, page 53*)



657 Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



## Window/Level Mode

The button with the **circle icon** (white top, black bottom) sets the Window/Level mode. In this mode, the cursor is the same circle as the icon.

Click the mouse and drag left to reduce the window value. Drag right to increase the window value. Drag up to reduce the level. Drag down to increase the level.

If you have loaded more than one image, select the desired image at the top left of the 2D display view and adjust the window and level for either the fixed or moving image. In split mode (A/B), the system automatically detects the image to adjust based on the cursor position.

You can also use histograms (*Figure 8 Window/Level Histogram, page 13*) to adjust the window and level of the display. The histogram is a representation of the distribution of the gray scale values. This representation allows you to hone in on the regions that have peaks along the histogram. For instance, to visualize bony anatomy on a CT image, narrow the display to the region around the peak centered near a CT number of 1400. To visualize soft tissue, narrow the display to the region around the peak centered near a CT number of 1000.

Select the tab to control the image for which you wish to view the histogram and adjust the window and level. You can use the histogram to adjust the Window and Level in any mode. You do not need to go to Window/Level mode to adjust those values, if you use the histogram to perform the adjustments.

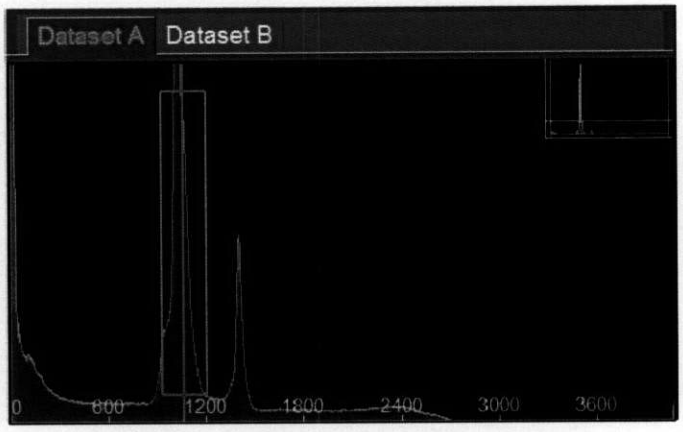



**Figure 8 Window/Level Histogram**



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



## Ruler Mode

Select the button with the **ruler icon** to enter the ruler mode. The cursor becomes a small diagonally oriented ruler with crosshair at the upper left. Depress and drag with the mouse to draw a line that measures a distance. When the ruler is drawing the crosshair on the cursor becomes an arrow.

*Figure 9 Rulers, page 14* shows a sample set of measurements created with the ruler. On the top right are buttons that allow you to **delete** the active measurement or to **clear all** the measurements. You can also adjust the active measure by grabbing either end and dragging it to a different spot on the screen.

The measurements are overlays on the 2D view. If you change slice, the measurements will remain unchanged. If you exit ruler mode the measurements will disappear. They will, however, return if you reenter ruler mode unless you had previously cleared them.

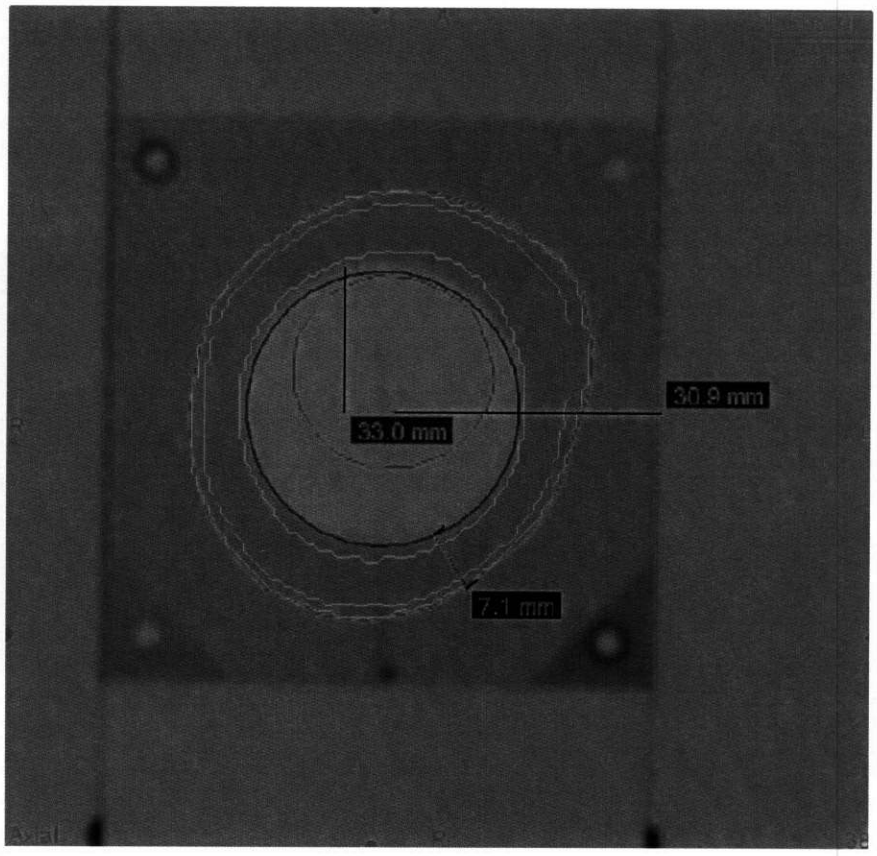



**Figure 9 Rulers**



659

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



## Screen Capture

The camera icon opens the screen capture function. A browser will appear that allows you to name the image and set the location of it (*Figure 10 Capture Image Dialog, page 15*). The default location is *c:\accuray\Image*. The default name is today's date and a counter. i.e., 20040317_002 is the second picture snapped on March 17, 2004. The image is always captured in JPG format.

**NOTE:** Because the image can only be saved in one image format, the **Save as Type** is not an active input. You cannot set a value in this field.

This function captures the whole screen. You can edit the image using a standard image editor, such as Paint.

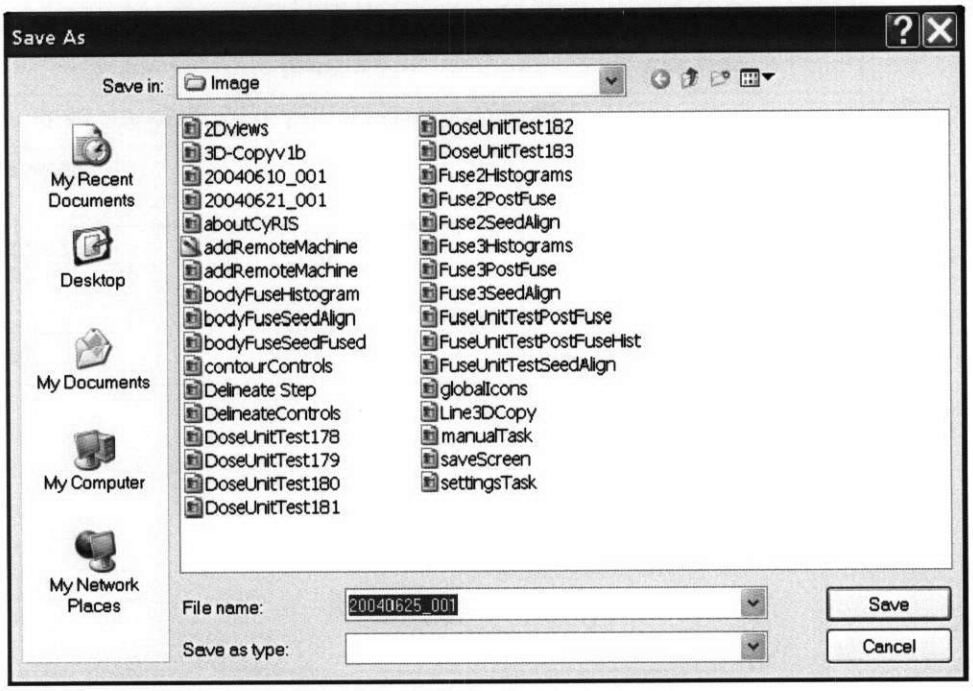



**Figure 10 Capture Image Dialog**

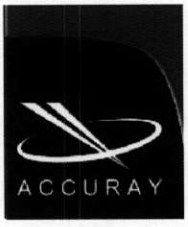



**Figure 11 Logo Overlaying Patient Identification**

The patient identification can be masked. Click the patient identification area, before the screen capture function is opened, and an Accuray logo will mask the patient name and medical id (*Figure 11 Logo Overlaying Patient Identification, page 15*).



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

660

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



# Keyboard Controls

InView provides the keyboard shortcuts tabulated in *Table 1: Keyboard Controls, page 16*.

**Table 1: Keyboard Controls**

| Shortcut | Keys | Comments |
|---|---|---|
| Previous slice | S, [left arrow], [up arrow] | |
| Next slice | D, [right arrow], [down arrow] | |
| Previous page | A, [Page up] | Step 5 slices up. |
| Next page | F, [Page down] | Step 5 slices down. |
| First slice | W, [Home] | |
| Last slice | E, [End] | |
| **Shortcuts available only in the Delineate Step** | | |
| Copy contour | C | Same as [Copy] button in the control window. |
| Paste contour | V | Same as [Paste] button in the control window. |
| Delete contour | X | Same as [Delete] button in the control window. |



661

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



# Ancillary Tasks

CyRIS InView has two ancillary tasks. The Settings task allows you to set display parameters and defaults for the isodose curves and Volumes of Interest (VOI).

The maintenance step allows you to remove selected patient data from the CyRIS InView database.

## Preferences

The display of the preferences task is shown in (*Figure 12 Settings Task, page 17*). The display has four groups of parameters with defaults that you can set.

**Figure 12 Settings Task**

The bottom left allows you to set up to five default VOI Set Templates. You can set the name, type, and color of up to 22 Volumes. The top left allows you to set the default **Isocurve Template**. You can set the %dose of the curve, the line width, the color, and whether or not to show any or all of the dose curves. The top right allows you to set the **Color Template** for the patient image views. You can set the color for labels, focus lines, controls, and the dose box boundary. The bottom right allows you to set the implementation of the zoom and pan functions. If checked, all 2D views will have the same zoom level and focus point.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

662

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



# Maintenance

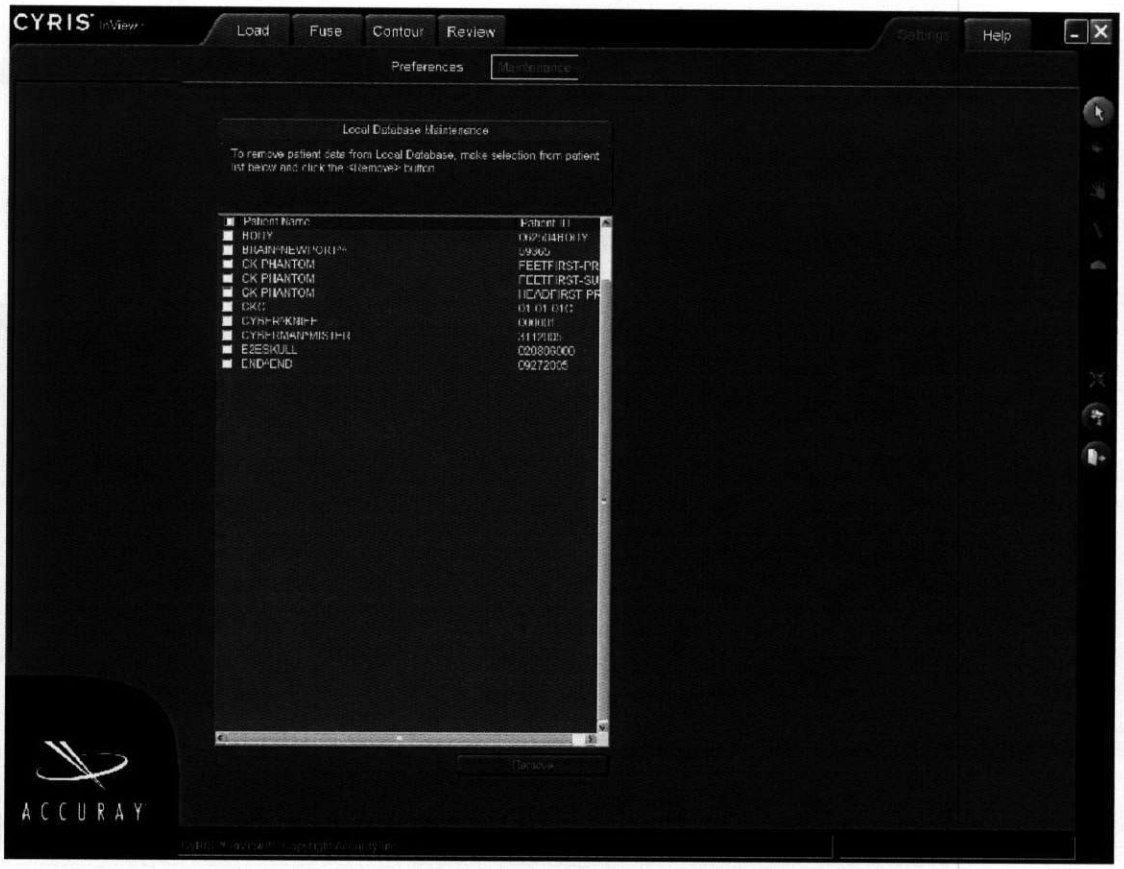



**Figure 13 Maintenance Screen**



663

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



The maintenance step allows you to remove patient information permanently from the local database. To ensure any fusion and contouring data are saved, use the Dicom Export feature to export these to a remote location (i.e., to the CyberKnife database) before removing.

**NOTE:** If the patient information is removed prior to exporting it to the CyberKnife database, that information will be lost.

**NOTE:** If the patient information has been exported to the CyberKnife database, removing it from the InView local database will not effect information stored on the CyberKnife System database.

To remove patient information from the local InView database:

**Step 1.** Select patient(s)

**Step 2.** Select **REMOVE**

**Step 3.** Confirm that the information should be removed (answer Yes to the warning message).

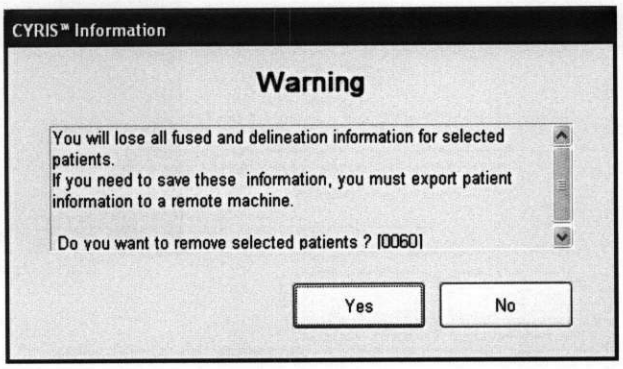



**Figure 14 Maintenance Warning**



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

664

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



## Help

The help task has two steps:

1. On-line access to this Manual (*Figure 15 User's Manual, page 20*). The manual is in PDF format. The bookmarks on the left allow you to go search for manual sections using a tree structure.

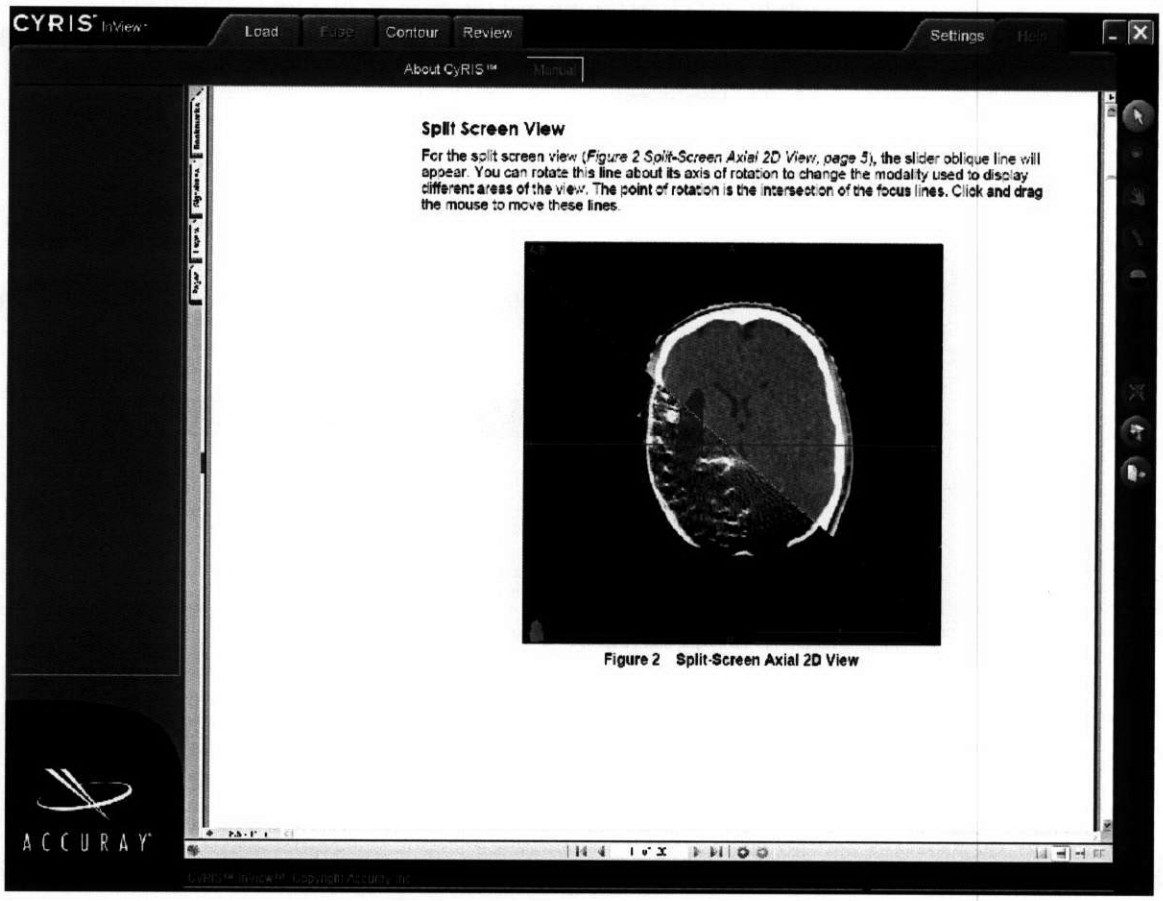



**Figure 15 User's Manual**



665

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



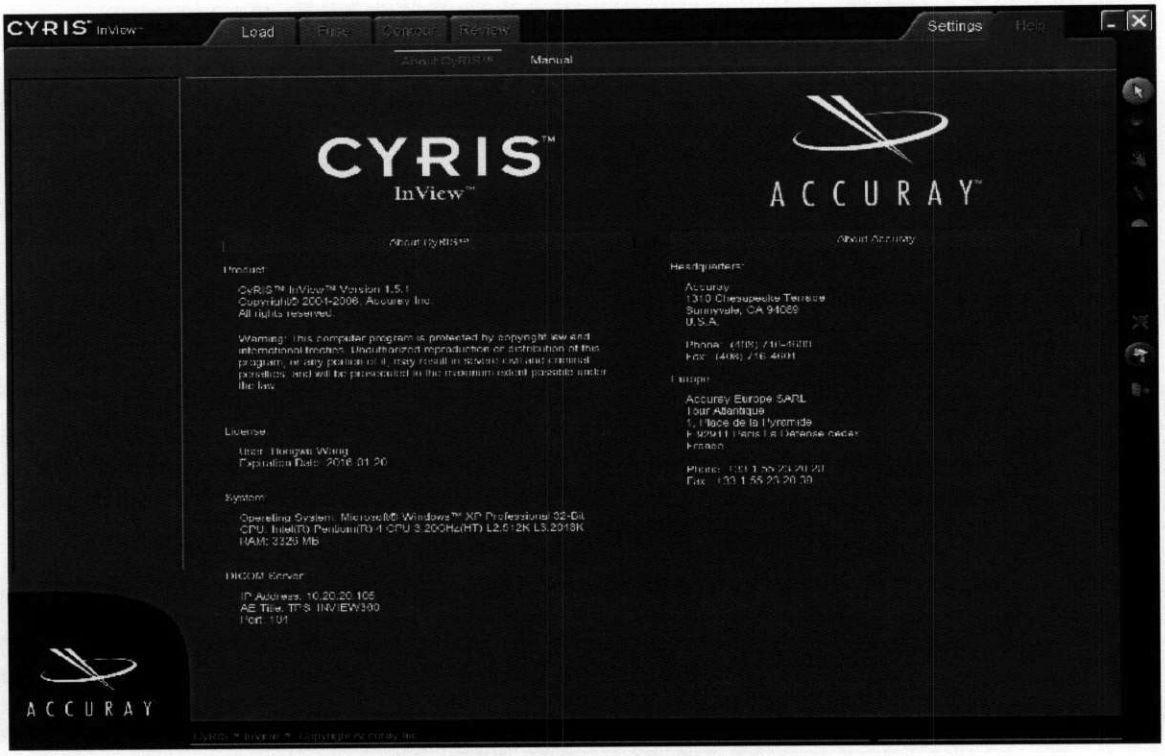



**Figure 16 About CyRIS InView**

2. Information about CyRIS InView (*Figure 16 About CyRIS InView, page 21*).



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

666

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



# LOAD DATA

When you open CyRIS InView, the first step you will enter is the **Load** task. The main purpose of this task is to load DICOM formatted patient data. This task also allows you to edit the image data by deleting image slices and to delete entire image series.

**NOTE:** If you have not loaded patient data, the only steps available are **Load**, **Setting**, and **Help**. All other steps are inaccessible.

## Load Data

You can load three types of DICOM data into CyRIS InView: Medical Images, anatomic delineations stored as DICOM RT Structure Sets, and dose distributions stored as DICOM RT Dose instances.

*Figure 17 Start the Load Step, page 23* shows the **Load** display configuration. The display view consists of three lists (a patient list, a study list, and a series list) and three medical image views.

The patient list has a list of the patients stored on the local database for CyRIS InView. When you select a patient from the patient list, the study list will display the DICOM studies that have been loaded for the patient. When you select the desired study, the series list will display the series that are part of the image study. Each series has a modality associated with it. Valid modalities are the image modalities CT, MR, XA, and PT, RTSS (for anatomical features), and RT DOSE (for dose distributions). A check mark and x field indicate if an image is selected and the role of the image. A is the fixed image; B is the moving image; V is a set of VOI; and, D is a dose distribution. Studies and series are identified using the Series and Study Descriptions from the DICOM header. If one or both of these are unset, then the Study UID or Series UID will be used.

When you first enter the **Load** step, the first entry in the patient list, study list, and series list are selected.



667 Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015

**Figure 17 Start the Load Step**

## Select the Fixed Medical Image

**NOTE:** The fixed medical image must be a CT image.

Select the patient, the study, and the series from the patient list. Then, select desired study from the study list and the desired CT series from the series list. The selected series will appear in the image view on the right. View all the slices using the **MOUSE-SCROLL** button.

**NOTE:** The first time you use the scroll bar, the system will sort through the images so that you can view them in order. This will cause a short delay, the length of which depends on the number of images in the scan.

Select the check box before the series identifier. A check mark and the A indicator will appear with the series. The center image of the study will appear in the left medical image view with identification data, as shown in (*Figure 17 Start the Load Step, page 23*).



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



## Select the Moving Image

As with the fixed image, you select the moving image by first selecting the patient, study, and series. When the series has been selected, you can view all the slice data using the mouse-scroll.

Select the check box before the series identifier. A check mark and the B indicator will appear with the series. The center image of the study will appear in the middle medical image view with identification data, as shown in (*Figure 17 Start the Load Step, page 23*).

**NOTE:** If the moving image is a CT series, then the fixed image should always be selected first. The system assumes the first selected CT series is the fixed image. If the moving image is PET, MR, or 3D Angio, it may be selected first.

## Select Anatomical Contours

Anatomical contours are saved as DICOM RT Structure Sets by CyRIS InView.

If a description is not added, the name of the RT Structure Set will be identified by its Series UID. This CyRIS InView and CyberKnife System TPS both incorporate a date and time stamp to help you identify which contour set to load. The time stamp will appear in the instance UID as follows

1.2.840.114358.<ID>.<YEAR><MONTH><DAY><HOUR><MINUTE><SECOND>.etc.

<ID> is the serial number of the CyberKnife System located at your site. The data and time are one string of data. For instance,

1.2.840.114358.0.**20031108144324**.1.etc. indicates that the contours were saved November 8, 2003 at 14:43:24 hours on a 24-hour clock.

As with the fixed and moving image series, select the check box before the series identifier. A check mark and the V indicator will appear with the series. Its description or Series UID indicator will appear below the fixed CT image.

**NOTE:** A DICOM RT Structure Set of anatomical contour data can only be loaded into CyRIS InView if it is a part of the same study as the fixed medical image.

## Select a Dose Distribution

A dose distribution is selected in a similar manner as anatomical contours. The dose distribution, however, is stored as a DICOM RT Dose series. You can apply the same convention to determine the date and time that a dose distribution was exported from the CyberKnife Treatment Planning System.

As with the other data series, select the check box before the series identifier. A check mark and the D indicator will appear with the series. Its description or Series UID indicator will appear below the fixed CT image.

**NOTE:** A DICOM RT Dose distribution can only be loaded into CyRIS InView if it is a part of the same study as the fixed medical image (CT).



669

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



## Load the Selected Image Data

- If you have made a mistake selecting the data you wish to load, deselect the unwanted series by unselecting the check mark before that series.
- If the data is consistent, the **LOAD SELECTED SERIES** button in the Control View is active. Choose that **LOAD SELECTED SERIES** to load the data and permit access to the other tasks and steps on CyRIS InView.

# Edit Image Data

The **Load** step also has some simple DICOM image editing tools. They are accessed from the Control View. An image can be edited if these tools are enabled and the trash can appears in the Series Preview window. (*Figure 18 Series Preview with Editable Image, page 26*)

**Merge Series** allows you to merge two or more series with the same modality into a single image set. This capability is especially useful for body scans in which the scan was completed in two or more series.

**Split Series** allows you to separate a single series into two series. This capability is useful for studies that include scans of different regions of the body in anticipation of creating two or more plans, or for reducing the number of slices in studies that are too large. Series are split into two series that become a part of a new study. The series is split at the displayed slice in the selected series 2D view. This slice becomes the last slice in the first series. The following slice becomes the first slice in the second series.

You can also choose **Delete Selected Series**, if the series is not necessary. This capability can be used to delete DICOM data no longer needed, such as contour or dose distribution data that has been modified and is now out of date.

If you delete all series in a study, CyRIS InView will automatically delete the study. If all the studies for a patient are deleted, CyRIS InView will delete that patient.

You can also delete individual slices in a medical image study. Use the forward-scroll and backward-scroll to view the slices of the selected series in the top image view (*Figure 17 Start the Load Step, page 23*). Click on the trash can in the lower left of (*Figure 18 Series Preview with Editable Image, page 26*). A warning popup will appear. Use this to confirm that you wish to delete the currently displayed slice. You may want to delete a slice if it is a repeat of an existing slice or is a scout. When deleting slices, be sure that the resulting image satisfies the criteria for image data loaded into CyRIS InView.

**NOTE:** Medical images loaded onto the CyRIS InView must have 300 or fewer slices, equal slice spacing, and be scanned Head First Supine (HFS) or Feet First Supine (FFS).

**NOTE:** Image editing tools are not available if you have selected a series to load.

**NOTE:** If an imported image study requires extensive editing to make it usable by the CyberKnife System, it is preferable to push the image to the CyberKnife System User Control Console and use the Medical Image Review and Import Tools (MIRIT), because it has image editing capability that is easier to use than the image editing tools on CyRIS InView.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



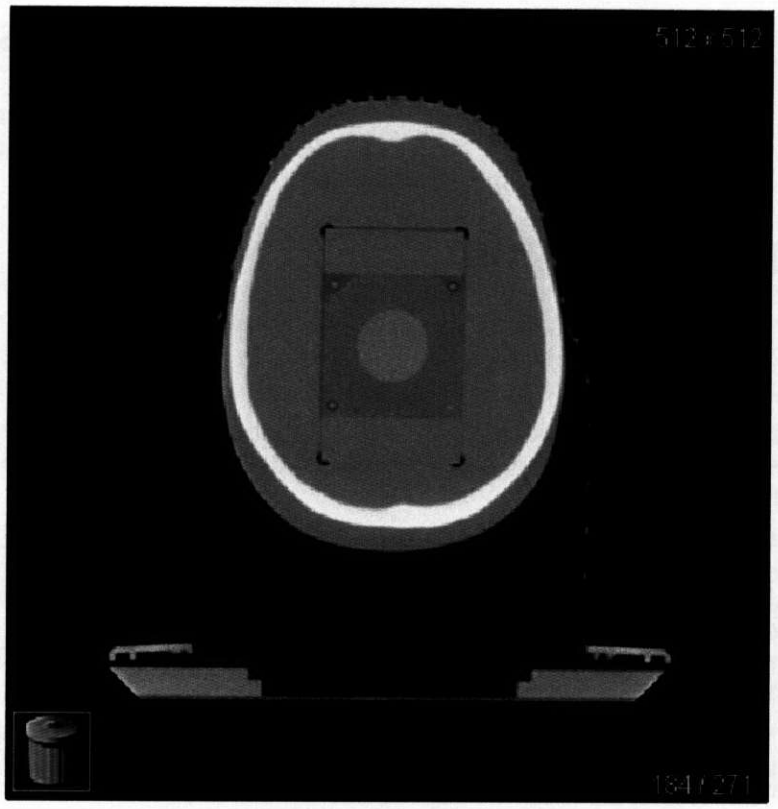



**Figure 18 Series Preview with Editable Image**



671

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



# FUSE TWO IMAGE SERIES

Once two images (a fixed and moving image) are loaded, the **Fuse** task is enabled within the user interface of CyRIS InView. To enter, click on the **Fuse** tab. The screen layout will change, and you will now be in the first step of the Fuse task, Seed Point alignment. (*Figure 19 Seed Point Selection with 3D Views, page 28*).

**WARNING: Be certain that the two images you will register are images of the same patient.**

## Seed-Point Alignment

The image fusion component of the CyRIS InView works by finding the transformation that maximizes the mutual information of the two loaded images. Once this transformation has been determined, the images may then be fused onto a common space. In order to function correctly, an approximation of the correct transformation must first be supplied. Do this by selecting three seed points in each image that correspond to the same anatomical landmarks. Select the landmarks in the same order on each image.

The seed points only need to represent approximately the same positions in each image; you do not need to spend a great deal of time and care selecting these points. If the refinement in the REGISTER step is successful, the final accuracy of the fusion is not affected by the initial choice of seed points. However, if the seed points differ too greatly in the two images, this may lead to a failure of the refinement in the **Register** step. In (*Figure 19 Seed Point Selection with 3D Views, page 28*), a CT and MR image are shown, with the seed points chosen to be the left and right eyes, and a point located on the forehead.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015

**Figure 19 Seed Point Selection with 3D Views**

## Set Seed Points

Select a seed point by double clicking when the cursor is at the desired location. When the 2D layout is selected, a seed point will be created at the desired position and displayed on both the axial and coronal image slices. When the 3D layout is selected, a seed point will be created at the surface point closest to the cursor position. To delete the last seed point in the fixed/moving image, click the appropriate **DELETE LAST** button on the control panel. To delete all the seed points in the fixed/moving image, click the appropriate **DELETE ALL** button on the control panel.

When three seed points have been selected in the fixed and moving images, the **Register** step is enabled.

**NOTE:** The transformation represented by the seed points becomes ill-defined as the points approach becoming collinear. For this reason, it is recommended that you choose seed points that are clearly non-collinear. (For example, the configuration shown in *Figure 19 Seed Point Selection with 3D Views, page 28* is acceptable.)



673

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



### 3D and 2D Layouts

Two layouts are available for seed point selection. The default layout has 3D volume renderings of the fixed and moving image in the top left and right of the Display View. Generally, this layout is preferable when using cranial images, because adequate seed points can be chosen on the skin surface. However, for extracranial images, it is often very difficult to select seed points with the 3D views. In these cases, a layout using 2D are preferred method seed point selection. Two 2D pairs are available: axial and sagittal images, and axial and coronal images. To change layouts, click on the desired layout in the Control View. Any seed points already selected will be retained and transferred to the new views.

### 3D Filter

The windows in the bottom left and right of the view contain the 3D filter controls for the fixed and moving images respectively. These controls work similarly to the window/level controls on the histogram discussed in *section, Window/Level Mode , page 13*. However, instead of operating on the brightness of the image, they operate on the opacity of the image. Hence anything in the image having intensity less than that of the left hand side of the rectangle is transparent in the volume rendering. Anything with intensity greater than that of the right hand side is fully opaque. By manipulation of the 3D filter, different structures in the image may be hidden or highlighted.

## Load a Preregistered Image

In some cases the fixed and moving images are already in a common space. This is most likely to occur if the moving image is the saved result of a previous fusion (*see section, Image Data, page 60*).

Check the **ALREADY REGISTERED** box to disable seed point selection and use the other steps without completing the REGISTER task.

If the Define Seed Points step is entered after the Register step is partially or fully completed, the **ALREADY REGISTERED** box will be checked. Uncheck the box to reenable seed point selection. Then, perform the Register step again if desired.

# Image to Image Registration

The Register step uses maximization of mutual information to refine the transformation relating the moving image to the fixed image. Select **Register** to enter the Register step *Figure 20 Register Step, page 30* appears.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118 674

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



## Intensity-based Registration

The Display View for the Register step has a single 3D and three 2D views. You can toggle through the split, overlay, and checkerboard for each 2D view.

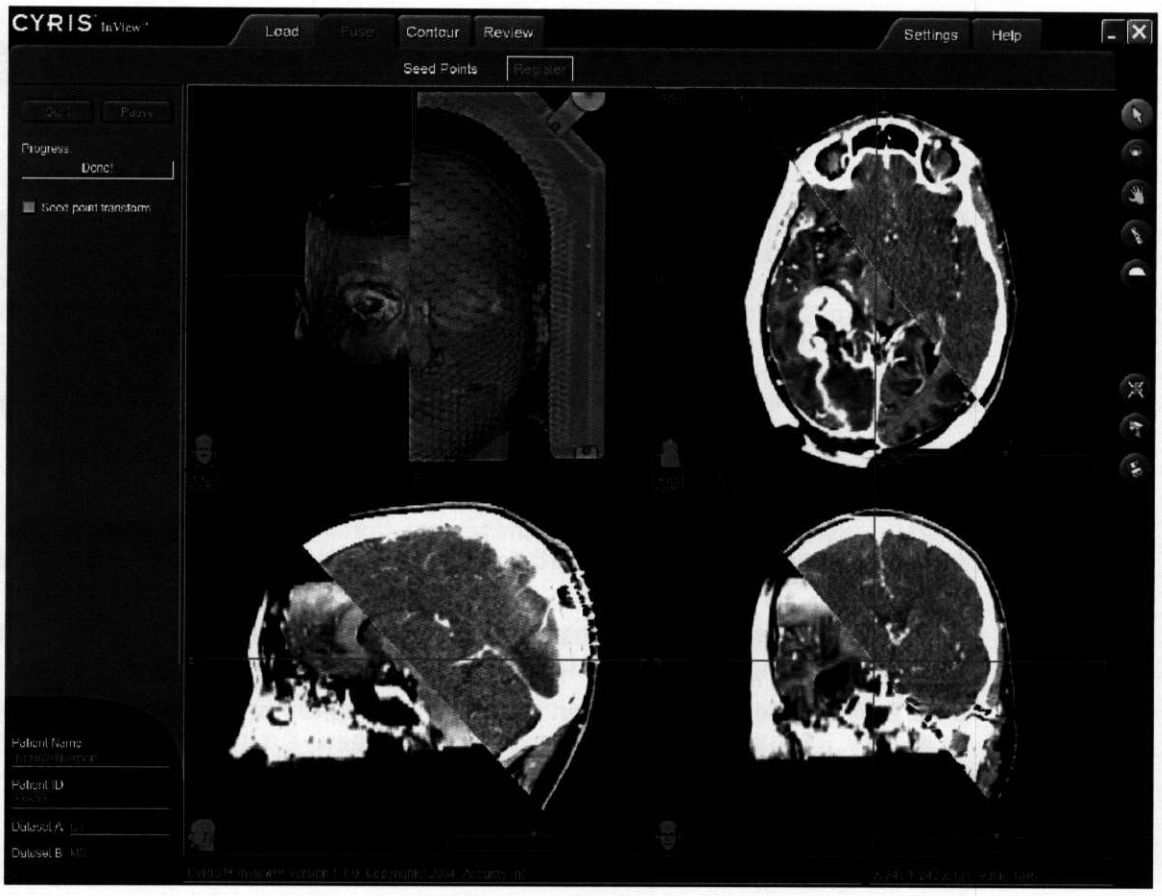



**Figure 20 Register Step**

The fixed and moving images are displayed, fused according to the transformation that was calculated using the seed points. This fusion will generally look approximately correct, but not perfect. Click the **START** button to begin the registration process. After a short pause, the progress bar will start expanding towards the right, and the images in the views will make small movements relative to each other as the fusion is refined.

During the refinement process, you may manipulate the split views to evaluate the quality of the fusion. Move the image partition in any of the 2D views by clicking the mouse at the intersection of the two green lines and dragging to the desired position. Rotate the image partition by clicking the mouse on the partition and dragging to rotate it. The position of the partition in the 3D view is automatically updated when the partition is moved or rotated in the 2D views.



675

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



Click the **PAUSE** button to suspend the refinement process, and use **CONTINUE** to resume it. When the progress bar reaches the right hand edge of the scale, the word Done! appears in the progress bar. **CONTINUE** and **PAUSE** are both disabled and the refinement has been completed.

If you are satisfied with the quality of the fusion before the refinement process has been completed, you may at any time proceed to another task; the refinement will be stopped, and the currently displayed fusion will be retained.

In some cases (for example, if the seed points do not correspond closely enough), the refinement process may fail. This will generally be immediately apparent: instead of the two images moving into closer alignment, they will move completely out of alignment during refinement. If this happens, the recommended corrective action is to return to the seed point selection screen, uncheck the **ALREADY REGISTERED** box, choose seed points more carefully, and perform the Register step again.

**WARNING: The intensity-based algorithm finds the optimal registration between the two images based on a specific mathematical model. The user, however, is responsible for assuring that the final registration is clinically acceptable for target and critical volume delineation. Use the overlay, split screen, and checkerboard display modes to visually check that the algorithm has adequately registered the two images.**

## Seed-Point Registration

Check the **SEED POINT REGISTRATION** box to use the transform based solely on the seed points to define the final fusion. It is generally not recommended that you do this; one example, however, in which it may be necessary, is the case in which fusion refinement cannot be done successfully on the two loaded images. In these cases, if seed points are chosen with sufficient care, an acceptable fusion can be achieved in this manner. When the **SEED POINT REGISTRATION** box is checked, the controls for refinement are disabled; while refinement is in progress, the **SEED POINT REGISTRATION** box is disabled.

**NOTE:** If you check the "Seed point registration" box after you have completed a refinement, you will lose the refined fusion result!

# Manual Registration

If the automatic registration is not acceptable, you can use the tools in the Manual Registration step (*Figure 21 Manual Fuse Step, page 32*) to update the transformation between the fixed and moving images.

You can translate or rotate the moving image in any of the three planar views. Drag the cursor to make gross changes to the transformation. The faint circle in the view defines the boundary of the translation and rotation portions of the screen. Inside the circle, cursor movements translate the moving image; outside the circle, cursor movements rotate the moving image.

Fine motion is controlled with the arrows at the bottom right of each planar view. The straight arrows translate the image one pixel (in screen coordinates) in the indicated direction. The arced arrows rotate the image one pixel in the indicated sense. Since the resolution of the transformation is based on screen pixel resolution, you can get finer movements by zooming in on the image.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



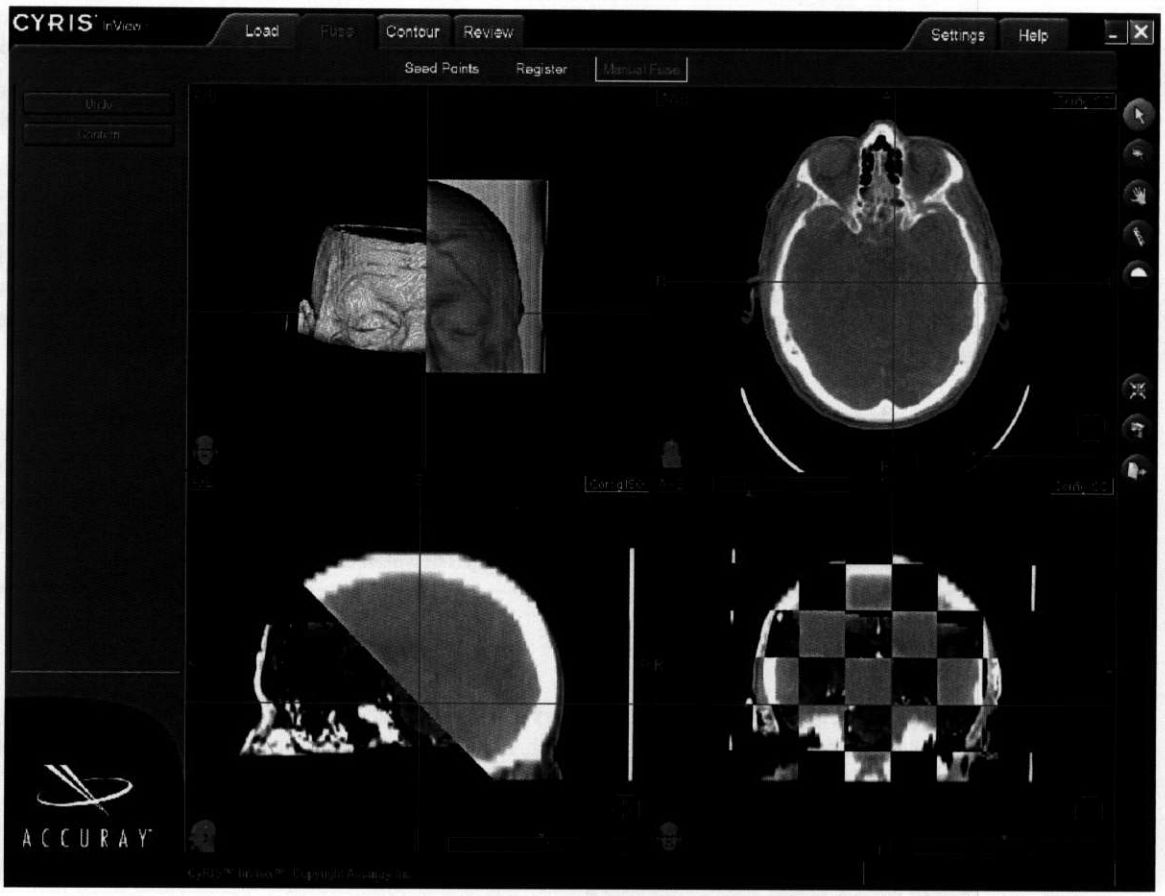



**Figure 21 Manual Fuse Step**

You can either **UNDO** or **CONFIRM** the transformation from the appropriate buttons in the Control View. If you leave the step without confirming the transformation, *Figure 22 Confirm Manual Registration, page 32* will appear. This prompts you to either accept or reject the manual transformation.

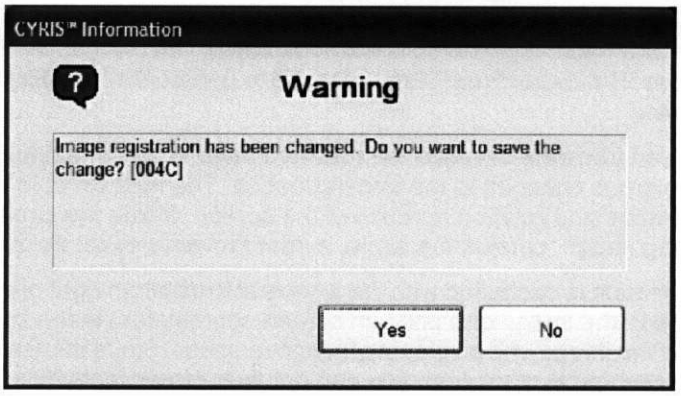



**Figure 22 Confirm Manual Registration**



677

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



# CONTOUR

You can create and modify anatomical volumes of interest in the Contour task. This task has two steps: **Delineate** and **Properties**. The Properties step allows you to change specific tags and display settings associated with each **Volume of Interest**. The Delineate step has the drawing tools you use to draw and edit Volumes of Interest.

## Volumes of Interest

A Volume of Interest (VOI) is a user defined region overlain on the medical images.

**NOTE:** CyRIS InView allows you to generate up to 22 Volumes of Interest. You can also classify each Volume of Interest as either a target or a critical region. The CyberKnife On-Target Treatment Planning System only allows you to uniquely identify up to 10 targets and 10 critical regions.

### Properties Step

*Figure 23 Properties Step, page 34* shows the **Properties** step of the **Contour** task. The list on the right of the Display View indicates the properties associated with each VOI. Each VOI has a name that you can set, as well as a type. Two types are available: **Target** and **Critical**.

The properties list also provides the volume of each VOI. The volume is a calculated for each volume of interest. Volumes are calculated by counting the pixels in the CT study that are enclosed or partially enclosed by the contours of the volume of interest. Therefore, the accuracy of the volume measure is the resolution and slice thickness of the CT study.

The volumes of the Volumes of Interest are identified through a grid both on the CyberKnife On-Target Treatment Planning System and CyRIS InView. Volumes on the CyRIS InView are calculated throughout the Fixed Image study at the resolution of the image study. Volume calculations on the CyberKnife On-Target Treatment Planning System are performed only in the dose calculation box and are performed at the resolution of the dose calculation grid. This can lead to differences in the calculated volumes in the two applications.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



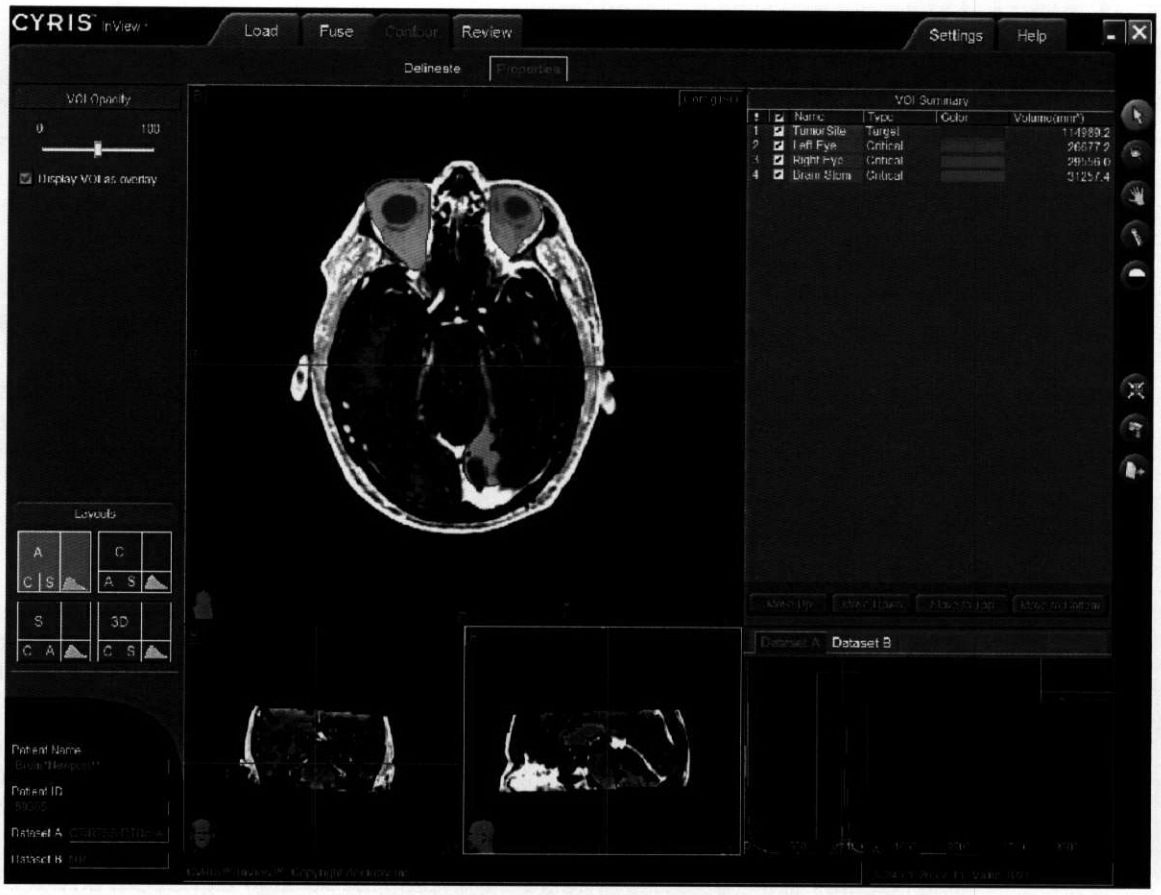



**Figure 23 Properties Step**

## Display Settings

*Figure 23 Properties Step, page 34* also indicates the display settings that you can use to portray the drawn volumes of interest. From the control view you can determine whether to fill or not fill the contours. You can also choose the transparency of the filled contours. Move the slider to the left for a fully transparent polygon. (This setting is the same as including no fill for the polygons.) Move the slider to the right for a fully opaque polygon.

The list on the right of the Display View allows you to choose to display or not display each VOI. (The active VOI in the Contour step is always visible, regardless of the setting chosen here.)

You can select the color of each VOI.

You can prioritize the display of overlapping VOI's. If two volumes overlap, the higher VOI in the list has the higher priority. To change priority, highlight a VOI and select **MOVE UP** or **MOVE DOWN** to step the priority up or down, respectively. Select **MOVE TO TOP** or **MOVE TO BOTTOM** if you want to give a VOI either the highest or lowest priority.

The layout switcher in the control view allows you to set either a 2D View (*Figure 23 Properties Step, page 34*) or a 3D View (*Figure 24 Properties Step with Volume Rendered Image, page 35*) as the large image at the top left of the display view.



679

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



Use the 3D View configuration to view the volume rendered anatomy to find a starting point for 2D contouring. This capability can be especially useful for locating the nidus of an AVM a 3D rotation angiographic image. To do this, filter the 3D angiography so that the circulatory system is visible. Then click on the nidus in the 3D view. The center of the 2D views will appear at the boundary of nidus selected in the 3D view.

**Figure 24 Properties Step with Volume Rendered Image**



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118 680

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



# Delineate Step

## VOI Properties

Properties for VOI can be set from the properties dialogue (*Figure 26 VOI Properties Dialogue, page 37*) accessed from the Delineate step. This dialogue also allows you to name the VOI, set its type and color. In addition, you can set the plane of delineation for the VOI. The default plane is the axial plane. You can also choose coronal and sagittal planes. Each Contour Set for a Volume of Interest must be drawn in the same plane. You can also select if a VOI is a boundary VOI. In this instance, the VOI will be treated like a surface in three dimensional space. Boundary VOI's can have only 1 Contour Set.

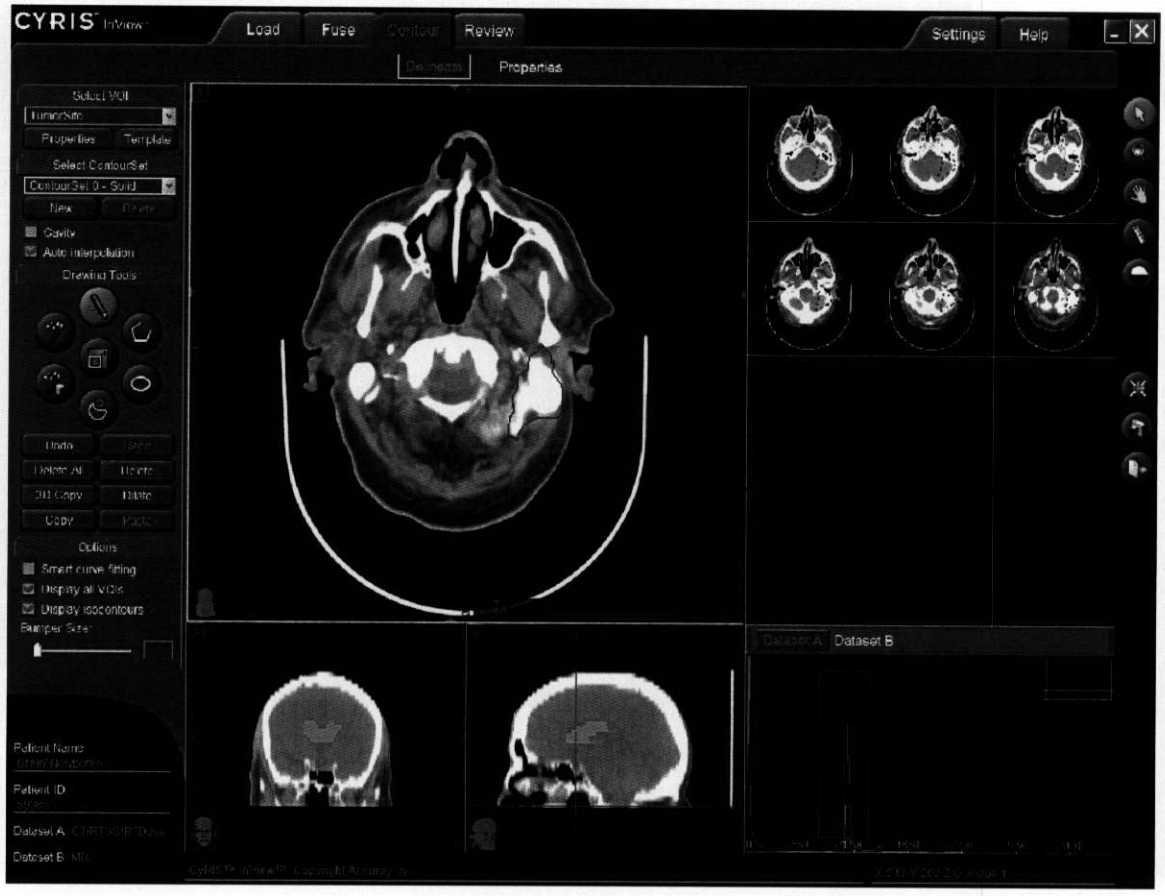



**Figure 25 Contour Step**



681

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



**NOTE:** The method of determining if a grid element is a part of a VOI differs on the CyberKnife On-Target Treatment Planning System and CyRIS InView. The On-Target Treatment Planning System treats every Voxel that partially includes a Volume of Interest as a part of the Volume of Interest. The CyRIS InView treats only voxels covered by more than 50% of a Volume of Interest as a part of the Volume of Interest. Therefore, this application will usually estimate a smaller volume than the CyberKnife On-Target Treatment Planning System estimates.

*Figure 25 Contour Step, page 36* presents the **Delineate** step of the **Contour** task. This task provides you access to the drawing tools you can use to create and modify Volumes of Interest.

From the top of the Control View, select the VOI to work on from the list of possible Volumes of Interest. The default VOI names, types, and colors are selected from the Preferences step. After selection of a VOI the Control View functions become active.

You have the option to choose how other VOI's and isodose curves are displayed when drawing a specific VOI. The Display All VOI and Display Isocontours options allow for display of all VOI and the isodose distribution when drawing a VOI. Visualizing isodose curves is especially helpful when creating tuning structures to tailor results during conformal inverse planning. When the Display All VOI is disabled, the other VOI will not appear. When the Display Isocontours is disabled, the isodose curves will not appear at all. Disabling visualization of these overlays allows you to draw based solely on the information in the medical image.

Select **Properties** to open the dialog (*Figure 26 VOI Properties Dialogue, page 37*). As noted earlier, you can rename the VOI from this dialog.

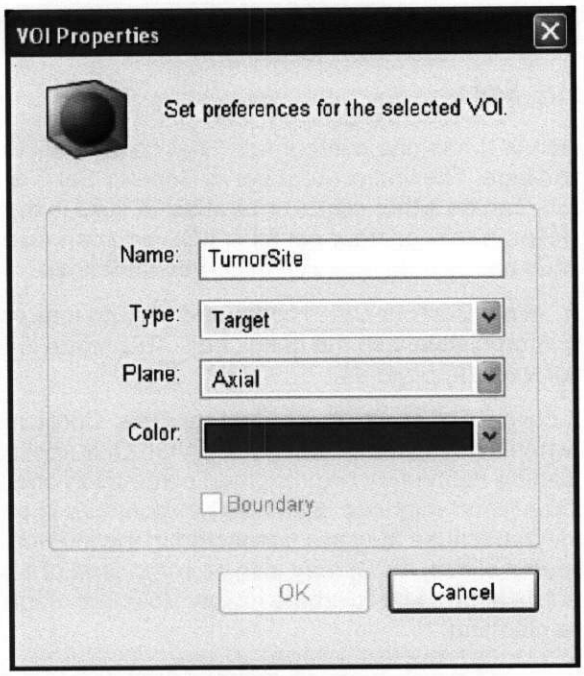



**Figure 26 VOI Properties Dialogue**



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



You can also change the display color of the VOI. A list of default colors will appear. The last option in this list opens a custom color creator that has a color grid you can use to choose any color.

You can also choose the VOI type (critical or target), set it as a boundary VOI, and choose the drawing plane for the VOI.

Select a Template to open the VOI Template Dialog window (*Figure 27 VOI Template Dialog, page 38*). This dialog presents a list of VOI Templates. Choose one template from the pull-down list and click the **APPLY** button to apply the template to the current VOI set. If the current VOI set has no VOI being defined, the whole set of VOI's will be replaced by the VOI definitions from the template. Otherwise, if an existing VOI has any contour defined, that VOI will not be replaced. VOI templates can be edited in Preference step (*Figure 12 Settings Task, page 17*).

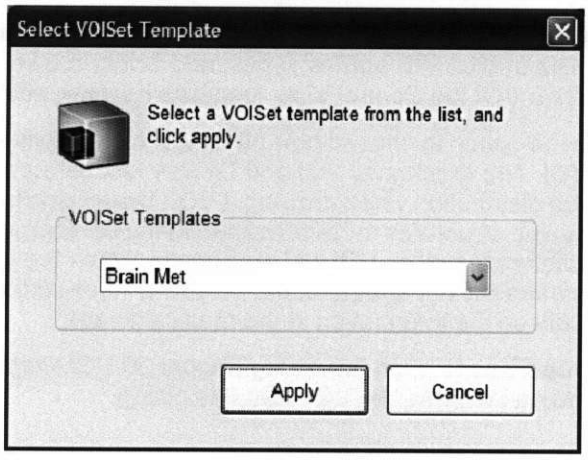



**Figure 27 VOI Template Dialog**

## Contour Sets

Initially each VOI has one contour set. That contour set is a solid. Contour sets are identified by number and type. The first contour set is 'Contour Set 0' and is always a solid contour. Subsequent contour sets can be either solids or cavities. A solid is the default for a contour set. Select **New** to begin to define a new contour set for a VOI. You can also Delete a contour set. If all the contour sets of a VOI are deleted, the VOI becomes undefined.

By default, every Contour Set is contoured in Auto Interpolation mode. You can opt to turn off automatic interpolation with the check box. This mode is explained in *section, Interpolation of Volumes of Interest, page 44*.

Each VOI consists of one or more Contour Sets. Contour Sets allow you to have substantial flexibility when defining the geometry of a VOI. One application for multiple contour sets might be a VOI that can be defined by two disjoined contours in one or more slice. For instance, the superior portion of the femur might be drawn as two contours in each axial slice. Though the contours are the same VOI because they are connected in the inferior slices, they are part of different contour sets in superior slices. A VOI may also be comprised of a solid contour set and a cavity contour set. This capability allows you to create hollow Volumes of Interest. This possibility is especially useful for inverse planning.

Each Contour Set is comprised of contours drawn on one of the primary orientations (axial, coronal, or sagittal) for the patient. Each Contour Set can have only one contour per slice.



683

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



## Drawing Tools

### Pen

Select **PEN** and the cursor will change to a pencil shape when over the 2D views. Depress the mouse and drag it around the contour to be drawn. The contour will automatically be closed and intersecting regions will be eliminated.

### Line

Select **LINE** and the cursor will become a crosshair when over the 2D views. Start the contour by clicking the mouse. Add vertices by clicking the mouse at points along the boundary of the region being contoured. Delete the contour by right clicking. End the contour by double-clicking; the contour will automatically be closed and intersecting regions will be eliminated.

### Ellipse

Select **ELLIPSE** and the cursor will be elliptically shaped when over the 2D views. Contour the region by clicking the mouse at one edge of the ellipse and then dragging across to the opposite edge. If the **CTRL** key is pressed, a circle will be drawn.

### Rescale

Select **RESCALE** and a square will envelope the selected Volume of Interest.

Eight rescale vertices are on the square, one at each corner and one in the middle of each side. When the mouse is over one of these vertices, the cursor becomes a line with arrows at each end. Depress the mouse at a vertex and drag the vertex to rescale the contour.

Two yellow control points are inside the square. The **Move** control point is at the center of the square. The **Rescale** control point is in the middle of the horizontal line between the center point and the right side of the square.

If the mouse is over the **Move** control point, the mouse cursor will change to a cross with arrows at the end of each line. Move the contour by depressing the mouse and dragging it in the 2D view.

When the cursor is in any other location, it becomes a small arrowhead and you cannot do anything.

### Magic Wand

The **Magic Wand** is a tool that allows you to automatically generate a contour on an image slice. Select Magic Wand and the cursor takes on the shape of a wand in the 2D view.

Adjust the Window & Level for the image so that the region of interest you wish to delineate has a large amount of contrast in relation to the surrounding anatomy. The contrast of the image should be such the object you plan to contour is a closed region. Otherwise, the delineated contour is likely to leak outside the object. Click the mouse toward the center of the region you wish to contour and it will be automatically contoured.

For some volumes, the boundary contrast may lead to the automatically drawn contour bleeding outside the volume. Use the Minimum Leakage Allowed slider at the bottom of the Control View to prevent leakage. The slider sets the length of boundary segments. This helps the magic wand bypass possible regions of leakage. It, however, yields more coarsely defined VOI.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



## 3D Magic Wand

The **3D Magic Wand** is similar to the Magic Wand. The only difference is that it will attempt to contour the VOI across the entire image volume instead of just within a single 2D slice. The main difficulty with the 3D Magic Wand is that over numerous slices, the contour can bleed into adjoining anatomy if the contrast within the image becomes less clear.

Use the Minimum Leakage Allowed slider at the bottom of the Control View to prevent leakage. The slider sets the length of boundary segments. This helps the 3D magic wand bypass possible regions of leakage. It, however, yields more coarsely defined VOI.

## Bumper

The **Bumper** is a tool for modifying an existing drawn, extrapolated, or interpolated Volume of Interest. When you choose to use the Bumper tool, the cursor appears as a circle in the 2D views.

Depress the left mouse button and drag the cursor around the contour to push the boundary the direction you wish to move it. The curvature of the "bump" is dependent on the size of the circle relative to the zoom level of the image. Zoom into the image to get more precise shape control.

In addition to adjusting the VOI boundary, you can erase or cut out parts of a contour. Simply use the contour to cleave off a portion of the VOI. The system will automatically delete the smaller piece cut with the Bumper. If the portion you wish to delete is larger than the portion you wish to keep, cut the contour multiple times to ensure you do not delete the portion you want to retain.

If you modify an interpolated or extrapolated curve, that curve will become drawn and the contour will be displayed with a solid line.

The Bumper tool can also be used to initiate a VOI. If no contour has been defined in a VOI, selecting Bumper tool and clicking on the image will create a circular contour, which has the same size as the current Bumper size, at the position of the mouse click.

Change the diameter of the bumper with the Bumper Size slider at the bottom of the Control View.

## Edit Commands

The Edit Commands below the drawing palette allow you to Undo the last drawing action you took. You can back through everything you have drawn since you entered the Delineate step. You can Redo drawing steps you have backed through, but did not intend to undo.

You can **Copy** a contour and **Paste** it onto another slice as the same or as a different VOI.



685

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



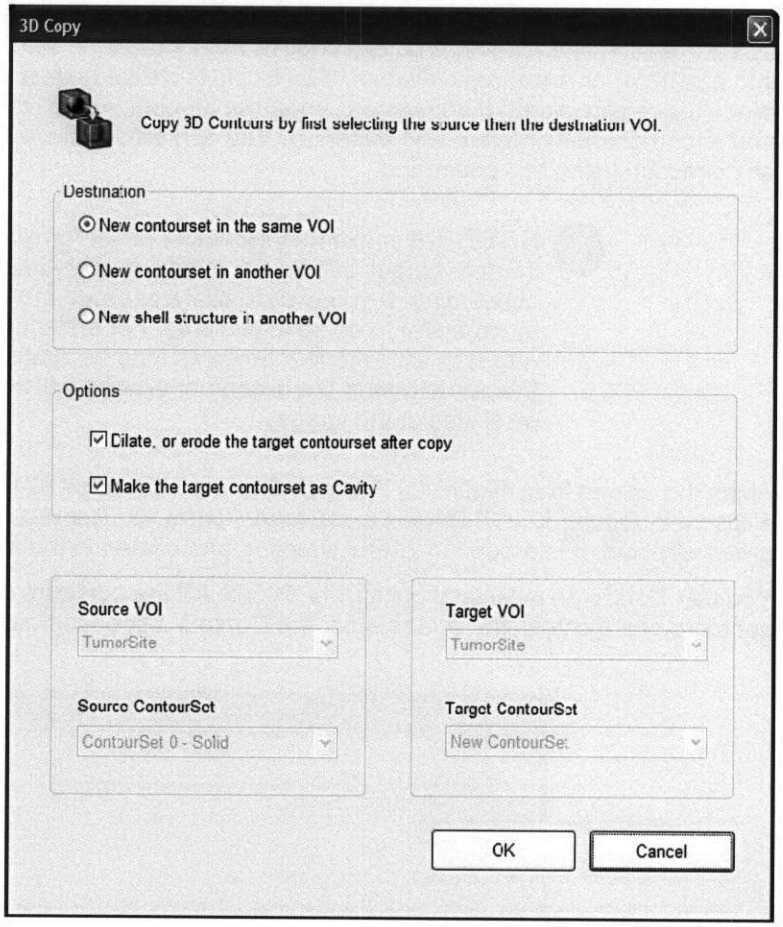



**Figure 28 3D Copy of a Contour Set**

Use the 3D Copy tool to copy all the drawn and interpolated contours of a contour set into another contour set. When you select this option, the popup (*Figure 28 3D Copy of a Contour Set, page 41*) appears. You have three options for the destination of the copied contour set. The first option copies the contour set into a contour set for the same VOI. The second option copies the contour set into a contour set for a different VOI. The third option copies the contour set into a shell contour for a different VOI. If the third option is chosen, the new VOI will have two Contour Sets. The inner contour will be a cavity. The outer contour will be a solid.

You also have the option to immediately proceed to the Dilate option and to choose whether the copied contour set will be a solid or a cavity. If the Dilate option is selected, *Figure 29 Dilate or Erode a VOI, page 42* opens immediately after *Figure 28 3D Copy of a Contour Set, page 41* closes.

Use the bottom cascade buttons to choose the Target VOI and the Target Contour Set. Although the default Source VOI and Source Contour Set is currently the selected VOI, you can select a different source with the left cascade buttons.

After the VOI Contour Set has been copied, the selected VOI and Contour Set is the target for the 3D Copy.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



A contour can be dilated or eroded with the Dilate option. Choose this option and *Figure 29 Dilate or Erode a VOI, page 42* appears. The algorithm for this option uses a rolling ellipsoid to provide true 3D dilation and erosion. You can choose **ISOTROPIC** (in which case the ellipsoid degenerates into a sphere) or Anisotropic dilation. If Isotropic is chosen, enter the amount you wish to dilate or erode the region in mm. If anisotropic, enter the amount in each cardinal patient direction (anterior, posterior, right, left, inferior, and superior). You can erode, dilate, or leave unchanged the VOI in any direction using this command.

**NOTE:** The maximum allowable offset for dilation and erosion is 15 mm. Larger offsets are overly memory intensive and time consuming. If you wish to dilate or erode more than 15 mm, it is much faster to do so in two step. For instance, to dilate 30 mm in one step will take four times as long as dilating 15 mm twice. Discrepancies in the dilation or erosion will be on the order of the pixel size of the image.

Apply the values from *Figure 29 Dilate or Erode a VOI, page 42* to a VOI shaped like the yellow ellipsoid in *Figure 30 VOI Dilated and Eroded, page 43*. The resulting VOI (in one plane) is the green ellipsoid. It is eroded in lateral direction and dilated in the anterior/posterior direction.

You can **Delete** an individual contour or **Delete All** the contours of the selected VOI. If all the contours of a Contour Set are deleted, the Contour Set becomes undefined.

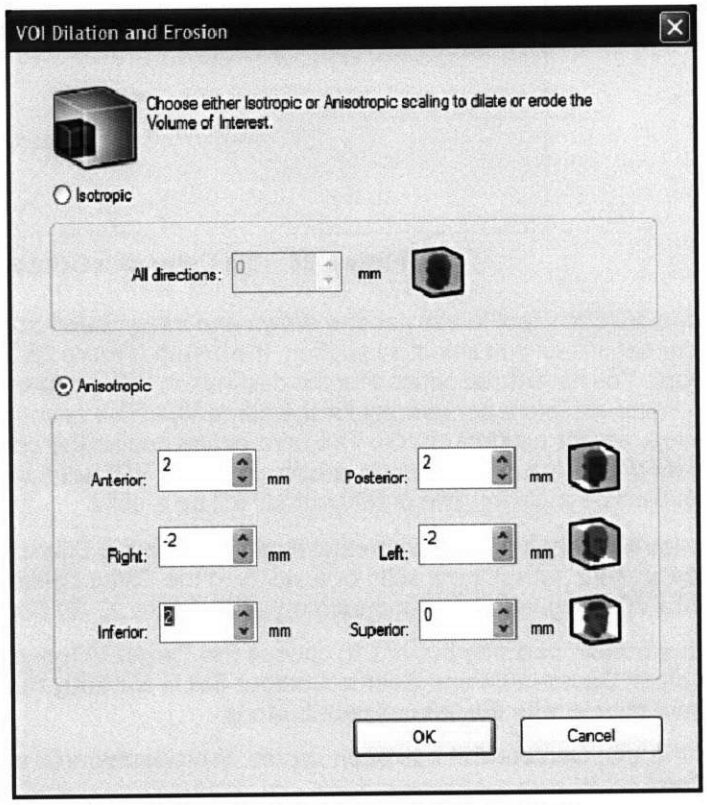



**Figure 29 Dilate or Erode a VOI**



687

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



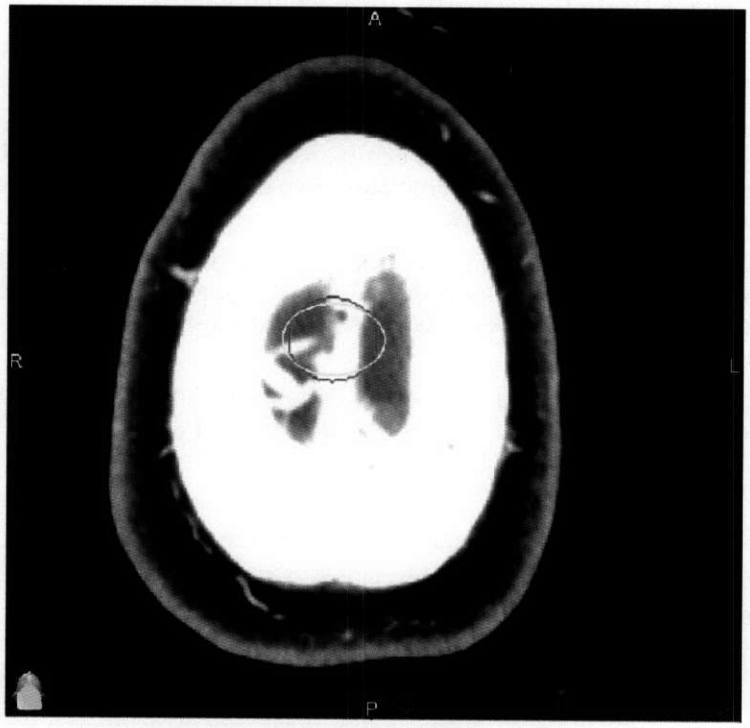



**Figure 30 VOI Dilated and Eroded**

Set the drawing tools from the palette of icons under the Drawing Tools label. The tool arrangement on the palette, clockwise from the top, is Pen, Point, Ellipse, Bumper, 3D Magic Wand, and Magic Wand modes. The middle button is the **RESCALE** mode

In addition to displaying VOI and isocontours while drawing, the Options at the bottom of the Control View include the ability to set manual drawing in Smart Curve mode. This mode allows you to use the image intensity to 'snap' a contour to a contrast boundary in the anatomy. *Section, Smart Curve Fitting Option, page 46* describes this option in more detail.

The Display View has a large image at the top left. This image is a 2D view of the drawing plane. Immediately below that are the 2D perpendicular views. To the left of the large view are twelve smaller views of the drawing plane. These views are the six slices preceding the axial view and the six slices following the axial view. In Pointer Mode, if you click the slice number in one of the smaller slices, the focus will change so that the slice becomes the large axial view. Typically, you should draw on the large view. It is possible, however, to draw on any of the smaller views. You can change the displayed modality of the large view or the perpendicular views. The viewed images are fixed image (A), moving image (B), and split image (A/B). The smaller drawing windows have the same mode as the larger window, except that the split image display displays the fixed (A) images in the small windows.

At the lower right of the Display View are the image histograms you can use to set the Window and Level of the 2D images (*see section, Window/Level Mode , page 13*).



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



## Interpolation of Volumes of Interest

As noted above, each VOI can use automatic interpolation to speed up generation of that VOI. You can also choose to turn off this feature for each VOI.

In automatic interpolation mode, you draw a contour on one slice and draw a second contour on another slice. The intermediate contours are automatically determined using linear interpolation. If a contour is drawn on an interpolated slice or an interpolated contour is modified, the other interpolated contours will be updated.

The system distinguishes between drawn and interpolated contours. Drawn contours are solid lines. (For example, examine the left eye in *Figure 31 Drawn Contour, page 44*) Interpolated contours are dashed lines. (For example, examine the right eye in *Figure 32 Interpolated Contour, page 45*.)

Extrapolated contours are shown as dotted lines and have the same shape as the nearest drawn contour. The dots have a larger separation than interpolated lines. These extrapolated contours are not a part of the contour set. They are shown to give you a visual reference for the shape and location of the closest drawn contour.

For non-active, gray volumes, extrapolated curves are not shown, because they are not considered part of the VOI. Interpolated curves are shown as solid lines because they are part of the VOI.

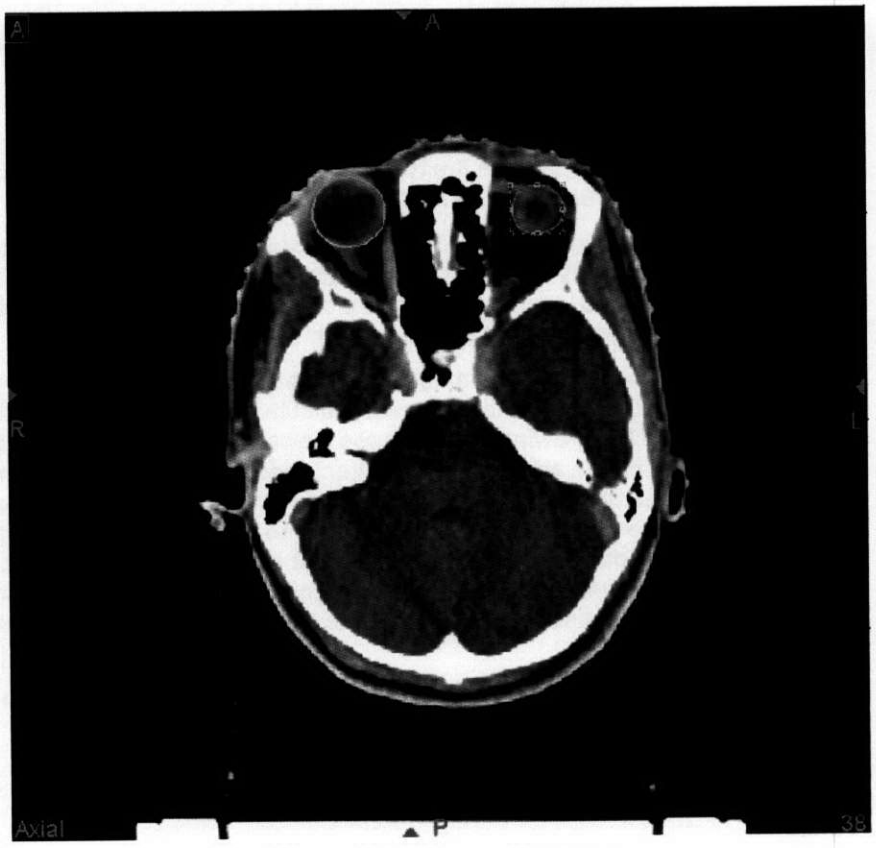



**Figure 31 Drawn Contour**



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

689

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



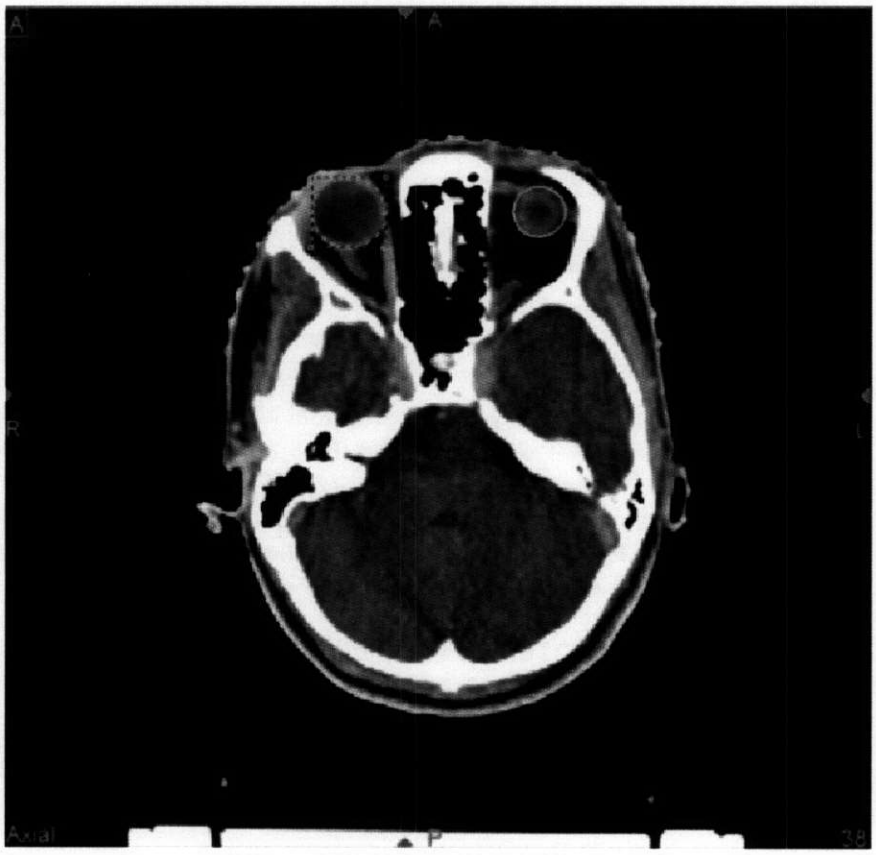


**Figure 32 Interpolated Contour**



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118 690

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



## Smart Curve Fitting Option

The **Pen**, **Line**, **Ellipse**, and **Bumper** drawing tools have available the **Smart Curve Fitting** option. This option is similar to the Magic Wand drawing tool, except that you start by drawing a contour, rather than by simply selecting a point. Smart contouring is a little more robust than using the Magic Wand but requires more effort by you.

Select **SMART CURVE FITTING** to use this option.

Before you select the desired drawing tool, adjust the Window and Level of the image to maximize the contrast between the volume you want to draw and the surrounding anatomy.

In **Pen**, **Line** or **Ellipse** mode draw close to the volume you want to contour. The curve will reshape to fit the boundary based on the contrast within the display. The curve fitting algorithm is most robust if the starting contour is fully inside the region you want to draw.

In Bumper mode, you modify the curve so that it is near the boundary and it will reshape based on the contrast within the display. If you are modifying an interpolated curve, reshape that contour by double-clicking it.

The **ALT** key also serves as an alternative to the current Smart Curve Fitting state. In any drawing section, If the **ALT** key is held just before the mouse button is about to released, the current Smart Curve Fitting state will be altered, and applied to the result contour.

**NOTE:** The automated drawing tools use the displayed image modality to determine boundaries. You set the modality by clicking the indicator at the top left of the 2D image display. This setting is unique for each view, so modifying one view does not affect the other views. This limitation includes the small axial views, which always display the reference image (A).

**WARNING: The magic wand, 3D magic wand, and smart curve tools use the current settings of window, level and image intensity to define boundaries. These contours may not always accurately match the volume boundary. Therefore, you should always visually inspect each contour to assure that it defines the intended volume.**



691

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



# PLAN REVIEW

You can use CyRIS InView to review the dose distribution for a plan generated using the CyberKnife On-Target Treatment Planning System.

**WARNING: CyRIS InView has been validated only to provide remote evaluation of treatment plans generated with the CyberKnife System treatment planning software. Do not use this workstation to evaluate plans generated on other systems.**

## Receiving Dose Distributions

Send dose distributions from the CyberKnife On-Target Treatment Planning System as DICOM RT Dose series.

Open Treatment Planning on the CyberKnife System User Control Console (or secondary workstation).

Create a plan and calculate the dose distribution.

Select **Plan->Export DICOM Data**. *Figure 1 Export DICOM Data from the UCC, page 3* will appear.

Select RT Dose and Dose Grid.

Give the DICOM Series a description. The default for this description will be the plan name, a time stamp, and the suffix '_DOSE'. You may choose the name, if desired.

Choose to Export the data to CyRIS InView host.

Select **OK**.

Only the Dose Grid portion of the DICOM RT Dose object is needed, because CyRIS InView calculates Dose Volume Histograms (DVH) and isodose contours.

The dose grid is a sub-volume of the fixed CT volume. The dose is calculated and exported at the resolution of the CT image. Dose can only be evaluated inside this sub-volume.

If you are using MultiPlan as your treatment planning system, send dose grid from MultiPlan as DICOM RT Dose Series (refer to the MultiPlan module, section Push DICOM Formatted Data).



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



# Layouts

*Figure 33 Dose Review with DVH and Dose Statistics, page 48* and *Figure 34 Dose Review with 3 Planar Views, page 49* show the user interface for the Dose Evaluation step of the Review task. Two layouts are available for the Display View. Use the two layout buttons at the bottom of the Control View to set the desired layout.

The Display View layout in *Figure 33 Dose Review with DVH and Dose Statistics, page 48* is the default. It includes a 3D view of the patient anatomy with a dose cloud, an axial view with isodose curves, three DVH graphs (one each for targets, critical regions, and the soft tissue in the dose grid), and a list of statistics for each Volume of Interest.

The Display View layout in *Figure 34 Dose Review with 3 Planar Views, page 49* includes the 3D view, as well as three planar views – axial, coronal, and sagittal.

In either layout, if multiple image modalities are used, the 3D view can display the fixed (A) image, the moving (B) image, or a mixed image (*see section, 3D Visualization, page 53*) that is designated as A&B. Change the image from the top left of the display, in the same manner as the 2D view is changed.

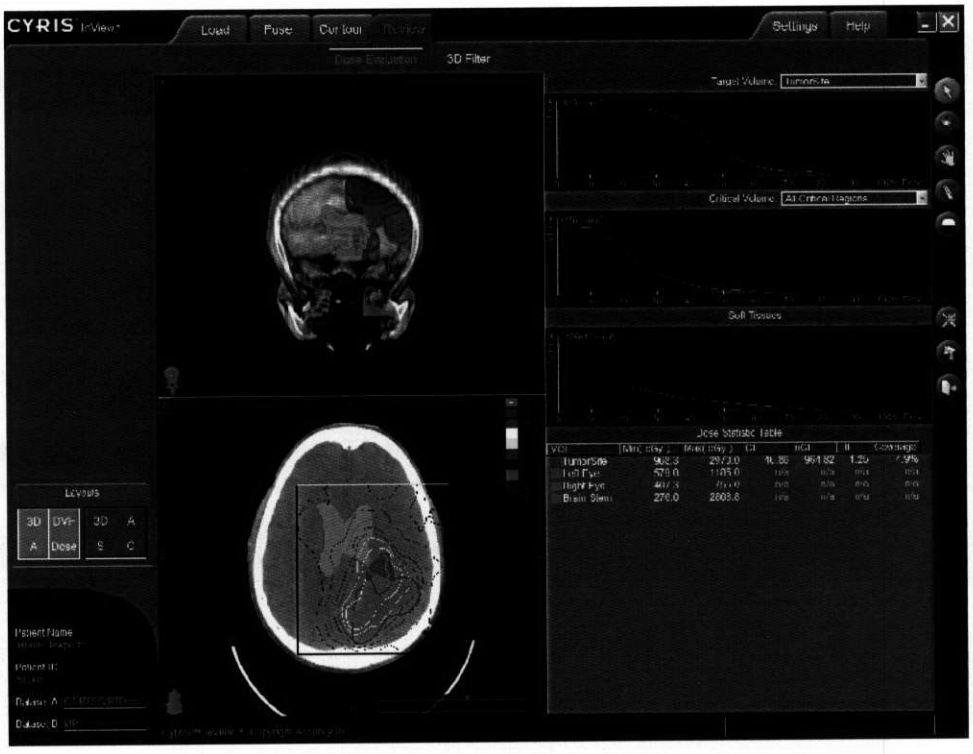



**Figure 33 Dose Review with DVH and Dose Statistics**



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

693

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



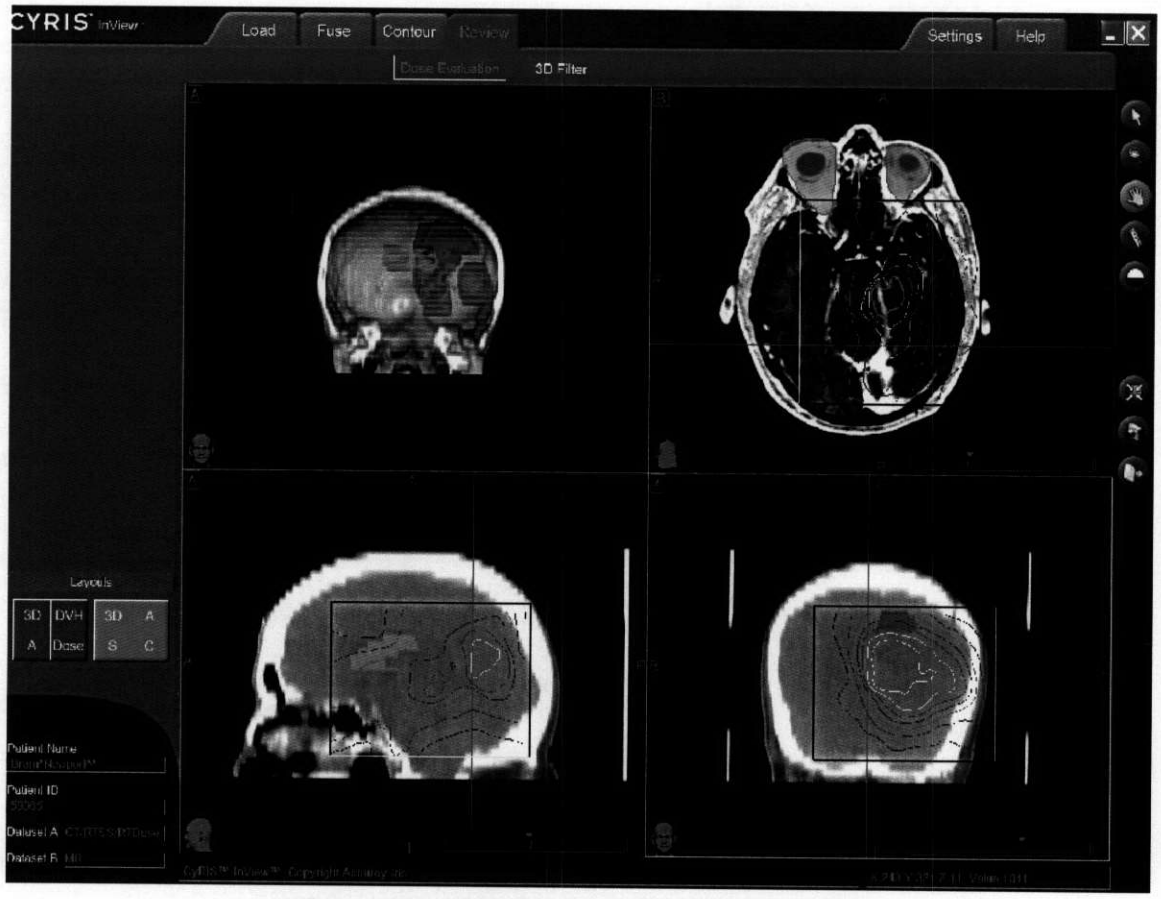



**Figure 34 Dose Review with 3 Planar Views**

## Displayed Dose

The dose exported from the CyberKnife On-Target Treatment Planning System has the same resolution as the CT study used to plan the treatment. The resolution is the pixel size in the axial plane and the slice separation of the axial pixels.

The dose grid sizes on CyRIS InView are always even multiples of the resolution of the CT study. The maximum number of grid elements is 128. So when a dose distribution is loaded, it may retain the same resolution or it may be down-sampled, so that the dose grid uses 128 or fewer elements in each dimension.

The sub-volume that includes the dose distribution is contained within the yellow box shown on the 2D views. The color of this box is configurable in the Settings (*Figure 12 Settings Task, page 17*) window.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118 694

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



## Isodose Curves

The dose distribution on the 2D views is displayed as isodose curves. You can display up to ten isodose curves. You set which the curves to display from the list at the top of the Control View.

The check box at the left allows you to choose the number of curves to display.

The top isodose curve is, by default, the prescription isodose. That this is the prescription isodose is indicated by the "P" in front of the percentage value. This percentage is used to calculate the dose statistics for target volumes.

Use the color bar to change the color of any curve. Like the VOI color settings, a **CASCADE** button with default colors is available by clicking on a color bar. The last option in the cascaded list is a custom color grid that you can use to choose any color for the isodose curve.

Choose the percent isodose to display from the text field next to the color bar. Only integer percentage values of the maximum plan dose are allowed.

The right option allows you to set the line thickness for any isodose curve. You can set the thickness to be any integer value between 1 and 5.

**NOTE:** The isodose curves are displayed by interpolating the dose between grid elements. The resolution of the stored dose on CyRIS InView is finer than generally used on the CyberKnife On-Target Treatment Planning System. The interpolation algorithms on the two systems are slightly different. Therefore, discrepancies up to one-pixel (in CT resolution) may occur in the generation and display of the isodose curves.

## Point Dose

You can also evaluate the dose on any 2D view by clicking the mouse over any point. You can drag the mouse to find the dose along a line. The dose will be displayed in cGy and as a percentage of the maximum dose value.



695

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



# Global Metrics

Use the layout in *Figure 33 Dose Review with DVH and Dose Statistics, page 48* to display global metrics for the plan.

## Dose Volume Histograms

On the upper right side of the Display View are three Dose Volume Histogram (DVH) graphs. The top graph has the target DVH. You can look at the DVH for individual targets or the sum result over all targets. Use the pull-down list control to choose the target you wish to evaluate. The middle graph has critical region DVH. You can look at the DVH for individual critical regions or for the sum of all the targets. Use the pull-down list control to choose the critical region you wish to evaluate. The bottom graph gives the DVH for the soft tissue within the calculation volume.

Use the left mouse button to get precise volume-dose pairs. The dose is displayed in cGy and as a percentage of the maximum dose. The volume is displayed as percentage of the total volume of the VOI. The total volume is at the top left of the graph.

**WARNING: Volumes used to determine the dose volume histogram include only the portion of a VOI that is enclosed by the dose calculation grid. Therefore, if a volume is only partially enclosed by that grid, the apparent total volume of the VOI for DVH calculation will be less than the volume calculated in the Properties step (*section, VOI Properties, page 36*).**

**NOTE:** Volumes of Interest are identified through a grid. The grid on the CyberKnife On-Target Treatment Planning System uses the dose calculation grid. The grid on CyRIS InView uses the fixed image study. Usually, the CyRIS InView will have a finer resolution than the CyberKnife On-Target Treatment Planning System. This will cause differences in the dose statistics, especially in areas where the dose distribution has a sharp gradient.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118 696

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



## Dose Statistics Table

Below the DVH graphs is a table of dose statistics associated with each VOI. The statistics calculated are the maximum and minimum doses for each VOI. The target volumes have calculations for the parameters listed below.

Conformality Index (CI) – The conformality index is the ratio of the tissue volume receiving the prescription isodose or more to the tumor volume receiving the prescription isodose or more.

New Conformality Index (nCI) – The new conformality is the CI multiplied by the ratio of the total tumor volume to the tumor volume receiving the prescription isodose or more.

Homogeneity Index (HI) – The homogeneity index is the ratio of the maximum dose to the prescription dose. For the current configuration of the CyRIS InView, the maximum dose is always the 100% isodose.

Coverage – The coverage is volume of the tumor receiving greater than or equal to the prescription dose divided by the total volume of the tumor times 100.



697 Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



# 3D Visualization

You can also visualize the VOI and dose distribution on 3D volumes.

*Figure 35 3D Filter with One Image Series, page 53* has the 3D Filter step of the Review task. The layout shown is for a plan with a single medical image. You can set the isodose curves in a similar manner as in *section, Isodose Curves, page 50*. Use the list of VOI to select which VOI to display in the 3D view.

*Figure 36 Window/Level 3D Image Filter, page 54* shows the 3D Filter layout for a plan with two fused medical images. The Display View differs for the two cases, because with two image sets you can see three volume renderings: the fixed image, a mixed fusion of the fixed and moving image, and the moving image. *Figure 37 Color 3D Filter, page 55* also has two image histograms, because two image sets are being sampled. The Control View with two image studies adds the control buttons to generate the mixed image. You can either Merge Data A to B (fixed to moving image) or Merge Data B to A (moving to fixed image).

When a plan has two images, the 3D view in the Review step will use the mixed image.

## Window/Level Filter

With the Enable Color 3D Filter mode inactive, you can adjust the presentation of the 3D image by changing the Window and Level settings, as described in *section, Window/Level Mode , page 13*. The setting shown brings out the vascular structure of the patient.

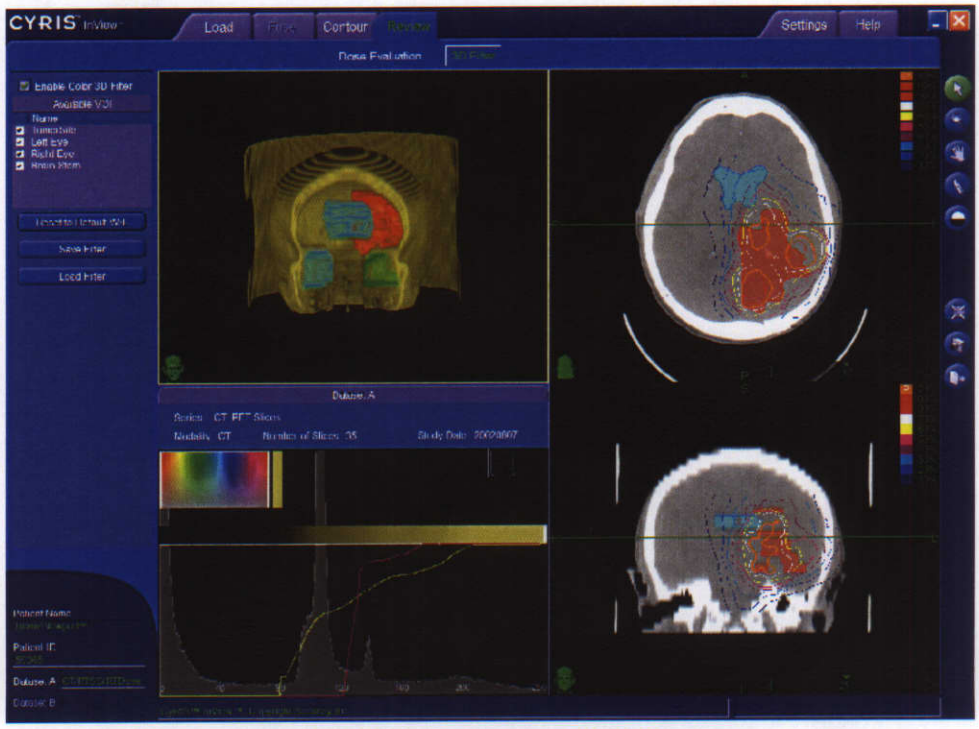



**Figure 35 3D Filter with One Image Series**



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118 698

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



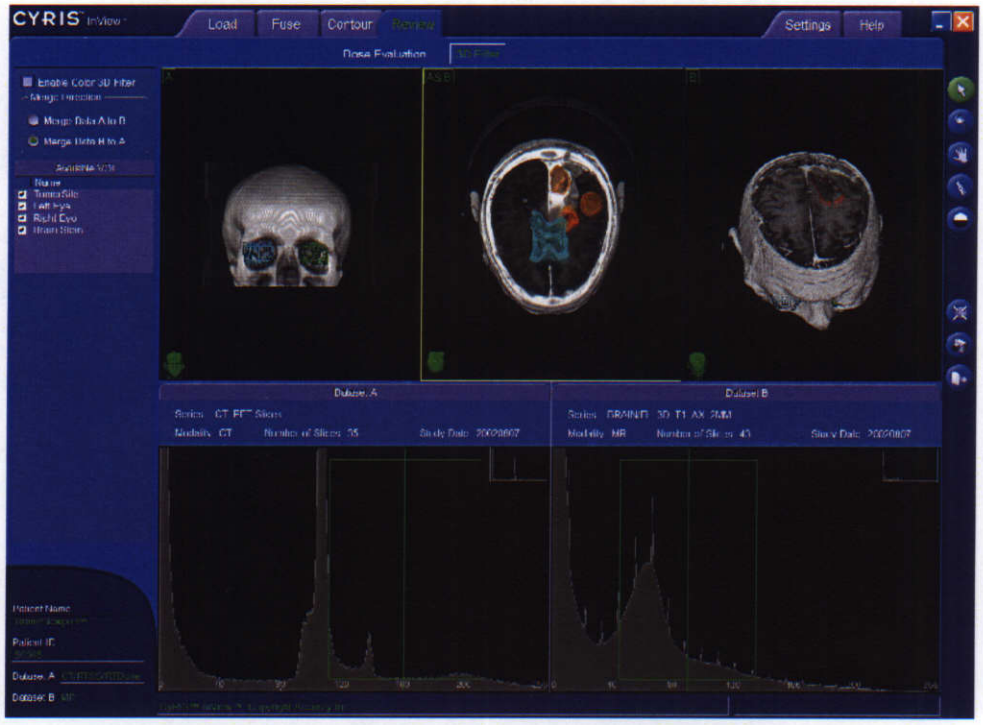



**Figure 36 Window/Level 3D Image Filter**



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

699

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



## Color Filter

You can display the 3D volume images in color. For instance, it may be preferable to present vascular structures in red. Select 3D color filter mode and the layout shown in *Figure 37 Color 3D Filter, page 55* will appear.

The image histograms have color filter controls rather than a Window and Level setting. The color filter is implemented by drawing two lines on the histogram.

Click and drag the left mouse button to draw the opacity function. The opacity is a magenta line on the graph. The opacity increases as the y-value increases, so values near the bottom of the scale are transparent, and values near the top of the scale are opaque.

Use the color grid to choose a color for the image. Click and drag the right mouse button to draw a color function. The color intensity increases as the y-value increases. The color function is a yellow line on the graph.

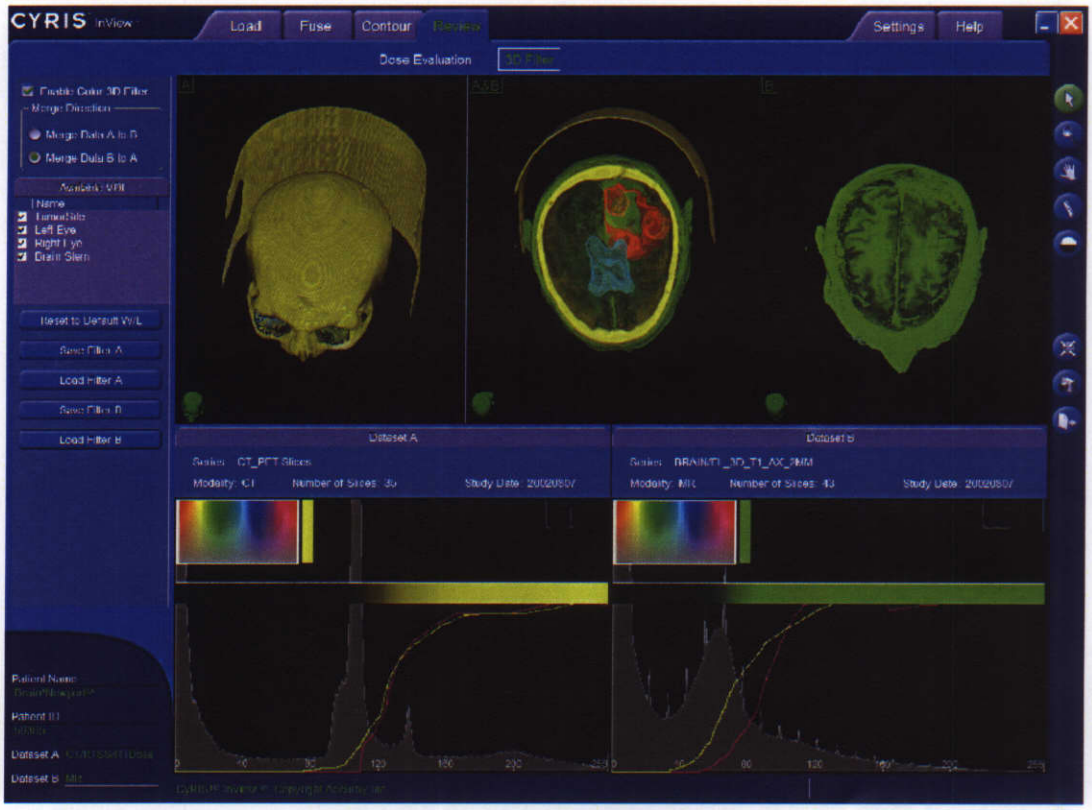



**Figure 37 Color 3D Filter**

After creating a color filter that satisfies you, save it to a directory using the **SAVE FILTER** button. The **left** button is for image A and the **right** button is for image B. You can load the filter using the **LOAD FILTER** button. The default directory for saving filters is *C:\accuray\filters*.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



## Dose and Anatomy Overlays

- The 3D view can display up to seven Volumes of Interest and a single isodose cloud. The isodose cloud displayed is the first active dose in the isodose contour list. The default is therefore the prescription isodose value. Select the VOI from the list in the Control View.
- Rotate the 3D view and change the cutting plane of the image to better view the displayed dose cloud and the VOI. The 3D view can be rotated by clicking and dragging the mouse in the 3D view. In the inner part of the screen, can roll the patient anatomy. If you move the mouse toward the boundary of the 3D view, the cursor will change to two arcs. In this mode, you can pitch or yaw the 3D image.
- Forward scroll and backward scroll with the mouse scroll-mouse to change the cutting plane through the image. Forward scroll cuts deeper through the image. Backward scroll cuts more shallowly through the image. In this way you can see the VOI as well as the dose distribution and evaluate how well they conform.



701 Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



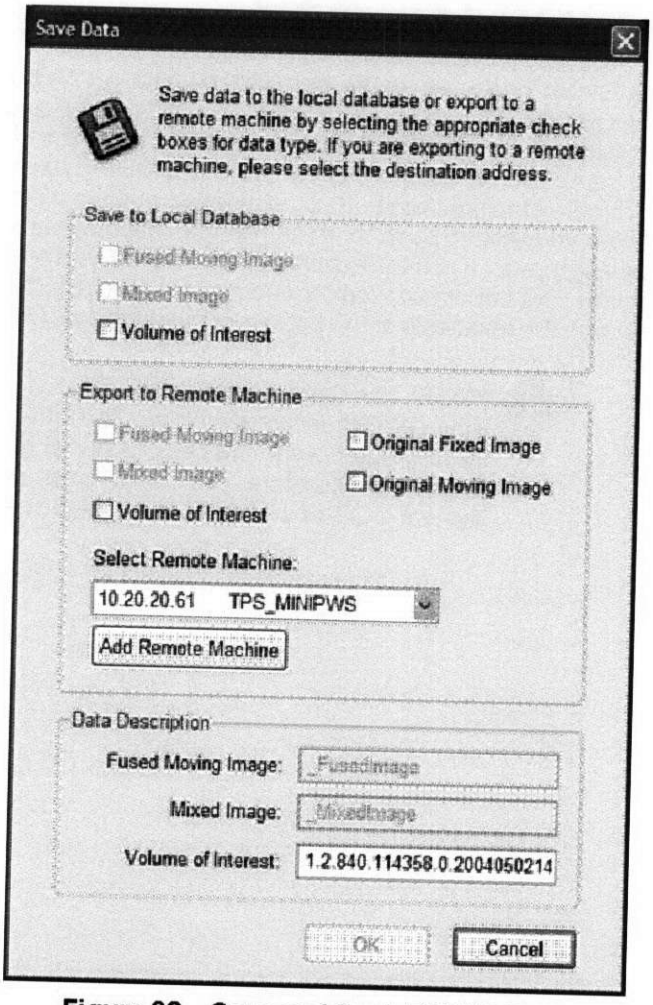



**Figure 38 Save and Push DICOM Data**



703 Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



# SAVE AND PUSH DATA

From the Global Tools, select the **EXPORT DICOM DATA** button. (The **EXPORT DICOM DATA** button has an icon of a paper and arrow.) *Figure 38 Save and Push DICOM Data, page 58* will appear. Select data to save to the local database using the check boxes in the Save to local machine frame. Select data to push to the CyberKnife System UCC by checking the boxes in the Push to remote machine frame. If you choose to push to a remote machine you will need to select the machine you wish to push to. If the Remote Machine will not accept the DICOM data, an error message will pop-up. If you will export data into a DICOM series, you will need to set the Description for the series. Set the description for each series modality (fused image, mixed image, and contours) with the text fields at the bottom of the interface. Choose OK to export and push the data.

**NOTE:** The CyberKnife System UCC will only accept DICOM data if the DICOM server is running. The DICOM server only runs when the computer is on. The DICOM server does not run during patient treatment. Therefore, you cannot push data to the CyberKnife System UCC while a patient is being treated.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



# Configure Hosts

You can add a machine to the list of machines to push DICOM data, if necessary. Select **ADD REMOTE MACHINE** from the dialog in *Figure 38 Save and Push DICOM Data, page 58* and appears *Figure 39 Add Remote Machine, page 59*. Type in the AE Title, IP Address and DICOM port for the machine to which you intend to push data.

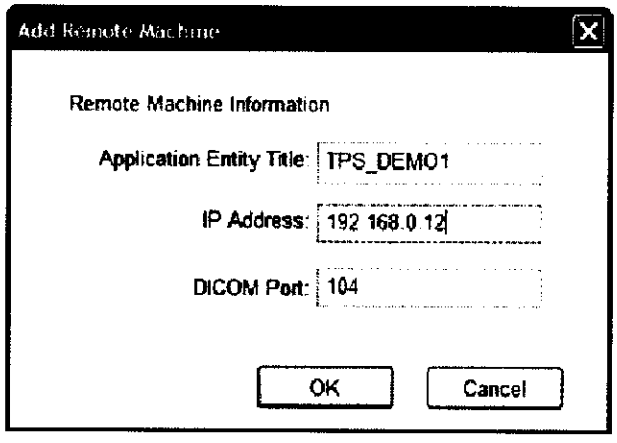



**Figure 39 Add Remote Machine**

**WARNING: Data from CyRIS InView (used to treat patients) should only be used with the CyberKnife Radiosurgery System.**



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118 704

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



## Volumes of Interest

You can push and save the contoured volumes of interest. All the contours you have created (or imported) will be saved in the DICOM RT Structure Set instance.

The Volumes of Interest will be saved with the name and color you set. The contours will be tagged as drawn or interpolated. CyRIS InView will only load the drawn contours and the interpolated contours will be regenerated based on the linear interpolation algorithm.

If the VOI are pushed to the CyberKnife System UCC, both interpolated and drawn contours will be loaded into the system. The CyberKnife Treatment Planning System cannot distinguish between a drawn and interpolated contour. (Obviously, if you export a set of interpolated contours is sent to the CyberKnife Treatment Planning System and then resent to CyRIS InView, all the contours in the returned series will be drawn.)

## Image Data

You can save two types of image data and push four sets of image data.

You can save or push a DICOM image series of the registered image. This image will have the same frame of view as the fixed CT image series. The gray scale values, however, will be calculated from the moving image. This image series will have the same modality as the moving image, except for XA images. For XA data, the registered image is set as a derived MR image, because the DICOM Library on the CyberKnife System UCC assumes that XA images are scanned as Coronal slices and the registered is transferred as axial slice data.

You can save or push a DICOM image series of a mixed image that is a fusion of the CT image and the moving image. The contents of this image are created in the 3D Filter step described in *section, Window/Level Filter, page 53*. Only a gray scale image can be saved and pushed. If 3D Filter has been used, it will be converted to a gray scale image before being exported to the DICOM image series. This image series will have the same modality as the moving image, except for XA images.

You can also push the fixed CT image series or the moving image. CyRIS InView merely sends the data to another machine. It does not alter it in any way.



705 Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



# GLOSSARY

## Terms

The following terms and their definitions are used in this guide:

**Cavity** – A contour set that removes volume from a Volume of Interest.

**Control Database** – The database that controls what scanners have permission to send medical image data to CyRIS InView.

**Contour Set** – A group of contours that are a part of the same VOI. A contour set can only have one contour on each slice.

**DICOM Host** – A DICOM server to which CyRIS InView can send medical image data

**DICOM RT Dose** – A means of transferring dose distribution data.

**Export** – Create a DICOM series from image, dose or volume data.

**Fixed Image** – The CT image used to localize the patient during treatment. Also known as Image A.

**Focus Line** – A line in a 2D view that indicates the displayed perpendicular plane of the medical image.

**Function** – An operation you can perform on CyRIS InView.

**Moving Image** – A Medical Image used to assist delineation and evaluation of specific Volumes of Interest. Also known as Image B.

**Push** – Send medical image data to DICOM server.

**Reference Image** – The Fixed Image

**Refined Registration** – The result of registering two images using the maximization of the Mutual Information between the two images.

**Registered Image** – A moving image that has been transformed so that it aligns with the Fixed Image.

**Seed Point** – A point placed on the patient anatomy to obtain a starting position for the Registration.

**Seed Point Registration** – Registering two medical images using only 3 seed points on each image.

**Step** – A group of functions organized into a single user interface layout.

**Task** – A group of steps.

**Volume of Interest** – A target or critical structure.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

706

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



# Acronyms and Abbreviations

The following acronyms and abbreviations are used in this guide:

**2D** – 2 Dimensional.

**3D** – 3 Dimensional.

**3DXA** – Rotational or 3-Dimensional X-Ray Angiography.

**CI** – Conformality Index.

**CT** — Computed Tomography.

**DICOM** – Digital Imaging and Communication in Medicine

**DICOM RTSS** – DICOM Radiotherapy Structure Set

**DVH** — Dose Volume Histogram.

**HFS** — Head First Supine.

**HI** – Homogeneity Index.

**MIRIT** – Medical Image Review and Import Tool.

**MR** — Magnetic Resonance.

**nCI** – New Conformality Index.

**PET** – Positron Emission Tomography.

**PT** – Positron Emission Tomography.

**RT** – Radio Therapy.

**TPS** — Treatment Planning System.

**UCC** – User Control Console.

**UID** – Unique Identifier

**VOI** – Volume of Interest.

**Voxel** — volume pixel.

**WRT** — with respect to.



707 Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



# WARNINGS AND ERRORS

*Table 2: Warnings and Error Messages, page 63* tabulates warning and error messages used by CyRIS InView. Warnings have codes that begin with a '0'; errors have codes that begin with an '8'. The table also includes recommendations to help resolve errors.

**Table 2: Warnings and Error Messages**

| Code | Error/Warning Message | Recommended Actions |
|---|---|---|
| | **WARNINGS** | |
| 0001 | Closing this application may cause loss of data. Do you want to close this application? | No action is needed. |
| 0010 | Your license will expire in %s days. Please contact Accuray Inc. to obtain a new license. | Contact Accuray to obtain a new license. |
| 0011 | This VOI is not empty. Changing the contour plane will erase all the existing contours. Do you want to proceed? | No action is needed. |
| 0013 | Deleting the current slice may cause the current series to become unloadable! Do you want to delete anyway? | No action is needed. |
| 0014 | Are you sure you want to delete the current series permanently? | No action is needed. |
| 0015 | Warning: If the merged series has variable slice thickness, it cannot be loaded! | No action is needed. |
| 0016 | This field only accepts integer values in the range of %s. The original value will be used! | Input an integer in the field. |
| 0017 | This field only accepts floating point values in the range of %s. The original value will be used! | The system does not support entry of special characters in this field. Please input a number. |
| 0018 | The VOI's have not been saved since the last modification. Do you want to proceed without saving them? | Save VOI's, if desired. If not, no action is needed. |
| 0019 | Please quit this application before logging off or switching to another user! | Log-off if changing user. |
| 001A | The previously selected series belongs to a different patient. Do you want to clear the previous selection? | No action is needed. |
| 001B | The images have not been registered. 3D images will not be shown correctly. Please go back to Fuse task. | Fuse the two loaded medical images, if desired. If not, no action is needed. |



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118 

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



**Table 2: Warnings and Error Messages**

| | | |
|---|---|---|
| 001C | The previous DICOM push process has not finished. Closing the application may result in the data not being fully transmitted. Do you want to quit the application? | Cancel CyRIS InView exit to prevent an incomplete data set being loaded onto CyberKnife System User Control Console. |
| 001D | The previously selected series belongs to a different patient. Do you want to continue? | No action is needed. |
| 001E | You do not need to split the currently selected slice! | No action is needed. |
| 001F | Only 7 VOI can be viewed on the 3D image! | Select only 7 VOI on the 3D view. |
| 0020 | You need to deselect the previous selection to select a new dataset! | Deselect a selected image or RT data set, before you attempt to select this data set. |
| 0021 | The system will sort the image first, then you can choose the slice to delete! | No action is needed. |
| 0022 | No VOI contour has been detected after erosion. The system has cancelled the operation, and the original VOI retained. If you wish to delete the VOI, please use the [Delete All] command instead | Enter smaller value to erode the VOI. |
| 0023 | Are you sure you want to save %s-? | No action is needed. |
| 0024 | Are you sure you want to discard current work and load new dataset? | No action is needed. |
| 0060 | Do you want to remove selected patients? To save this information, you must export patient information to a remote machine. | No action is needed. |
| | **ERRORS** | |
| 8000 | Unknown system error! | Call Accuray. |
| 8001 | System does not have enough memory to load this data! | Close all non-CyRIS InView related applications. Close and restart the application.<br>If this fails, reboot the system.<br>If this fails, attempt to reduce the size of the medical images. If this fails, call Accuray. |
| 8002 | The current operating system does not support this application. Please run this application on Windows XP Pro or higher version of windows system. | Contact Accuray service to arrange a Window's operating system upgrade. |



709 Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



**Table 2: Warnings and Error Messages**

| | | |
|---|---|---|
| 8003 | Please set your display resolution to 1600 x 1200 and 32 color bits. | Select the Control Panel from the Start Menu. Select Appearance and Themes. Select Display. Open the Settings tab.<br>Set the Screen resolution to 1600x1200 and the Color quality to Highest (32 bit). |
| 8004 | Failed to capture image! | Try to recapture image. |
| 8005 | Failed to save file [%s]! Please make sure the disk has enough space and is not write protected. | If saving data to a floppy disk, verify that the disk is writable. |
| 8006 | Graphics system failed! Error found in OpenGL [%s]. | Reboot the computer. If same error recurs, call Accuray. |
| 8007 | The license file is missing. Please contact Accuray Inc. to obtain a new license. | Contact Accuray to obtain a new license. |
| 8008 | Invalid license. Please contact Accuray Inc. to obtain a new license. | Contact Accuray to obtain a new license. |
| 8009 | License has expired. Please contact Accuray Inc. to obtain a new license. | Contact Accuray to obtain a new license. |
| 800A | Another instance of this application is running! | Close CyRIS InView application. |
| 800B | The seed points you have defined are collinear. Please redefine one or more seed points. | Redefine one or more seed points so that all three are not collinear. |
| 800C | The seed points you have defined are too close to each other. Please redefine one or more seed points. | Redefine one or more seed points and separate them further. |
| 800D | Wrong filter file cannot be loaded! | Attempt to load a different filter file. |
| 8100 | Invalid database connection! | Reboot system. |
| 8101 | No connection to TPS_DICOM Database via ODBC [DNS:DICOMServer]! | Call Accuray. |
| 8103 | Failed to start the DICOM Archive Server! Please make sure [archive_server.exe] is in the right folder. | Reboot system. |
| 8104 | Could not find the local configuration files! | Call Accuray. |
| 8200 | Failed while reading image! | Resend DICOM data from scanner or workstation. If that fails, call Accuray. |
| 8201 | Failed while loading image! | Call Accuray. |
| 8202 | Image slice count error! The image may have fewer than 2 slices. | Rescan or send image so that it has at least two slices. |
| 8203 | The image does not contain valid slice spacing! | Delete slices that create erroneous slice spacing. |
| 8204 | The image does not have valid patient position! | Rescan patient as HFS or FFS. |



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118 710

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



**Table 2: Warnings and Error Messages**

| | | |
|---|---|---|
| 8205 | The image contains SAGITTAL slices, which are not supported by this application. | Delete sagittal slices, or rescan patient. |
| 8206 | The pixel format of the image is not supported by this application. | Rescan image or call Accuray. |
| 8207 | The slice thickness of this image set is not consistent! The system cannot load this image. | Rescan image or delete slices that cause unequal slice thickness. If that fails, call Accuray. |
| 8208 | The slice sizes of this image set are not consistent! The system cannot load this image. | Rescan image or delete slices that cause unequal slice size. If that fails, call Accuray. |
| 8209 | The pixel spacing for this image set is not consistent! The system cannot load this image. | Rescan the image or delete slices that cause unequal pixel spacing. If that fails, call Accuray. |
| 820A | Some slices of the image are missing. The system cannot load this image. | Resend or rescan image. If that fails, call Accuray. |
| 820C | Failed to read image data. The image data may be broken. | Rescan or resend image. If that fails, call Accuray. |
| 820D | The system does not allow an image study with more than <n> slices to be loaded! | Delete enough slices to assure the study has no more than 300 slices. |
| 820E | The Slice thickness is not in the range (min, max) = <f>! | Rescan image with a valid range for the slice thickness or call Accuray. |
| 820F | Rescale Intercept or Slope has no value! | Rescan image or resend image with appropriate image header. |
| 8210 | Gantry/Detector Tilt is not ZERO! | Rescan image with zero gantry tilt. |
| 8211 | <s> patient position is not supported! | Rescan image in a valid patient position. |
| 8212 | The image is blank! Failed to load image. | Try to reload a different image. |
| 8300 | Failed to load the RTDose dose distribution! | Resend the RT Dose from the CyberKnife System. If that fails, call Accuray. |
| 8301 | Failed to load the RTSS volumes of interest! | Resend RTSS Volumes. If that fails, call Accuray. |
| 8302 | Invalid RTSS data, or the RTSS structure does not contain any VOI! | Resend RTSS data with VOI. |
| 8303 | Failed to export the volumes of interest file! | Reboot system. Call Accuray. |
| 8304 | Failed to export the fused image file! | Reboot system and retry export. If the error recurs, call Accuray. |
| 8305 | Failed to export the mixed image file! | Reboot system and retry export. If the error recurs, call Accuray. |
| 8306 | Failed to export the merged image file! | Reboot system and retry export. If the error recurs, call Accuray. |



711

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



**Table 2: Warnings and Error Messages**

| | | |
|---|---|---|
| 8307 | Failed to export the split image file! | Reboot system and retry export. If the error recurs, call Accuray. |
| 8308 | Failed to save the volumes of interest! | Reboot system and retry export. If the error recurs, call Accuray. |
| 8309 | Failed to push the original image [%s] to the remote computer %s! | Reboot inView and reboot destination workstation. If the error recurs, call Accuray. |
| 830A | Failed to push the volumes of interest to computer %s! | Reboot inView and reboot destination workstation. If the error recurs, call Accuray. |
| 830B | Failed to push the fused moving image to computer %s! | Reboot inView and reboot destination workstation. If the error recurs, call Accuray. |
| 830C | Failed to push the mixed image to computer %s! | Reboot inView and reboot destination workstation. If the error recurs, call Accuray. |
| 830D | Failed to push the merged image to computer %s! | Reboot inView and reboot destination workstation. If the error recurs, call Accuray. |
| 830E | Failed to push the split image to computer %s! | Reboot inView and reboot destination workstation. If the error recurs, call Accuray. |
| 830F | Failed to add the remote machine! | Call Accuray. |
| 8310 | The fused volume data is invalid to export! | Verify the moving image is properly registered in Fuse Task. |
| 8380 | Failed to connect to DICOM server! The server could be dead or there may not be a network connection to %s! | Reboot inView and reboot destination workstation. If the error recurs, call Accuray. |
| 8381 | Interrupted DICOM network connection to %s! | Reboot inView and reboot destination workstation. If the error recurs, call Accuray. |
| 8382 | DICOM server aborted this Association request to %s! | Reboot inView and reboot destination workstation. If the error recurs, call Accuray. |
| 8383 | Request for this Association rejected by the DICOM Server because of the wrong calling AE title for %s! | Modify the calling AE title for the remote machine. Resend DICOM data. If that fails, call Accuray. |
| 8384 | Timeout ( %s secs) for pushing DICOM files: SCU application is hanging because of a AEs error or the network may be too slow to %s! | Modify the calling AE title for the remote machine. Resend DICOM data. If that fails, call Accuray. |



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118 712

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



**Table 2: Warnings and Error Messages**

| | | |
|---|---|---|
| 8385 | Failed to run C_STORE application as SCU. It could be that send_image.exe is missing! %s | Call Accuray. |
| 8386 | Failed to either verify AEs or write to DICOM database %s! | Reboot inView and reboot destination workstation. If the error recurs, call Accuray. |
| 8387 | Request for this Association rejected by the DICOM Server because of an illegal calling AE title for %s! The maximum string length of AE title is 16 characters. | Modify the calling AE title for the remote machine. Resend DICOM data. If that fails, call Accuray. |





Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



# Treatment Planning System
## Table of Contents


**Introduction to On-Target™ TPS** ..... 1

**Start TPS and Set Display Options** ..... 2

- **Launch the Planning Program** ..... 2
- **Select the Display Options** ..... 3
  - Window & Level ..... 4
  - 3D View Window ..... 5
  - Region Names ..... 6
  - Lesion Names ..... 7
  - DVH % Dose ..... 8
  - Isodose Line ..... 9
  - Layout & Graphics ..... 10
- **Set the Display Preferences** ..... 11

**On-Target™ TPS Basics** ..... 12

- **Create a New Plan** ..... 12
  - Select New in Plan Menu ..... 12
  - Set Anatomy/Imaging Parameters ..... 13
    - Set Tracking Method and Treatment Mode ..... 14
    - Set Beam-On Time ..... 15
    - Set Fraction ..... 15
  - Add Windows to the CT Displays ..... 16
- **Modify an Existing Plan** ..... 17
- **Recover the Plan** ..... 18
- **Save the Plan** ..... 18
  - Low Dose Warning ..... 19
  - Invalid Dosimetric Calculation ..... 19
  - Printing Plan Documentation ..... 20
- **Delete the Plan** ..... 22

**CT Image Displays** ..... 23

- **Features of 2D CT Displays** ..... 23
  - Axial View Window ..... 23
- **Sagittal View Window** ..... 24
  - Coronal View Window ..... 25




Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118 714

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



**CT Window Tools** ..... **25**
Zoom In ..... 25
Zoom Out ..... 26
Copy ..... 26
Paste ..... 26
Delete ..... 26
Delete All ..... 26
Undo ..... 26
Ruler ..... 26
Collimator Visibility Toggle ..... 26
Isodose Curves Visibility Toggle ..... 26
Region of Interest (ROI) Visibility Toggle ..... 26
**Additional 2D Framing Tools** ..... **27**
Zoom Factor ..... 27
Zoom and Center ..... 27
Pan Image ..... 27
**Multiple Slice Axial View** ..... **29**
**Display Registered Image** ..... **30**
**3D View Window Tools** ..... **31**
Rotation and Throw ..... 31
Translation ..... 31
Scale ..... 31
Display Options Menu ..... 32
3D View Sliders ..... 33
**The Reference Plan** ..... **33**
View a Single Plan ..... 35
Sum Plans ..... 35
Calculation Grid ..... 36



715 Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



# TREATMENT PLANNING SYSTEM (TPS)

## INTRODUCTION TO ON-TARGET™ TPS

This module explains the operational procedures for the CyberKnife® Treatment Planning System (TPS).

Accuray's On-Target Treatment Planning System gives physicians and medical physicists the ability to plan safe and deliverable treatments. It is specifically designed to optimize the flexible nature of the robotic treatment delivery system.

**In planning a treatment:**

**Step 1.** Click **PLANNING** from the main menu.

**Step 2.** Display the patient's computed tomography (CT) data.

**Step 3.** If needed, fuse multiple images (i.e., CT and magnetic resonance (MR) imaging) using AccuFusion™.

**Step 4.** Identify and delineate tumors and critical regions.

**Step 5.** Generate plans for the prescribed treatment.

**Step 6.** Evaluate, modify, and compare plans.

**Step 7.** Save plans. Saved plans are stored in treatment files associated with a patient.

**Step 8.** Simulate the treatment.

You can return to previous steps after completing any step.

**WARNING: Do not attempt to modify a treatment file. Improperly changed data could result in death or injury of the patient.**



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118 716

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



# START TPS AND SET DISPLAY OPTIONS

## Launch the Planning Program

At the main menu, click **PLANNING** from the selection screen. After the "loading process" message, the Accuray Treatment Planning System window appears.

When you first start the planning system, only the Plan and Tools menus are available on the menu bar (*Figure 1 Menu Bar, page 2*).

- Use the Tools menu to begin image fusion. (*see module, Treatment Planning, section, AccuFusion™ Image Fusion, page 21*).
- Use the Plan menu (*Figure 2 Plan Menu, page 2*) to manipulate patient plan files.

**Figure 1 Menu Bar**

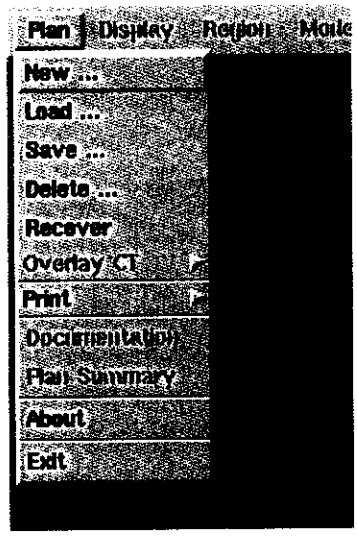



**Figure 2 Plan Menu**



717

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



**Plan functions:**

- **New** - Creates a new plan based on the CT data. (*see section, Create a New Plan, page 12*)
- **Load** - Opens an existing plan from the database for modification. Elements of the database are accessible by all CyberKnife modules. (*see section, Modify an Existing Plan, page 17*)
- **Save** - Saves a plan to the database. (*see section, Save the Plan, page 18*)
- **Delete** - Deletes a plan from the treatment-planning database. Elements of the treatment planning database are only accessible by the On-Target Treatment Planning System (*see section, Delete the Plan , page 22*). Plans cannot be deleted from the secondary workstation.
- **Recover** – Recovers the last automatically saved plan. (*see section, Modify an Existing Plan, page 17*). The Treatment Planning System automatically saves the existing plan approximately every five minutes. If the planning session inadvertently ends, this allows you to partially recover work from the previous session.
- **Overlay CT** - Overlays CT data to a plan. This function is used for plan simulation. (*see module, Treatment Planning, section, Overlay CT, page 89*).
- **Print** - Print the selected Dose Volume Histogram (DVH), beam, or path data to a file or the printer. (The saved plan indicated in the title bar is printed.)
- **Documentation** - Print a summary of the selected saved treatment plan and a beam checklist for each path. (The saved plan indicated in the title bar is printed.)
- **Plan Summary** - Display a summary of the treatment plan including number of paths, non-zero nodes, and total nodes. This feature allows you to estimate treatment time. This button becomes active after the planning system calculates a deliverable plan. (*see module, Treatment Planning, section, Plan Summary, page 84*)
- **Exit** - Ends the TPS session. (*see module, Treatment Planning, section, End Treatment Planning System, page 94*)

## Select the Display Options

Use the Preference menu to set display options and save them as part of a given plan or set them as machine defaults. Seven preference windows are available for setting the display. Click **PREFERENCES** from the Display menu (*Figure 14 Display Menu, page 16*) to open the Preference For Display window.

The seven categories are:

1. Window & Level
2. 3D View Window
3. Region Names
4. Lesion Names
5. DVH % Dose
6. Isodose Line
7. Layout & Graphics

Use the **CASCADE** button to select the desired category. Changes from all seven windows take effect when you select **OK**, regardless of which window is currently displayed.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118 718

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



## Window & Level

The Window & Level Preference Option (*Figure 3 Window & Level Preference Menu, page 4*) changes the Window and Level indicators in the Toolbox and 2D Window & Level displays. Adjust the Window and Level settings to improve the screen display of the tumor target or critical structures.

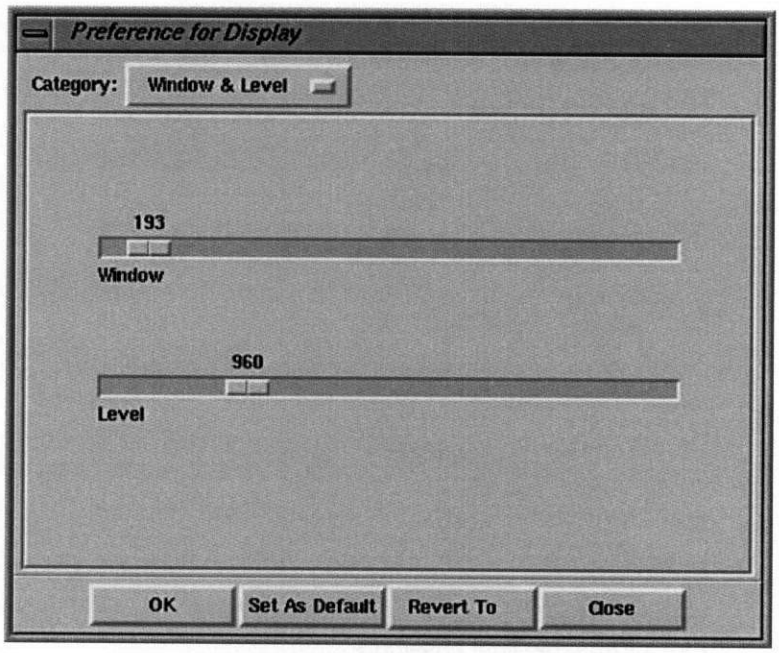



**Figure 3 Window & Level Preference Menu**



719

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



## 3D View Window

The 3D View Window (*Figure 4 3D Window Preference Menu, page 5*) preference menu options include whether or not to display specific features, the percentage of the isodose surface to display, and the CT number used to display the surface of the head.

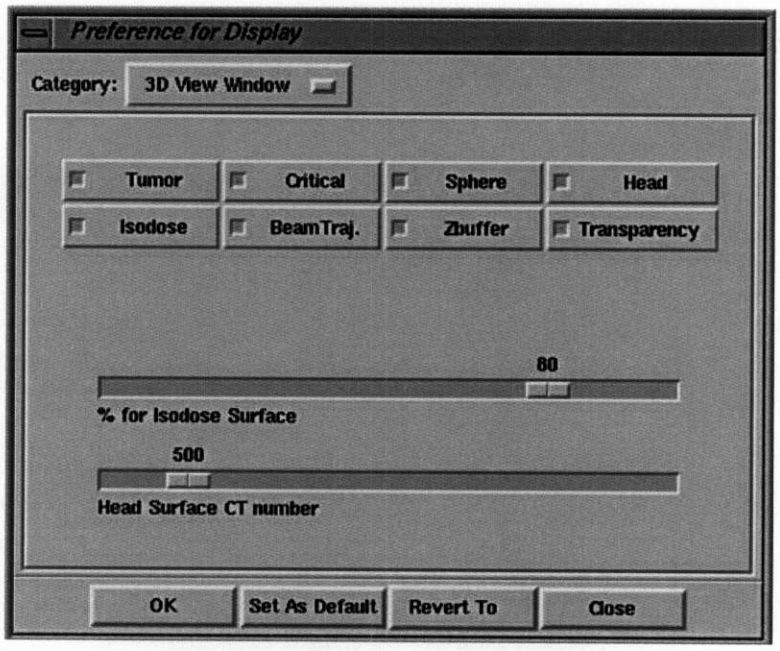



**Figure 4 3D Window Preference Menu**



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



## Region Names

Specify names for the ten critical regions in the Region Names preference menu (*Figure 5 Region Name Preference Menu, page 6*). You can also set priorities for these ten regions and the soft boundary. The priorities are used to resolve the tissue type for regions drawn with overlapping polygons. The highest priority is 1; the lowest priority is 21.

**NOTE:** These priorities are used in conjunction with the priority preferences set in the Region Names window.

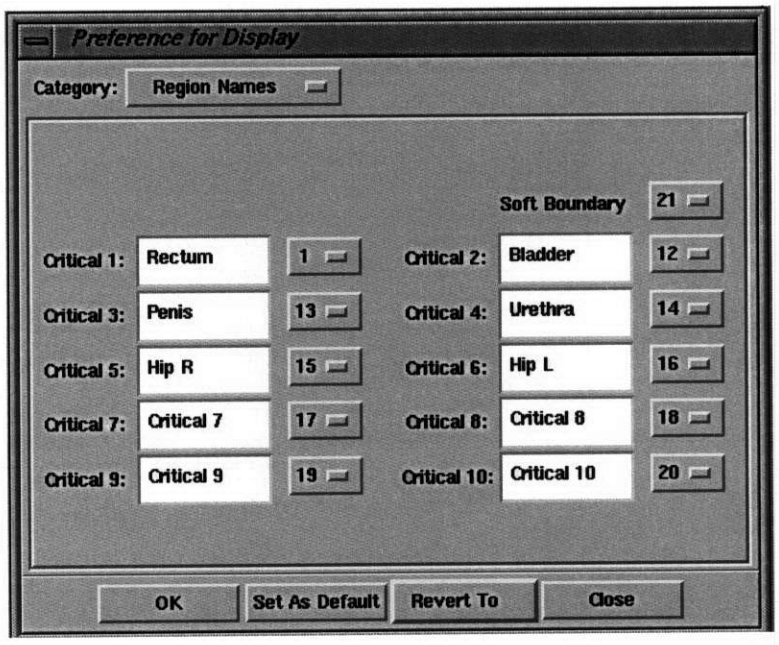



**Figure 5 Region Name Preference Menu**



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



## Lesion Names

The Lesion Names preference menu (*Figure 6 Lesion Names Preference Menu, page 7*) allows you to name ten tumor sites. You can also set priorities for these ten lesions. The priorities are used to resolve the tissue type for regions drawn with overlapping polygons. The highest priority is 1; the lowest priority is 21.

**NOTE:** These priorities are used in conjunction with the priority preferences set in the Region Names window.

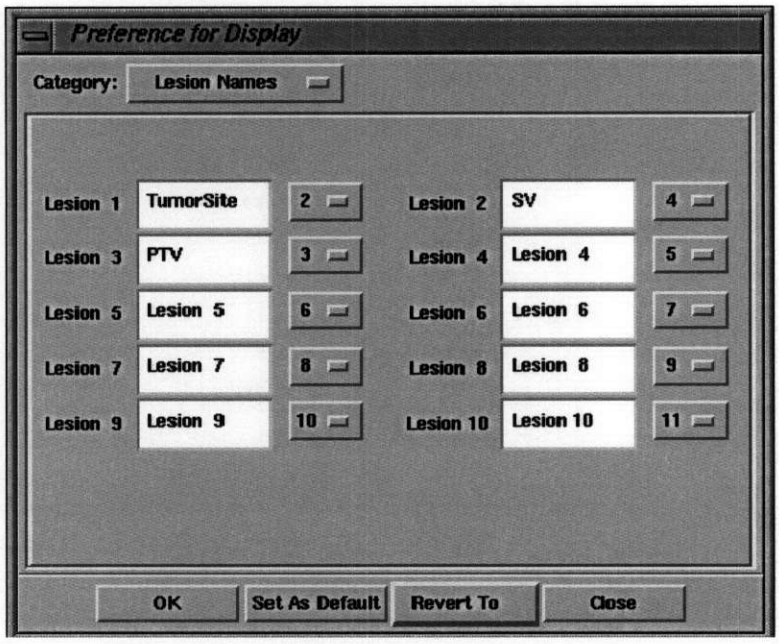



**Figure 6 Lesion Names Preference Menu**

**NOTE:** Lesion 1 cannot have spaces or special characters. If these characters are used, the planning systems will delete them.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



## DVH % Dose

The DVH % Dose to tabulate is given in the Preference menu. (*Figure 7 DVH Percent Dose Preference Menu, page 8*). This table affects the dose value histogram used in plan evaluation. see section, Dose Volume Histogram in module, Plan Evaluation Tools, for detailed information on this display.

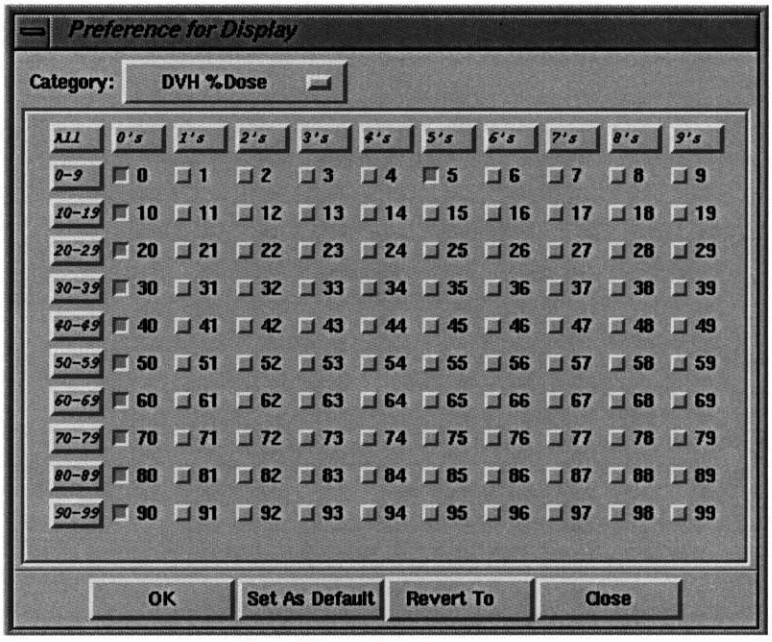



**Figure 7 DVH Percent Dose Preference Menu**



723

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



## Isodose Line

The isodose line width, colors, and dose percentages are set with the Preference menu (*Figure 8 Isodose Line Preference Menu, page 9*). The four sliders set the colors and percentages for each line. Select the isodose line to edit by clicking the appropriate box from the color legend below the four sliders. The preferred on/off status of each line can also be set. When the toggle button below a color block is green, that isodose line is on. When the toggle button is gray, that isodose line does not appear in the 2D CT views.

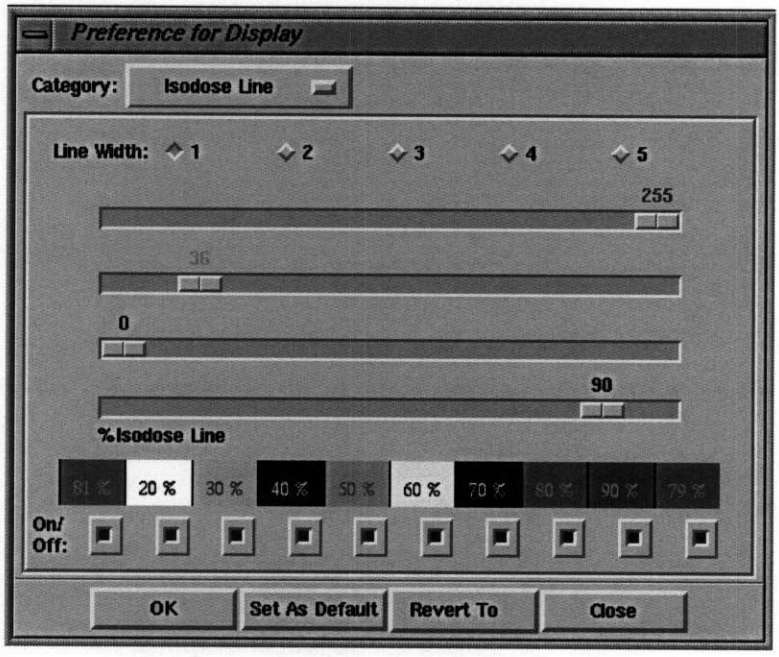



**Figure 8 Isodose Line Preference Menu**



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



## Layout & Graphics

The Layout & Graphics preference menu (*Figure 9 Layout & Graphics Preference Menu, page 10*) allows you to set the relationship between the Axial, Sagittal, and Coronal View windows and border width for region polygons. The CT windows can either be equally scaled or they can be scaled such that Axial View 1 is larger than the others. The Reference window has the same scale as Axial View 1. The polygon width can be set to either 1 pixel, 2 pixels, or set proportionally to the zoom level.

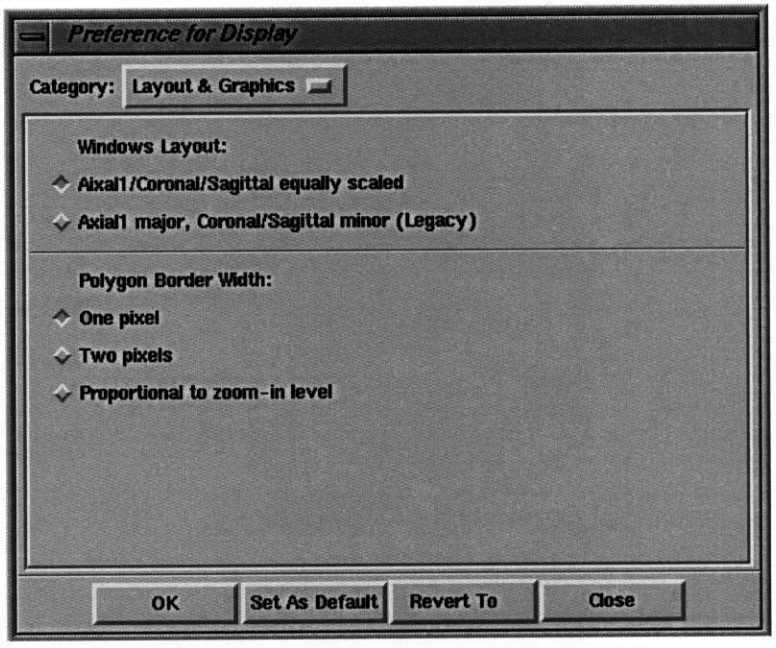



**Figure 9 Layout & Graphics Preference Menu**



725 Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



## Set the Display Preferences

After the display preference options are selected, you have four options.

1. **OK** sets the new preferences for the plan you are editing. These preferences are saved when the plan is next saved. Select ok to exit the preference menu. If the windows layout was changed, the 2D views zoom out and the center slices of the CT study are displayed.
2. Click **SET AS DEFAULT** to reset the machine preferences. Selection of set as default does not exit the preference menu.
3. You can **revert to** the existing plan, machine, or factory default settings. The plan settings will be the preferences set when the plan was last saved. You set new machine-specific defaults with the Set As Default option. Clicking **REVERT TO** does not exit the Preference menu.

   **NOTE:** If the current plan is a new plan (one that has never been saved), the plan preferences are the same as the machine preferences. You can also revert to factory preference settings, which cannot be changed.

4. Click **CLOSE** to exit the Preference menu without updating the plan display preferences.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118 726

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



# ON-TARGET™ TPS BASICS

## Create a New Plan

Treatment planning is based on the anatomical information in the patient's CT data. Begin a planning session by displaying the CT data of the patient.

### Select New in Plan Menu

From the Plan menu (*Figure 2 Plan Menu, page 2*), click **NEW**. The New Plan window (*Figure 10 New Plan, page 12*) lists the available patients from the CyberKnife database in the upper window. Select the patient by clicking the patient's name in the list. The available CT's associated with the selected patient are listed in the lower window.

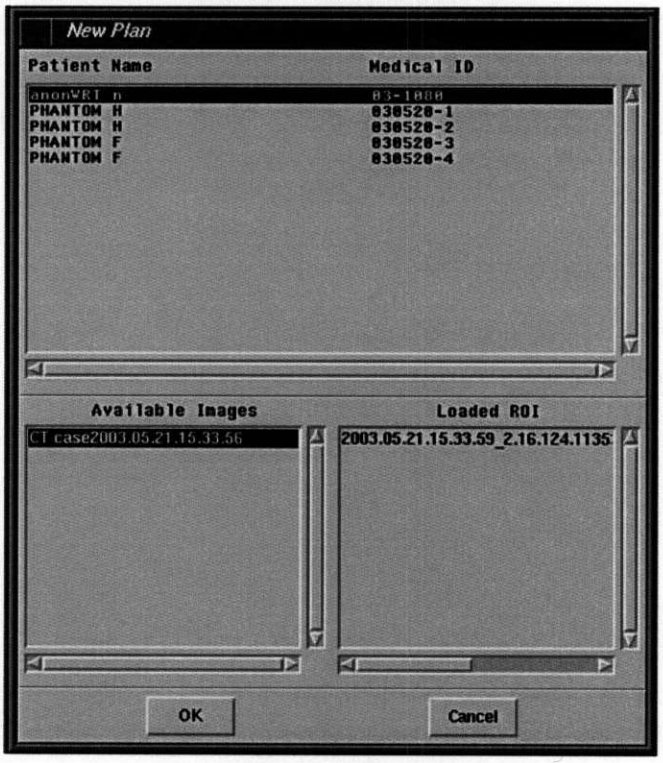



**Figure 10 New Plan**

Select the CT study by highlighting the study name in the lower left window. If DICOM RT Structure Sets were loaded with the selected image, they will be listed in the lower right. Highlight the set you wish to load. Click **OK** to start a new plan. A Job In Progress message (*Figure 11 Job in Progress Message, page 13*) indicates Load Patient Image Data. It closes after reading the CT data.



727

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



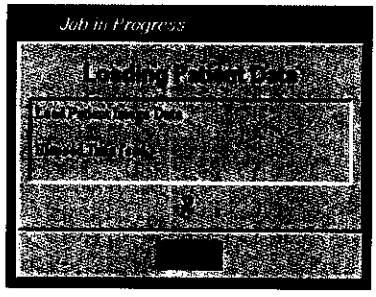



**Figure 11 Job in Progress Message**

After the CT study is read, the CT windows appear, including axial view 1, sagittal view, coronal view, and 3d view window (*see section, CT Image Displays, page 23*). A Job In Progress message indicates Creating 3D Image status. The message closes when the 3D CT images are displayed. The Toolbox window then appears at the left side of the screen, making the tools available for use when you need them. The Toolbox window is discussed in detail in *module, Program Treatment Beams Using Wizards, page 33.*

## Set Anatomy/Imaging Parameters

The last window, Set Anatomy/Imaging Parameters (*Figure 12 Set Anatomy/Imaging Parameters, page 14*), appears and prompts you to select the anatomical region to be treated. Each region has one or more sets of treatment nodes associated with it. Generally, these sets are based on the nominal source-axis distance (SAD) for the treatment beams generated from these nodes. The node sets can have any name.

For example, the head template list shown in the left window includes 650 mm and 800 mm SAD treatment nodes. The body template list, in the right window includes only the 800-plus set of nodes. The anatomical site for a given plan is indicated in the title bar, above the menu bar.

Every plan can have only one anatomy and one path set. For Xsight™ Spine Tracking System treatments, you must set a region. The tracking algorithm requires knowledge of whether the specific anatomical region is the crucial, thoracic, or lumber spine.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118 728

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



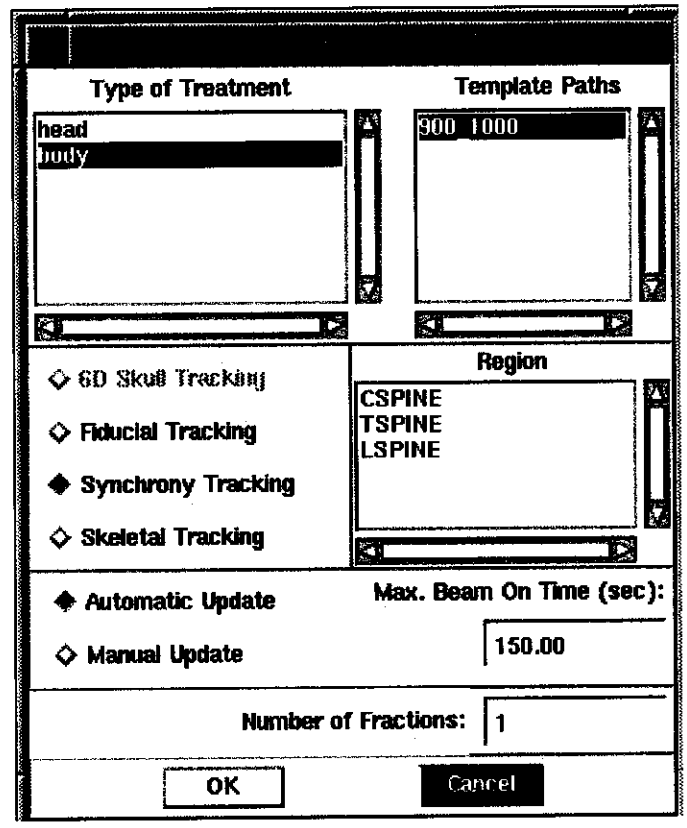



Figure 12 Set Anatomy/Imaging Parameters

## Set Tracking Method and Treatment Mode

You can also set the tracking method and treatment modes from the Set Anatomy/Imaging Parameters window.

**Tracking method** is the imaging method that locates the patient during treatment. 3D and 6D Skull Tracking use the entire diagnostic X-ray image to position the patient. Fiducial tracking uses embedded fiducials to find the patients position and orientation.

**Treatment mode** indicates how diagnostic images are taken and position updates sent to the manipulator. This patient positioning can either be timed automatically by the system or coordinated through the user's manual mode intervention. Manual mode is most appropriate when breath-holding is used during treatment, because it provides more reliable timing between patient breath-holding, imaging, and treatment.

**NOTE:** Not all tracking methods and treatment modes are available for each anatomy. Labels for any unavailable methods are grayed out and cannot be selected.

**NOTE:** Fiducial Tracking and Manual Position Updates are not available for the Head treatments and 3D and 6D Skull Tracking are not available for Body treatments.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



## Set Beam-On Time

You can also set the maximum beam-on time from this window. If a treatment beam requires more than the specified maximum beam-on time, that beam is divided into multiple beams when treatment paths are generated.

## Set Fraction

Use the bottom entry to set the number of fractions anticipated for the treatment. This value will be used to adjust beams that may have doses below the minimum threshold dose for the linear accelerator. You can reset this value when the plan is saved.

**WARNING: Never use node sets for one anatomical site to treat another anatomical site. Using the wrong node creates a risk of collision with the patient, because the couch model may not accurately represent the patient position. As a safety measure, TPS requires you to confirm the node sets selected. (see 3.4.).**

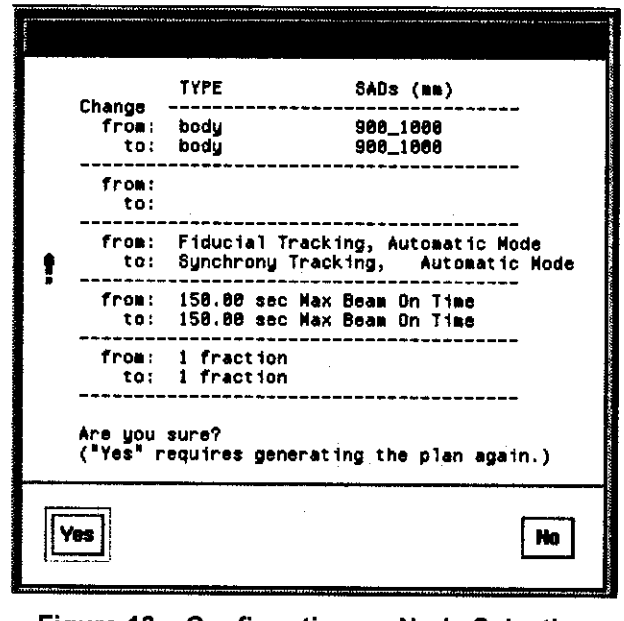



**Figure 13 Confirmation on Node Selection**



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



## Add Windows to the CT Displays

From the Display menu (*Figure 14 Display Menu, page 16*), you can click add window to add more Axial View windows to the new plan. (Make any obscured CT window visible by clicking the specific window under the Pop Window menu item.)

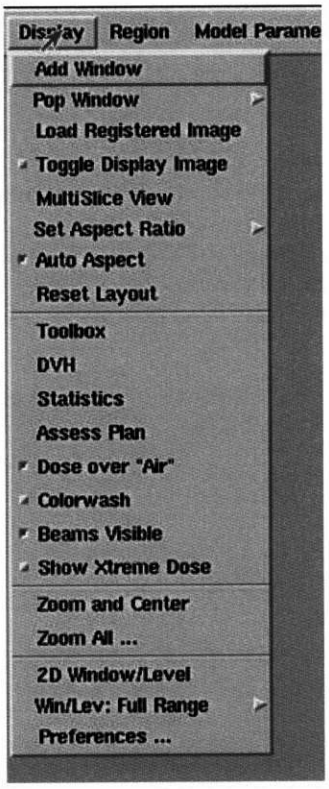



**Figure 14 Display Menu**

**NOTE:** To close the CT view windows, double-click the square close box on the upper left corner of the window frame.



731 Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



# Modify an Existing Plan

From the Plan menu (*Figure 2 Plan Menu, page 2*), click **LOAD**. The Load Plan window with a list of the available patients appears in the upper window. Select the desired patient by clicking the patient's name in the list. A list of available plans appears in the lower window. (see *Figure 15 Load Plan, page 17*). The **NEW** button activates when a patient is selected, allowing you to begin a new plan. If **NEW** is selected, a New Plan window appears (*Figure 10 New Plan, page 12*).

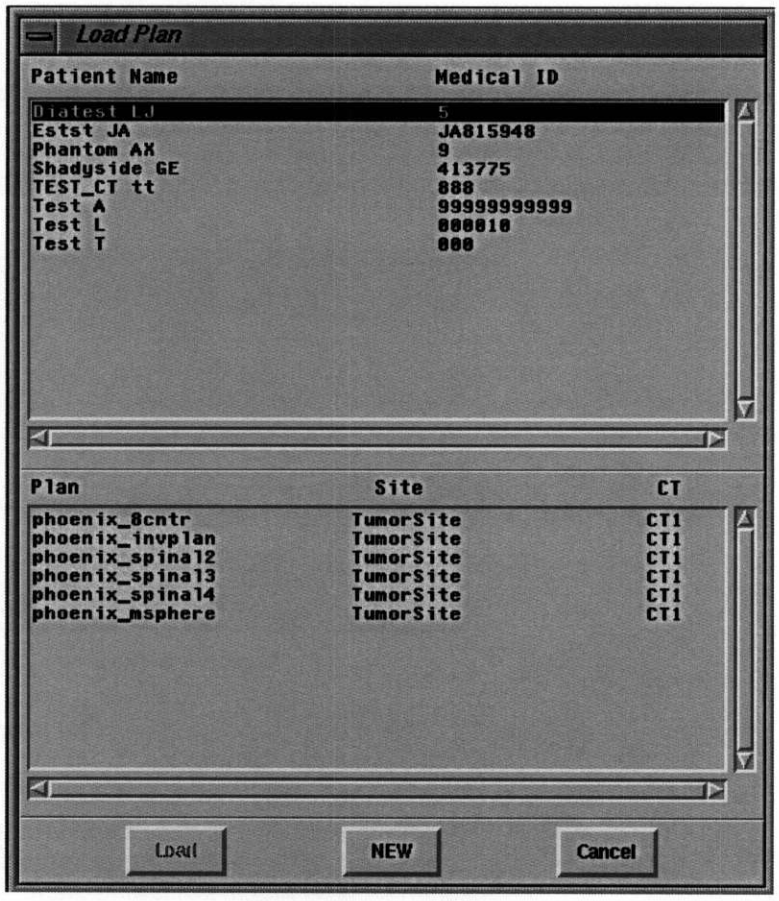



**Figure 15 Load Plan**

Select the desired plan file to modify by clicking the plan name in the lower window. For reference, this list also contains the CT and tumor site associated with each plan. Then click **LOAD** to load a plan. A Job In Progress message indicates Reading CT File. (*Figure 11 Job in Progress Message, page 13*). Follow the same process for changing the plan as you used in opening a new CT data file (see section, *Create a New Plan, page 12*).

**NOTE:** Double-clicking the desired item of the list in the lower window also activates the Load function.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



## Recover the Plan

Occasionally, a planning session may end unexpectedly. To recover a portion of the lost work, click Recover from the Plan menu (*Figure 2 Plan Menu, page 2*). A Job In Progress message indicates Reading CT file. (see *Figure 11 Job in Progress Message, page 13*). Follow the same process as in loading a saved plan. Save the recovered plan to a new plan name, then you can continue work on that plan. Generally, no more than five minutes of work should be lost.

## Save the Plan

Once a plan is created, save it for future modification or for delivery. Click **SAVE** from the Plan (*Figure 2 Plan Menu, page 2*) menu. The Save Plan window (*Figure 16 Save Plan, page 18*) appears. Type in the name of the plan you want to save and the number of fractions to treat. The prescribed dose is divided by the number of fractions to determine the dose per fraction.

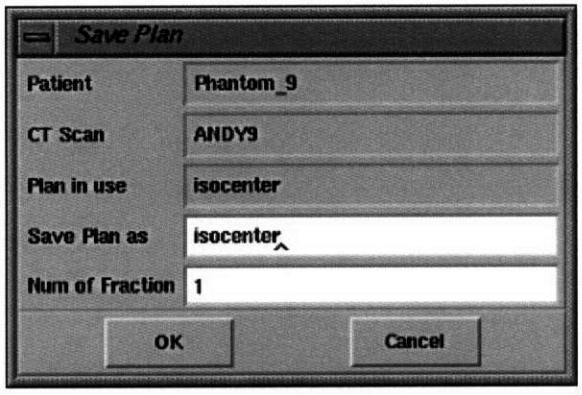



**Figure 16 Save Plan**

**NOTE:** TPS does not allow a plan to be overwritten by another plan. A plan can only be replaced by itself.

**NOTE:** Changes made from the Finetune menu are not saved with the plan. So, it is generally a good idea to manually record adjustments made with the Finetune menu.



733 Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



## Low Dose Warning

If a plan is generated with beams that have dose less than 1.0 MU in the treatment paths, the planning system warns you that these beams may not be delivered correctly (*Figure 17 Beams with Low Dose Warning, page 19*). To view the effect of discarding low dose beams, click **NO**, and use the Finetune menu to set a zero dose for beams that deliver fewer monitor units than half the number of fractions. Then, recalculate and display the dose distribution. Click **YES** to continue.

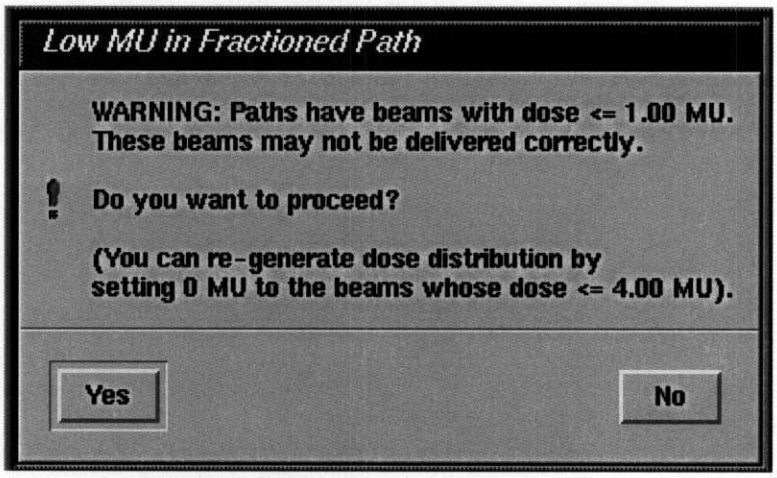



**Figure 17 Beams with Low Dose Warning**

## Invalid Dosimetric Calculation

If you save a plan before a valid dosimetric calculation is done, the plan is categorized as *non-deliverable.* A non-deliverable plan is also created if the Fiducial Tracking mode is designated and no fiducials have been identified. A non-deliverable plan will not be available for simulation or treatment and is saved for planning modification only. If you modify a plan that was saved for simulation or treatment and then save the modified plan without a valid dosimetric calculation, TPS notifies you with a non-deliverable plan warning message (*Figure 18 Non-deliverable Plan Warning, page 19*). A fiducial tracking plan without identified fiducials also cannot be delivered. TPS will also warn you of this situation.

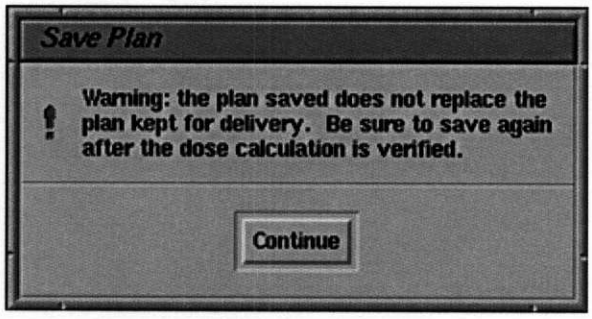



**Figure 18 Non-deliverable Plan Warning**

In contrast, when a deliverable plan is saved, a message appears to indicate that the database has been updated with a modified or a new plan. Click **CONTINUE** to close the message.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118 734

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



## Printing Plan Documentation

There are three methods for printing plan documentation.

1. Activate the snapshot function by right-clicking in the dark blue background of the SGI terminal. Use the mouse to draw a rubber band around the object you want to print and click **PRINT IMAGE**.
2. Print DVH tables, robot paths, and beam data from the **PRINT** function under Plan. The most recently saved version of the plan named in the title bar is printed.
3. Open Documentation under Plan to open print documentation. This function allows you to print a plan summary (*Figure 19 Plan Summary, page 20*) and path checklist (*Figure 20 Path Checklists, page 21*). You can select or omit data to print from either data sheet. The most recently saved version of the plan named in the title bar is printed.

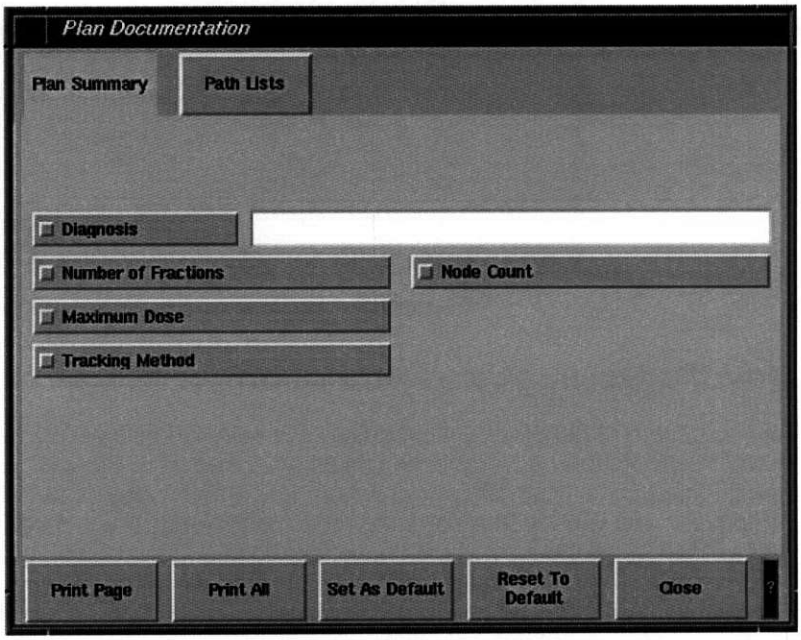



**Figure 19 Plan Summary**



735 Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



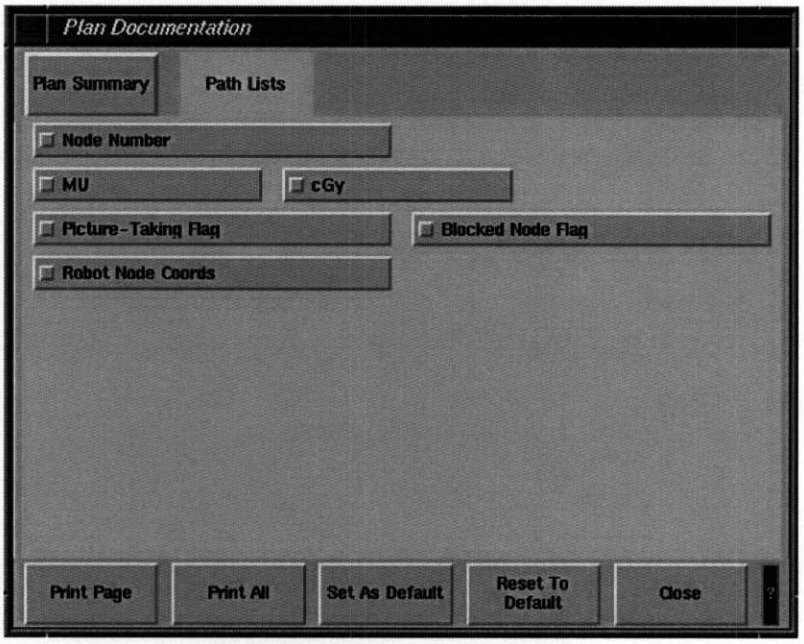



**Figure 20 Path Checklists**



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

736

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



# Delete the Plan

Click **DELETE** from the Plan menu (*Figure 2 Plan Menu, page 2*). The Delete Plan window (*Figure 21 Delete Plan, page 22*) appears. The upper portion contains the patient list. Select the patient, then the plan to be deleted from the list of plans in the lower window. Click **DELETE** to remove the Plan, and **CANCEL** to leave the plan unchanged. A message appears to confirm plan deletion.

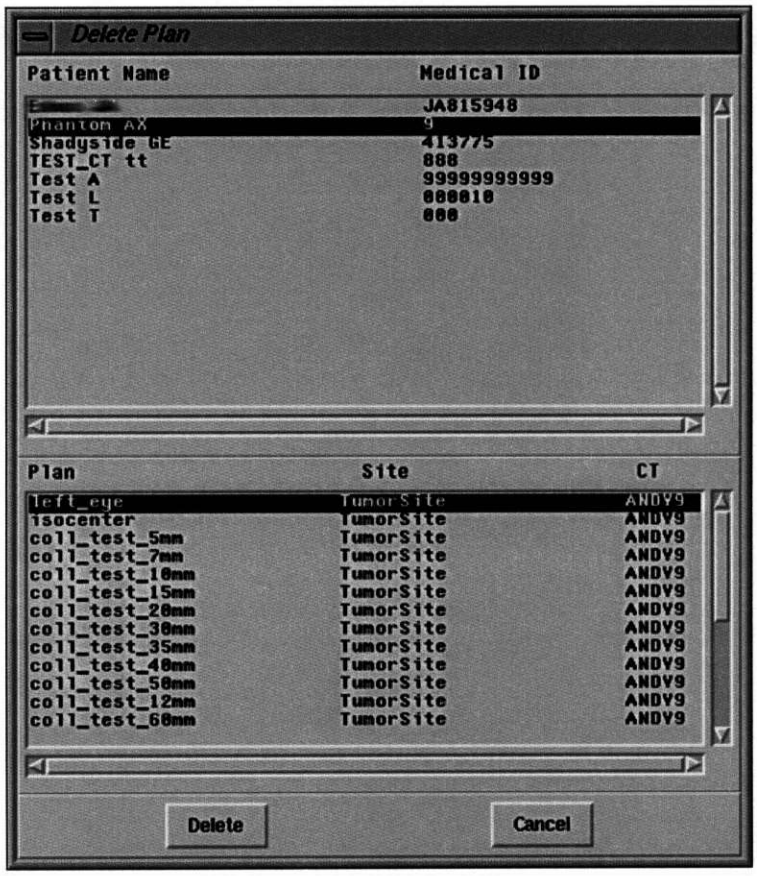



**Figure 21 Delete Plan**

**NOTE:** Plans cannot be deleted from a secondary Silicon Graphics workstation.



737 Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



# CT IMAGE DISPLAYS

After a plan is started, Axial View 1, Sagittal View, Coronal View, and 3D View windows display the patient's anatomical information. Most work is done in the Axial View 1 window.

## Features of 2D CT Displays

### Axial View Window

For Axial View windows (*Figure 22 Axial View, page 23*), the current axial slice number is shown in the lower-left corner. A length scale appears in the upper-right corner. Red vertical notches and green horizontal notches allow you to view different sagittal and coronal slices, respectively.

Only one region of interest (ROI), such as a tumor or critical structure, can be edited at a time. The name of the active region of interest appears at Axial View 1 window's upper-left corner. The isodose color legend appears at the lower-right corner of Axial View 1 after the dose distribution is calculated. These two features appear only in the Axial View 1 window.

If the patient was scanned head-first-supine (HFS), the axial view slice number increases from the patient's inferior to superior. The scrollbar at the left side of the toolbar at the bottom of the Axial View window is used to view different axial slices. Click the left arrow of the scrollbar to decrease and the right arrow to increase the axial slice number by one. Drag the middle block to view an arbitrary slice number. Click the space between block and arrows to increase or decrease slice number by ten.

**Figure 22 Axial View**



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118 738

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



# Sagittal View Window

The sagittal view window (*Figure 23 Sagittal View, page 24*) shows the current sagittal slice number at the lower left corner. The yellow vertical crosshair indicates the current axial slice and the green horizontal crosshair indicates the current coronal slice. The triangles at the ends of the crosshairs can be moved to change axial view 1 slice or coronal view slice. Sagittal view slice numbers increase from patient's right to left if the patient was scanned HFS.

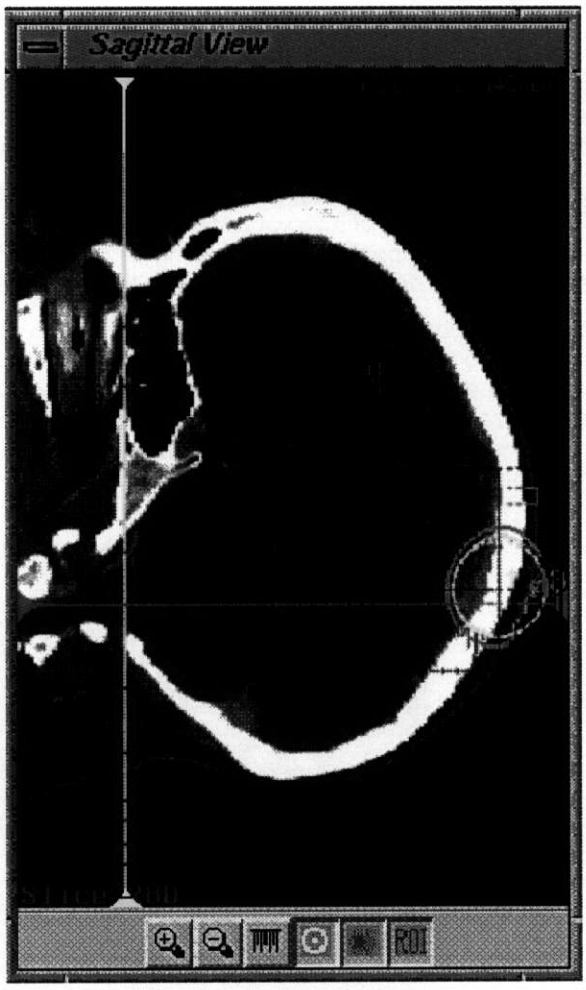



**Figure 23 Sagittal View**



739 Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



## Coronal View Window

The coronal view window (*Figure 24 Coronal View, page 25*) shows the current coronal slice number at the lower left corner. The yellow horizontal crosshair indicates the current axial slice and the red vertical crosshair indicates the current sagittal slice. The triangles at the ends of the crosshairs can be moved to change axial view 1 slice or sagittal view slice. Coronal view slice numbers increase from patient's posterior to anterior if patient was scanned HFS.

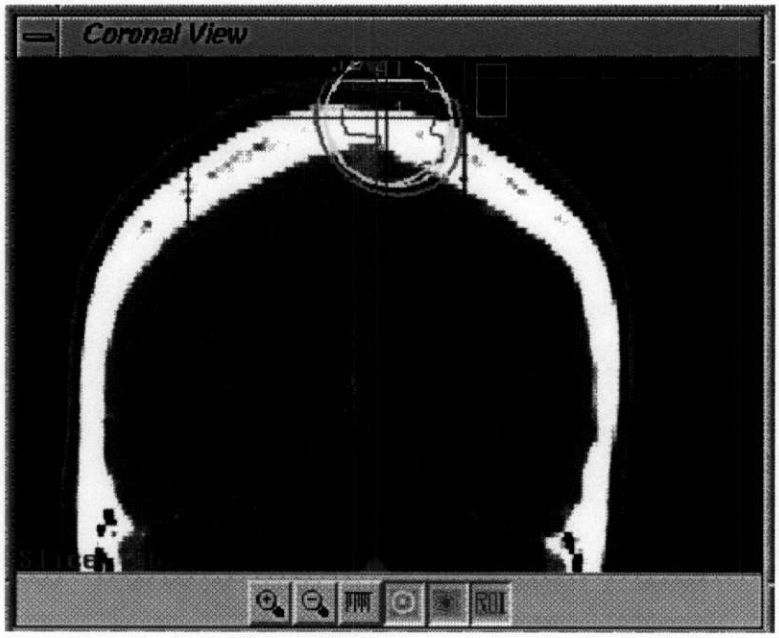



**Figure 24 Coronal View**

## CT Window Tools

The following tool buttons (*Figure 25 Axial View 1 Tools, page 25*) are located in the toolbar at the bottom of the 2D CT windows. Only the Axial View 1 window contains all the tools.

**Figure 25 Axial View 1 Tools**

### Zoom In

Select this option to change the cursor to an expanding square and indicate ZOOM IN mode. The display returns to the initial magnification setting. Drag a square in the associated CT window and the content inside the square is magnified to fit into the specific CT window.

An incremental zoom-in feature is available by pressing the <Control> key on the keyboard, while clicking the **ZOOM IN** button. The image will zoom in without changing the image center.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118 740

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



## Zoom Out

Returns the window magnification to the initial setting.

An incremental zoom-out feature is available by placing the cursor over the **ZOOM OUT** button and control-left click. The image zooms in without changing the image center.

## Copy

Copies the active region of interest (ROI) from the displayed CT slice to the clipboard.

## Paste

Pastes the ROI on the clipboard onto the CT slice being displayed. If a polygon for the active ROI is already on the current CT slice, it is replaced.

## Delete

Deletes the active ROI on the CT slice being displayed.

## Delete All

Deletes the active ROI on all the CT slices.

## Undo

Undoes the last (i.e., one level backward) Paste, Delete, or Delete All.

## Ruler

Changes the cursor to a dot inside a square, which indicates the ruler is in effect. It displays the distance between two selected points. Click at one point, hold, and drag the arrow to any other point in the window to display the distance in millimeters between the two points.

## Collimator Visibility Toggle

If the button is **ON**, the button looks pushed in, a circle, which represents the intersection of the prospective spherical dose distributions and the current CT section, is displayed. If the button is **OFF**, the circle does not appear.

## Isodose Curves Visibility Toggle

If the button is **ON**, the button looks pushed in, the dose distribution isodose lines are displayed. If the button is **OFF**, the lines do not appear.

## Region of Interest (ROI) Visibility Toggle

If the button is **ON**, the button looks pushed in, the regions of interest are displayed. If the button is **OFF**, the ROI do not appear.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



# Additional 2D Framing Tools

Additional tools are available from the menu bar to frame the 2D CT images.

## Zoom Factor

From the Display menu, click **ZOOM ALL** (*Figure 26 Zoom All, page 27*). A zoom factor window appears. Move the slider to set the same zoom factor for all three 2D windows.

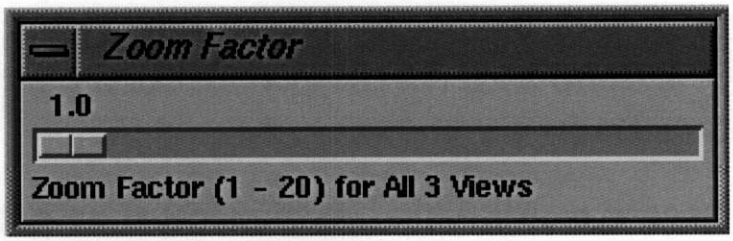



**Figure 26 Zoom All**

## Zoom and Center

The Zoom and Center function, also found in the Display menu, zooms the image so that each image is centered on the fine calculation box (the blue box with hashed edges seen in the 2D views) and so that the axial 1 view is sized slightly larger than the box. The sagittal and coronal views have the same zoom factor.

## Pan Image

Once you are satisfied with the window magnification, you can center each 2D image using the **PAN IMAGE** toggle button found under the Tools menu (*Figure 27 Tools Menu, page 27*). Turn pan image **ON** and the small button to the left of Pan Image is highlighted and a "+" double-arrow cursor (*Figure 28 Pan Image Cursor, page 28*) appears in the 2D windows. After centering each image as desired, remember to turn off the Pan Image mode.

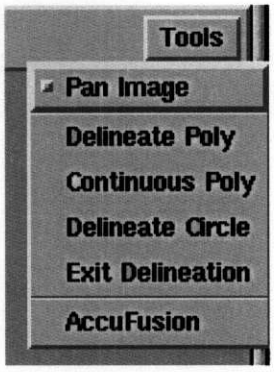



**Figure 27 Tools Menu**



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118 742

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



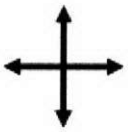


**Figure 28 Pan Image Cursor**

The size of the 2D windows can be increased and decreased by clicking the corner of the window and dragging it across the screen, however, this process can create a distorted image. The aspect ratio is automatically set if the **AUTO ASPECT** button is selected under the DISPLAY menu. If it is not, the correct aspect ratio can be reset with the Set Aspect Ratio menu (*Figure 29 Set Aspect Ratio Submenu, page 28*) under the Display menu. Set the aspect ratio individually for all three planar views. To return the display to its default arrangement, click **RESET LAYOUT** under the Display menu.

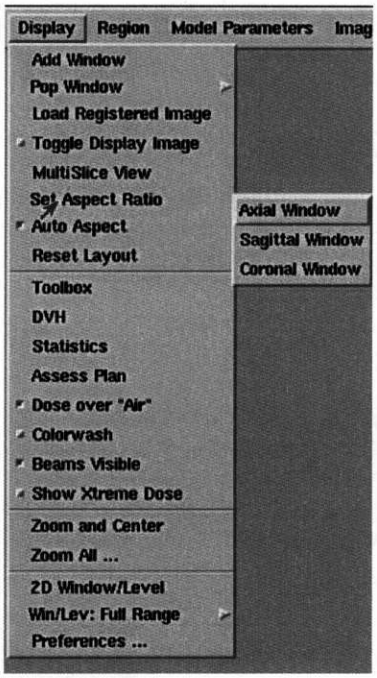



**Figure 29 Set Aspect Ratio Submenu**



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



# Multiple Slice Axial View

In addition to the individual 2D CT windows, you can simultaneously display twenty axial views with the Multiple Slice CT display (*Figure 30 Multiple Slice CT, page 29*), opened from the Display menu. The zoom level of the display is the same as the Axial 1 View when the multiple slice view is first opened. To change the zoom level, change the zoom level on the Axial 1 View and click **REFRESH** from the Multiple Slice CT display. The starting slice is selected from the slider at the lower left. That slice and the next nineteen slices are displayed.

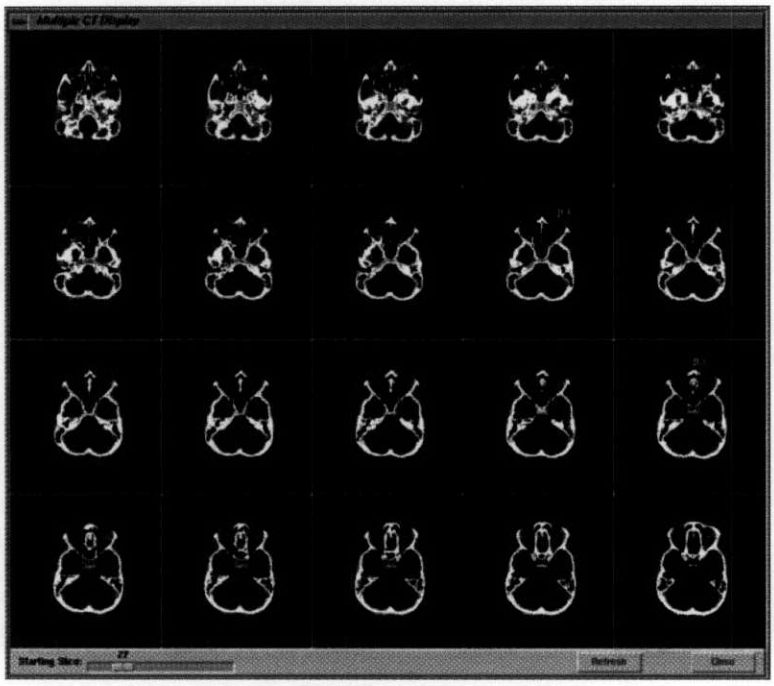


**Figure 30 Multiple Slice CT**



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118 744

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



# Display Registered Image

If the patient has an alternative image that has been registered with the treatment CT image, you can view the plan overlain on that image if:

The second image is registered with the CT using the CyberKnife System AccuFusion module, or it is imported into the CyberKnife System, already registered and resampled into the field of view of the CT.

From the Display menu, click **LOAD REGISTERED IMAGE**. The Load Registered Image interface (*Figure 31 Load Registered Image, page 30*) will appear.

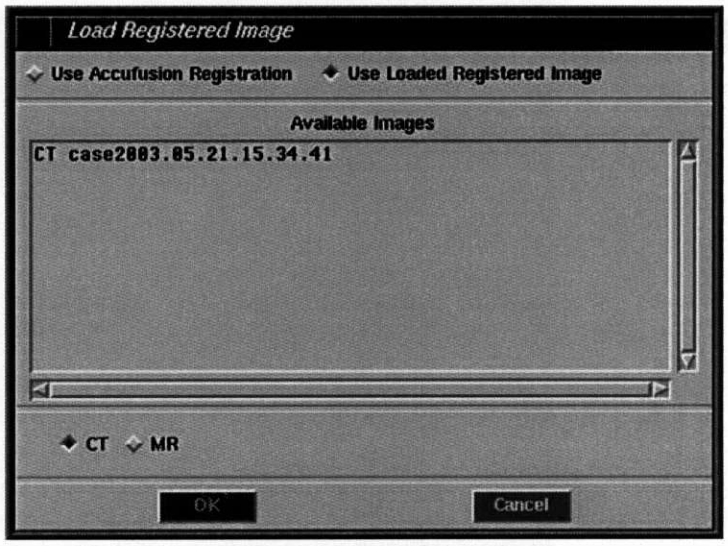



**Figure 31 Load Registered Image**

Select whether the image registration was performed using AccuFusion or loaded from another registration system. If AccuFusion registered the images, simply click **LOAD**. A Job in Progress window will appear while the image is loaded and transformed. If the registered image was loaded directly a list of available images will appear. Select the appropriate image and image modality. Then click **LOAD**. A Job in Progress window will appear while the registered image is loaded.

Immediately after it is loaded, the displayed image will be the registered image. To toggle between display of the primary CT and registered image, click **TOGGLE DISPLAY IMAGE** from the Display menu.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

745

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



# 3D View Window Tools

Images displayed in the 3D View window can be manipulated in several ways. Use the designated mouse button to perform the following:

- **LEFT BUTTON** - rotation and throw
- **MIDDLE BUTTON** - translation
- **RIGHT BUTTON** - scaling

## Rotation and Throw

The image can be rotated along the horizontal and vertical axes in the plane of the window. For rotation, click and hold, then move the mouse. To rotate about the vertical axis, move in the horizontal direction. To rotate about the horizontal axis, move in the vertical direction. To stop the rotation, stop moving the mouse and release the button. To cause the image to keep rotating (the *throw* effect), release the button while moving the mouse. The more rapid the movement at the moment the button is released, the faster the image rotates. To stop the rotational motion, click in the 3D view.

## Translation

Translation can be accomplished along any line in the plane of the window. Place the cursor on the 3D image, middle-click and, then move the mouse. To stop the translation, stop moving the mouse and release the button.

## Scale

To magnify the image, right-click and hold, then move the mouse horizontally to the right. To shrink the image, move the mouse horizontally to the left. The image center is preserved, so you should translate the 3D image to the center of the window before magnifying to keep the image displayed in the window.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118 746

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



## Display Options Menu

With the Display Options Menu, you can toggle **on** or **off** certain features.

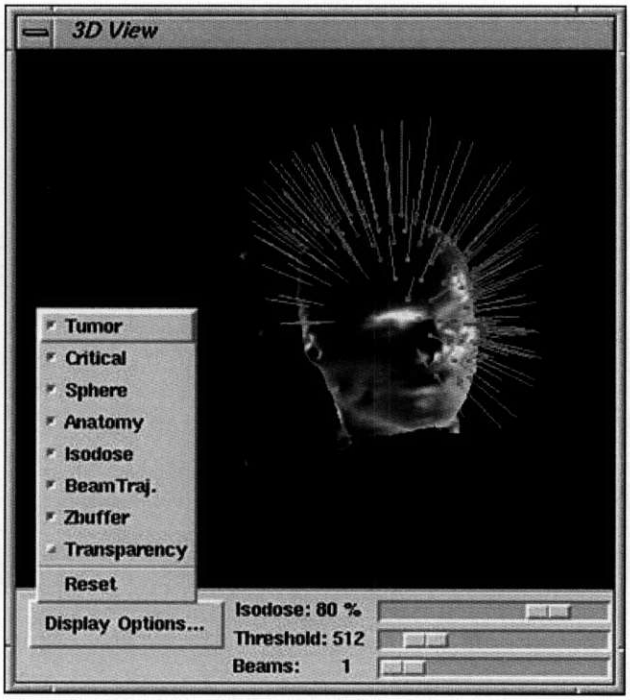



**Figure 32 3D View Tools**

**Display Options Menu features:**

- **Tumor** - toggles the red 3D rendering of the defined lesions.
- **Critical** - toggles the green 3D rendering of the critical structures.
- **Sphere** - toggles the yellow sphere representing the collimator size.
- **Anatomy** - toggles the 3D reconstruction of the patient CT study.
- **Isodose** - toggles the 3D rendering of the isodose surface defined by the Isodose slider (described below) once the dose has been calculated.
- **Beam Traj.** - toggles the beam trajectories that terminate at the center of the target or the target surface.
- **Z buffer** - toggles the hidden surface removal feature.
- **Transparency** - toggles the CT image between fully visible to translucent so that the internal structures and beam trajectories can be visualized in relation to the CT image.
- **Reset** - initializes all the previous functions including rotation, translation, and scaling.



747 Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



## 3D View Sliders

The **Isodose** slider sets the percentage isodose surface of dose distribution once the dose has been calculated. The default is 80 (percent). Clicking the space between the slider block and slider-bar ends changes the percentage value by 10.

The **Threshold** slider sets the cut-off CT number for head rendering. A value of 500 allows the skin surface to be seen. Usually, a value of 1200 masks the headrest, but allows the skull to be seen. To prevent the system from drawing the patient's surface anatomy, select a value greater than 3000. Clicking the space between slider block and the slider-bar ends changes the threshold value by 50.

The **Beams** slider selects the highlighted beam in the 3D View. The highlighted beam is green if it is turned **on**, and is yellow if flagged as passing through critical region. The highlighted beam is red if it is turned **off**. All other beams are light blue.

# The Reference Plan

The Reference Plan window allows comparison of two plans (the active and reference plan) that treat the same lesion. The reference plan can only be viewed; it cannot be changed. Open the Reference Plan window by selecting Axial Window from the Pop Window submenu of the Display menu. (*Figure 33 Pop Window Submenu, page 33*).

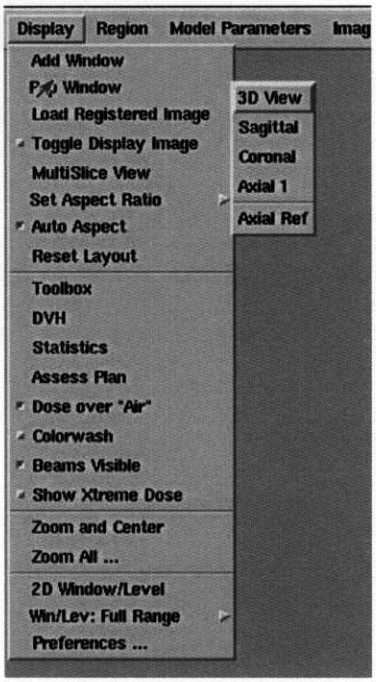



**Figure 33 Pop Window Submenu**

The Reference Plan window (*Figure 34 Axial Reference, page 34*) appears. The slice, zoom, isodose line status, and sphere display status are always the same as the Axial 1 view. The CT viewed is the same as for the active patient plan. The window includes the slice number and the scale. It does not note the active region, nor does it contain an isodose color legend.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118 748

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



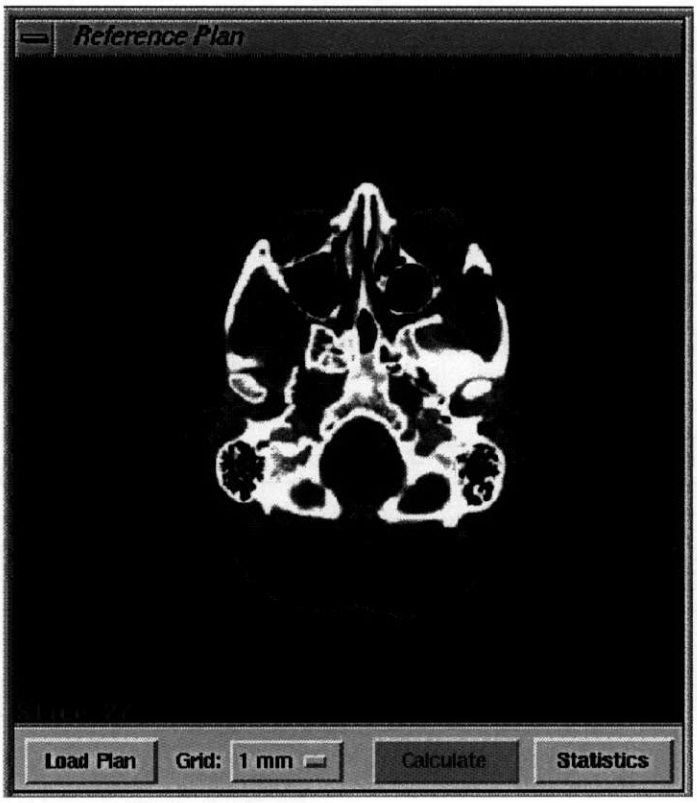



**Figure 34 Axial Reference**

This display can show a previously saved plan or sum multiple plans delivered to the same patient. To do either, click **LOAD REFERENCE PLAN**. The Load Reference Plan window appears. (*Figure 35 Load Axial Reference Plan, page 35*). This window looks similar to the Load Plan window, except the patient list is empty, because the only option available is the patient whose treatment is actively being planned. The names of saved plans are listed in the Plan list.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

7\$9

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



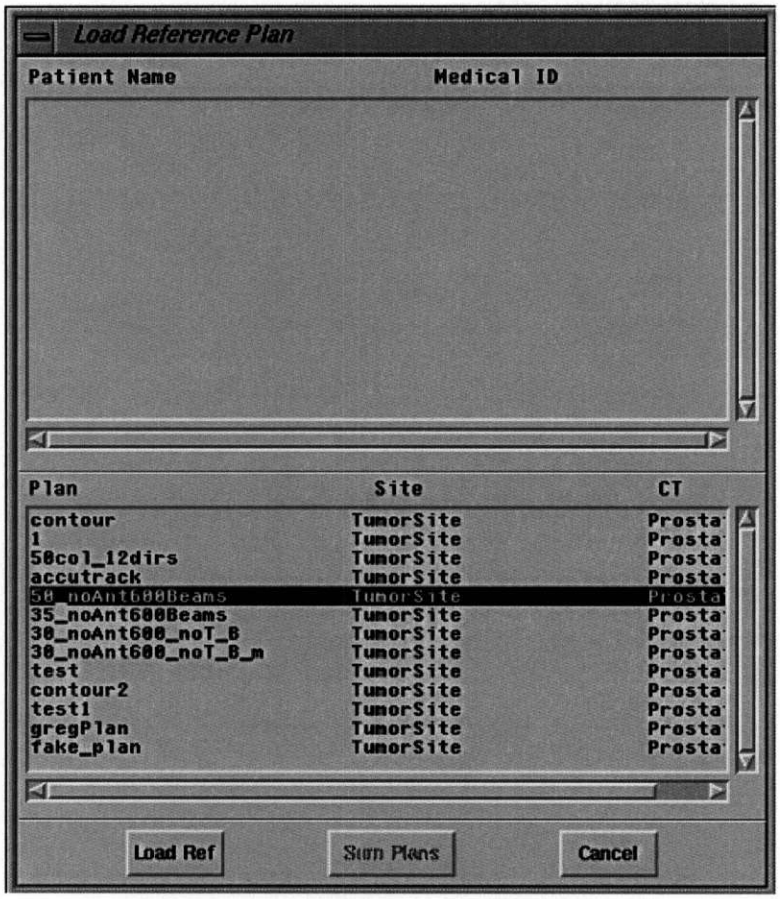



**Figure 35 Load Axial Reference Plan**

## View a Single Plan

To view a single plan, select it and click **LOAD REF** to display it. (When one plan is selected, the **SUM PLANS** button is not available.) The name of the plan selected is augmented onto the Reference Plan title. The plan is loaded and the dose distribution calculated. The planning system has three methods of comparison: dose statistics (*see module, Treatment Planning, section, Statistics, page 81*), dose volume histograms (*see module, Treatment Planning, section, Dose Volume Histogram, page 78*), and isodose lines.

## Sum Plans

To sum multiple plans, select the plans and choose **SUM PLANS** to display the result. (When more than one plan is selected, the **LOAD REF** button is not available.) The plans are loaded, summed, and the dose distribution is displayed. The title bar changes so that it reads *Sum Plans for <name_ID>*, where name is the patient's last name and ID is the patient's medical identification number. The same three comparison methods can be used to assess the distributions for summed plans.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118 750

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



## Calculation Grid

The calculation grid for the reference plan or summed plans is the same as for the first plan selected from the plan list. The grid size can be increased to include tumors or critical structures that do not initially fall within the displayed calculation region. If the selected grid size is larger than the CT study, a warning appears and the last grid size remains in effect. Changing the grid size automatically recalculates the dose distribution. You can also manually recalculate dose distribution for the reference plan or summed plans by clicking **CALCULATE**.



751

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



# Treatment Planning
## Table of Contents

**Identify and Delineate Regions of Interest** ..... 1
- **Import a DiCOM RT Structure Set** ..... 1
- **Adjust CT Window and Level Values** ..... 3
- **View Different CT Sections** ..... 5
- **Specify Regions of Interest (ROI)** ..... 6
  - Rename an ROI ..... 7
  - ROI Priorities ..... 8
- **Delineate a Polygon in the Axial View** ..... 8
  - Select ROI to Delineate ..... 8
  - Outline an ROI in a Plane ..... 9
  - Delineate a Circular ROI ..... 9
  - Delineate an ROI in 3D ..... 10
- **Automatically Draw Polygons** ..... 10
  - CT Number Delineation ..... 11
  - Grow Existing Polygon Delineation ..... 12
  - Filter ROI Vertices ..... 13

**Identify CT Center** ..... 14
- **Fiducial Tracking Mode** ..... 14
  - Identify a Fiducial ..... 15
  - Mark a Fiducial ..... 16
  - Fiducial Tracking Using DRR ..... 17
- **Skull Tracking Mode** ..... 19

**AccuFusion™ Image Fusion** ..... 21
  - Start AccuFusion ..... 22
  - Initiate Fusion Process ..... 23
    - Create a New Fusion ..... 23
    - Modify an Existing Fusion ..... 24
  - CT/MR Images Displays ..... 25
    - 2D Image Displays ..... 25
    - Display Options ..... 27
  - Automatic Fusion Procedure ..... 28
    - Specify Landmarks ..... 28
    - Automatic Fusion ..... 29



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

752

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



Manual Fusion Procedure ..... 30
Keyboard Adjustment ..... 30
Mouse Adjustment ..... 30
Fusion Results ..... 30
Apply Results to Treatment Planning ..... 30
Save Results ..... 30
Exit AccuFusion ..... 30
**Model the Depth ..... 31**
**Program Treatment Beams Using Wizards ..... 33**
**The Toolbox ..... 33**
Select and Position Center ..... 34
Wizards ..... 35
**Generate Beam Geometries ..... 36**
Single Center ..... 36
Multiple Center ..... 37
Multi-Centers Beam Assignment ..... 37
Center Assignment ..... 39
Multi-Centers Dose Assignment ..... 40
Conformal Shape ..... 41
Conformal Beam Assignment ..... 41
Collimator Assignment ..... 42
Tumor Assignment ..... 43
Conformal Dose Assignment ..... 44
**Assign Dose to Beams ..... 45**
Single Center Dose Assignment ..... 45
Forward Planning Dose Assignment ..... 45
Multiple Center Dose Assignment ..... 47
Inverse Planning Dose Assignment ..... 48
Assign Constraints ..... 50
Set Aggression ..... 52
Select Tumor Constraint Type ..... 54
Set Manual Constraints ..... 55
Determine Plan ..... 58
Assess Constraint Violations ..... 58
Individual Tumor Constraints ..... 59
**Finetune Beam Geometry and Dose ..... 60**
Beam Selection ..... 61
Selection Options ..... 61
Selection Logic ..... 64
Modify Selected Beams ..... 65
Target Selected Beams ..... 66
Set Collimator Size ..... 66
Set Beam Flags ..... 66



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



Modify Beam Weights ..... 66
Set Beam Dose ..... 67
Set Dose Tolerance ..... 67
Forward Planning ..... 67
Multiple Tumor Inverse Planning ..... 68
Scaled Dose ..... 68
**Finetune Planning History ..... 69**
General Purpose Functions ..... 70
Beam and Center List ..... 70
Keep Beam Setting ..... 71
Flag Critical Beams ..... 72
Close Finetune Menu ..... 72
**Export Data from the CyberKnife User Control Console ..... 72**
**Plan Evaluation Tools ..... 73**
**Plan Evaluation Tools ..... 73**
Treatment Dose Calculation ..... 73
Dose Calculation Volume ..... 73
Reference Dose Location ..... 74
Calculation Menu ..... 74
Contour Correction ..... 76
Point Dose ..... 76
Isodose Lines ..... 77
Isodose Surface ..... 78
Dose Volume Histogram ..... 78
Statistics ..... 81
Colorwash ..... 82
Reference Plan ..... 83
Plan Summary ..... 84
Plan Assessment ..... 85
**Simulations ..... 87**
Manipulator Motion Simulation ..... 87
Phantom Simulation ..... 89
Overlay CT ..... 89
Determine Film Location ..... 90
Adjust Film Location ..... 91
Dose Distribution on Overlaid CT ..... 91
**Multiple Workstation Option ..... 92**
Open Secondary Workstation ..... 92
Patient Planning Locks ..... 92
Save Plan from a Secondary Workstation ..... 93
End Treatment Planning System ..... 94



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



**Dose Generation Algorithms** ..... **94**
Forward Planning ..... 94
Single Center Inverse Planning ..... 94
Multiple Center Inverse Planning ..... 95
Multiple Center Dose Exact Solution Algorithm ..... 96
Multiple Center Dose Iterative Algorithm ..... 96
Conformal Shape Inverse Planning ..... 96
Beam Geometry Algorithm ..... 96
Dose Weighting Algorithm ..... 97
**Dose Calculation** ..... **98**
Standard Algorithm ..... 98
Coarse vs. Fine Grid ..... 99
Density Compensation ..... 100
Contour Correction ..... 101
Example Error Assessments ..... 101
Acceptance Test Error Evaluation ..... 101
Film Test Study ..... 101
**Glossary** ..... **104**
Terms ..... 104
Acronyms and Abbreviations ..... 104



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



# TREATMENT PLANNING

The On-Target™ Treatment Planning System (TPS) requires that a set of parameters be defined before a valid plan can be generated. Those parameters include identifying the CT center, specifying depth model, and delineating regions of interest (ROI).

## IDENTIFY AND DELINEATE REGIONS OF INTEREST

Regions of interest (ROI) can be imported as DiCOM Radiotherapy Structure Sets (DiCOM RTSS) or delineated interactively using the mouse. You can define up to ten tumors and ten critical structures. A tumor or a critical region is defined by drawing a polygon with user-specified vertices in any Axial View window. The polygon is delineated on a set of axial CT slices to cover the entire tumor or critical region. Tools (*see module, Treatment Planning System, section, CT Image Displays, page 23*) are implemented to aid the delineation process.

You must delineate each critical structure to enable the beam selection algorithm to automatically set the beam weight to appropriate values for beams passing through a critical region.

### Import a DiCOM RT Structure Set

The CyberKnife Treatment Planning System can import Regions of Interest delineated on other workstations and transferred using the DiCOM RTSS standard. Only one DiCOM RTSS instance can be imported for a given plan and must be imported at the beginning of the planning stage when a new plan is created (*see module, Treatment Planning System, section, Create a New Plan, page 12*). You can load up to ten lesions and ten critical structures.

**NOTE:** If a DiCOM RTSS has more than 20 Regions of Interest, only the first 20 will be available for import.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118 756

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



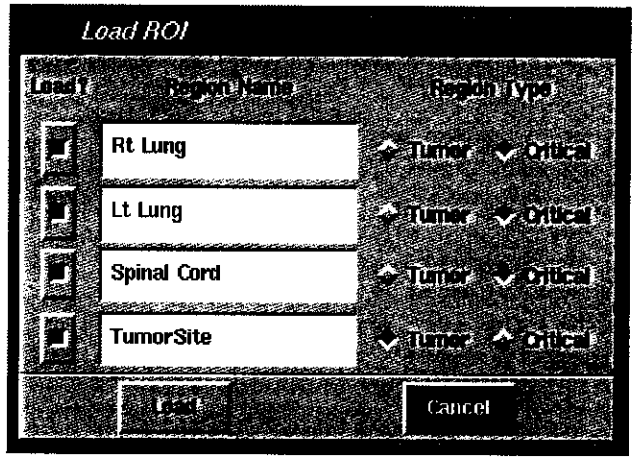



**Figure 1 Load DiCOM RTSS Contours**

If a DiCOM RTSS is opened with a new plan, the Load DiCOM RTSS Contours window appears (*Figure 1 Load DiCOM RTSS Contours, page 2*) after the Node Selection window. Use the left button (**LOAD?**) to choose whether or not to import a particular Region of Interest. The system will automatically suggest that some ROIs (such as the Skin or Body of the patient) should not be loaded. You can rename an ROI. Designate the ROI as either a Tumor or Critical Structures. (The initial setting for most Regions of Interest is a Critical Structure. Some region names, however, such as PTV or TumorSite, are initially set to Tumor.)

**NOTE:** Some delineation workstations:

- Require you to delineate the entire surface of the patient anatomy in order to export a DiCOM RTSS. These ROIs are usually very large and can overload the graphics processor. It is recommended that these delineated structures never be imported.
- Allow you to contour ROIs in planes other than the axial plane. If a non-axial defined ROI contour is imported to the CyberKnife® System, it may not display properly.
- Allow you to delineate more than one contour of the a single ROI on one axial slice. This capability is not supported by the CyberKnife System. If a ROI has more than one contour on a slice only one of the contours will be imported.
- Allow you to automatically modify the name of the first tumor on the list, if the chosen name has something other than alphanumeric and underscore characters.



757

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



# Adjust CT Window and Level Values

Whenever a new set of CT data is loaded, the TPS assigns default Window and Level values. The factory default is preset to Window 100 and Level 1024. You can select a different default using the Preference menu. You may need to adjust the Window and Level settings to see the tumor target or critical structures.

**To adjust the Window or Level, use the following procedure:**

**Step 1.** Drag the upper slider of the Window & Level section in the Toolbox window (*Figure 2 Window (upper) and Level (lower) Sliders, page 3*) to the desired Window value.

**Step 2.** Drag the lower slider of the Window & Level section in the Toolbox window to the desired Level value.

**Step 3.** Click the space between the slider block and the slider-bar ends to change the value by 10.

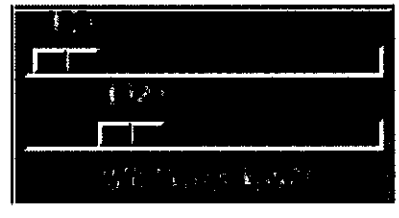


**Figure 2 Window (upper) and Level (lower) Sliders**

**NOTE:** The CT number scale follows the Hounsfield Units scale, but with 1000 added to all CT numbers. This avoids the use of negative numbers for tissues less attenuating than water.

Alternatively, click **2D WINDOW/LEVEL** from the Display menu. The 2D Window/Level window appears. (*Figure 3 2D Window/Level, page 4*) Adjust the window and level by moving the intersection of the crosshairs with the mouse.

**NOTE:** The left button allows changes to Window and Level simultaneously. The middle button only allows changes to Window. The right button only allows changes to Level.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118 758

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



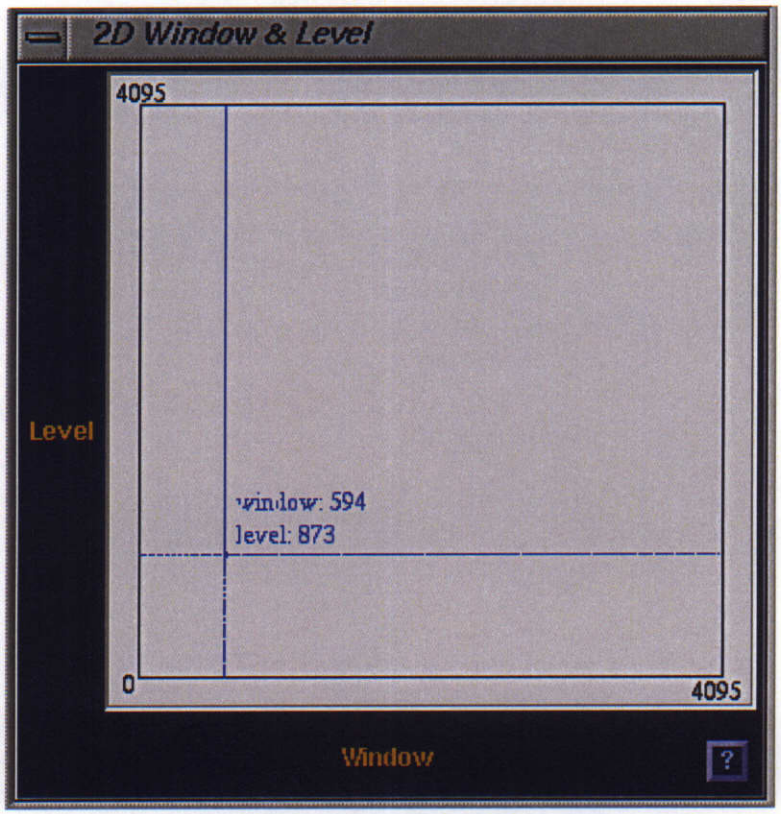



**Figure 3 2D Window/Level**

The default range for the Window/Level adjustments is 0-4095. This range assumes that the data is stored within a 12-bit data field. Some image types store and use 16-bits of image data. From the Display Menu, use Win/Lev range (*Figure 4 Select the Range for Window & Level Adjustments, page 5*) to use the full range of the image data or a 14-bit portion of it. If full range is set, the window/level range will be up to 4095 for 12-bit data or 65535 for 16-bit data.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



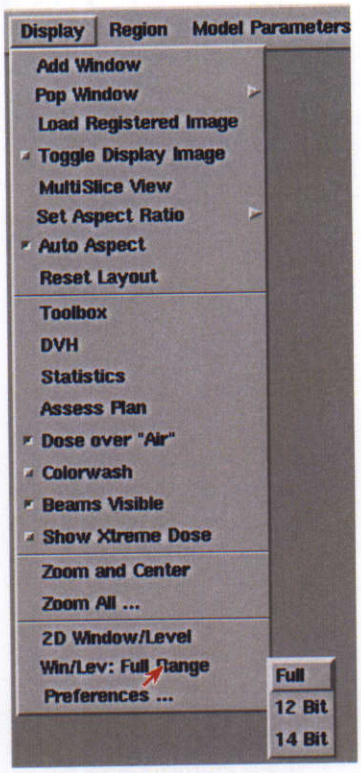



**Figure 4 Select the Range for Window & Level Adjustments**

## View Different CT Sections

Use the scrollbar in the Axial View windows to view other axial CT sections.

- **Axial or Coronal View**, drag one of the vertical triangular notches (red) to display a different CT section in the Sagittal View.
- **Axial or Sagittal View**, drag one of the horizontal triangular notches (green) to display a different CT section in the Coronal View.
- **Coronal View or Sagittal View**, drag one of the yellow triangular notches to display a different CT section in the Axial View 1.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



# Specify Regions of Interest (ROI)

From the Region menu (*Figure 5 Region Menu, page 6*) of the menu bar, click a **TUMOR SITE, SOFT BOUNDARY**, or one of the ten critical structures to make it active. The Tumor Site menu lists the available tumors you can select. Typically, the list of tumor sites include all tumors previously delineated and one tumor not yet delineated.

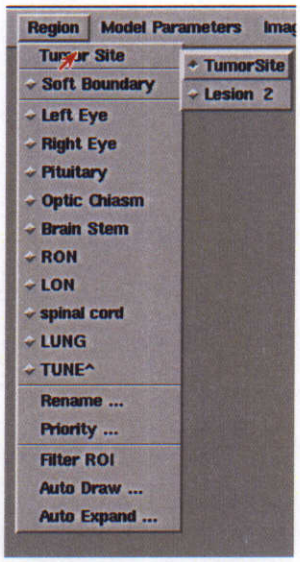



**Figure 5 Region Menu**

Only one ROI, the active one, can be delineated at a time. The active ROI label is shown on the upper left corner of Axial View 1.

The tumor polygons are in shades of red: bright red for the active one, dark red for the others.

The soft boundary polygon is light-blue, and the critical structure polygons are in shades of green: light-green for the active one, dark green for others.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

761

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



## Rename an ROI

The Rename function of the Region menu (*Figure 5 Region Menu, page 6*) allows you to assign a user-specific name to critical structures and the tumor target. Click **RENAME** and the Rename Regions window appears (*Figure 6 Rename Regions of Interest, page 7*). Update the desired names in the respective text fields and click **OK** to change or **CANCEL** to leave the names unchanged.

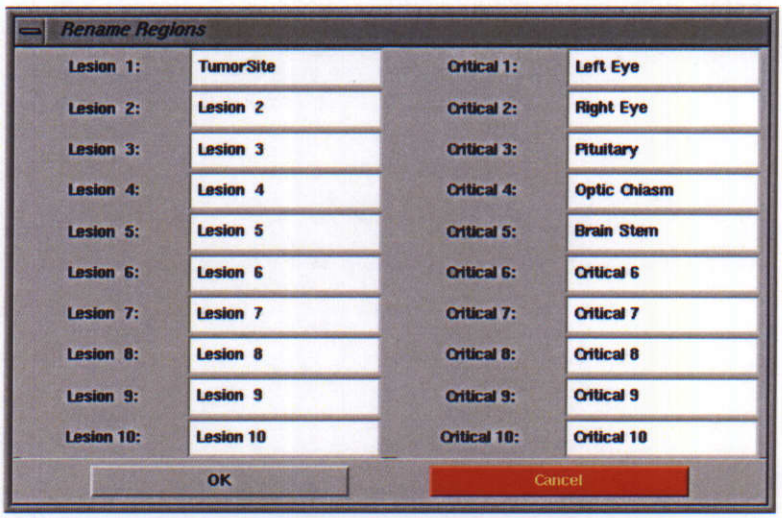



**Figure 6 Rename Regions of Interest**

**NOTE:** The Treatment Site name used in the delivery system is defined by the name of Lesion 1. The soft boundary region is used mainly for inverse planning to define a constraint that does not apply to tumor or critical structures. It cannot be renamed.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



## ROI Priorities

Each ROI has a priority of 1 through 21 given to it. This priority resolves overlapping regions. The highest priority is one, and the lowest priority is 21. If two or more regions intersect at a voxel, the voxel is identified with the region with the highest priority. Priorities are set with the Set Region Priorities window, (*Figure 7 Set Region Priorities, page 8*). To display this window, select the **PRIORITY** button from the Region menu (*Figure 5 Region Menu, page 6*). For *Inverse Planning*, a voxel has only one region type. For volume calculations, areas of overlapping regions of interest are treated as part of each region.

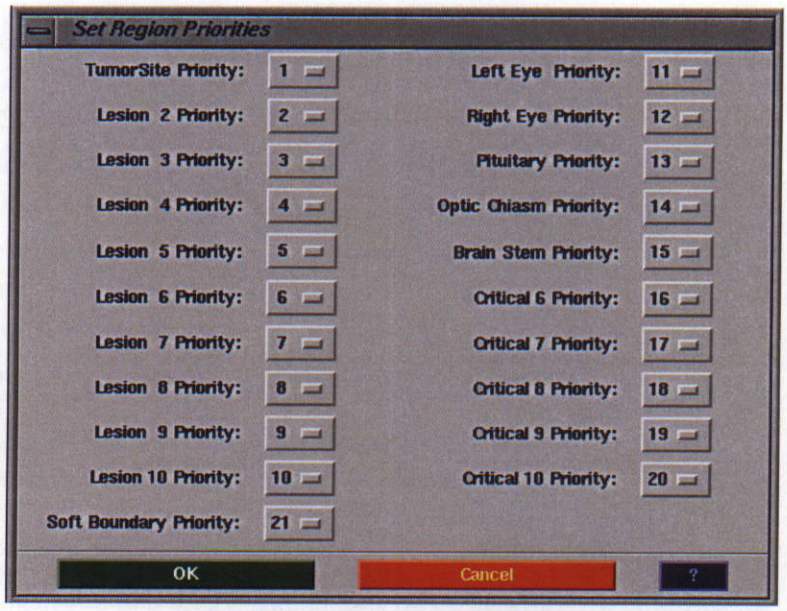



**Figure 7 Set Region Priorities**

# Delineate a Polygon in the Axial View

Regions of interest are composed of polygons that can only be drawn in the axial slices of the CT (or MR) study. There are several methods for drawing polygons.

## Select ROI to Delineate

The default ROI to delineate is the tumor site or Lesion 1. Two options are available to change the active ROI. The primary method is to select the desired region from the Region menu (*Figure 5 Region Menu, page 6*). The region can also be changed by picking the boundary of the desired region while the <Shift> key is pressed.

**WARNING: Selecting the boundary of an ROI changes the active region of interest. When drawing regions, be certain that the desired region is the active region.**



763

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



## Outline an ROI in a Plane

**Hold the <Shift> key and start delineating a polygon using the following procedure:**

**Step 1.** Click to add a vertex

**Step 2.** Click any side of the polygon to insert a vertex

**Step 3.** Select and drag an existing vertex to modify its location

**Step 4.** Click the middle button at a vertex to delete it.

You can hold the <Alt> key, click, and use the cursor as a pencil to draw around the region of interest. The region of interest is drawn to a finer resolution if the motion of the cursor is slower. Release the left button when the region is drawn.

**NOTE:** The minimum polygon side is 2 mm.

You can draw with one hand (and not hold keys with the other hand) using the Tools menu. Choose from two drawing modes. Delineate Poly is the same as using the <Shift> key and allows point-by-point drawing. Continuous Poly is equivalent to using the <Alt> key and allows hand-drawn delineation.

The mouse will grab a vertex or a polygon side if the pointer is within five screen pixels from it. Otherwise, the polygon connects the last vertex to the first vertex automatically. Release the <Shift> key to stop delineation.

To delete nodes, hold either the <Shift> or <Alt> key down and middle-click the node to be deleted. To delete the active polygon on a slice, click the **DELETE** button in the toolbar.

**WARNING: The polygon must NOT be self-intersecting. Otherwise, an error on volumetric calculation of the ROIs will result.**

## Delineate a Circular ROI

**Hold the <Ctrl> key and drag a circular ROI:**

**Step 1.** Click at a spot on the boundary of the desired region.

**Step 2.** Drag the mouse along a diameter of the ROI to size and orient it.

**Step 3.** Release the button when the ROI is correctly sized and oriented.

**Step 4.** Release the <Ctrl> key to complete the operation.

The circular ROI replaces the active ROI when you release the mouse button. The circle then may be modified to any shape by following the procedure described for general polygons (*section, Outline an ROI in a Plane, page 9*).

If you want to draw using only one hand (and not press keys with the other hand), enter the drawing mode from the Tools menu. Delineate Circle allows a circle to be drawn in the displayed axial slice.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

764

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



## Delineate an ROI in 3D

Move through CT slices to ones that contain ROIs. Outline the ROI as seen in each image in which the structure of interest is visible. The ROIs delineated on multiple-axial-slice are stacked up to form a volume. The volumetric ROI appears in the 3D View window simultaneously as the delineation is performed, with tumor in red and critical structures in green. As an aid to visualizing the ROI in 3D, set the red and green notches intersecting at the ROI so that it is visible in the sagittal and coronal views.

As an additional aid, the active ROI may be copied from any other axial section. Display the CT section in which the original ROI is active; then click the **COPY** button on the toolbar. Select the destination CT section and click the **PASTE** button. Modify the pasted ROI (*section, Outline an ROI in a Plane, page 9*).

To delete the active ROI polygon on all slices, click the **DELETE ALL** button in the toolbar.

# Automatically Draw Polygons

Sometimes it is easier to automatically draw polygons than manually draw them from the view anatomy in the 2D windows. There are two methods to automatically draw polygons. The first uses the CT numbers to find the outline of a polygon. It is generally only effective for high contrast objects, such as the lung. The second method allows you to define a polygon by "growing" an existing polygon. This feature is useful when a defined treatment volume around a smaller tumor volume is desired.



765 Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



## CT Number Delineation

Select **AUTO DRAW** from the Region menu (*Figure 5 Region Menu, page 6*) to display the window (*Figure 8 Automatic Polygon Delineation, page 11*) you will use to automatically generate polygons using the CT number. The default Window (820) and Level (10) are good for delineation of the lung. The Window and Level display can be modified by changing the top two sliders. The third slider sets the spacing of the vertices. The lower the number, the denser the node spacing.

If the **ON/OFF** button is On, a polygon is drawn when you click in the Axial 1 View window. To draw the polygon, click near the border inside the desired region. The polygon can be modified by using a different starting point, changing the Window and Level settings, or manually editing the vertices.

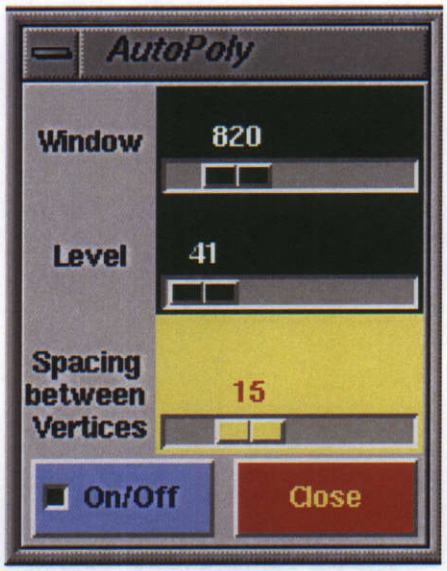



**Figure 8 Automatic Polygon Delineation**



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



## Grow Existing Polygon Delineation

To draw an ROI by "growing" a previously drawn ROI, select **AUTO EXPAND** from the Region menu (*Figure 5 Region Menu, page 6*). The menu in appears. The basis region is a preexisting polygon. The grown region is the ROI you wish to generate.

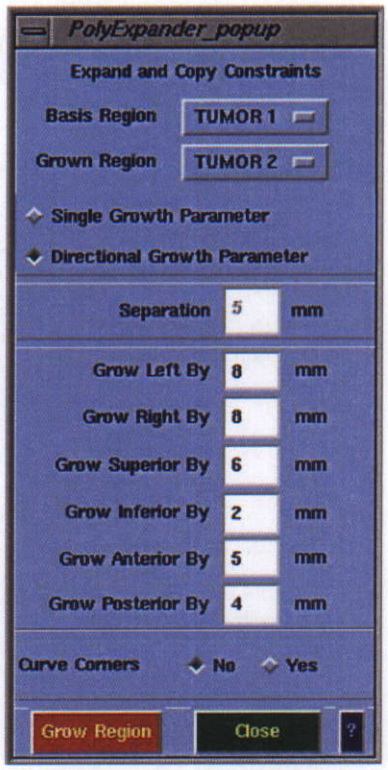



**Figure 9 Grow Polygon**

There are two modes for growing polygons. Click **SINGLE GROWTH PARAMETER** if you want the polygon to grow the same amount in all directions. The expansion dimension is set in the Separation text field. The other text fields cannot be set. Click **DIRECTIONAL GROWTH PARAMETER** if you want to change the polygon by a different amount in different directions. Values are set for the six cardinal directions of the patient coordinate system (patient left, patient right, superior, inferior, anterior, and posterior). Growth in the inferior and superior directions is achieved by copying grown polygons for the number of slices (rounded to the nearest integer) in each given direction.

For instance, if 2.5 mm slices are used for the case, the grown polygon has one more slice than the basis polygon in the anterior direction and two more slices in the superior direction.

To curve the edges for the grown polygon, click **YES** for Curve Corners. If sharp edges are okay, or if the basis polygon does not have sharp edges, click **NO** for Curve Corners.

To grow the polygon, select **GROW POLYGON**. A warning appears if the basis and grown regions are the same. Otherwise, the revised polygon appears in all the CT windows.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

767

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



## Filter ROI Vertices

Occasionally, Regions of Interest representation are improved by filtering redundant vertices. This ability is especially useful when ROIs have been imported through the DiCOM RTSS standard, because other planning systems allow intersecting line segments in ROI representations or use consecutive pixels as vertices.

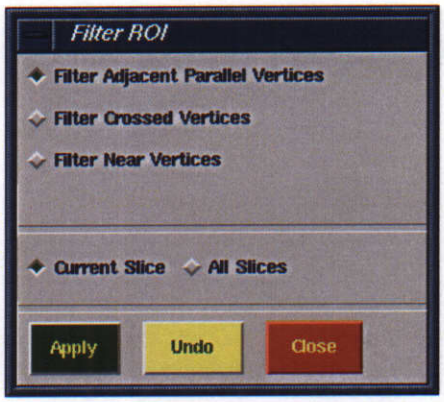



**Figure 10 Filter the Vertices for Regions of Interest**

Select Region Filter ROI. *Figure 10 Filter the Vertices for Regions of Interest, page 13* will appear, you can filter the vertices for the selected ROI.

1. Filter vertices for consecutive line-segments that are Parallel. The filter checks the two line segments created by three consecutive vertices. If the angle between the segments is less than $2^{o}$, the middle vertex is deleted.
2. Filter vertices that are creating intersecting line-segments. The filter checks non-adjacent line segments to determine if there is a point of intersection and deletes one of the vertices for each line segment. The filter will always delete the lobe of an intersecting region that requires deletion of the fewest number of vertices.
3. Filter vertices that are close together. This filter checks three vertices and if the middle vertex is less than 1.5mm from the both end vertices, the filter deletes it.

**APPLY** You can Apply the filter to the displayed saxial slice (Current Slice) or to All Slices in the image study.

**UNDO** If the result is not desirable, you can Undo the last filter operation.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



# IDENTIFY CT CENTER

The CT center is a reference point associated with CT image data, which is placed near the center of the imaging system during treatment delivery. The CT center establishes the correspondence between treatment plan and delivery system. You can display the CT center by turning on the Show CT Center option under the Imaging menu (*Figure 11 Imaging Menu, page 14*).

**NOTE:** If you have purchased the Xsight™ Spine Tracking System option, refer to section, CT Center Selection, page 4 in the Xsight module located in tab "16" in the Treatment Delivery manual.

## Fiducial Tracking Mode

If the imaging method is fiducial tracking, the CT center is defined at the geometric center of fiducials. You need to identify and locate the implanted fiducials in the CT study. To identify fiducials in the CT images, click **LOCATE FIDUCIAL** from the Imaging menu (*Figure 11 Imaging Menu, page 14*). The Locate Fiducial window (*Figure 12 Fiducial Window Box, page 15*) appears.

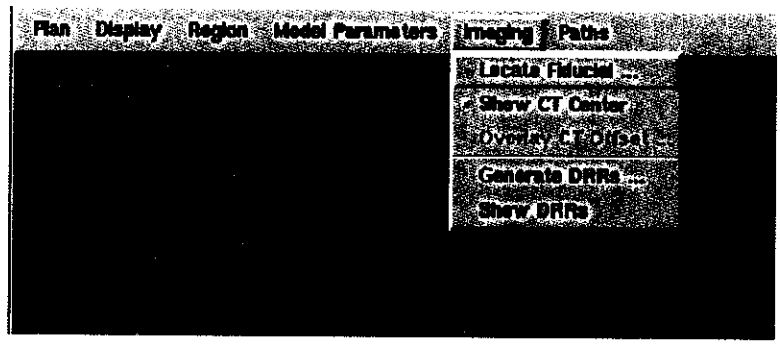



**Figure 11 Imaging Menu**



769 Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



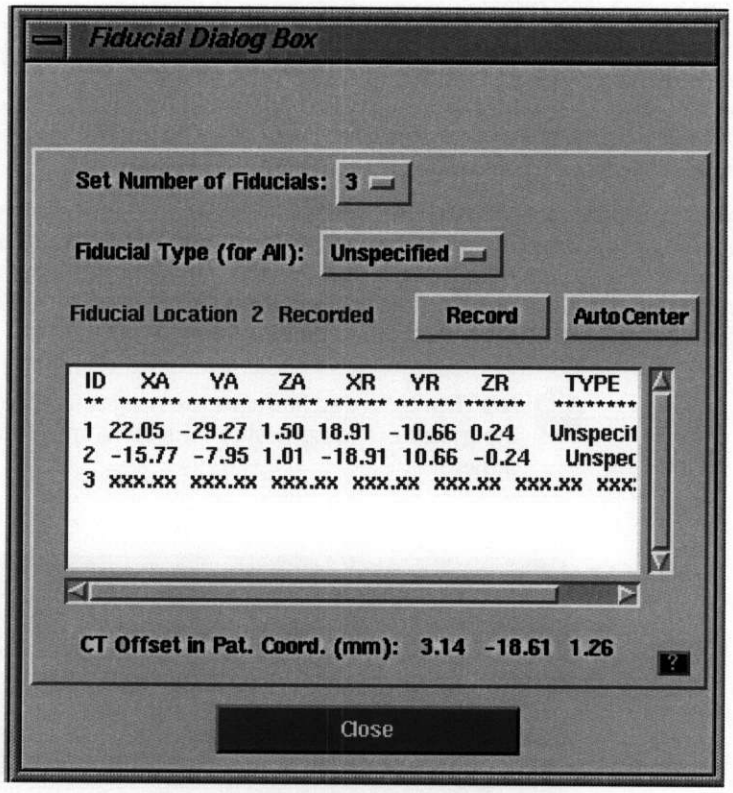



**Figure 12 Fiducial Window Box**

## Identify a Fiducial

To identify fiducials, first select the number of fiducials desired. The maximum number allowed is 8. When the number of fiducials is selected, a list is formed with a series of fiducial ID numbers and the values 'xxx' for the positions and type. The fiducial type is selected from the pull-down list shown. Each fiducial in a plan must be the same type.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



## Mark a Fiducial

To mark a fiducial, begin with an axial slice that contains a fiducial. It is also helpful, though not necessary, to display sagittal and coronal slices that contain the fiducial. Highlight a fiducial from the list (*Figure 12 Fiducial Window Box, page 15*). A light-blue crosshair appears in the axial (*Figure 13 Axial View with Fiducial Markers, page 16*), sagittal, and coronal views. Move the crosshair (in any 2D view) over the fiducial.

Then click either **RECORD** or **AUTOCENTER**. Record records the manually located position of the fiducial. Autocenter uses a weighted center of gravity to find the middle of the fiducial. The fiducial list is updated to include the recorded fiducial position; the label above the list indicates that the fiducial location has been recorded; and the CT Offset is adopted so that it is in the center of the fiducial array. The light-blue crosshair becomes magenta.

**NOTE:** Recorded fiducials are magenta and cannot be moved with the mouse. The light-blue fiducial is unrecorded and can be moved.

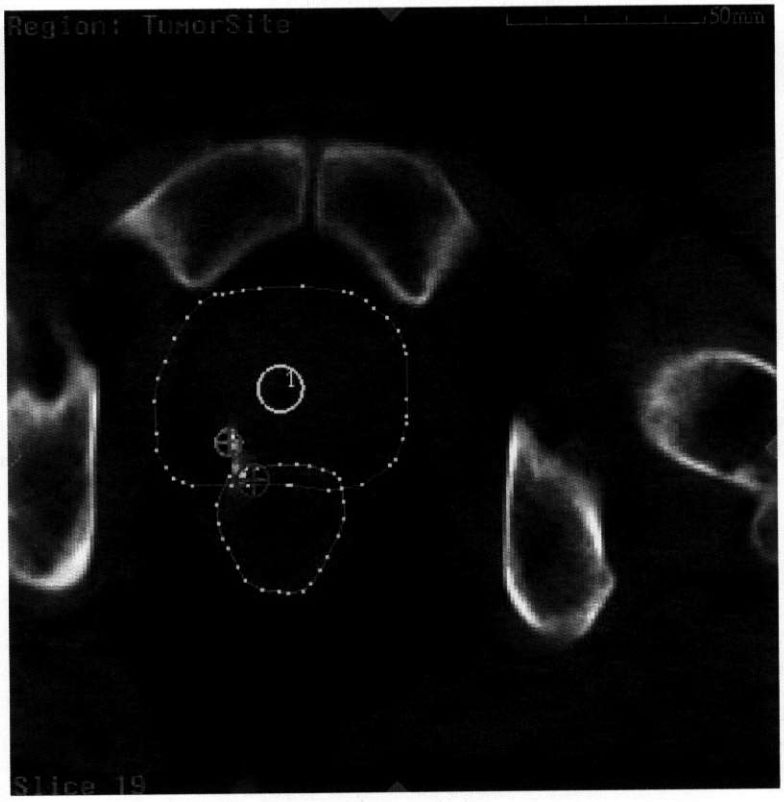



**Figure 13 Axial View with Fiducial Markers**

To change the location of a previously recorded fiducial, highlight that fiducial from the list. A moveable light-blue crosshair is placed over the magenta recorded fiducial. Move this crosshair to the desired location and click **RECORD** or **AUTOCENTER**.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



## Fiducial Tracking Using DRR

For fiducial tracking, the digitally reconstructed radiographs (DRR's) are for display only and are not for any calculations. After the fiducials are identified, you may want to confirm that the anatomy appears at the correct location within the imaging system. You can generate DRR's in TPS and verify them visually. Click **GENERATE DRR'S** from the Imaging menu and the Input DRR Parameters window appears (*Figure 14 DRR Generation Parameters, page 17*).

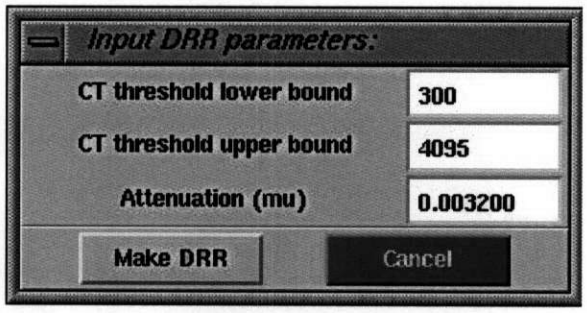



**Figure 14 DRR Generation Parameters**



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

772

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



Type in the desired parameters and click **MAKE DRR** to start DRR generation. When the task is done, the DRR's are displayed and their window and level can be adjusted from the DRR Adjustments window (*Figure 15 DRR's and Adjustments, page 18*). Clicking the **MARK FIDUCIALS ON DRR's** button will overlay the fiducial locations on the DRR's.

To close the windows, double-click the square close box at the upper left corner of either DRR A or B window.

**NOTE:** You can also click **SHOW DRR's** from the Imaging menu to display the DRR's that are generated already.

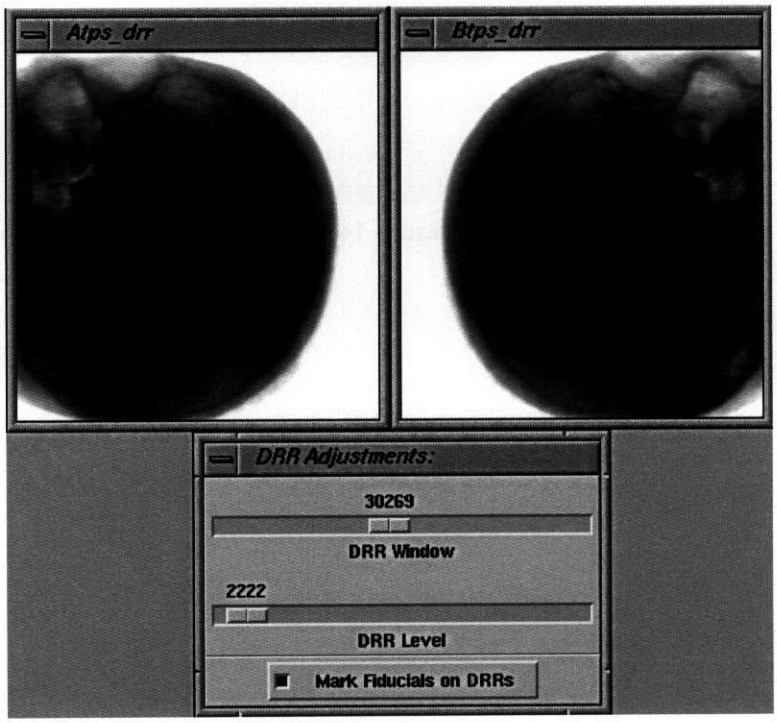



**Figure 15 DRR's and Adjustments**



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

773

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



## Skull Tracking Mode

If the imaging method is skull tracking, the CT center is automatically defined based on the dimensions of CT image data. You do not need to define it. The Locate Fiducial (*Figure 11 Imaging Menu, page 14*) is replaced by Move CT Center, and the buttons disappear for **GENERATE DRR'S** and **SHOW DRR'S**. You can view the CT center values by clicking **MOVE CT CENTER** and a window indicates the CT center values (*Figure 16 Move CT Center, page 19*). In some instances, you can reset the CT center based on the position of the skull in the Field of View of the TLS detectors. This position is seen using the DRR generation tool of *section, Fiducial Tracking Using DRR, page 17*.

Even though a default center has been set, you should verify the location of the CT center. You can move the CT center values by selecting **MOVE CT CENTER** and a window indicating the current and updated (new) CT center values (*Figure 16 Move CT Center, page 19*) appears. You can reset the CT center based to adjust the position of the skull in the Field of View of the TLS detectors. This position uses the DRR generation tool of *section, Fiducial Tracking Using DRR, page 17*.

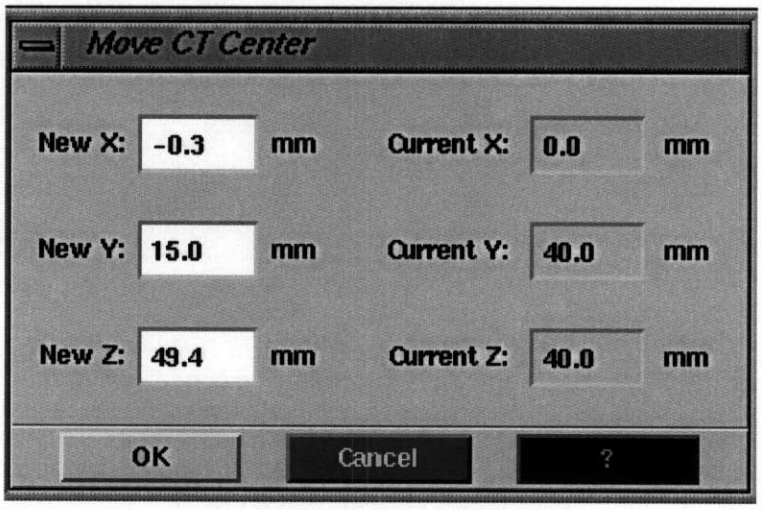



**Figure 16 Move CT Center**



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015

**Figure 17 Position of the CT Center**

To update the position of the CT center use the mouse to select the desired position. You can change the location in any of planar views. The current center is displayed in bright yellow. The new center is displayed in pale yellow. The updated position (relative to the geometric center of the CT study) will appear in the left hand column of the Move CT Center (*Figure 16 Move CT Center, page 19*) dialog window. You have the option to type in the desired values in the Move CT Center dialog window. If you do this, the pale yellow indicator will move.

The new CT center is accepted when you select **OK**. If you select **CANCEL**, the current CT center does not change.

**WARNING: The CT Center is NOT updated until you select OK. If you move the CT center and fail to verify it, the current CT center is used for all subsequent plan generation.**



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

775

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



# ACCUFUSION™ IMAGE FUSION

This section describes the use of the Accuray Fusion System, *AccuFusion*™, delivered as part of the Accuray CyberKnife® system for stereotactic radiosurgery and radiotherapy.

AccuFusion allows you to overlay and register two image data sets. Typically, you transform magnetic resonance (MR) image data so that it aligns with a computer tomography (CT) image data. The CT data set is the baseline image set used by the On-Target Treatment Planning System (TPS) and the target locating system (TLS).

You can view registered data sets simultaneously and define tumors and critical regions in the medium in which they are most visible. This tool is most useful for anatomy that appears in MR images but is invisible to CT. Use the following general procedure when registering image sets and manipulating the registered image sets.

- Display the patient's CT and MR image data.
- Identify and delineate the same anatomical landmarks in both the CT and MR images.
- Use the autofuse algorithm to register the image sets.
- Evaluate the fusion and make manual or automatic adjustments.
- Identify and delineate the regions of interest for treatment planning.
- Save the fusion results and use as a baseline for treatment planning.

The 'look and feel' of the AccuFusion tool is similar to the rest of TPS. Most features are identical to those in the TPS program.

**NOTE:** When image fusion is part of the treatment planning process, it should be the first step, because it can better identify and delineate regions of interest. Another fusion option is by using the Cyris™ InView™. It fuses two medical images, contours Volumes of Interest for export to the CyberKnife On-Target Treatment Planning System, and imports and reviews dose distributions created with the CyberKnife On-Target Treatment Planning System.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118 776

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



## Start AccuFusion

Start TPS and click **ACCUFUSION** from the Tools menu. The TPS window and menu bar close and the Accufusion menu bar appears.

When you first start the fusion system, only the FUSION menu (10.1) is available on the menu bar. The functions available in the FUSION menu are:

- **Choose a CT** – Selects a CT image.
- **Choose a MR** – Selects a MR image.
- **Load Fusion** – Loads a saved fusion from the CyberKnife database for modification.
- **Save Fusion** – Saves a fusion to the CyberKnife database.
- **Exit** – Ends the AccuFusion session.

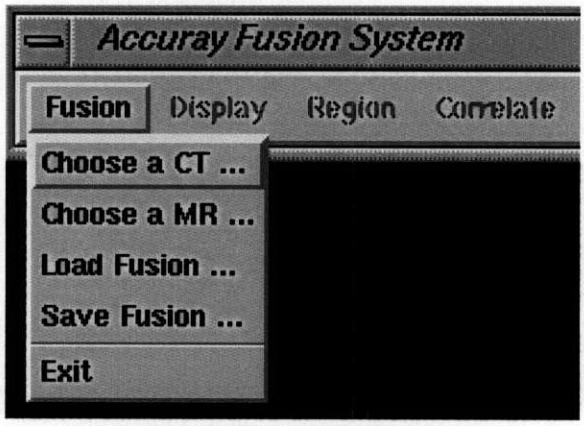



**Figure 18 Fusion Menu**

**NOTE:** AccuFusion won't start if there is any planning operation in progress. A message (*Figure 19 AccuFusion Run Information Message, page 22*) appears to inform you to exit and restart TPS.

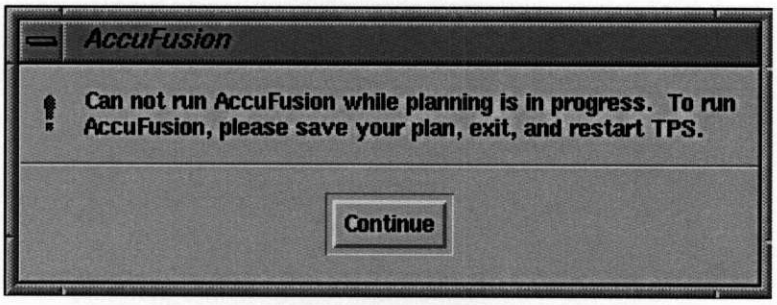



**Figure 19 AccuFusion Run Information Message**



777 Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



## Initiate Fusion Process

A fusion session begins by displaying the CT and MR data of the patient. Begin with the CT image set; then, display the corresponding MR image.

### Create a New Fusion

From the Fusion menu, click **CHOOSE A CT**. The Choose An Image window lists the available patients from the CyberKnife database in the upper window. This window is similar to the New Plan window. Select the patient by clicking the patient's name. The lower window lists the available images associated with the selected patient.

Select the desired CT study and OK to load the CT image. A Job In Progress message indicates Reading CT file. It closes when it finishes reading CT data.

A set of windows appears, including Axial View, Sagittal View, Coronal View, Toolbox, and the Window and Level window (*Figure 20 Window & Level Adjustment Windows for CT and MR Images, page 23*). Click **CHOOSE A MR**, and select the patient and image to load. The MR image appears in the same Axial View, Sagittal View, and Coronal View windows. The MR option becomes available on the Window and Level window.

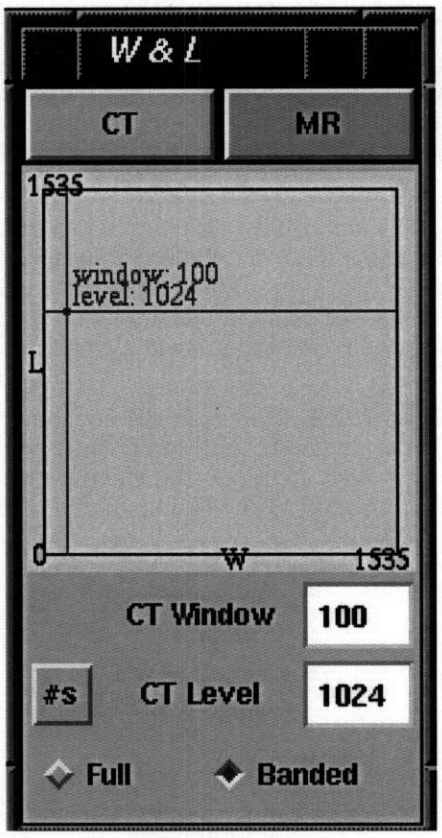



**Figure 20 Window & Level Adjustment Windows for CT and MR Images**



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



You can adjust the Window & Level by either directly inputting the values or by adjusting the crosshairs (*Figure 20 Window & Level Adjustment Windows for CT and MR Images, page 23*). Initially the adjustment range for the CT and MR images extends to the **Full** range of the input data. To limit the range of the graphic interface, select **Banded**. Set the range for the **Banded** option with the Set Limits for Banded (*Figure 21 Upper Limits for Banded 2D Window & Level Adjustment, page 24*) window that is opened with the **#s** button.

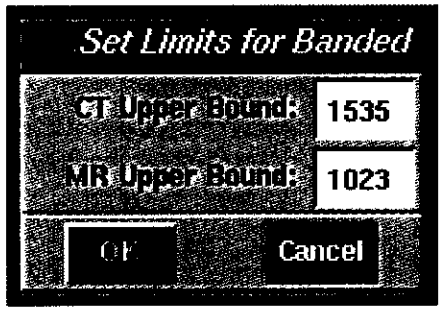



**Figure 21 Upper Limits for Banded 2D Window & Level Adjustment**

## Modify an Existing Fusion

From the Fusion menu, click **LOAD FUSION**. The Load Fusion window with a list of the available patients appears in the upper window. The Load Fusion window is similar to the Load Plan window. Select the desired patient from the list, and available fusion results are listed in the lower window. The fusion results, represented by a file, are associated with a treatment plan and bear the same name.

Select the desired fusion file by clicking the fusion/plan name in the lower window. For reference, this list also contains the CT and tumor site associated with each plan. Then click **LOAD** to load a fusion. A Job In Progress message indicates Reading CT file. After the CT study is loaded, the *Reading MR file* message appears in the same window. When both images are loaded, the same process continues as in *section, Create a New Fusion, page 23.*

**NOTE:** Some plans do not have any fusion data. If you select such a plan, AccuFusion notifies you that the fusion file does not exist. Also, AccuFusion indicates that a treatment plan was generated based on the fusion loaded for modification.



779 Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



## CT/MR Images Displays

Fuse images in the Axial View, Sagittal View, and Coronal View windows. The views contain the patient's anatomical information and are similar to those used in the main TPS, except that they contain both CT and MR images.

### 2D Image Displays

The Axial View (*Figure 22 AccuFusion™ Axial View, page 25*) has features and tools nearly identical to those in TPS. The differences are the **ISODOSE CURVES VISIBILITY** toggle and **ROI VISIBILITY** toggle are no longer available and the button that was the **COLLIMATOR VISIBILITY** toggle is now the **HANDLE VISIBILITY** toggle. The *handle* is a yellow circle with a crosshair at the center. The crosshair is the pivot of rotation for the MR image. *Section, Mouse Adjustment, page 30* describes the handle and its use.

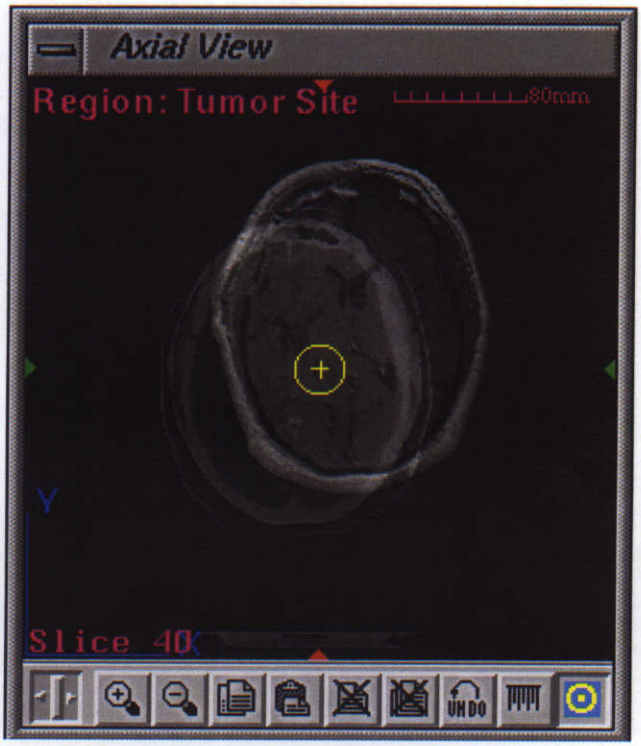



**Figure 22 AccuFusion™ Axial View**

Similarly, the Sagittal View (*Figure 23 AccuFusion™ Sagittal View, page 26*) and the Coronal View (*Figure 24 AccuFusion™ Coronal View, page 26*) are similar to their TPS counterparts except for those three toggle buttons.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

780

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



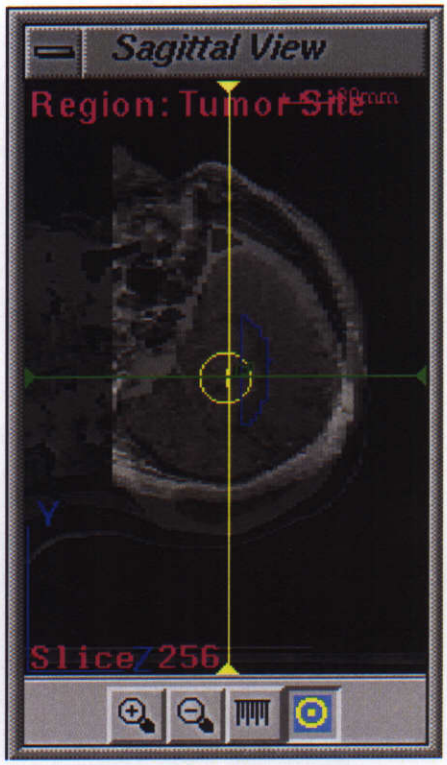



Figure 23 AccuFusion™ Sagittal View

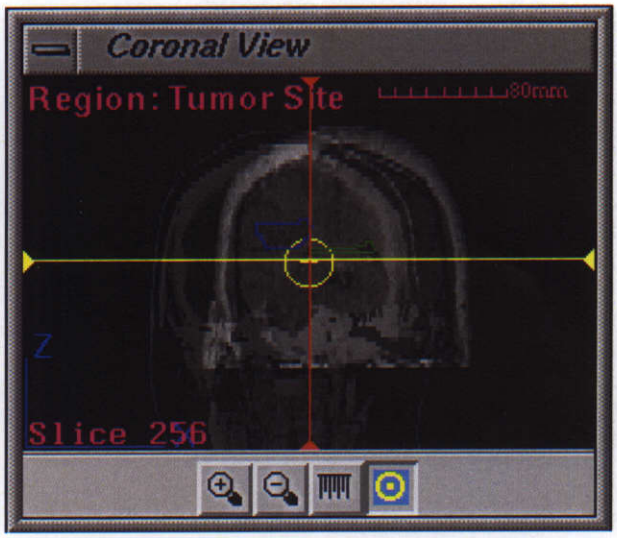



Figure 24 AccuFusion™ Coronal View



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

781

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



## Display Options

AccuFusion lets you determine the fusion results based on visual evaluation. You can apply visual tools at any stage of the MR transformation to determine how good the fusion is. There are different options under the Display menu (*Figure 25 AccuFusion™ Display Options, page 27*) for changing the appearance.

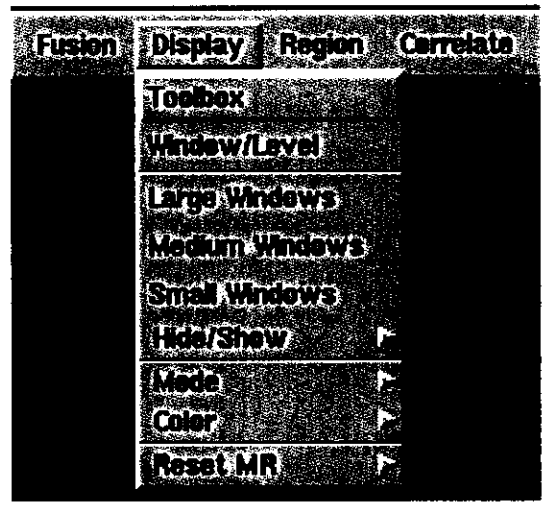



**Figure 25 AccuFusion™ Display Options**

- **Window/Level** adjusts the brightness and contrast of the CT and MR images.
- **Select different window sizes** from Large windows, Medium windows, and Small windows.
- **Hide/Show option** allows you to select which window to show and is useful when you use the Large windows option, since one window can occupy the whole screen.
- **Mode option** shows the images in different settings:
- **Merged mode**, the CT and MR images are stacked on each other and appear translucent.
- **MR % For Merged Display** slider in the Toolbox window (*Figure 27 AccuFusion™ Toolbox Window, page 29*) allows you to adjust the percentage contribution of the MR image in the overlaid display.
- **Split mode**, each window is divided into a quadrant and CT and MR images appear in the alternate partitions. Vary the partition by clicking and dragging the blue crosshair in the display.
- **Checker mode**, each window is divided into 8x8 fixed-size sections (as in a checkerboard), in which CT and MR images appear in alternate sections.
- **Color option** allows you to show the MR image in different colors, including gray (default), red, green, yellow, blue, magenta, and light blue.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118 782

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



# Automatic Fusion Procedure

The automatic fusion algorithm correlates MR and CT image data by finding the best match for the geometric centers of defined landmark pairs. A landmark is defined using a polygon with user-specified vertices in the Axial View. The polygon is delineated on a set of axial CT slices to represent the volumetric nature of the landmark.

## Specify Landmarks

The process is almost identical to delineating a region of interest (ROI) in TPS.

**Step 1.** Click the **MERGED** display mode.

**Step 2.** Adjust the MR percentage slider to show only CT or MR depending on which modality you are working with.

**Step 3.** From the Correlate menu (*Figure 26 Correlate Menu, page 28*), select one of the ten Landmark structures for either CT or MR. Only one landmark, the active one, can be delineated at a time. The active landmark label is shown on the upper left corner of all the 2D image windows. The landmark polygon is in shades of blue for CT (light blue for the active one, royal blue for others) and in shades of green for MR (light green for the active one, dark green for others).

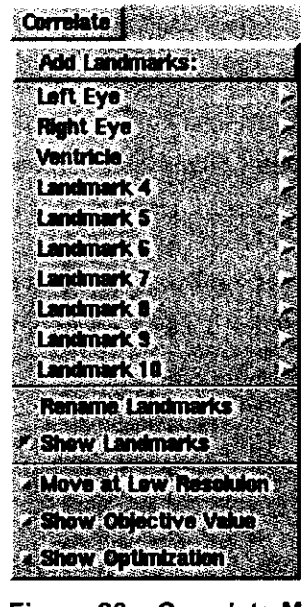



**Figure 26 Correlate Menu**

**Step 4.** Use the same functions to delineate ROIs as in the main TPS. You can label the landmarks by using the Rename Landmarks option. You can hide or show the landmarks using the Show Landmarks toggle.

**NOTE:** You must delineate a corresponding pair of landmarks for both CT and MR images to make the automatic fusion work.



783

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



## Automatic Fusion

After you complete delineation, select AUTOFUSE in the Toolbox window (*Figure 27 AccuFusion™ Toolbox Window, page 29*) to 'fuse' the CT and MR images. The software then:

1. Determines the geometric centers of the delineated landmarks.
2. Transforms the MR image set to find the best match between the paired centers.
3. Identifies the resulting MR transformation.
4. Applies the transformation to the MR image and displays its new location.

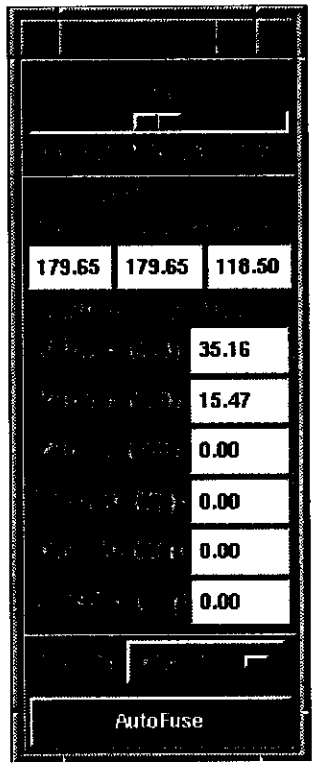



**Figure 27 AccuFusion™ Toolbox Window**

AutoFuse can begin with one of three initial MR positions. For the Calculated position, the software finds the initial position automatically. For Current position, the software uses the current MR position. For Zero position, the software uses the loaded position of the MR.

Under the Correlate menu, you can observe the Autofuse in progress by choosing the following options:

- **Move at Low Resolution** – The MR image is displayed in low resolution as the transformation proceeds. This setting speeds up movement of MR image.
- **Show Objective Value** – Set this option to display the sum of the distances between landmark pairs as the fusion progresses. This option slows the process.
- **Show Optimization** – The process of MR transformation is displayed as it proceeds. This too slows down the fusion.

These options do not affect the fusion results.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118 784

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



# Manual Fusion Procedure

Use the keyboard and mouse to manually reposition the MR image. The adjustment tools control all six degrees-of-freedom of the MR transformation.

## Keyboard Adjustment

Keyboard adjustments include three translations and three rotations (the Translation & Rotation area in the Toolbox window). (Figure 27 AccuFusion™ Toolbox Window, page 29). You can also specify the location of the axis of rotation (i.e., the pivot point). This point is the Reference Point (X, Y, Z) in the Toolbox window.

## Mouse Adjustment

Mouse adjustments also control three translations and three rotations, as well as the pivot point represented by the center of the *handle*. These controls work in all three 2D windows. To translate the image, right-click-hold and drag the image across the plane of the 2D window.

To change the pivot point, right-click-hold at the crosshair of the handle and move it to the desired location. To rotate the image, right-click-hold inside the circle of the handle and drag the image.

The rotation is always about the axis perpendicular to the plane of the window at the pivot point. As the image moves, you can see the values of the text fields change in the Toolbox window.

**NOTE:** You can speed up mouse adjustments of the MR image by turning on the Move At Low Resolution option from the Correlate (*Figure 26 Correlate Menu, page 28*) menu.

# Fusion Results

The fused images can be used to delineate regions of interest. The fusion session can then be saved.

## Apply Results to Treatment Planning

After the two image sets are fused, you can either name or delineate ROIs. To delineate the ROIs, follow the same procedure as outlined in TPS.

## Save Results

Save the fusion when you finish delineating the ROI, then exit, and return to the main TPS. The saved plan (from AccuFusion) is available for further planning, reference, or modification with regions of interest defined already. Fusion results are always associated with a plan, but a plan may not have a fusion.

Click **SAVE FUSION** from the Fusion menu. The Save Fusion window appears. Type the filename, and click **OK**.

# Exit AccuFusion

To exit AccuFusion, click **EXIT** from the Fusion menu. The Exit Confirmation message appears. Click **YES** to quit AccuFusion and return to TPS, or click **NO** to continue with the fusion task.



785 Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



# MODEL THE DEPTH

TPS requires you to specify accumulated depth based on the tissue it passes through to calculate the dose correctly. To specify the depth model, click **TISSUE MODEL** from the Model Parameters menu (*Figure 28 Model Parameters Menu, page 31*) and the Beam Parameter Model window (*Figure 29 Beam Parameter Models, page 31*) appears. There are three options:

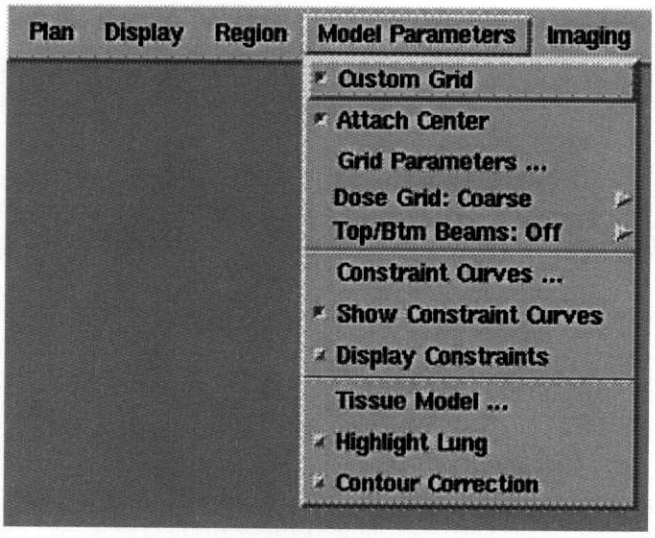



**Figure 28 Model Parameters Menu**

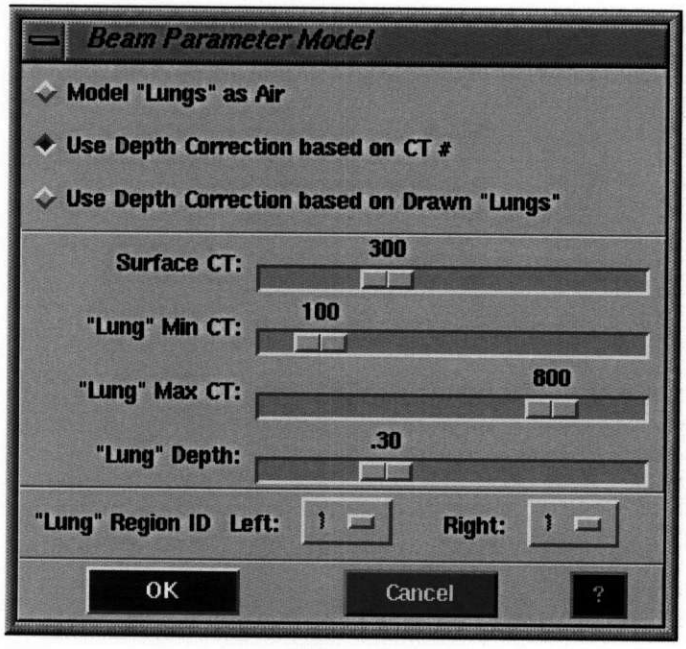



**Figure 29 Beam Parameter Models**



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



1. **Model "Lungs" as Air** treats the tissue, whose CT number is less than or equal to the number defined by the Surface CT slider, as air (i.e., depth equals zero). The Surface CT number also determines the intersection of beam with the anatomy surface.
2. **Use Depth Correction based on CT #** sets the beam accumulated depth to be the actual depth multiplied by the factor specified by the "Lung" Depth slider. This depth factor applies to the tissue that has CT number falls between "Lung" Min CT and "Lung" MAX CT. The Surface CT number determines the intersection of beam with the anatomy surface.
3. **Use Depth Correction based on Drawn "Lungs"** specifies two critical regions, defined by the "Lung" Region ID Left and RIGHT that have the beam accumulated depth as the actual depth multiplied by the factor specified by the "Lung" Depth slider. You have to delineate those regions on the anatomy (*see section, Identify and Delineate Regions of Interest, page 1*). The Surface CT number determines the intersection of beam with the anatomy surface.

Option 2 is the default configuration for the system. For this option, you can visually verify if the tissue defined is correct by clicking **HIGHLIGHT LUNG** under the Model Parameters menu. The tissue that is within the CT number range is displayed in light-green in the Axial View 1 window.



787 Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



# PROGRAM TREATMENT BEAMS USING WIZARDS

## The Toolbox

The Toolbox (*Figure 30 Toolbox, page 33*) is a menu with sliders and buttons that appears at the upper left area of the monitor. Among its features are the Window & Level sliders. It indicates the size and coordinates of the selected center of the tumor as discussed in the *section, Select and Position Center , page 34.* It allows you to start plans using the Planning Wizards and provides access to the Finetune menu. *Section, Wizards, page 35* describes the Planning Wizards and *section, Finetune Planning History, page 69* describes the Finetune menu.

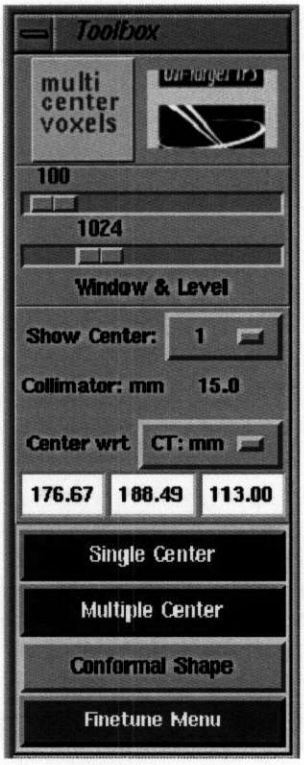



**Figure 30 Toolbox**



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



## Select and Position Center

Center WRT is an important feature of The Toolbox. TPS uses a sphere to show the tumor center and the collimator size, and to indicate the prospective spherical dose that would be delivered by isocentric beams. The intersection of the sphere with any displayed CT section (axial, coronal, or sagittal) appears as a circle on the displayed CT section. It appears in the 3D View window as a yellow sphere. Use the **ATTACH CENTER** function from the Model Parameters menu to set the Reference Dose to Center 1. The diameter of the sphere equals the size of collimator at 80 cm source-axis distance (SAD).

Use **SHOW CENTER** to highlight each center on the CT views and manipulate or identify its coordinates. The location of the sphere can be changed to suit the particular clinical needs of the patient. Drag the circle to the desired position in the Axial, Sagittal and Coronal View windows. Alternatively, type the coordinates in the three text fields to specify the center of the sphere. The highlighted sphere has a brighter yellow.

The coordinates of the center of the selected sphere are displayed in the three text fields in the Toolbox window. One of three coordinate references (CT, patient, and manipulator) may be chosen by selecting from the **CENTER WRT** option (*Figure 31 Center WRT Option, page 34*), where the manipulator coordinate reference is labeled Robot). Assuming the patient is scanned head-first-supine (HFS), these three coordinate frames are (*Figure 32 Coordinate Frame Definitions, page 35*) defined as follows:

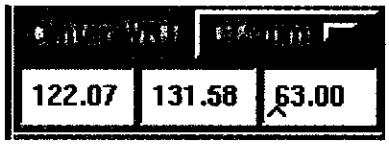



**Figure 31 Center WRT Option**

1. The **CT coordinate frame** has its origin at the starting pixel of the CT study, which is the lower (operator's) left corner of the first CT section. All coordinates in the study are positive; **x** is horizontal in the axial plane and positive to the patient's left; **y** is vertical and positive to the patient's anterior; **z** is parallel to the normal to the axial plane and positive to the patient's superior. Two units are used for this coordinate reference, millimeters and slice number. In (*Figure 32 Coordinate Frame Definitions, page 35*), the CT subscript indicates the CT coordinate frame.
2. The origin of the **patient coordinate frame** is automatically set within the CT image based on either the field of view for the imaging system or the centroid of the locus of fiducials. The axes are: **x** is positive to the patient's right; **y** is positive to the patient's anterior; **z** is positive to the patient's superior. The units are millimeters. In (*Figure 32 Coordinate Frame Definitions, page 35*), the **p** subscript indicates the patient coordinate frame.



789 Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



3. The **manipulator coordinate frame** has its origin at the patient coordinate frame origin. Its **x** and **y** axes depend on where the manipulator is located with respect to the patient. If the manipulator is at the patient's right-superior, **x** is positive to the patient's left-inferior and is roughly 45 degrees from the patient's inferior; **y** is positive to the patient's left-superior and is roughly 45 degrees from the patient's left.

   If the manipulator is at the patient's left-superior, **x** is positive to the patient's right-inferior and is roughly 45 degrees from the patient's right; **y** is positive to the patient's left-inferior and is roughly 45 degrees from the patient's inferior. The z-axis is positive to the patient's anterior regardless of where the manipulator is. The units are millimeters. The exact orientation of the robot with respect to the patient coordinate frame is found when the imaging system is calibrated. In (*Figure 32 Coordinate Frame Definitions, page 35*), the m subscript indicates the manipulator coordinate frame.

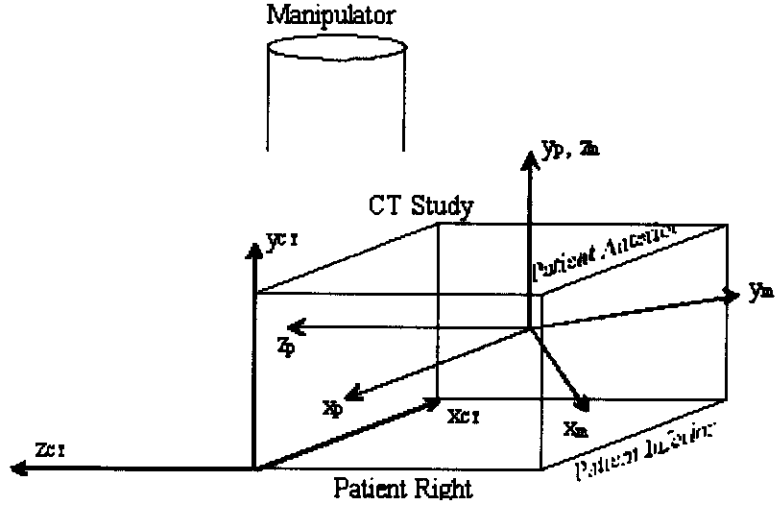



**Figure 32 Coordinate Frame Definitions**

## Wizards

The four buttons at the bottom of the Toolbox access the Planning Wizards and the FINETUNE menu. The Planning Wizards are a quick method for you to plan single isocenter, multiple isocenter, and conformal shape plans. Their operation is detailed in Sections Generate Beam Geometries, page 36 and Assign Dose to Beams, page 45. The Finetune menu allows you to refine a plan or generate a plan with features not supported through the Planning Wizards. Its operation is detailed in *section, Finetune Beam Geometry and Dose , page 60.*



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118 790

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



# Generate Beam Geometries

The Treatment Planning System gives you the ability to target and set the dose for over 1000 treatment beams. To simplify the initial construction of plans, you have the option of using one of three wizards that can quickly assign target beams and assign doses. These wizards consist of a series of windows that prompt you to select design parameters for the treatment. The three wizard packages assign doses for single isocenter treatments, multiple center treatments, and conformal targeted treatments.

The wizards are divided into two types. The first ones you use to define the geometry of the treatment beams. These wizards are described later in this section. The last wizard in each sequence sets the dose for each beam. These wizards are discussed in *section, Assign Dose to Beams, page 45*.

## Single Center

A single center treatment uses beams that all intersect at a single point. This point is referred to as the *isocenter*. This beam geometry is advantageous because it is simple and inherently yields rapid dose drop-off. It offers an inflexible dose distribution shape. The dose distribution will always be nearly spherical. To plan for a single center treatment, click **SINGLE CENTER** from the Toolbox.

The Single Center Beam Assignment window (*Figure 33 Single Center Beam Assignment, page 36*) appears. Select the diameter of the center. The center appears as a yellow circle, centered on the delineated tumor volume. If the tumor volume is not delineated yet, the center appears at the center of the calculation volume. The calculation volume is defined by a blue square. If desired, the calculation volume can be moved at this time. It is usually best that this volume surrounds the tumor and other ROIs. Move the center by click-hold-drag on the center boundary. The center can be moved in the Axial 1 View, Coronal View, or Saggital View windows. Make sure you move the center to the desired location before assigning dose, because beam doses are determined by the center location.

**NOTE:** The **?** button provides on-screen help for the wizard. Each wizard has a help window.

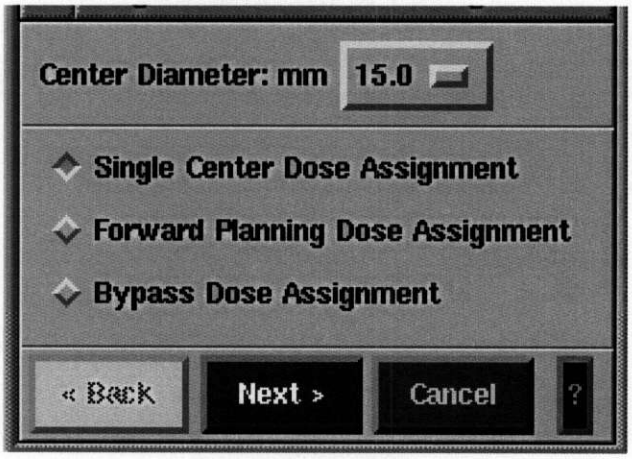



**Figure 33 Single Center Beam Assignment**



791

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



After the center diameter and position are set, select the dose assignment method. The wizard offers three choices.

1. **Single center dose assignment** leads the planning system to a menu that allows you to select the dose at the isocenter. This method is discussed in *section, Single Center Dose Assignment, page 45*.
2. **Forward planning dose assignment** allows you to select the contribution of beams to the center dose, based on whether or not they pass through a delineated critical structure. This method is discussed in *section, Forward Planning Dose Assignment, page 45*.
3. **Bypass dose assignmen**t, which doesn't assign a beam dose at this time.

Select **NEXT** to advance to the chosen dose assignment method. Before the Dose Assignment wizard appears, the *flag critical beams job in progress* message is displayed. **CANCEL** exits the wizard.

**NOTE:** If you move the center after assigning center dose, the beam doses do not change. You may need to reassign the dose at the isocenter to the desired value.

## Multiple Center

Multiple center treatments have beams that intersect at two or more points. Multiple center treatments may be useful when treating more than one tumor or when using multiple spheres to create an irregularly shaped dose distribution.

### Multi-Centers Beam Assignment

**To plan for a multiple center treatment:**

**Step 1.** Click **MULTIPLE CENTER** from the Toolbox. The Multi-Centers Beam Assignment wizard appears (*Figure 34 Multiple Center Beam Assignment, page 37*). Initially, it indicates one center with 0.0 diameter, and it has one direction per node.

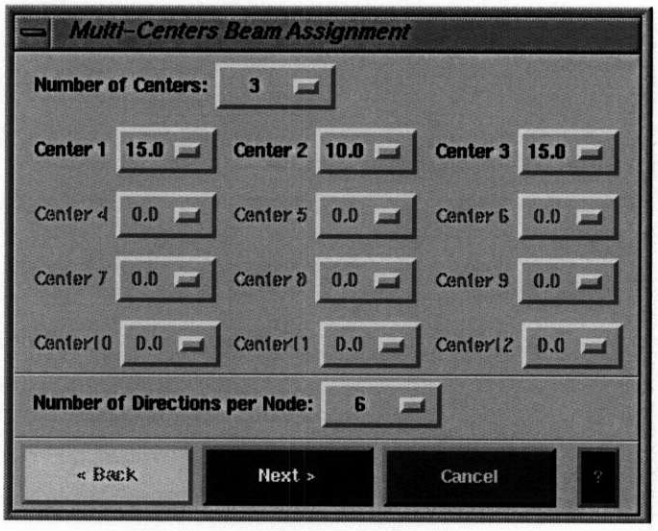



**Figure 34 Multiple Center Beam Assignment**



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



**Step 2.** Select the number of desired centers, then select the diameter for each center. As each diameter is selected, the center appears as a yellow circle near the delineated tumor center. The unselected centers are green. The selected center is indicated on the Flexible Planning Toolbox by the **SHOW CENTER** button. As in the Single Center wizard, each center can be moved with the mouse. Again, you want to move the centers to the desired locations because they affect the beam doses. You can increase or decrease the number of spheres or change their sites while this window is displayed.

**Step 3.** Select the number of directions per node. This parameter indicates the number of directions the manipulator points at each spatial location from the baseline paths. Most commonly, you will want one direction for each center, so that at each node, the Linac points at each center. If different size collimators are used or some other special condition applies, you may want to treat one or more isocenters using two or fewer paths.

**Step 4.** Click **NEXT** to advance to the CENTER ASSIGNMENT (*Figure 35 Path/Direction Center Assignment, page 39*) window, if the plan has more than one center. If the plan has only one center, next advances to the Multi-Centers Dose Assignment (*Figure 36 Multiple Centers Dose Assignment Methods, page 40*) window. Click **CANCEL** to exit the wizard.





Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



## Center Assignment

The Center Assignment window assigns a center to each combination of path and direction. You can assign centers for each direction and path pair or for all directions in one path or beams with the same direction ID. Generally, it is a good idea to assign centers such that each path uses as few different collimator sizes as possible. This helps reduce treatment time.

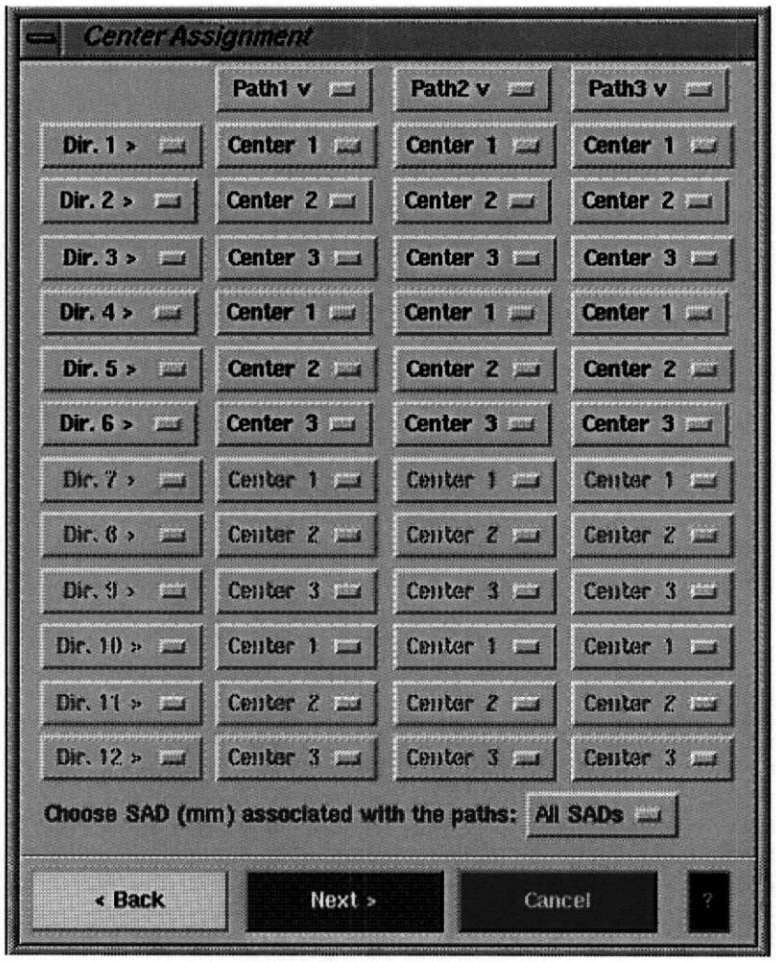



**Figure 35 Path/Direction Center Assignment**

Click **NEXT** to continue to the Multi-Centers Dose Assignment (*Figure 36 Multiple Centers Dose Assignment Methods, page 40*) window. **BACK** returns the planning system to the previous wizard. **CANCEL** exits the wizard.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



## Multi-Centers Dose Assignment

You have three dose assignment choices, or you can choose to bypass dose assignment at this time.

1. **Multi-center dose tolerance** (*see section, Multiple Center Dose Assignment, page 47*) is similar to single center dose assignment, except dose is calculated and assigned to more than one center.
2. **Forward planning dose assignment** is detailed in *section, Forward Planning Dose Assignment, page 45*.
3. **Inverse planning dose assignment** is detailed in *section, Inverse Planning Dose Assignment, page 48*.

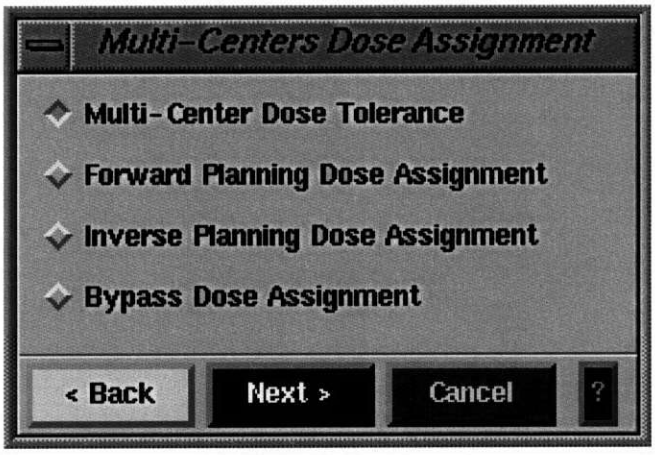



**Figure 36 Multiple Centers Dose Assignment Methods**

Click **NEXT** to advance to the indicated dose assignment wizard. Click **BACK** to return to the Center Assignment window. Click **CANCEL** to exit the wizard.

**WARNING: If you move the centers after assigning center doses, the beam doses do not change. You may need to reassign the doses at the isocenters to the desired values.**



795

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



## Conformal Shape

Use the conformal shape to create plans for irregularly shaped tumors and to create plans that have constraints on critical regions. This option creates beams that target points around a defined offset from the boundary of the tumor. Click **CONFORMAL SHAPE** from the Toolbox and the Conformal Beam Assignment window (*Figure 37 Conformal Beam Assignment, page 41*) appears.

### Conformal Beam Assignment

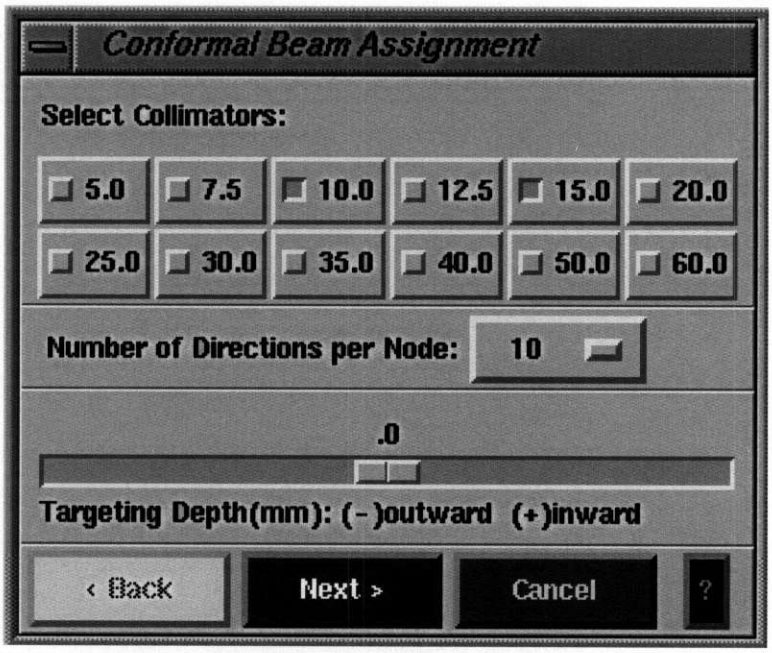



**Figure 37 Conformal Beam Assignment**

**Step 1.** Select the desired collimators by turning on the appropriate toggle buttons. Selected collimators have light-blue bubbles. Conformable targeted beams aim at points along the boundary of the tumor. The number of target points at each robot position is the number of directions per node.

Instead of pointing at the tumor boundary, you can choose to aim either inside the boundary or outside the boundary. Set the target depth to control this factor.

**NOTE:** A positive target depth aims inside the tumor boundary and a negative target depth aims outside the tumor boundary.

**Step 2.** Click **NEXT** to advance to the Collimator Assignment (*Figure 38 Path/ Direction Collimator Assignment, page 42*), if more than one collimator was selected. If you are planning with one collimator, but will treat more than one delineated lesion, **NEXT** advances to the Tumor Assignment (*Figure 39 Path/ Direction Tumor Assignment, page 43*) window. **NEXT** advances to the Conformal Shape Dose Assignment (*Figure 40 Conformal Shape Dose Assignment Methods, page 44*) window. Click **CANCEL** to exit the wizard without creating a plan.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



## Collimator Assignment

Use the Collimator Assignment window to assign a collimator to each path and direction combination. You can assign collimators for each direction and path pair or for all directions in one path or beams with the same direction ID. To reduce treatment time, it is advantageous to have as few collimator sizes as practical for each path.

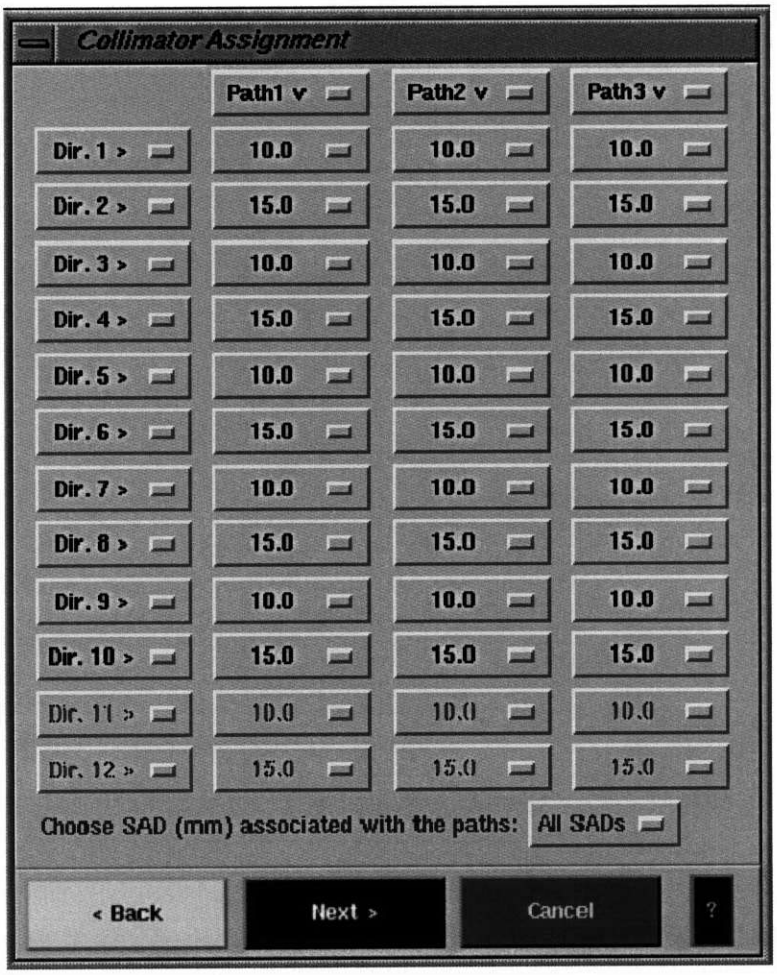



**Figure 38 Path/Direction Collimator Assignment**

Click **NEXT** to continue to the Tumor Assignment (*Figure 39 Path/Direction Tumor Assignment, page 43*) window, if more than one tumor has been delineated. **NEXT** advances to the Conformal Shape Dose Assignment (*Figure 40 Conformal Shape Dose Assignment Methods, page 44*) window. **BACK** returns the planning system to the Conformal Beam Assignment window. **CANCEL** exits the wizard.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



## Tumor Assignment

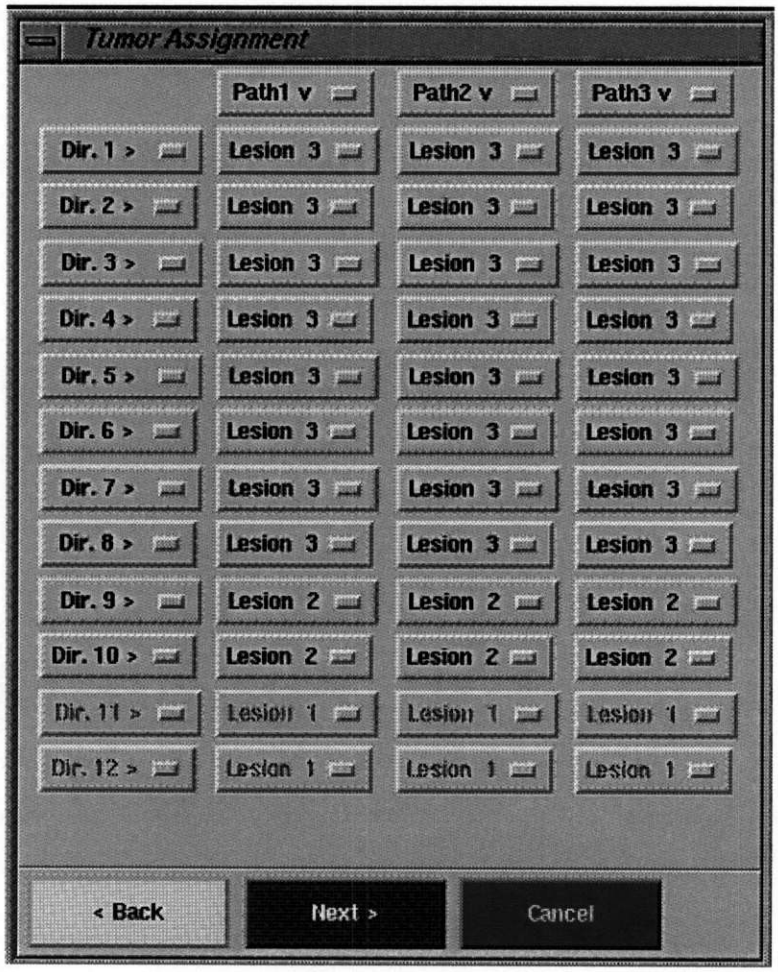



**Figure 39 Path/Direction Tumor Assignment**

Use the Tumor Assignment window to assign a tumor to each path and direction. This forces the beam generation algorithm to point at points around or offset from the identified tumor.

**NOTE:** The tumor is always indicated by its identifier (i.e., "Lesion 1") rather than its assigned name. Remember which tumor corresponds with each ID number.

Click **NEXT** to continue to the Conformal Shape Dose Assignment (*Figure 40 Conformal Shape Dose Assignment Methods, page 44*) window. **BACK** returns the planning system to the previous window. **CANCEL** exits the wizard.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



## Conformal Dose Assignment

The conformal dose assignment wizard offers three choices:

1. **Inverse planning dose assignment**
2. **Forward planning dose assignment**
3. **Bypass dose assignment**.

**INVERSE PLANNING** allows you to set constraints on doses to the tumor and critical regions and find a plan that best meets these constraints.Inverse Planning is described in more detail in *section, Inverse Planning Dose Assignment, page 48*. **FORWARD PLANNING** is detailed in *section, Forward Planning Dose Assignment, page 45*. You can also choose to bypass dose assignment at this time.

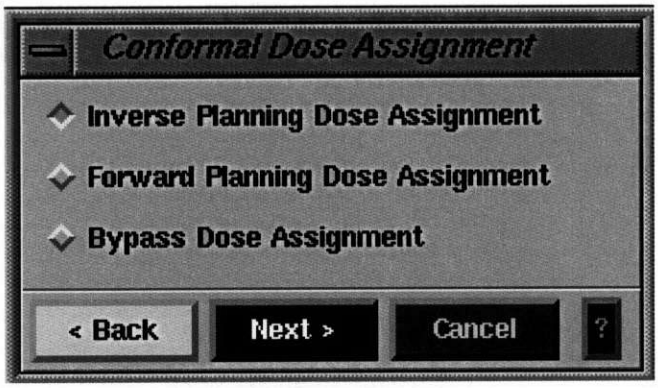



**Figure 40 Conformal Shape Dose Assignment Methods**

Click **NEXT** to proceed to the Dose Assignment window. Click **BACK** to return to the previous window. Click **CANCEL** to exit the wizard.



799

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



# Assign Dose to Beams

In *section, Generate Beam Geometries, page 36*, simple methods for creating beam geometries were discussed. The next step is to set the dose for each beam. This section discusses dose assignment methods called by the planning wizards.

## Single Center Dose Assignment

Select **SINGLE CENTER DOSE ASSIGNMENT** (*Figure 41 Single Center Dose Assignment, page 45*) to activate the wizard, set the desired center dose in cGy in the text box. Click **DO NOT USE CRITICAL BEAMS**, if you want no dose from beams that pass directly through delineated critical structures. Click **USE CRITICAL BEAMS** if dose through critical structures is acceptable. *See sections, Plan Evaluation Tools, page 73, and Single Center Inverse Planning, page 94,* for further details on the Single Center Dose Assignment algorithm.

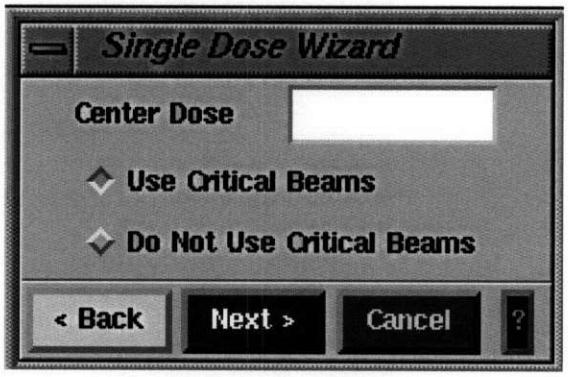



**Figure 41 Single Center Dose Assignment**

Click **NEXT** to assign the dose. The Calculation menu appears in Quick Calculation mode. Click **BACK** to return to the Single Center Beam Assignment window (*Figure 33 Single Center Beam Assignment, page 36*) or **CANCEL** to exit the wizard.

## Forward Planning Dose Assignment

When you click **FORWARD PLANNING DOSE ASSIGNMENT**, the Forward Panning window (*Figure 42 Forward Planning Dose Assignment, page 46*) appears. You prescribe beam dose on a per-region of interest basis. In other words, the beam dose set for the tumor region means any beam that intersects the tumor may be assigned that dose. Similarly, a beam dose is set for all beams that intersect each critical region.

**NOTE:** In this instance, dose refers to the absorbed radiation at the target due to one beam, not the total or the contributed dose at the critical structure.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

800

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



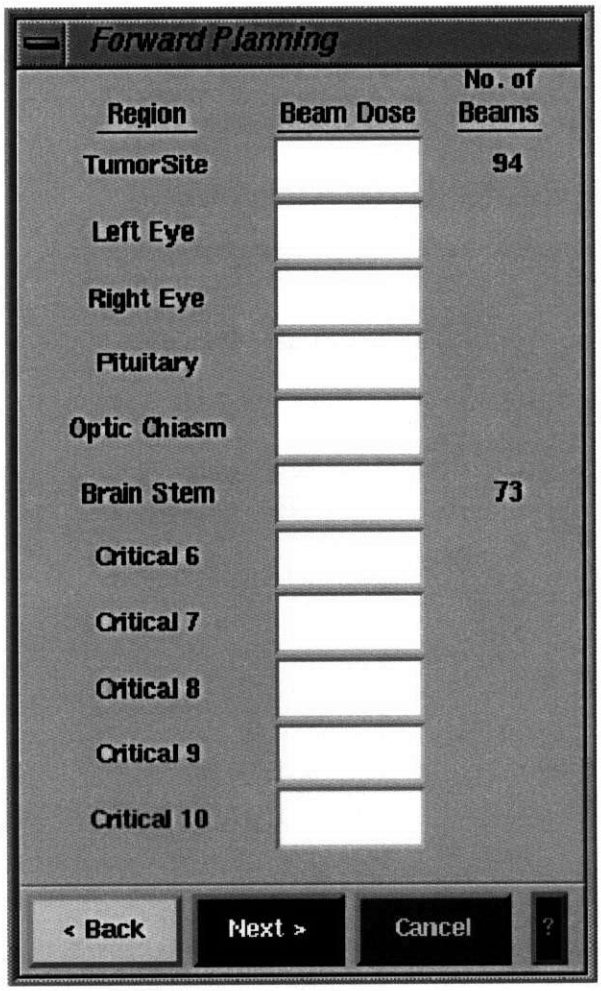



**Figure 42 Forward Planning Dose Assignment**

The numbers to the right of the text window indicate the number of beams passing through each region of interest. Generally, all beams pass through the tumor. This figure helps estimate the total dose delivered for single center or multiple center beam geometries.

Click **NEXT** to assign the dose. The Calculation menu appears in Quick Calculation Mode. Click **BACK** to return to the referring Dose Assignment Method Wizard or **CANCEL** to discard the partially created plan.



801

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



## Multiple Center Dose Assignment

The Multiple Dose Assignment Wizard is shown in (*Figure 43 Multiple Centers Dose Assignment, page 47*). The number of center doses corresponds to the number of centers. Set the desired dose in cGy for each center and select whether or not critical beams should have nonzero dose. Click **NEXT** to set the beam doses. Click **BACK** to return to the Multiple Centers Dose Assignment Methods (*Figure 36 Multiple Centers Dose Assignment Methods, page 40*) window. Click **CANCEL** to discard the partially created plan.

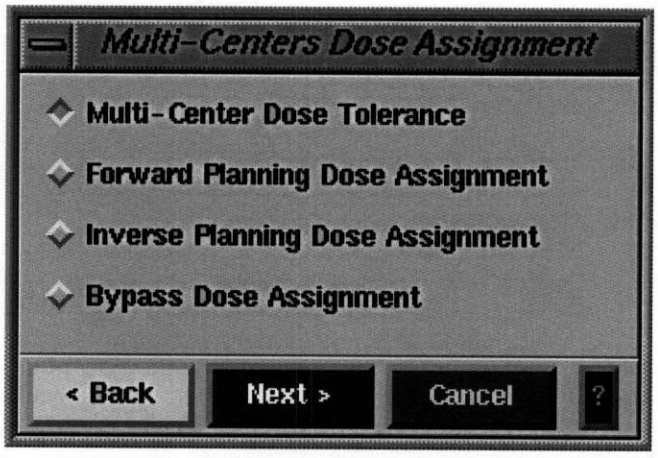



**Figure 43 Multiple Centers Dose Assignment**

Occasionally, selected center doses cannot all be obtained for the chosen center locations. If that occurs, an approximation is used to assign dose. When the approximation is used, a warning (*Figure 44 Multiple Center Dose Assignment Warning, page 47*) appears that gives the calculated dose at each center.

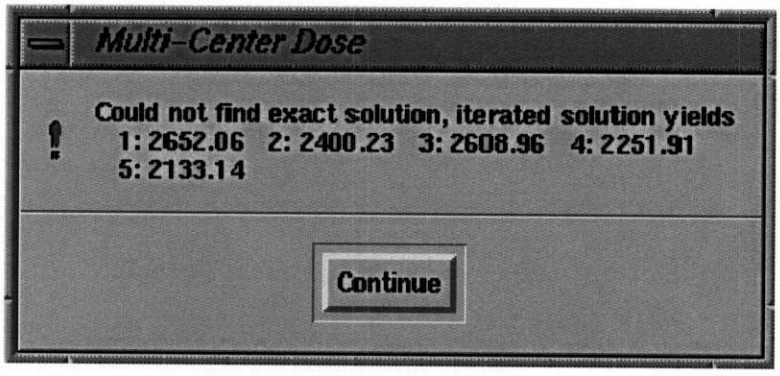



**Figure 44 Multiple Center Dose Assignment Warning**



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

802

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



## Inverse Planning Dose Assignment

Inverse Planning allows you to set constraints on doses to each tumor and critical region and find a plan that best meets these constraints. The Inverse Planner uses an optimization algorithm. This algorithm minimizes the total number of monitor units delivered such that your specified constraints are met.

In this option, you set dose constraints on different ROIs and allow the planning system to find a solution for the beam dose (in MU) that meets the constraints. This can be viewed in the Inverse Planning window (*Figure 45 Inverse Planning Dose Assignment, page 49*), set the multiple parameters to create a meaningful problem for the inverse planning algorithm to solve. This section describes those parameters and how to set them.

**NOTE:** When the system is in Coarse Calculation mode, the Inverse Planning algorithm may give solutions that slightly violate constraints. This discrepancy arises because the region constraints are set at one of every eight voxels.

**NOTE:** The alternative of using a fine calculation mode has two drawbacks. One, the solution search usually requires significantly more time -- eight times as long or more. Two, the size of the problem may overload the memory of the workstation. Therefore, we recommend use of the coarse calculation mode despite the possibility of constraints being violated.



803 Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



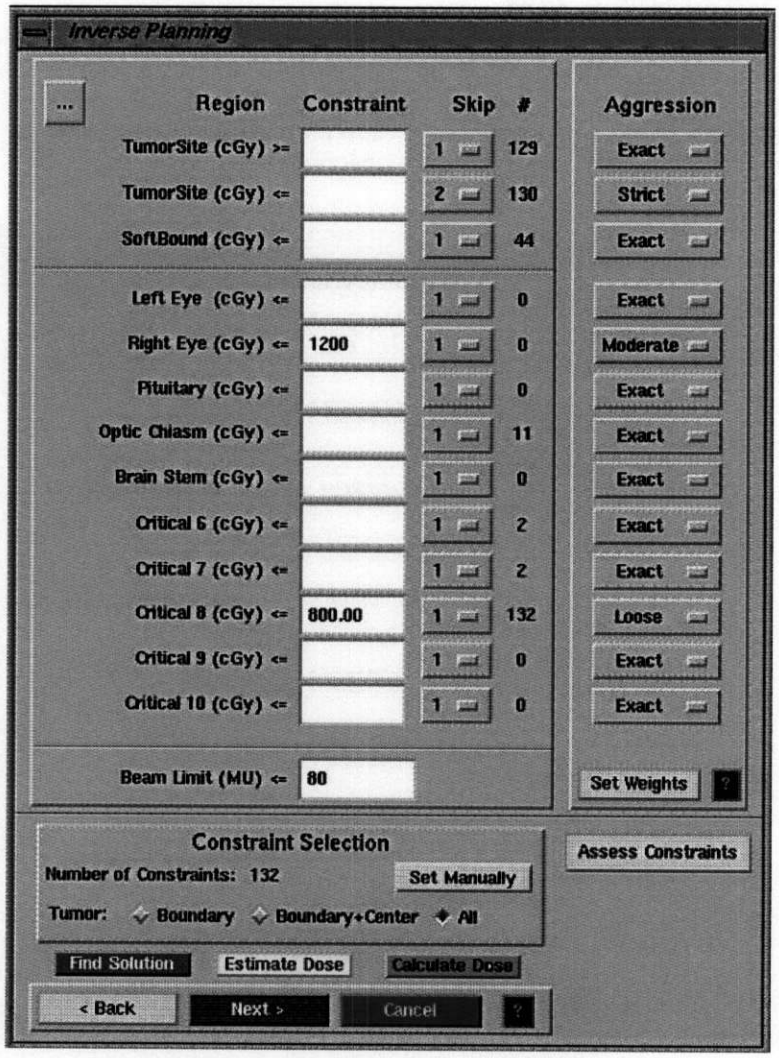



**Figure 45 Inverse Planning Dose Assignment**



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



## Assign Constraints

Assign constraints by setting a minimum dose for the tumor in the top text field and maximum doses for the tumor, soft boundary, and critical structures. The Inverse Planning Constraint Set window is detailed in *Figure 46 Set Inverse Planning Constraints, page 50*. A tumor minimum must be set (in cGy) and it must be less than the tumor maximum. Constraints on all other ROIs, including the maximum dose to the tumor, are optional.

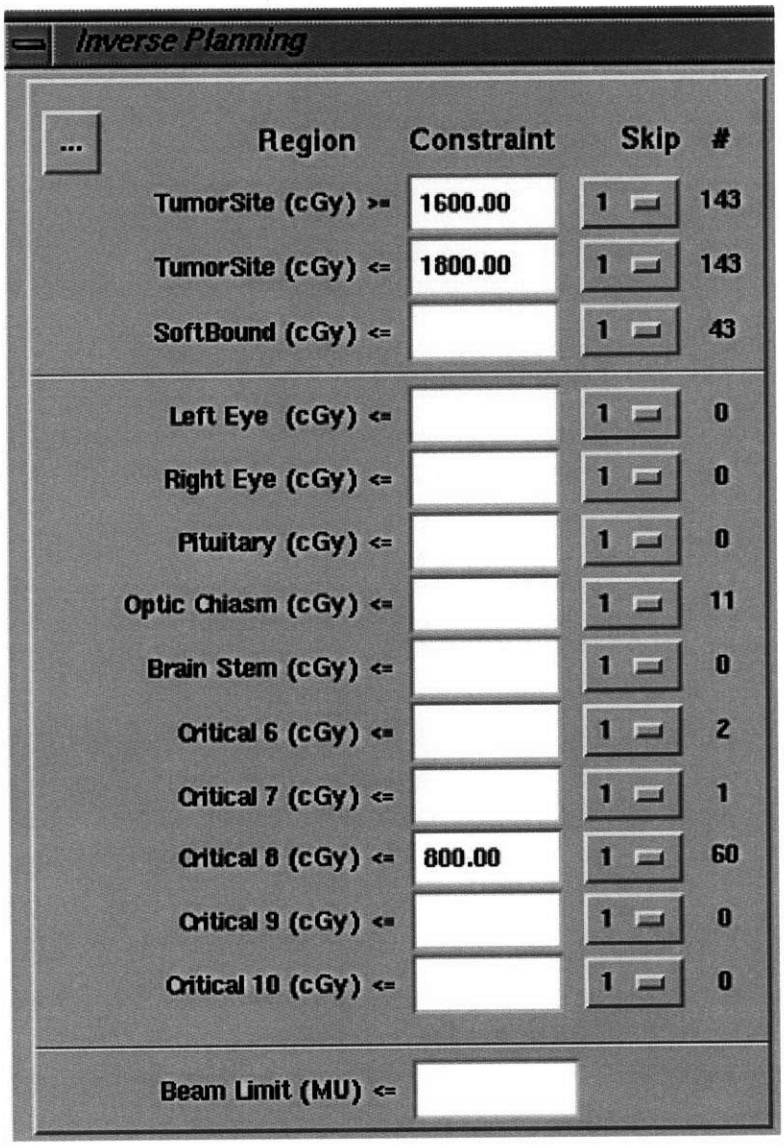



**Figure 46 Set Inverse Planning Constraints**



805 Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



**NOTE:** If more than one tumor is delineated, this window sets the same constraint for voxels in every tumor. If you wish to set different constraints for different tumors or not constrain a tumor at all, use the individual tumor Inverse Planning method described in *section, Individual Tumor Constraints, page 59.*

The number of constraints created by setting each variable is listed on the right side of the submenu. The number of constraints is based on the size of the tumor, whether the constraint is to be met exactly or not, and if a skip factor is set. The total number of constraints for the problem appears toward the bottom of the Inverse Planning menu. (*Figure 49 Constraint Selection Submenu, page 54*)

It is generally a good idea to keep the number of constraints as small as practical. This can be achieved by using the skip factor to the right of each dose assignment text box. The skip factor reduces the number of constraints on the ROI by a factor approximately equal to the value of the skip factor. A skip factor of 1 constrains every constraint point in that ROI. A skip factor of 2 uses every other constraint point in that ROI. A skip factor of 20 uses 1 in 20 constraint points. This often does not have an adverse effect on the solution, because many of the constraints within a ROI are redundant to linear combinations of other constraints.

You can also set a dose limit (in machine units) for every beam.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118 806

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



## Set Aggression

Occasionally, you may set constraints that the Inverse Planning algorithm cannot achieve. Generally, this happens when a high minimum dose is very near a low maximum dose. In this situation, you can either change the constraints or relax the constraints. The aggression setting (*Figure 47 Set Aggression, page 52*) allows you to relax the constraints by determining how aggressively the inverse planning algorithm should try to meet each constraint.

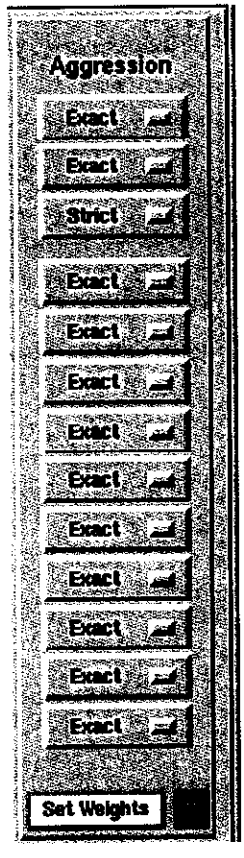



**Figure 47 Set Aggression**

Four levels of aggression are available: exact, strict, moderate, and loose.

An exact constraint only finds a solution that completely satisfies the specific constraint. The inverse planning algorithm allows constraint violation for strict, moderate, and loose aggressiveness. The total violation is limited by adding a weighted cost for each constraint violation. This cost augments the total MU cost optimized by the inverse planner. You set these weights by clicking **SET WEIGHTS**.



807 Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



The Set Aggression Weights (*Figure 48 Set Aggression Weights, page 53*) window appears. Input the desired numbers for strict, moderate, and loose. The larger the number, the more strictly the planning algorithm attempts to adhere to the constraint.

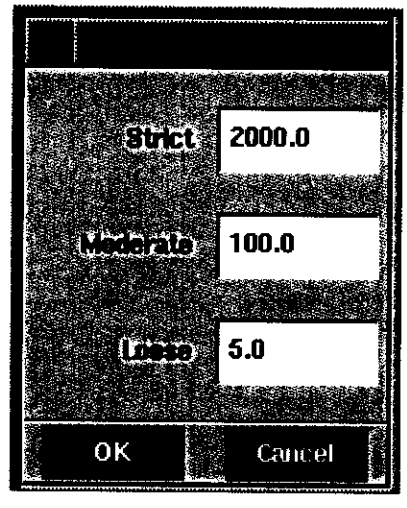



**Figure 48 Set Aggression Weights**

When strict, moderate, or loose constraints are used, the number of constraints is double the number when exact constraints are used.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



## Select Tumor Constraint Type

You have three options to set tumor constraints (*Figure 49 Constraint Selection Submenu, page 54*). The Inverse Planner can evaluate constraints only on the tumor boundary, only on the tumor boundary plus one point in the middle of the tumor, and on all grid points within the tumor. The effect of changing the tumor constraints appears in the count of the total number of constraints, above the selection buttons, as well as in the number of constraints listed (*Figure 46 Set Inverse Planning Constraints, page 50*). The total number of constraints, of course, also includes critical region and soft boundary constraints.

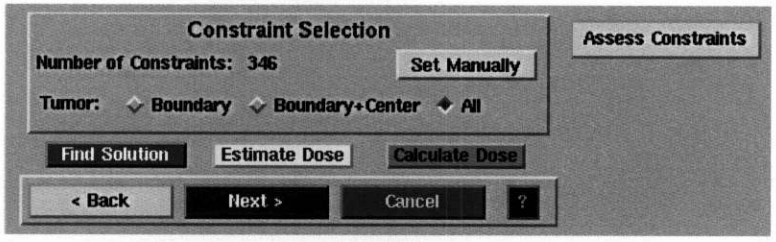



**Figure 49 Constraint Selection Submenu**

If the inverse planning problem becomes too large, a warning (*Figure 50 Memory Limit Warning, page 54*) appears to warn you that the system may run out of memory before the problem can be solved. The size of the inverse planning problem is a multiple of the number of constraints and the number of beams. To avoid overloading the system memory, reduce the number of beams per node or increase skip factors to reduce the number of constraints.

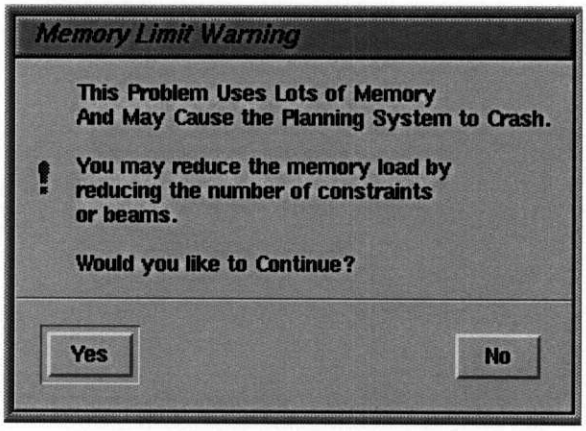



**Figure 50 Memory Limit Warning**



809 Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



## Set Manual Constraints

In addition to automatically generated constraints, you can manually create constraints. This can be done when in inverse planning by clicking **SET MANUALLY**. Alternatively, if the inverse planning window is not displayed it can be set from the Constraint Curves option in the Model Parameters menu. Either selection displays the Set Constraints Manually (*Figure 51 Manual Constraint Curves, page 55*) window.

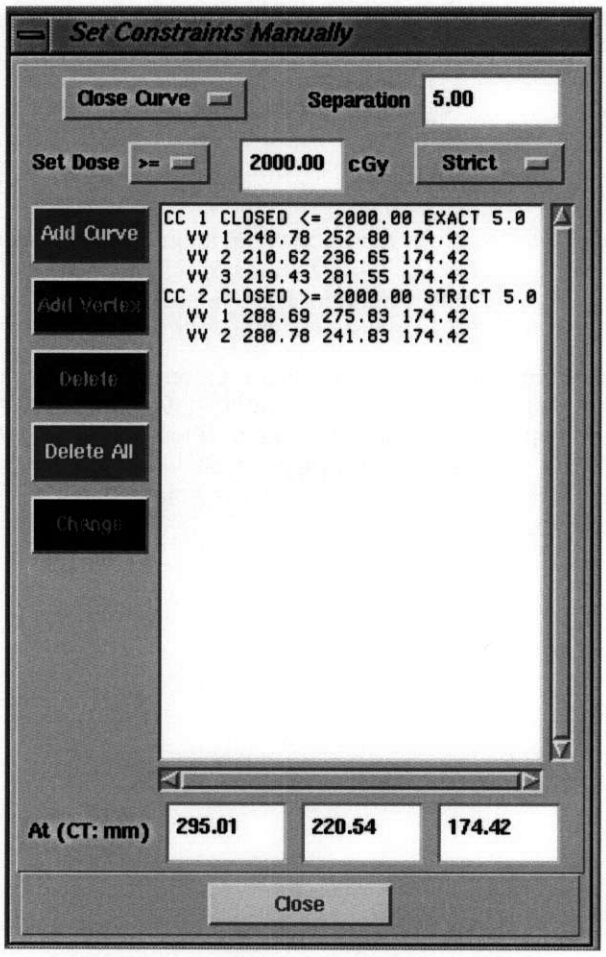



**Figure 51 Manual Constraint Curves**

The top two windows ask you to select whether the constraint is point, open curve, or closed curve. If the constraints are open or closed curves, you need to set a separation distance for how far separated the two constraints need be. This number is the maximum separation. The actual separation is an even divisor of the distance between two points.

The three windows on the second line indicate if the constraint is a maximum (<=) or minimum (>=), the limiting dose, and how aggressively the inverse planner needs to achieve this constraint.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

810

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



**ADD CURVE** creates a constraint. The constraint is added to the list. The constraint is indicated by a line such as, "CC 1 OPEN <= 2000.00 STRICT 8.0".

- The CC indicates that it's a constraint.
- The number 1 is the identifier.
- Open indicates that the constraint is an open curve.
- "<=" indicates that the constraint is a maximum. 2000.00 is the constraint limit.
- Strict indicates that the constraints should be aggressively adhered to.
- 8.0 is the maximum separation (in mm) between constraint points.

**Step 1.** Highlight the constraint and use the cursor to select a point in the Axial, Sagittal, or Coronal View windows. A magenta +, marked *0*, appears at the point, and its coordinates in the CT coordinate frame appear at the bottom (*Figure 51 Manual Constraint Curves, page 55*).

**Step 2.** Click **ADD VERTEX** to include it as part of the constraint. The constraint on the screen changes to red and is marked with two numbers. The first indicates the constraint ID. The second indicates the vertex ID. The vertex is added to the constraint list as "*VV ID x-coordinate y-coordinate z-coordinate*".

Point constraints have red "+" markers. Open curves have connected red lines between each sequential pair of vertices. Closed curves have connected red lines, but for these curves, the last vertex and first vertex in the list connect. (*Figure 52 Manual Constraints Shown on the Axial View, page 57*) The constraints are always visible when the Inverse Planning window (*Figure 45 Inverse Planning Dose Assignment, page 49*) is displayed or when Show Constraint Curves is activated from the Model Parameters menu.



811

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



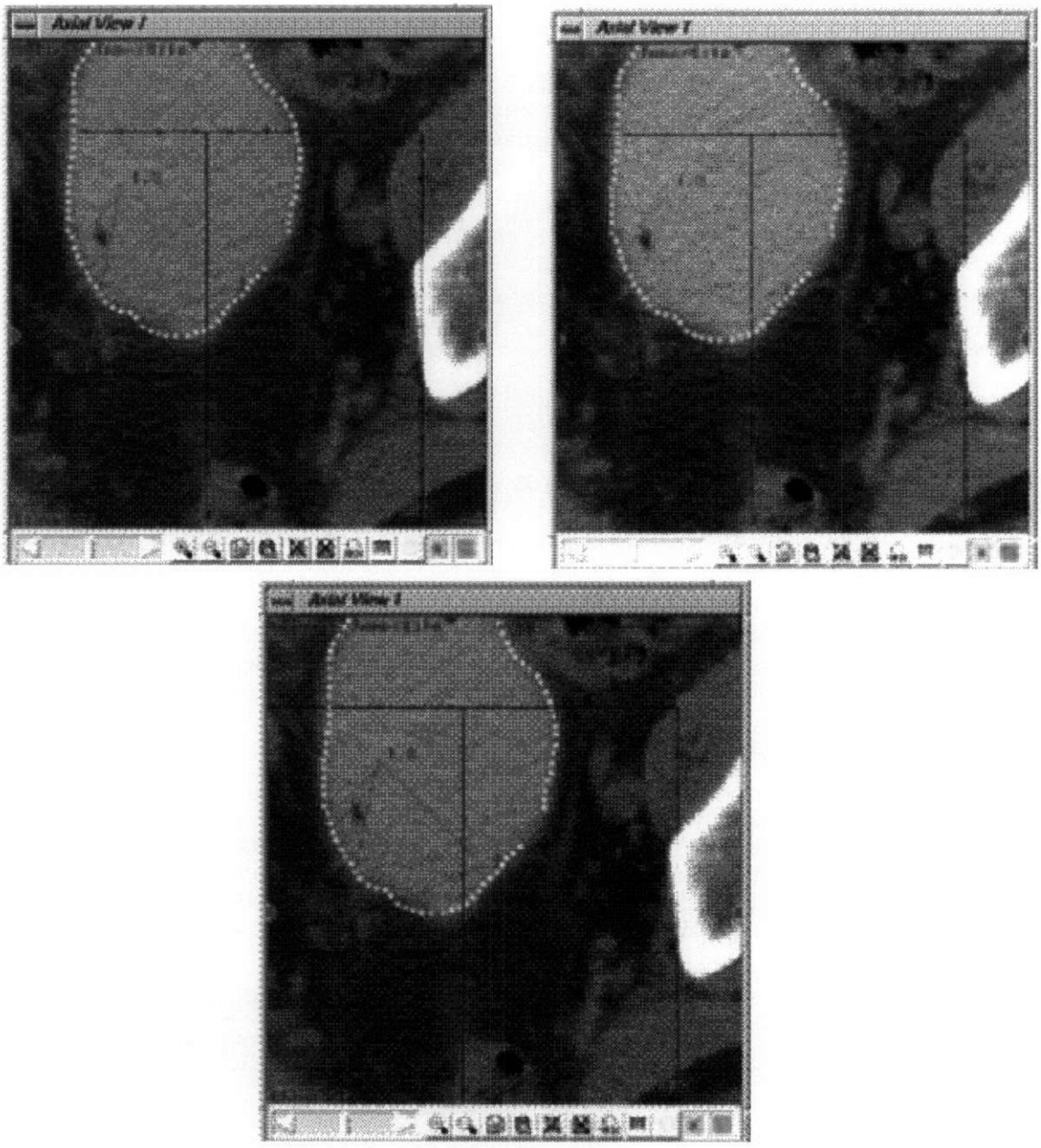



**Figure 52 Manual Constraints Shown on the Axial View**



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



## Determine Plan

Once the constraints have been set, you can click **FIND SOLUTION** to determine whether an acceptable plan can be found. If a solution is found, a window (*Figure 53 Inverse Planning Found a Solution, page 58*) appears. If a solution cannot be found, a warning indicates no solution is available. To get past this point, change the maximum dose per beam, the constraints, or the aggression on one or more constraints until the inverse planner can find a solution.

**Figure 53 Inverse Planning Found a Solution**

If you want to view the resulting dose distribution, click either **ESTIMATE DOSE** or **CALCULATE DOSE**. Calculate Dose is a more accurate calculation. It takes longer than Estimate Dose.

You can accept the solution and proceed to calculate the dose distribution by clicking **NEXT**. After **NEXT** is selected a prompt appears to ask you to verify that it is okay to exit the Inverse Planner. You can also click **BACK**, which causes the Inverse Planner to close and the appropriate Dose Assignment wizard to reappear. **CANCEL DISCARDS** the plan.

## Assess Constraint Violations

After a solution is found, you can check for constraint violations using the Assess Constraints feature. This only includes data if one or more constraint was relaxed so that its aggression parameter is weaker than Exact. When **ASSESS CONSTRAINTS** is selected, the Summarize Constraint Violations (*Figure 54 Assess Constraint Violations, page 58*) window appears. This text box allows you to see the maximum constraint violation and the maximum (or minimum) value for each type of constraint. It also lists individual constraint violations.

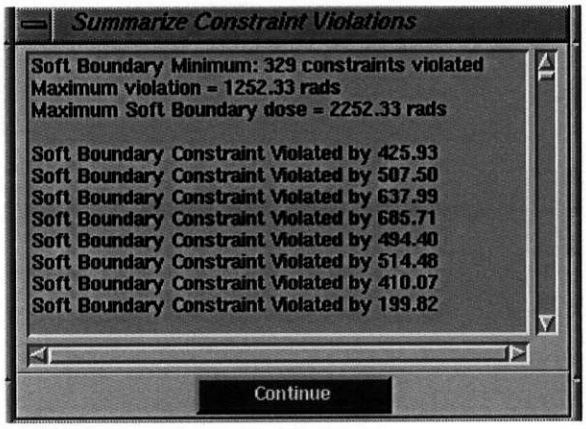



**Figure 54 Assess Constraint Violations**



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

813

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



## Individual Tumor Constraints

If a patient has multiple tumors or a single tumor that has been delineated with two or more tumors, you may want to treat each tumor with different doses. You can do this by using the Multiple Tumor Dose Assignment window (*Figure 55 Individual Tumor Inverse Planning Constraint Assignment, page 59*). This display is activated by clicking the upper left corner of the Inverse Planning Constraints window (*Figure 46 Set Inverse Planning Constraints, page 50*). Activating this option desensitizes the text fields for minimum and maximum tumor dose.

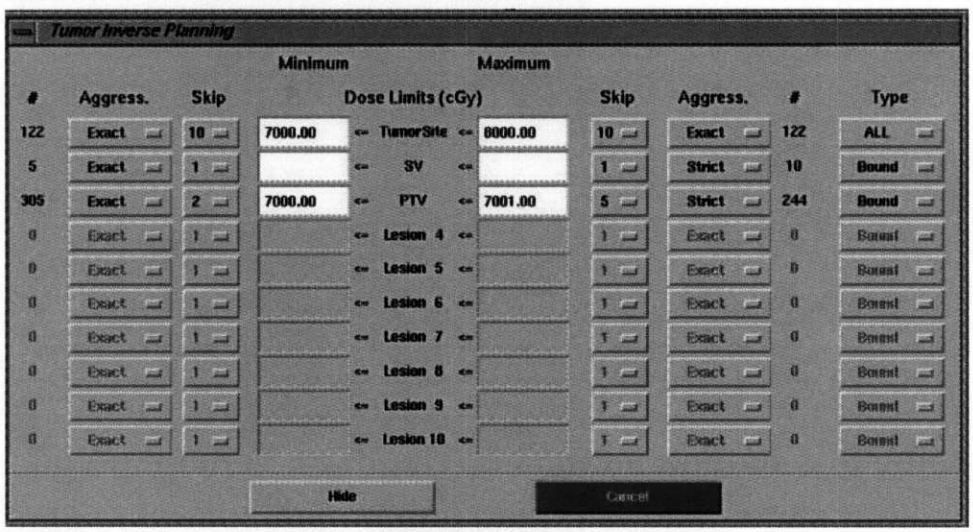



**Figure 55 Individual Tumor Inverse Planning Constraint Assignment**

You can set constraint limits for minimum and maximum dose to each tumor. Each constraint limit can be modified with an aggression setting and the number of constraints limited by setting a skip factor and setting constraints on the entire tumor, the boundary, or the boundary plus a single tumor center point (*see sections, Assign Constraints, page 50 and Select Tumor Constraint Type, page 54*).

If an individual tumor constraint limit is not set, that limit is unconstrained. For the program to search for a solution, at least one tumor must have a minimum dose. If a tumor has both minimum and maximum dose limits, the maximum dose limit must be greater than the minimum dose limit.

The HIDE button hides this display. The settings are kept and the program uses them. The **CANCEL** button returns the Inverse Planner to a single tumor solution mode and tumor dose limits are set as described in Section Assign Constraints, page 50.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



# Finetune Beam Geometry and Dose

The On-Target Treatment Planning System includes a Finetune adjustment function to select and adjust beams individually or in groups. Open the Finetune menu (*Figure 56 The Finetune Menu, page 60*) by clicking **FINETUNE** from the Toolbox.

**Figure 56 The Finetune Menu**



815

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



The Finetune menu is divided into five submenus.

1. The top submenu has beam selection options. This submenu allows you to flag beams to be modified using the action options in the second submenu.
2. Second submenu actions include the ability to resize a collimator, retarget beams, reset flags, or modify dose weights.
3. The third submenu displays a history of selections and actions taken since the FINETUNE menu was opened.
4. The fourth submenu is a list of beams and centers. This menu can be hidden or displayed using the **SHOW BEAMS/CENTERS** toggle button in the fifth submenu. In *Figure 56 The Finetune Menu, page 60*, the Beam and Center lists are hidden.
5. The bottom submenu has administrative functions.

Each submenu (except the Beam and Center list) includes a help window reached by clicking the appropriate **?** button.

## Beam Selection

The top submenu (*Figure 57 Beam Selection Options, page 61*) offers options for selection of groups of beams.

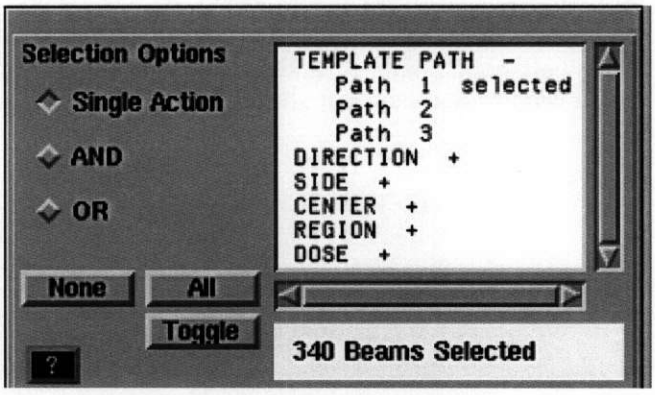



**Figure 57 Beam Selection Options**

Selected beams are highlighted in the Beam List. (*section, Beam and Center List, page 70*) The label on the lower right of the Selection submenu indicates the number of selected beams. The selected beams are displayed in the History submenu (*see section, Finetune Planning History, page 69*). When the Finetune menu is opened, initially no beams are selected.

### Selection Options

Beams can be selected and grouped in different configurations. Use **NONE** to select no beams, or **ALL** to select all beams. The **TOGGLE** button simultaneously deselects selected beams and selects deselected beams.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



The other six selection types are listed in the upper right text field. These selection types are select by **TEMPLATE PATH**, **DIRECTION**, **SIDE**, **CENTER**, **REGION**, **DOSE**, and **TUMOR ID**. The selected beams are indicated in the HISTORY submenu (*see section, Finetune Planning History, page 69*).

- **Template Path:** Each plan can be created from multiple paths. Generally, three template paths are created for each system. To select beams for a single template path, highlight Template Path + in the selection list. The **+** changes to **–** and the available paths are listed. When you highlight the desired path, the word "selected" is appended to the highlighted path.

  Deselect by clicking that group again, and "selected" disappears. Click **TEMPLATE PATH -** again to deselect the beams selected by path and compact the list so that the individual template paths are no longer visible. When the list is compacted, the – is replaced by +.
- **Direction:** From each robot node, multiple beams are available, and each beam has a direction. To select all the beams in a single direction, highlight Direction +. The **+** changes to **–** and the list of available directions appears. Highlight the desired direction, and the word "selected" is appended to the highlighted direction.

  Deselect by clicking that group again, and "selected" disappears. Click **DIRECTION -** again to deselect the beams selected by direction and compact the list so that the directions are no longer visible. When the list is compacted, the – is replaced by +.
- **Side**: You can select beams based on the side of the patient from which the beam emanates. To make this type of selection, highlight SIDE +. The **+** changes to **–** and the list of sides (left, right, posterior, anterior, superior, and inferior) appears. Select the desired side and a window appears. (*Figure 58 Select Beams Entering the Left Side of the Patient, page 62*)

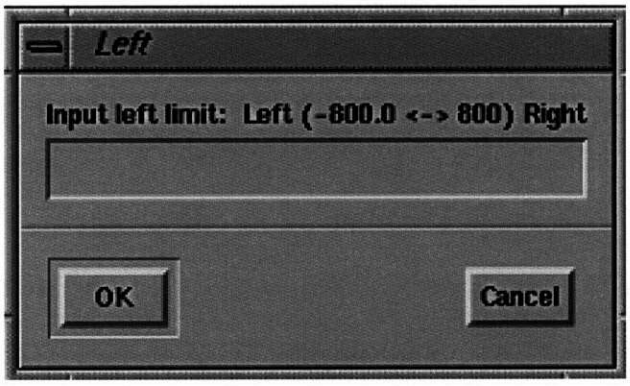



**Figure 58 Select Beams Entering the Left Side of the Patient**

This window prompts you to input a value that determines how far toward the desired side to select beams. The values used are based on the source coordinates of the beams in patient coordinates. For example, 6.29 shows the left side selection window. In patient coordinates, left is the negative x direction. Therefore, the farthest left source beam will have an x coordinate of –800 mm. If you input –300, all beams with a patient x source coordinate –300 mm or less are selected, after the OK button is pressed.



817

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



On the other hand, if right had been selected and –300 mm input, all beams with a patient x source coordinate –300 mm or greater would be selected, because right is in the positive x direction. Posterior is the patient negative y direction. Anterior is the patient positive y direction. Superior is the patient positive z direction. Inferior is the patient negative z direction. The word "selected" is appended to the highlighted side.

Deselect by clicking that group again, and "selected" disappears. Select SIDE - again to deselect the beams selected by side and compact the list so that the sides are no longer visible. When the list is compacted, the – is replaced by +.

- **Center**: Select all beams pointing at a particular center by highlighting Center +. The + changes to – and the available centers are listed. Highlight the desired center, and the word "selected" is appended to the center.

  Deselect by clicking that group again, and "selected" disappears. Click **CENTER** - again to deselect the beams selected by center and compact the list so that the centers are no longer visible. When the list is compacted, the – is replaced by +.

- **Region**: Select all beams that intersect with a given critical region by highlighting Region +. The + changes to – and the available critical regions are listed. Highlight the desired region, and the word "selected" is appended to the region.

  Deselect by clicking that group again, and "selected" disappears. Click **REGION** - again to deselect the beams selected by region and compact the list so that the regions are no longer visible. When the list is compacted, the – is replaced by +.

- **Dose**: You can select beams based on dose limits by highlighting Dose +. The + changes to – and the dose limit options are listed. The beams can be selected by dose (in MU, rads, and reference point rads) less than or greater than a specified value. Select the desired dose limit option, and a Dose Limit Selection window appears.

  *Figure 59 Select Beams with Dose Less Than a Prescribed Value, page 64*, is the window for selection of all beams with rads less than a specified value. Plug the desired value in, the appropriate beams are selected, and the word "selected" is appended to the dose limit.

  You can select every beam with rads less than the input value, or you can select every other beam, every 3rd beam, etc. to every 12th beam. You can also select beams skipping every other beam, every 3rd beam, etc. to every 12th beam.

  Deselect by clicking that group again, and "selected" is erased. Click **DOSE** - again to deselect the beams selected by dose limit and compact the list so that the dose limits are no longer visible. When the list is compacted, the – is replaced by +.

  **NOTE:** Beam list dose values are rounded to the nearest integer. So, it may occasionally appear as though some beams were erroneously selected or not selected.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



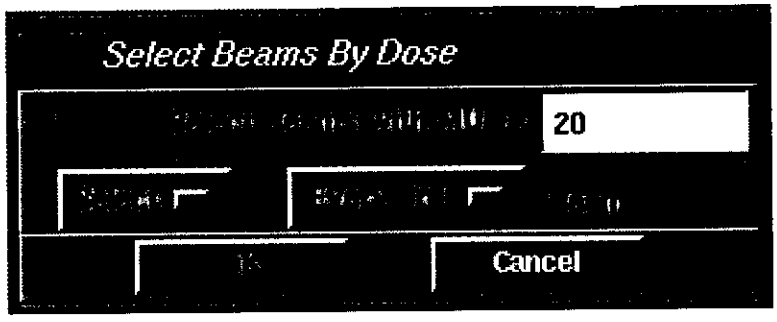



**Figure 59 Select Beams with Dose Less Than a Prescribed Value**

- **Tumor:** You can select beams based on which tumor a beam is assigned to by highlighting TUMOR +. The + changes to – and the drawn tumors are listed. Highlight the desired tumor, and the word "selected" is appended to the tumor.

  Deselect by clicking the tumor again, and "selected" disappears. Click **TUMOR** – again to compact the list so that the tumors are no longer visible. When the list is compacted, the – is replaced by +.

## Selection Logic

Beams can be selected in single groups or using Boolean logic operators. When the Single Action option is active, only the last selection is acted upon. When the And option is active, the intersection of the individual beam groups is selected.

For example,

**Step 1.** Click **PATH 1** and **REGION LEFT EYE**

**Step 2.** Click all beams that are in Path 1 and pass through the drawn left eye. When the **OR** option is active, the union of the individual beam groups is selected. For instance, Clicking **PATH 1** or **REGION LEFT EYE** selects all beams that are either in Path 1 or pass through the drawn left eye.

**NOTE:** When the selection option changes, all the beams are deselected and **Select None** becomes the last entry in the Finetune History.



819

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



## Modify Selected Beams

After you select the desired beams, these beams can be changed using the Action Options submenu (*Figure 60 Options to Alter Properties of Selected Beams, page 65*). When an action is taken, the beam list is updated and the history list indicates the action. Most actions affect only selected beams. The only exceptions are the Forward Planner and Inverse Planner, which act on every beam that is turned on.

The four basic actions available are:

1. Target Beams
2. Set Collimator Size
3. Flag Beams
4. Set Beam Weights.

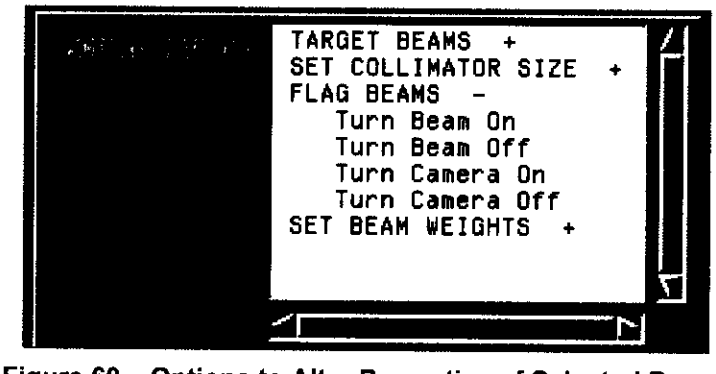



**Figure 60 Options to Alter Properties of Selected Beams**



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

820

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



## Target Selected Beams

To target beams, highlight target beams +, and the + changes to –. Below are the targeting options. Only selected beams are targeted.

- **Conformal Shape wizard**, conformable targeted beams aim at boundary points around the delineated tumor associated with each beam.
- **Random Center Assignment**, assigns each beam to a center randomly.
- **Sequential Center Assignment**, assigns the first beam to the first center, the second beam to the second center (if there is one), until the *n*th beam, which is assigned to the *n*th center, where *n* is the number of centers. The (n+1)th beam is assigned to the first center, (n+2)th beam is assigned to the second center, etc., through all the beams.
- **Manual Center Assignment**, allows you to manually enter the three coordinates of the target. The frame for the coordinates is indicated in the Beam and Center list. You can target the selected beams to a specific center.
- **Beam Targeting**, targets selected beams to a specific area.
- **Assign a Tumor ID**, does not actually change the beam target. They change the tumor area to which the beam is assigned. The wizards only allow you to set the target flag for conformal shape planning. The other wizards assign beams to Tumor Area 1, regardless of which part of the anatomy the beam actually points at. Click **TUMOR AREA N**, where *n* is the tumor area to which the selected beams should be flagged, to change the tumor identifier.

## Set Collimator Size

To set the collimator size, click **COLLIMATOR SIZE** +. The + changes to – and the available collimator sizes are listed. Select the desired collimator size from the list.

## Set Beam Flags

To set beam flags, click **FLAG BEAM** +. The + changes to – and the set flag options are listed. Two flags can be set. Beams can be turned On or Off. When a beam is turned Off, it will not deliver a dose.

The Camera Taking flag can also be turned On or Off. If the Camera Taking flag is turned Off during treatment, the camera will not be used to reposition the patient immediately before that beam is delivered. Some nodes never have pre-treatment imaging, because either the Linac or manipulator blocks one of the cameras.

## Modify Beam Weights

To alter the beam weights, click **SET BEAM WEIGHTS** +. The + changes to – and the dose setting options, which set the beam MU, are listed. To set radiation absorbed at the anatomical target by each selected beam, you can use either the Single or Multiple Center Set Dose Tolerance function, the Forward Planning function, the Inverse Planning function, or Scale the dose by a multiplicative factor.



821

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



## Set Beam Dose

**To set the MU:**

**Step 1.** Click **SET BEAM MU**, the Set Beam Dose window (*Figure 61 Manually Set Beam Dose, page 67*) appears.

**Step 2.** Type in the dose and click **OK**.

**Step 3.** To set the radiation in rads at the anatomical target, click **SET BEAM CGY**, and a similar window (with 'MU' replaced by 'cGy') to the Set Beam Dose window appears.

**Step 4.** Type in the desired dose for each beam and click **OK**.

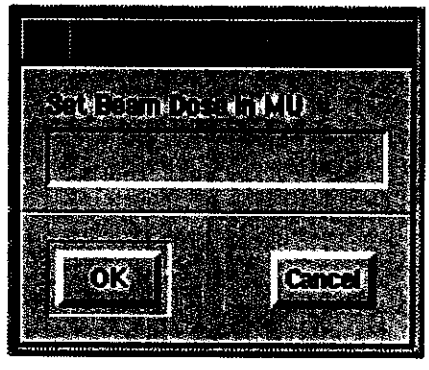



**Figure 61 Manually Set Beam Dose**

## Set Dose Tolerance

The Set Dose Tolerance action is nearly identical to the single center and multiple center dose assignment functions described in *sections, Single Center Dose Assignment, page 45 and Multiple Center Dose Assignment, page 47*. The windows are slightly different, because only the **OK** and **CANCEL** buttons are available. The dose assignment algorithm acts only on selected beams. Clicking **OK** implements the input dose requirement, and **CANCEL** exits the window.

## Forward Planning

The Forward Planning action is nearly identical to the Forward Planning Dose wizard described in Section, *Forward Planning Dose Assignment, page 45*. The window slightly different, because only the **OK** and **CANCEL** buttons are available.

**NOTE:** The dose assignment algorithm acts on all beams that are turned on. It does not consider which beams are selected.

Clicking **OK** implements the input dose requirement, and **CANCEL** exits the window.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



## Multiple Tumor Inverse Planning

To implement the Multiple Tumor Dose Assignment window within the Finetune menu, click **MULTIPLE TUMOR INVERSE PLANNING**. This selection displays the same Inverse Planning window (*Figure 45 Inverse Planning Dose Assignment, page 49*) called by the wizards. Both **BACK** and **CANCEL** close the window without saving the results. **NEXT** displays an "Are you sure?" dialog box. Clicking **YES** closes the window and updates the beam weights.

**NOTE:** Multiple Tumor Inverse Planning actions are not indicated in the History List discussed below. **NOTE** also that the dose assignment algorithm acts on all beams that are turned on. It does not consider which beams have been selected.

## Scaled Dose

The Scale Dose option scales the doses of the selected beams by a multiplicative factor. To scale the entire treatment, be sure to first select **ALL** beams, before scaling dose. The Scale Dose window in *Figure 62 Scale Dose, page 68* appears. Input the desired scale factor and click **OK**. **CANCEL** closes the window without changing the beams.

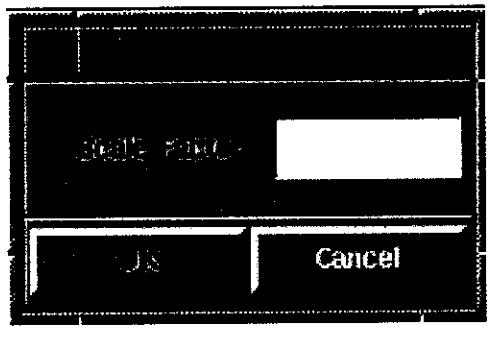



**Figure 62 Scale Dose**



823 Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



# Finetune Planning History

The Finetune menu includes a History list (*Figure 63 Finetune History List , page 69*) that allows you to see what steps have been taken to revise the current plan. When the Finetune menu is opened, the current beam configuration is saved as the baseline beam configuration. Every subsequent modification to the plan then alters the beam configuration. The History list is cleared if the Finetune menu is closed, and its contents are not saved with the plan.

**Figure 63 Finetune History List**

The Finetune History menu lists each selection and action taken since the Finetune menu was opened. When the Finetune menu is opened, the history reads select none to indicate that no beams are selected yet. You can review the steps taken to modify a plan. If the selection mode is single action, and a selection follows a selection, the first selection is overwritten with the second selection. Toggling the selected beams and beam actions are never overwritten.

You can modify the history in three ways.

1. If an action or selection had an unsatisfactory affect on the plan, that step can be deleted. Highlight the item to be removed, and click **DELETE**. The system recalculates the beams and dose distribution as if that step had not occurred.
2. If the adjustments you've made so far are completely unsatisfactory, click **DISCARD** to return to the baseline beam configuration.
3. If the adjustments are satisfactory, you can select **KEEP** and overwrite the baseline beam configuration with the current beam configuration. The last two options replace the History list with Select Nnone.

**NOTE:** The Multiple Tumor Inverse Planning action is not incorporated in the Finetune History list. Therefore, regenerating the beams from the Finetune History function will be incomplete, if this action was used to modify beam weights.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



## General Purpose Functions

The Finetune menu has general-purpose functionality that is displayed and implemented in the bottom two submenus. The bottom submenu (*Figure 64 Finetune Menu General Purpose Functions, page 70*) has the buttons that control these general functions.

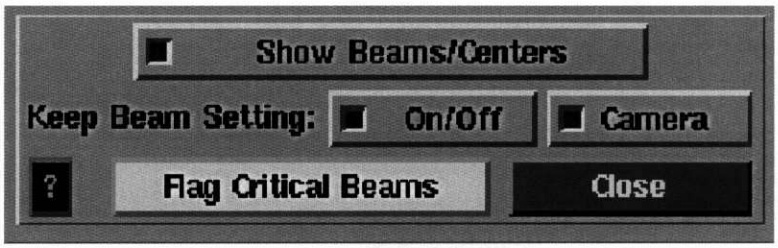



**Figure 64 Finetune Menu General Purpose Functions**

### Beam and Center List

You have the option of displaying or hiding Beam and Center lists as shown in *Figure 65 Beam and Center Lists, page 70*. The **SHOW BEAMS/CENTERS** button toggles this display. The right list is the Center (or Sphere) list. The left list is the Beam list.

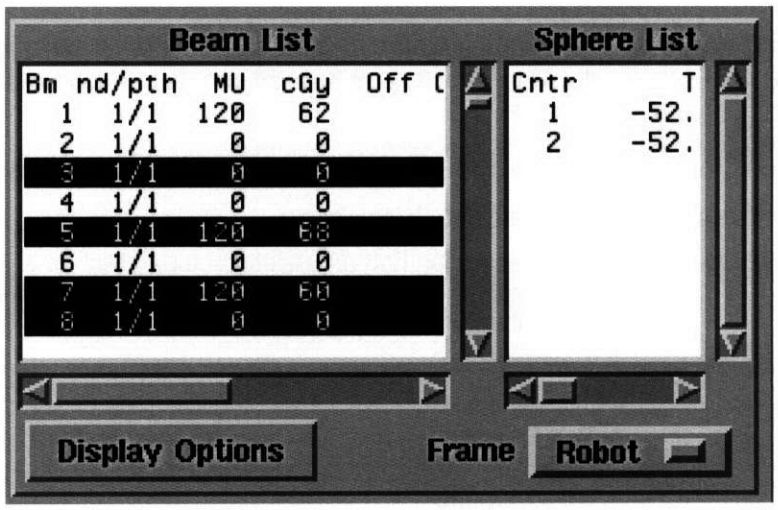



**Figure 65 Beam and Center Lists**

The Center list displays the center ID number, the coordinates of the center, and the diameter of the center. The coordinates can be displayed in the robot frame, the CT frame, or the patient frame. The button on the bottom right indicates which frame is currently showing.

The Beam list always includes the beam ID, the node ID, and the path ID. You can also opt to display the MU's, the absorbed dose at the target, the reference dose, the beam on flag, the camera flag, the critical regions intersected, the target flag, the collimator diameter, the source coordinates of the node, the target coordinates, and the tumor ID. The coordinates are displayed with coordinates selected from the frame cascade button. To change a display parameter use the toggle buttons accessed from the Display Options. (*Figure 66 Beam List Display Options, page 71*)



825 Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



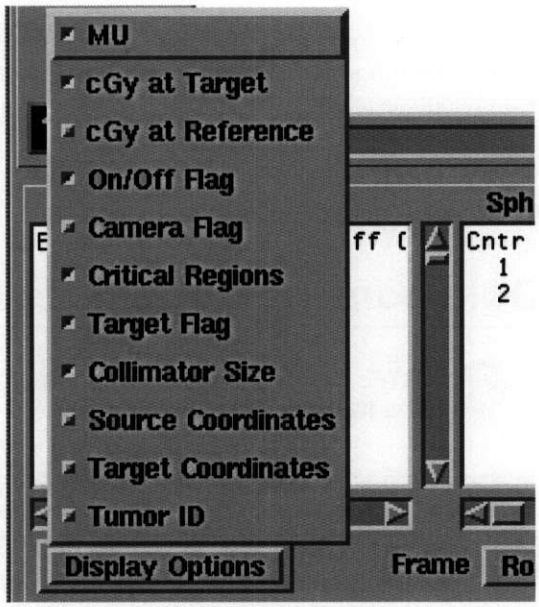



**Figure 66 Beam List Display Options**

## Keep Beam Setting

You may modify the beam flags and later wish to regenerate a plan using the wizards described in Sections *Generate Beam Geometries, page 36* and Assign Dose to Beams, page 45. For instance, you may want to turn off the beams going through the most superior and inferior slices because they may not produce the correct dose calculation results.

If the number of beams generated does not change and the Keep Beam Setting on/off function is on, the beams retain their on/off setting. If the Keep Beam Setting Camera function is on, the beams retain their camera flag setting. If these functions are off or if the new beam set generated has fewer or more beams, the beams generated will all be on and the beams have a picture-taking flag determined by whether the camera is blocked or not.

**NOTE:** Beams going through the most superior (top) and inferior (bottom) slices are flagged according to their intersection with the anatomy surface. These intersection points are determined by the **Surface CT** threshold set in the Beam Parameter Models. It is possible that not all the top/bottom beams be flagged if the surface CT threshold is not set correctly. Use the 3D View display to assess if all the top/bottom beams are turned on or off as desired.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



### Flag Critical Beams

Changing the beam target may affect whether that beam intersects a critical structure. Flag Critical Beams (*Figure 64 Finetune Menu General Purpose Functions, page 70*) reassesses the beams that intersect a critical structure.

### Close Finetune Menu

Click **CLOSE** to exit the Finetune menu.

## Export Data from the CyberKnife User Control Console

**NOTE:** CyRIS InView must be turned on in order for DICOM data to be transmitted to it.

One disadvantage of importing data directly from the scanner to CyRIS InView is that the image editing tools are not as sophisticated as on the CyberKnife System User's Control Console (UCC). It may be simpler for you to import the medical images to the UCC and then push those images to CyRIS InView workstation.

For more information on CyRIS InView, *refer to tab "9" CyRIS InView, in this manual.*



827

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



# PLAN EVALUATION TOOLS

## Plan Evaluation Tools

After a plan is created, several evaluation tools, such as the Dose Volume Histogram (DVH) and Isodose Lines, will help you assess the efficacy of the plan.

**WARNING: The CyberKnife is specified to reproduce total dose at ± 1% or 1 MU, whichever is greater, for accumulated doses between 10 and 1000 MU. Beams with lesser or greater dose may exceed these error limits.**

## Treatment Dose Calculation

To evaluate a plan, first calculate the dose distribution through the patient anatomy. The dose is calculated through two defined volumes. A large volume with a gross grid characterizes the dose through the majority of the patient CT study. Near the target region, a finer dose calculation grid is used to calculate and display (using either colorwash or isodose lines) the dose distribution.

### Dose Calculation Volume

The size and location of the fine calculation grid is indicated by the blue box seen in the axial, coronal, and sagittal views (see *module, Treatment Planning System, section, CT Image Displays, page 23*). The border of the volume has hashmarks every five units of the dose volume grid. The default dose volume has 64 x 64 x 64 grid elements. Each element is 1 mm x 1 mm x 1mm.

Click **GRID PARAMETERS** (*Figure 67 Change Dose Grid Dimensions, page 73*) under Model Parameters to vary the number or size of the grid elements. Each direction can have between 2 and 64 grid elements. Grid elements can range from 0.05 mm to 5.00 mm. Alternatively, you can vary the element size by grabbing the bottom right corner of the grid in either the Axial, Sagittal, or Coronal Views and expanding or contracting the blue box.

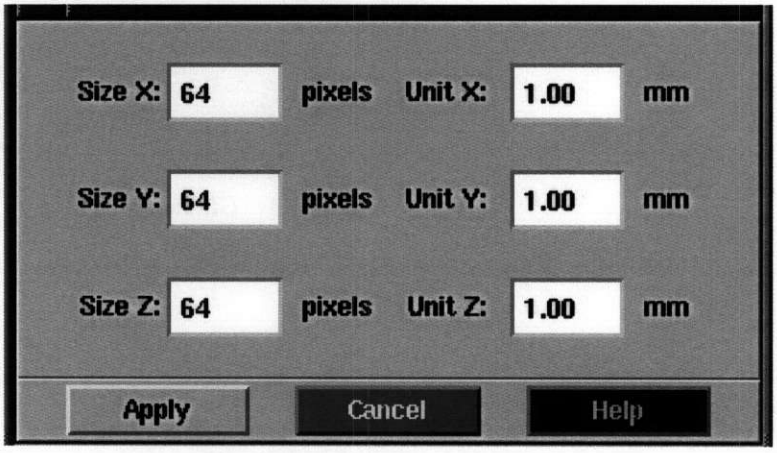



**Figure 67 Change Dose Grid Dimensions**



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



Adjust the position of the dose calculation volume by grabbing the top of the blue box and moving it. The fine dose volume must fit fully within the CT study for dose calculations to proceed.

## Reference Dose Location

The crosshairs that intersect inside the dose volume locate the reference point for calculation of the prescription plan dose. Move the reference point by selecting one of the lines, left-click, and sliding it with the mouse.

If the dose volume is moved, the reference point stays in the same location, unless the volume moves beyond the range of the reference point. If the reference is no longer in the dose calculation volume, it is reset to the center of the dose calculation volume.

You can attach the reference dose crosshairs to Center 1. This is very useful when doing a single center plan, and is helpful for visualizing the reference dose location. To detach or attach to Center 1, toggle the **ATTACH CENTER** button from the Model Parameters menu. The default Attach Center setting is On.

## Calculation Menu

You can use two methods to calculate the dose distribution. Select the desired calculation method with the appropriate button, **QUICK CAL** or **CALCULATE**, from the Calculation menu (*Figure 68 Calculation Menu, page 74*).

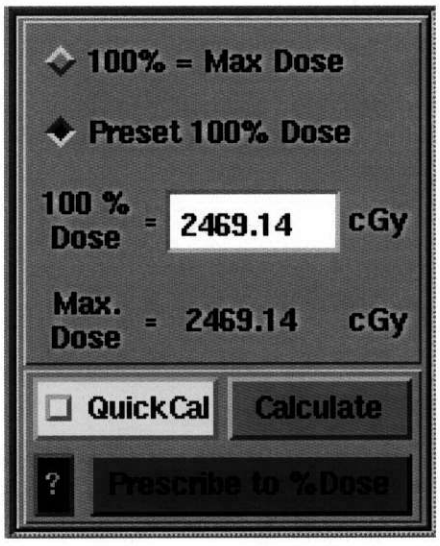



**Figure 68 Calculation Menu**



829

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



### Quick Calculation

Quick calculation gives you a quick estimate of the dose distribution of the plan and displays it using colorwash or isodose lines. This calculation only calculates through the dose calculation volume. It uses a coarser grid than the full calculation, and it is only done in the displayed axial, coronal, and sagittal slices and at the reference location.

Quick calculation automatically updates the dose calculation when anything affects that distribution. For instance, if a viewed slice is changed, a center is moved, or the dose is changed, the system automatically estimates the effect on the dose distribution when quick calculation is on. Quick calculation is On when the bubble to the left of Quickcal is light blue. It is off when the bubble is yellow.

**NOTE:** Because of the limited range of calculation grid points, this mode usually does not find the absolute maximum dose, although for most plans the calculated maximum dose is close to the actual maximum.

### Full Calculation

Full calculation calculates the dose distribution throughout the CT study. A full calculation is necessary to determine the dose volume histogram (DVH), dose statistics, and to create a plan summary. You must do a full calculation after all modifications to save a plan for treatment.

Click **CALCULATE** from the Calculation menu to do a full calculation. If Quick Cal is On, clicking **CALCULATE** turns it off. The Job In Progress window appears and indicates that the dose is being calculated, the DVH is being generated, and the isodose surface is being drawn.

The dose calculation will warn you if the maximum dose exceeds a preset value, if one beam contributes more than a preset percentage of the total dose, or if the maximum dose is not in a defined tumor or at the reference dose location. An example of the warning is shown in (*Figure 69 Sample Dose Maximum Dose Warning, page 75*).The default maximum dose warning limit is 10000 cGy; the default warning limit for one beam's percent contribution to the total dose is 25%. Accuray can change the limit settings for these warnings, if you wish.

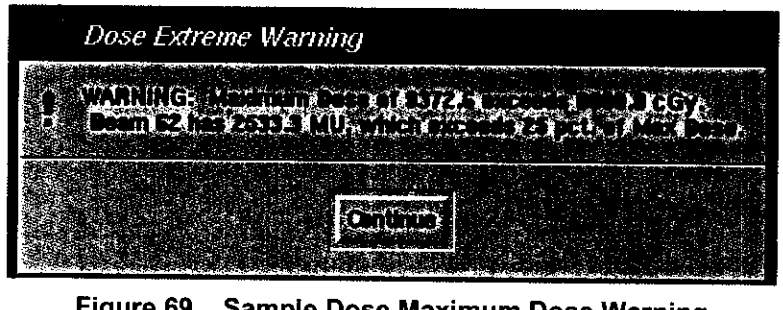



**Figure 69 Sample Dose Maximum Dose Warning**



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



### Prescribe to Dose

When you are satisfied with the appearance of the dose distribution to set a specific dose to a percent isodose line, click Prescribe to % Dose. The Prescribe Dose (*Figure 70 Prescribe to Dose, page 76*) window appears.

Set the desired dose in cGy for a given isodose curve (in percent) and select OK to scale the beam weights, recalculate the dose distribution, and close the display. **CANCEL** closes the display without modifying the beam weights.

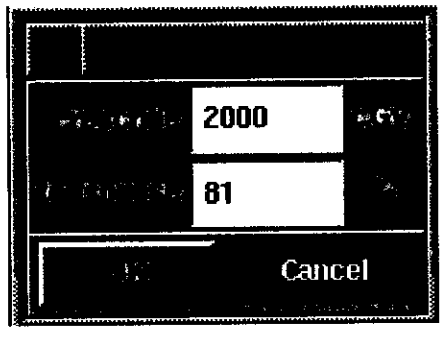



**Figure 70 Prescribe to Dose**

### Isodose Line Reference

By default, the maximum dose is the 100% isodose. You may want to use a different dose as the basis for drawing isodose curves. Set the 100% dose manually by clicking **PRESET 100% DOSE** and set the desired 100% dose value. If this dose is greater than or equal to the maximum dose, the maximum dose appears in black. If the manually set 100% isodose line is less than the maximum dose, the maximum dose appears in red. When a manual 100% dose is entered and you hit return within the text box, the isodose curves are redrawn in the 2D CT windows.

## Contour Correction

The default calculation algorithm models the beam cross-section with a uniform depth at the beam central axis. Sometimes this may be insufficient to generate the dose distribution accurately; for example, a large collimator size is used to treat an anatomy with high curvature surface. When necessary, you can click **CONTOUR CORRECTION** to model the beam depth. This option uses the actual depth along the beam cross-section, not the depth at the beam central axis, for dose calculation. Thus, the resulting dose distribution is more accurate. The disadvantage is that it takes much longer to finish a calculation. (Expect a typical dose calculation with contour correction to take 20 minutes to an hour.)

# Point Dose

The dose at a point on the anatomy can be displayed by clicking any of the 2D CT windows. The point dose tracks the mouse's movement if you click-hold.

**NOTE:** The dose will not appear if the point selected is a center or the border or crosshairs of the dose calculation volume. If dose at those points needs to be known, make these items invisible using the appropriate toggle button, or click-hold a different point and drag the mouse toward the point of interest.



831 Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



## Isodose Lines

The isodose lines appear in the 2D CT windows after the dose calculation is finished. Their color legend is shown in the Axial View 1 window. You can modify the colors and dose percentages.

Right-click to pick one of the color/dose percentage pairs. The Define Isodose Color window (*Figure 71 Define Isodose Color and Percentage, page 77*) appears. It has three sliders that can be used to specify the red, green, and blue component of the color, respectively. The resulting color appears inside the rotation frame.

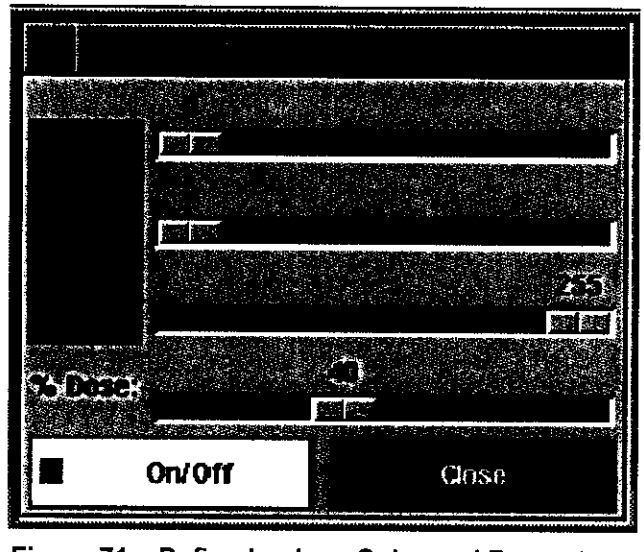



**Figure 71 Define Isodose Color and Percentage**

Another slider defines the dose percentage associated with the color. Move those sliders to get the desired levels. The color legend is updated simultaneously. If you do not want the selected isodose line to be visible, turn it off using the **ON/OFF** toggle button.

Normally TPS does not display the isodose lines overlaid on the CT that has CT number less than the surface CT threshold. However, you can overwrite this feature by clicking **DOSE OVER "AIR"** under the Display menu. This is necessary, for instance, when you want to display the dose on a low-density tissue such as lung.

**NOTE:** Turning off an isodose line erases it from the legend at the lower right of Axial View 1. So, if you turn off an isodose curve and view a different isodose curve or close the Define Isodose Color display, that line can only be turned on again from the Preference window.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118 832

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



## Isodose Surface

The percentage isodose surface (light blue) shows up in the 3D View window after the dose calculation finishes. For a complete discussion, *see module, Treatment Planning System, section, Multiple Slice Axial View, page 29.*

### Dose Volume Histogram

From the Display menu, select **DVH**. The Dose Volume Histogram (DVH) window (*Figure 72 Dose Volume Histogram (DVH) , page 78*) appears. It includes DVHs for each defined tumor, all critical structures, and soft tissue. Those three DVHs do not have the same scale, as can be seen from the respective volumes at the 0% dose. The 100% dose is defined to be the maximum dose value and is shown below the DVHs.

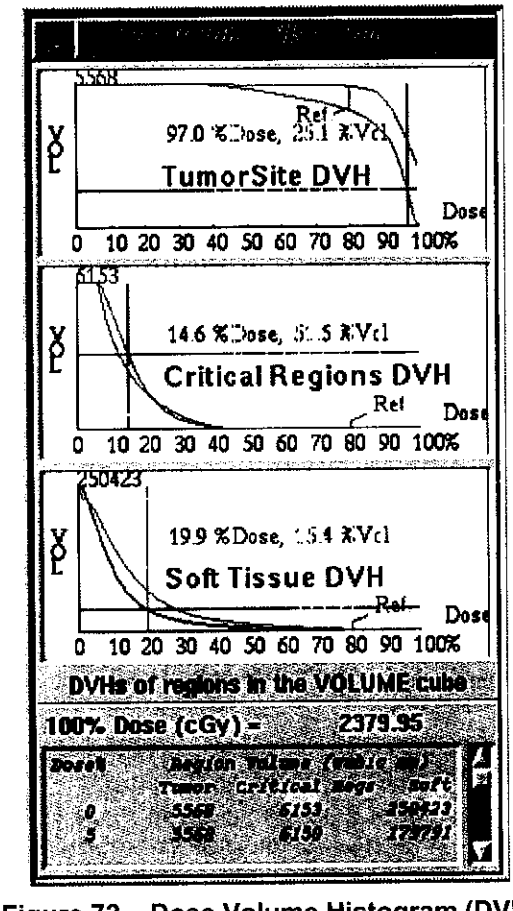



**Figure 72 Dose Volume Histogram (DVH)**

Two curves can appear on each DVH diagram. The curve in magenta on each diagram is the DVH associated with the Reference Plan (*see section, Reference Plan, page 83*). Each display includes a crosshair that allows you to determine the % Dose and % Volume of any point on each DVH curve. Use the mouse (left-click) to control the crosshairs for the active plan. Right click to control the crosshairs for the Reference plan.



833 Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



**Tumor DVH** can be viewed for each individual tumor. Right-click in the middle of the DVH diagram and a pulldown menu appears with choices of ALL TUMOR REG. and the ten individual lesions. Select the lesion you want to view, and the lesion is indicated on the DVH graph.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



**Critical Regions DVH** can be viewed for each individual critical region. Right-click in the middle of the DVH diagram and a pulldown menu appears with choices of All Critical Regions and the ten critical structures. Select the critical region you want to view, and the critical region is indicated on the DVH graph.

The bottom portion is the data table for those three DVHs. You can decide the percentages shown in the table. Double-click the data table to display the DVH % Data Option window (*Figure 73 DVH % Data Option, page 80*). One hundred toggle buttons represent 0 through 99 percent dose of the maximum dose. (100% dose is always displayed.) Select the desired percentages by setting the corresponding toggle buttons. Click **OK** to select or **CANCEL** to leave the table elements unchanged. The window closes and the data table is updated according to your selection.

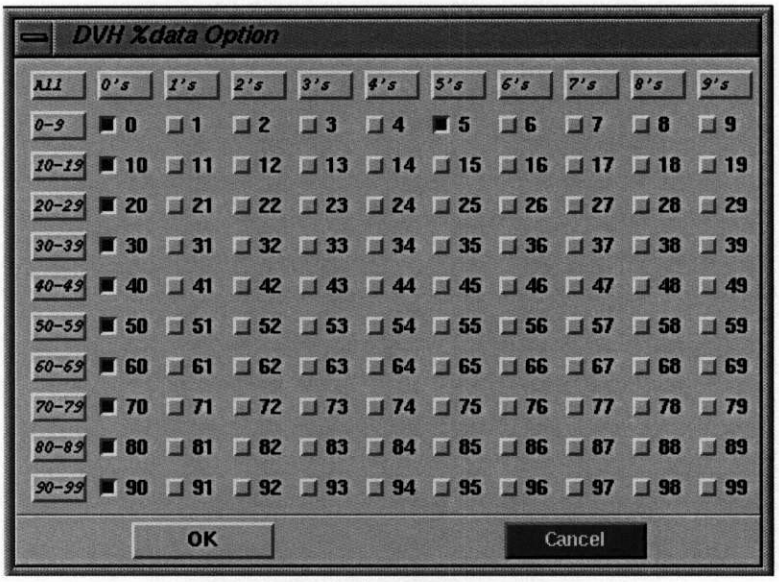



**Figure 73 DVH % Data Option**



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

83S

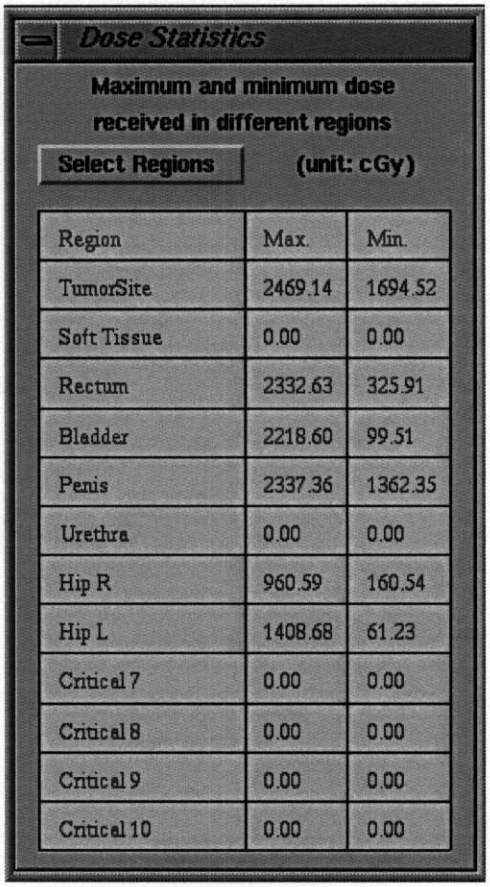
Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



## Statistics

Click **STATISTICS** from the Display menu. The Dose Statistics window (*Figure 74 Dose Statistics, page 81*) appears. It contains the maximum and minimum doses to the ROIs listed, and can show up to eleven ROIs at a time. The default regions are Lesion 1 and the ten critical structures. The soft tissue limits are always displayed.

To change the viewed ROIs, click the **SELECT REGIONS** button. The statistics list shows the first eleven ROI and the soft tissue limits. The first entries are the tumors, and the last entries are the critical structures.




| Region | Max. | Min. |
|---|---|---|
| TumorSite | 2469.14 | 1694.52 |
| Soft Tissue | 0.00 | 0.00 |
| Rectum | 2332.63 | 325.91 |
| Bladder | 2218.60 | 99.51 |
| Penis | 2337.36 | 1362.35 |
| Urethra | 0.00 | 0.00 |
| Hip R | 960.59 | 160.54 |
| Hip L | 1408.68 | 61.23 |
| Critical 7 | 0.00 | 0.00 |
| Critical 8 | 0.00 | 0.00 |
| Critical 9 | 0.00 | 0.00 |
| Critical 10 | 0.00 | 0.00 |

**Figure 74 Dose Statistics**



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

836

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



## Colorwash

Colorwash displays bands of color where outlines are drawn. From the Display menu, toggle on **COLORWASH**. Bands of color are overlaid on the anatomy and the Colorwash Legend window (*Figure 75 Colorwash Legend and Colorwashes on an Axial View , page 82*) appears at the top of the TPS working area. Unlike isodose lines, you cannot specify the color/dose percentage pair. The colors are always graded at 10% increments of the 100% dose. To view outlines in place of colorwash, toggle off Colorwash from the Display menu. The Colorwash Legend window closes as well.

**Figure 75 Colorwash Legend and Colorwashes on an Axial View**



837

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015

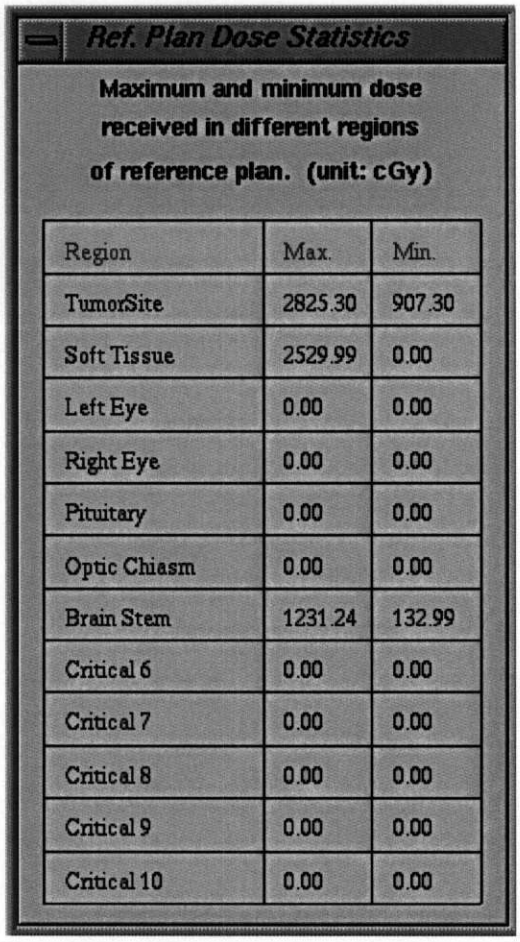


## Reference Plan

You can compare an active and a previously saved reference plan (*see module, Treatment Planning System, section, The Reference Plan, page 33*). When a reference plan is loaded, its dose distribution is calculated (using the full calculation method). The Reference Axial window displays the isodose curves and colorwash for the reference plan. You can compare this visually to the Axial View 1 window.

If the loaded fine dose volume is not large enough to display the dose distribution for all areas you wish to see, the size of the volume can be changed. The new volume is centered at the same position as before, unless it includes area outside the CT study. If it goes outside the CT study, the volume is automatically shifted to place it is inside the CT study. If the new grid size yields a volume larger than the CT study, in one or more directions, you will not be able to set that grid size.

You can also compare DVH curves (*see section, Dose Volume Histogram, page 78*) and statistics. Click **STATISTICS** from the Axial Reference window and a Ref. Plan Dose Statistics table appears (*Figure 76 Reference Plan Dose Statistics, page 83*).



*Ref. Plan Dose Statistics*

**Maximum and minimum dose received in different regions of reference plan. (unit: cGy)**

| Region | Max. | Min. |
|---|---|---|
| TumorSite | 2825.30 | 907.30 |
| Soft Tissue | 2529.99 | 0.00 |
| Left Eye | 0.00 | 0.00 |
| Right Eye | 0.00 | 0.00 |
| Pituitary | 0.00 | 0.00 |
| Optic Chiasm | 0.00 | 0.00 |
| Brain Stem | 1231.24 | 132.99 |
| Critical 6 | 0.00 | 0.00 |
| Critical 7 | 0.00 | 0.00 |
| Critical 8 | 0.00 | 0.00 |
| Critical 9 | 0.00 | 0.00 |
| Critical 10 | 0.00 | 0.00 |

**Figure 76 Reference Plan Dose Statistics**



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



## Plan Summary

After a plan has been prepared, a summary can be viewed by clicking **PLAN SUMMARY** from the Plan menu (2.2). The Summarize Plan (*Figure 77 Plan Summary, page 84*) window appears. This summary allows you to estimate the time to treat the patient using this plan. Factors that affect treatment time are number of nodes, number of nonzero nodes, total MU, and number of paths. These factors appear in the Plan Summary.

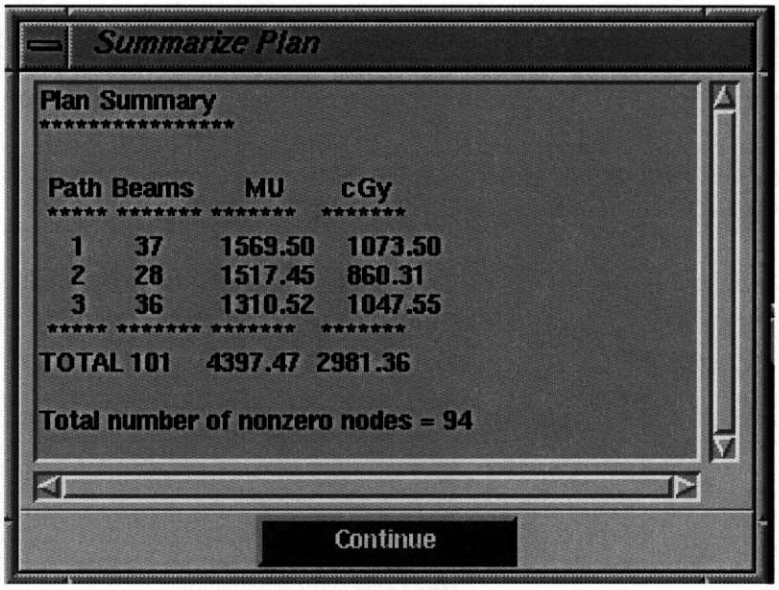



**Figure 77 Plan Summary**



839

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



## Plan Assessment

The Plan Assessment window provides a means to analyze plan parameters. Currently, two metrics, dose coverage and region of interest volume, are given in this feature. To view this window, click **ASSESS PLAN** from the Display menu. *Figure 78 Assess Dose Coverage, page 85* appears.

The dose distribution for a plan can be analyzed to compare the dose delivered to the tumor to that absorbed by healthy tissue. The Coverage option provides a method to compare tumor dose to healthy tissue dose.

Enter the desired prescription dose in the Prescription Isodose Pct. text field or the percent of tumor volume covered in the Tumor Pct. Covered text field. The tumor volume in cubic millimeters is displayed. Also displayed are the volumes (in cubic millimeters) of the tumor, critical structures, and healthy tissue that receive the dose. The software fills in the value for the text field not entered by the user. Three non-dimensional ratios are calculated and displayed.

1. The tumor-tissue ratio is the ratio of the anatomy volume to the tumor volume that receives the prescription dose.
2. The normalized tumor-tissue ratio is the tumor-tissue ratio multiplied by the ratio of the tumor volume and the tumor volume that receives the prescription dose.
3. The homogeneity index is the maximum dose divided by the prescription dose.

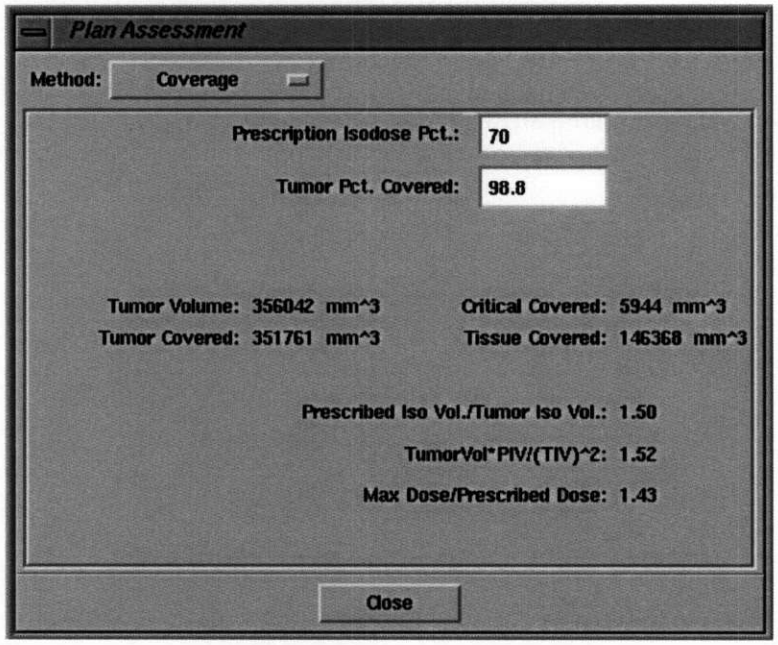



**Figure 78 Assess Dose Coverage**



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



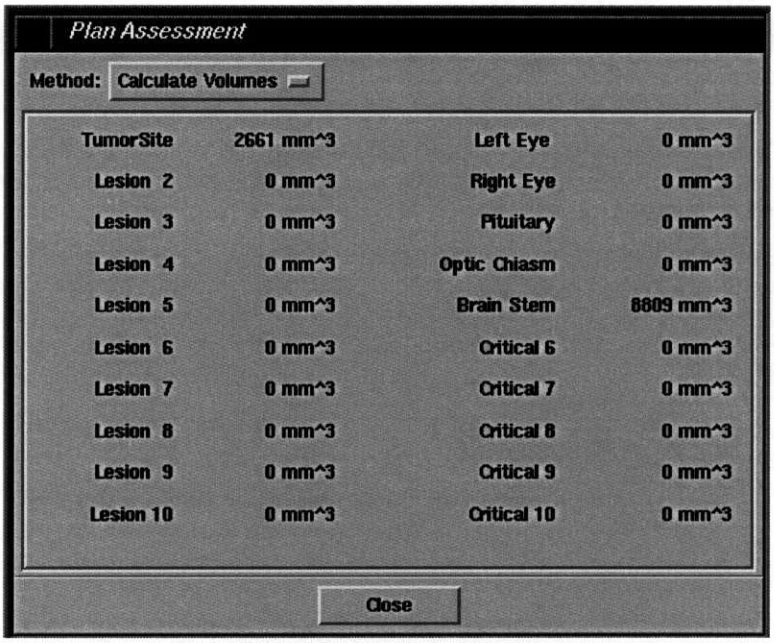



**Figure 79 Region of Interest Volumes**

The Calculate Volumes option (*Figure 79 Region of Interest Volumes, page 86*) gives the volume of each defined region of interest. The volumes are given in $mm^3$. These values are the total volumes. That is, if two regions overlap, that overlapping area is considered as part of both regions.



841

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



# Simulations

## Manipulator Motion Simulation

A fully integrated manipulator simulation program is provided with the Treatment Planning System as a tool to preview the motion of the manipulator. The program accurately models the kinematics of the manipulator as well as the geometry of the room, including all the equipment in the treatment room. This shows you the exact motion of the manipulator and helps you check for potential collision hazards.

Select the desired path or the entire treatment from the Paths menu of the main menu bar. The Robot Motion window (*Figure 80 Robot Motion, page 87*) appears. The upper portion of the window contains a 3D graphic of the treatment room, the rotation angles about the x, y, and z axes, path number, node number, and total nodes of the path. The lower portion includes three sliders to specify the rotation angles, and **REWIND**, **REVERSE**, **STOP**, **PLAY**, or **FAST FORWARD** buttons.

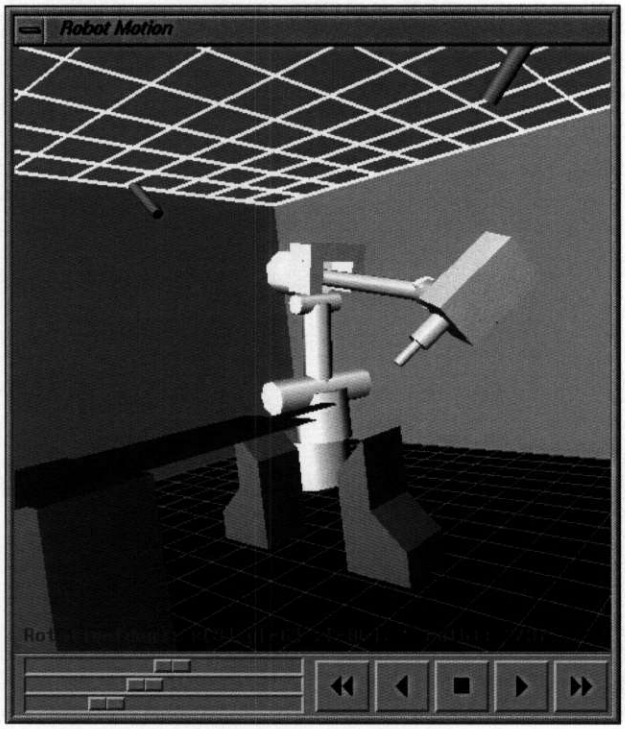



**Figure 80 Robot Motion**

Set the rotation at different angles to see the room configuration from different viewpoints. Click **REWIND**, **REVERSE**, **PLAY**, or **FAST FORWARD** to observe the manipulator motion. Any potential collisions are shown in the configuration in red, with a message at the top of the 3D graphic indicating which objects may collide.

The Robot Simulation Status window (*Figure 81 Robot Simulation Status, page 88*) also appears during simulation to give the viewer information on the robot simulation.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



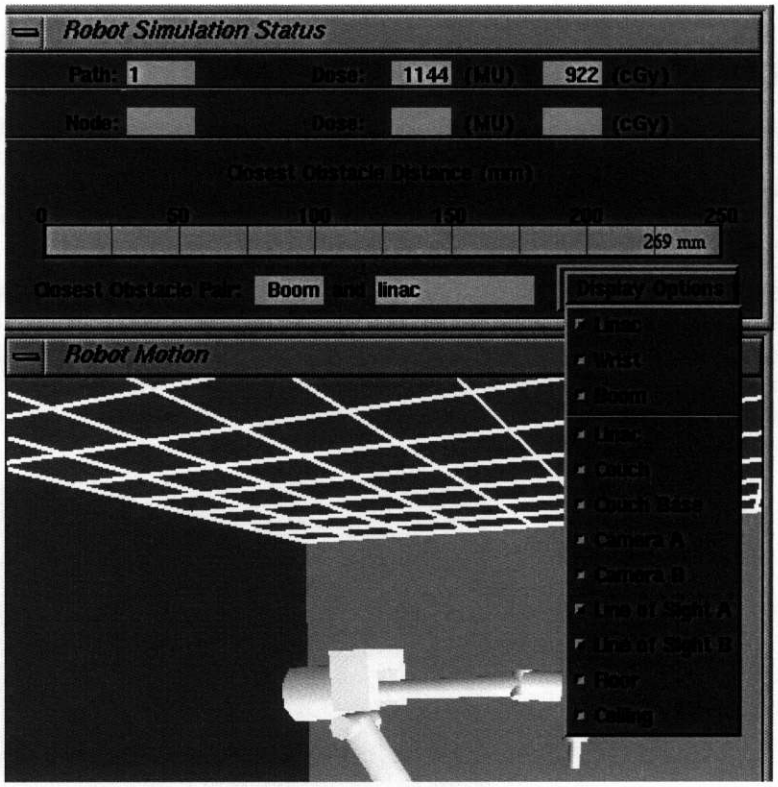



**Figure 81 Robot Simulation Status**

The top row of data boxes indicates the simulated path and the dose in machine units and cGy. If the entire treatment is being simulated, the path is All. The second row indicates the node and the dose for that node. If the dose is zero, the beam is green in the Robot Motion window. If it is a value, it is red. The slider indicates the distance between the displayed moving and fixed obstacles.

**NOTE:** The Linac is checked as a stationary obstacle relative to the wrist and the boom.

The closest pairs of obstacles are indicated in the text below the slider. You can choose the obstacles to check from the pulldown menu at the lower right of the Robot Simulation Status window. Pushed in buttons indicate that the item is checked. By default, all obstacles are displayed, except the camera lines of sight. A collision with the line of sight may be indicated in the Robot Motion window while the Robot Simulation Status window shows that the robot configuration has no collision.

**NOTE:** The manipulator motion simulation is available only after the dose calculation is done. If the entire treatment is simulated, the accumulated dose appears in the Axial 1 View.



843

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



## Phantom Simulation

A phantom simulation that exposes film to the treatment plan dosages can help ensure the delivery system accomplishes the treatment plan. You place a cartridge containing several sheets of film at an appropriate location inside the Lucite phantom (nicknamed Lucy) provided by Accuray as part of the CyberKnife System. During the simulation, the Linac beam exposes the film to validate the pointing accuracy of the CyberKnife System. Currently, Accuray suggests using Gafchromic film to validate targeting and dose distribution.

This section describes the tools available to aid this process.

### Overlay CT

Load the desired plan first. After the CT displays appear, click **OVERLAY CT** from the Plan menu. Click either **PATIENT** or **PHANTOM**, (*Figure 82 Overlay CT Menu Item, page 89*). The load Warning message appears to ask for confirmation. Once confirmed, the New Plan window appears. Select the patient from the list in the upper window, the CT from the lower list, and the CT data is then loaded.

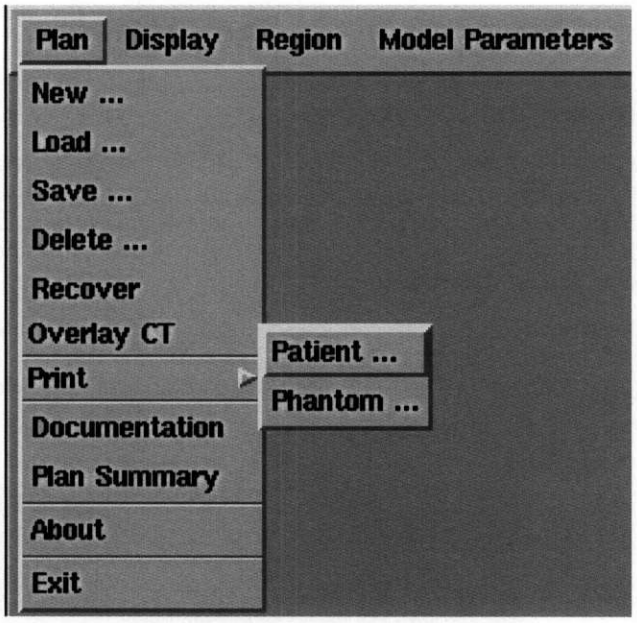



**Figure 82 Overlay CT Menu Item**

If the overlaid CT has different pixel dimensions from the original CT, a warning message (*Figure 83 Overlay CT Message, page 90*) appears.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



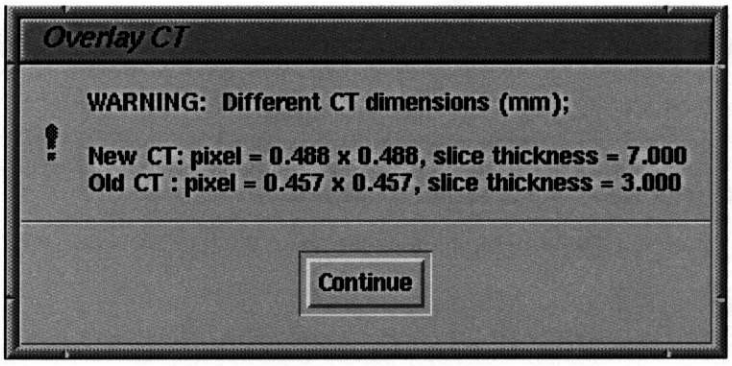



**Figure 83 Overlay CT Message**

**NOTE:** The target center coordinates in both manipulator and patient coordinate systems stay constant between the original CT and the overlaid CT. Under this condition, the delineated polygons of the original CT are mapped to the closest axial slices of the overlaid CT.

## Determine Film Location

To locate where the film stack should be positioned, load the patient plan, locate the fine calculation volume (blue box), and overlay a phantom CT. From the Imaging menu click **OVERLAY CT OFFSET**. The Overlay CT Offset Adjustment window (*Figure 84 Overlay CT Offset Adjustment, page 90*) appears. Click **CREATE OVERLAY PLAN**. The fine calculation volume and reference dose location will move.

Measure where the calculation volume appears in the phantom CT as a reference. Use this reference to position the film in the Lucy phantom. The film-loaded phantom should be scanned nearly identically to the test phantom used to locate the film to ensure that the target is in the same position within the film stack.

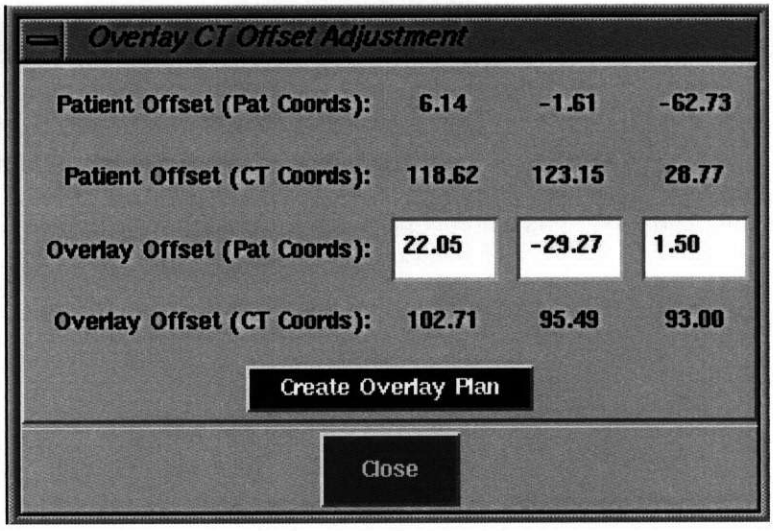



**Figure 84 Overlay CT Offset Adjustment**



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



## Adjust Film Location

The Overlay CT Offset Adjustment window gives the CT center for both the phantom and the patient in patient coordinates and CT coordinates. The patient coordinates for phantom overlay CT center can be edited.

If the location of the calculation volume in the overlay is at position that does not support placing the film, you need to change the CT center for the phantom. To change the center, close the Overlay CT Offset Adjustment window (*Figure 84 Overlay CT Offset Adjustment, page 90*) and click **SHOW CT CENTER** from the Imaging menu. Note the location where you want the reference position to be with respect to the designated position in the phantom plan.

You can use the film center to find the new patient coordinates for the desired CT center. Adjust the phantom CT center by this amount. Open the Overlay CT Offset Adjustment window and enter these coordinates in the Overlay Offset (Pat Coords) text fields. Click **CREATE OVERLAY PLAN** and verify that the dose distribution is at a location that supports a film cube.

Load the phantom with the film cube in the predetermined location and scan the phantom with the appropriate number of slices and field of view corresponding to the directions that the CT center was moved. The new size should be twice as large as the distance the CT center moves. For instance, if you wish to move the CT center 8 mm superior, the CT study should be 16 mm larger in the superior direction. The most inferior slice should be roughly at the same location as in the test phantom CT.

## Dose Distribution on Overlaid CT

After the original patient CT and its associated plan are loaded, calculate the plan and the dose distribution. Load the overlay phantom CT. The CT center, as noted above, generally differs from the offset associated with the patient. To adjust the patient plan for the phantom study, open the Overlay CT Offset Adjustment window and select **CREATE OVERLAY PLAN**. Calculate and view the resulting dose distribution. This can be used for comparison with the films after treatment simulation is finished.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



# Multiple Workstation Option

Some CyberKnife Systems include extra workstations for treatment planning. The systems have two types of workstations: The primary workstation is for planning and delivering treatments, as well as administering patient records. The secondary workstations only allow treatment planning. The secondary workstation database and data files are remotely linked to the primary workstation database and data files.

## Open Secondary Workstation

A login screen that includes the user—cks —is visible on the monitor. Open the user cks and the On-Target™ Treatment Planning System automatically starts. This treatment planning system is identical to the treatment planning system on the primary workstation.

## Patient Planning Locks

Systems with multiple workstations allow plans to be created for a patient from only one machine at a time. When you open a plan for a patient, that patient is locked, and other machines cannot save plans made for that patient. Ending the planning session or planning for a different patient clears the lock.

If you load or begin a plan on a locked patient file, the window in *Figure 85 Patient Locked Indicator, page 92* appears. You have the option of overriding the previous lock. This option is given in case the previous planning session ended inadvertently and the patient lock was not cleared.

**CAUTION:** Before unlocking a patient, be certain that another user is not planning a treatment for the same patient.

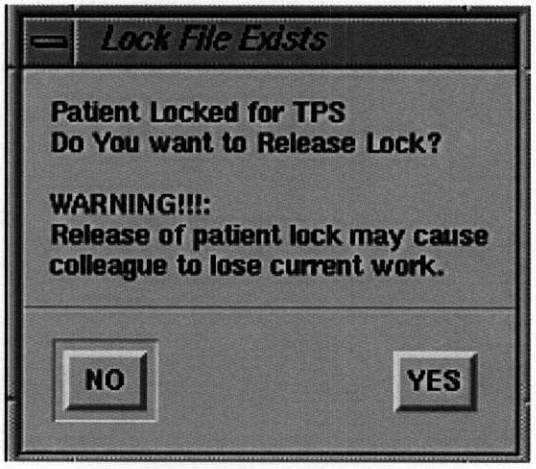



**Figure 85 Patient Locked Indicator**



847

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



You can look at plans for locked patients. However, you cannot save modifications to plans or create new plans for that patient if the session began with the patient locked, or if the patient was locked by another machine before the save is requested. The warning in *Figure 86 Patient Locked Warning, page 93* appears if you try to save a plan for a locked patient.

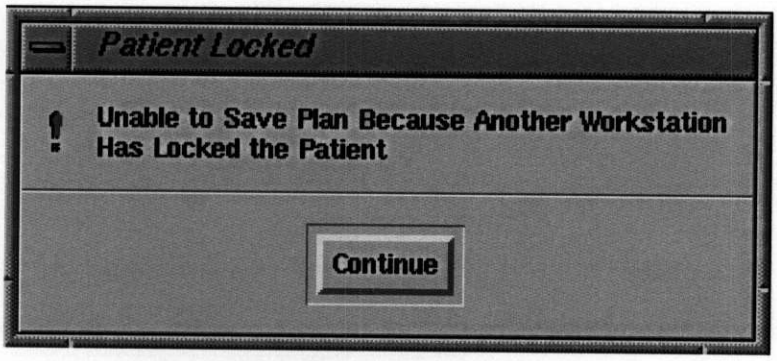



**Figure 86 Patient Locked Warning**

## Save Plan from a Secondary Workstation

Plans can only be delivered after they are saved from the primary workstation. Plans saved from the secondary workstation only update the plans in the database; they do not create deliverable plans available for prescription and delivery. Thus, a plan saved from a secondary workstation must be loaded and calculated on the primary workstation before delivery.

A plan saved from the primary workstation cannot be overwritten by the secondary workstation. If a user on a secondary workstation opens a plan saved by the primary workstation, a warning (*Figure 87 Plan Overwrite Not Allowed Warning, page 93*) appears. A new plan (with a new name) can be created on a secondary workstation from the plan saved from the primary workstation. This new plan, however, must be saved from the primary workstation before it is deliverable.

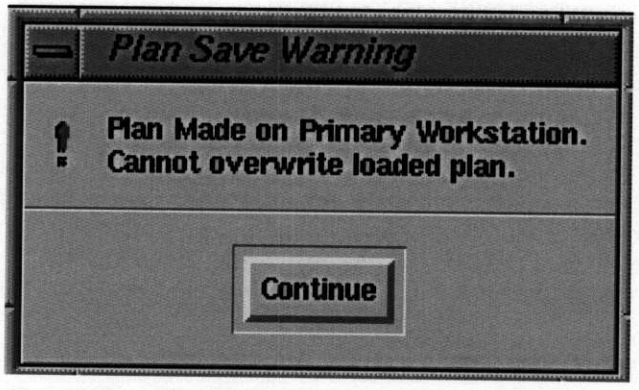



**Figure 87 Plan Overwrite Not Allowed Warning**



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



## End Treatment Planning System

To end a planning session, click **EXIT** from the Plan menu. The Exit Confirmation window (*Figure 88 Exit Confirmation, page 94*) appears. Click **YES** to quit TPS, or **NO** to continue the session.

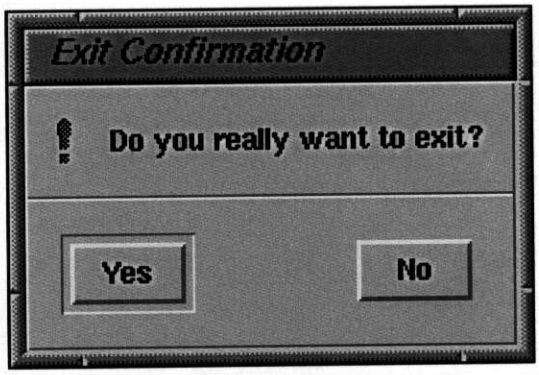



**Figure 88 Exit Confirmation**

# Dose Generation Algorithms

The CyberKnife On-Target Treatment Planning System uses four dose generation algorithms, presented in this section.

## Forward Planning

*Section, Forward Planning Dose Assignment, page 45*, describes the user interface for Forward Planning Dose Assignment. For each defined region of interest (ROI), input the maximum dose each beam is allowed. The dose defined with this interface is the absorbed dose at the beam target point. This point is at an isocenter for single and multiple center plans or is defined by the tumor boundary for conformal shape plans.

If a beam passes through more than one region, the assigned dose is the lowest for the regions that that beam goes through. For instance, a beam that passes through tumor with maximum dose set to 15 cGy, left eye with dose set to 1 cGy, and brain stem with maximum dose set for 2 cGy, will have 1 cGy of dose at the target point. This dose is the contribution of a single beam at the target point. Remember, you define the dose for the target point, not the ROI. Therefore, the contribution of this beam to the dose at the left eye generally would not be 1 cGy. It could be either larger or smaller. Note that, for the forward planning algorithm, all tumors are treated as the same. You cannot distinctly set the contribution to each defined tumor. To separately define dose contributions, you must select beams and set doses with the FINETUNE MENU.

## Single Center Inverse Planning

*Section, Single Center Dose Assignment, page 45,* describes the user interface for Single Center Dose Assignment. You input a desired absorbed dose at the center of the sphere. If you choose **Use Critical Beams**, every available beam is used to create the dose distribution. If you choose do not use critical beams, any beam passing through any critical structure is unavailable and has 0.0 MU assigned.



849 Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



The absorbed dose set at the center point of the sphere is divided by the number of available beams to obtain the dose contribution for each beam. Then, the geometry of the beam in relation to the patient anatomy determines the MU for each beam.

## Multiple Center Inverse Planning

*Section, Program Treatment Beams Using Wizards*, describes the user interface for Multiple Center Dose Assignment. You input a desired absorbed dose at the center of each sphere. If you choose use critical beams, every available beam is used to create the dose distribution. If you choose do not use critical beams, any beam passing through any critical structure is unavailable and has 0.0 MU assigned.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

850

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



### Multiple Center Dose Exact Solution Algorithm

This algorithm divides the beams based on the center at which they point. Every beam pointing at Center n will have the same MU. The solution is then given by the equation:

$$\mathbf{c} = \underline{\underline{\mathbf{D}}}^{-1}\,\underline{\mathbf{m}},$$

where **c** is an n-vector of absorbed dose at the defined centers, $\underline{\underline{\mathbf{D}}}^{-1}$ is an *n x n* matrix that sums the off-axis scale factor for the beams aimed at each center, and $\underline{\mathbf{m}}$ is an n-vector of the absorbed dose contribution for individual beams aimed at each center. Then, the geometry of the beam in relation to the patient anatomy determines the MU for each beam.

The solution to this problem can sometimes yield negative dose values. If this occurs an iterative algorithm is used to find dose values for each beam.

### Multiple Center Dose Iterative Algorithm

This algorithm also divides the beams based on the center at which they point. This algorithm is similar to the Single Center Inverse Planning algorithm.

For each center, the desired dose is divided by the number of available beams aiming at that center. Then, the geometry of the beam in relation to the patient anatomy determines the MU for each beam.

The actual dose at each center is calculated.

The desired center dose is adjusted by the scale factor of the (actual_dose/desired_dose).

For each center, the desired dose is divided by the number of available beams aiming at that center. Then, the geometry of the beam in relation to the patient anatomy determines the MU for each beam.

The solution from this algorithm usually differs from the desired center doses. Most often this algorithm is called if the centers are close together.

## Conformal Shape Inverse Planning

Inverse planning has two steps:

1. Determination of beam geometries
2. Determination of beam weights.

### Beam Geometry Algorithm

The first element of the conformal shape algorithm is determining where to point the treatment beams.

Create a list of all voxel elements along the boundary of each lesion.

Create a list of target voxels from the boundary voxels by targeting x mm toward the center of mass point of the center slice. The value x is set in the interface of 6.8.

For each beam determine the lesion at which to point. Randomly select a target point for that beam to shoot at.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

851

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



## Dose Weighting Algorithm

This inverse planning algorithm, though designed for conformal shape beam geometry, can actually be used for assigning dose to isocentric geometries.

### Basic Optimization Problem

The Treatment Planning System uses a linear optimization problem to determine beam weights. The optimization problem is:

Minimize the total MU delivered during treatment, subject to minimum and maximum absorbed dose constraints in the lesions and maximum absorbed dose constraints in the critical structures and along the soft boundary.

Mathematically, this is represented as:

Minimize $\Sigma x_j$, where $x_j$ is the MU for each beam, subject to

$\Sigma t_{ij} x_j \leq T_{imax}$, at each point in the lesion

$\Sigma t_{ij} x_j \geq T_{imin}$, at each point in the lesion

$\Sigma c_{ij} x_j \leq C_{imax}$, at each point in the critical structure

where $0 \leq xj \leq x_{max}$.

The number of lesion constraints can be set in three ways:

1. If All is set, then voxels are constrained throughout the lesion volume.
2. If Boundary is set, then only voxels around the boundary of the tumor are constrained.
3. If Boundary Plus Center is set, then voxels around the boundary of the tumor and a point at the center of mass of the center slice are constrained.

The points to constrain are found only in the blue calculation box discussed in *section, Dose Calculation Volume, page 73*. The dispersion of the constraints is given by the grid element size. If the skip factor is 1, then every voxel is constrained if the calculation grid is implemented as Fine. If the calculation grid is Coarse, then 1 in every 8 points is constrained.

This optimization is solved with Simplex linear programming. For details on the set up and solution of this problem, see Luenberger, *Linear and Nonlinear Programming, 2nd Edition,* Addison-Wesley, 1984.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

852

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



Aggression

It is possible to set up a problem with the basic algorithm that does not have a solution. If this happens you can implement a variable aggression for each ROI. Four aggression factors exist: exact, strict, moderate, and loose. The exact aggression is the default value and is what is used for the basic algorithm. The other three setting affect the optimization problem set up.

When the aggression is not exact, deviation factors, $\delta_i$, are added to the optimization problem. These factors are incorporated into the constraints and the cost function as shown below.

Minimize $\Sigma x_j + \Sigma \Omega_i \delta_i$, where $x_j$ is the MU for each beam, $\delta_i$ is the deviation factors, and $\Omega_i$ are user set weighting factors for the deviation factors, subject to

$\Sigma t_{ij} x_j + \delta_i \leq T_{imax}$, at each point in the lesion

$\Sigma t_{ij} x_j + \delta_i \geq T_{imin}$, at each point in the lesion

$\Sigma c_{ij} x_j + \delta_i \leq C_{imax}$, at each point in the critical structure

$\delta_i \geq 0$, for all i

where $0 \leq xj \leq x_{max}$.

**Point Constraints**

Point constraints are augmented to the optimization problem in an identical fashion as constraints on defined ROIs. Point constraints can either be maximum or minimum constraints.

# Dose Calculation

The CyberKnife On-Target Treatment Planning System dose calculation is based on a ray-tracing algorithm. This section describes the algorithm and its different variations.

## Standard Algorithm

The standard algorithm uses a ray-tracing function based on stored beam percent depth dose data (PDD) and off-axis ratios (OAR). The PDD values are separated into two tables, an output factor that depends only on the collimator, DM, and a tissue maximum ratio (TMR). *CyberKnife Beam Commissioning Manual*, Accuray Part No. 018963, provides a method for generating the data that comprise these tables.

At each point, the contribution from each beam is given by the equation:

$d = (SAD/800)^{-2} * DM * TMR * OAR * MU$,

where SAD is the source axis distance, along the central axis of the beam, to the point of the dose calculation, and MU is the number of monitor units for the beam.

The value for DM is found from the collimator size of the beam. The value for TMR is dependent on the field size and the depth of the point. Values are linearly interpolated from calculated points for the PDD. The value for OAR depends on the field size, beam depth, and radial distance between the point of interest and the beam central axis. Values for the OAR are also interpolated linearly, based on stored measured points. Interpolations are done based on perturbations of field size, depth, and radial distance from the central axis. Plots of typical dose calculation results are given in Axial View, Sagittal View, and Coronal View. The number of stored beam data points, the number of beams, and the beam geometry affect the amount of error associated with this dose calculation. Generally, more beams in a plan will yield smaller interpolation errors, because each beam's error should be random.



853 Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



## Coarse vs. Fine Grid

Isodose curves and dose volume histograms (DVH) are generated based on dose calculated along the grid points of the dose calculation volume described in Section Dose Calculation Volume, page 73. Dose between grid elements is calculated by linearly interpolating between calculation points. All errors, therefore, depend on the grid element sizes. A smaller grid element size will yield smaller errors in the dose calculation used to create isodose curves and DVH graphs.

Volumes of regions of interest also depend on the grid element size. Each element in the dose calculation grid is identified as being a part of a region of interest. Sum the number of elements for a particular ROI and then multiply these volumes by the volume of a grid element to calculate the overall volume. A smaller grid element size permits are more precise calculation of region volumes.

The dose distribution can be calculated using either a Fine or Coarse grid. Select the grid element coarseness from the Model Parameters button.

For the Fine grid calculation, every grid point is calculated using the technique described in *section, Standard Algorithm, page 98*. For the coarse grid calculation, only grid elements with three even array indices are directly calculated. Other grid points are found through linear interpolation. If the number of grid elements is even in a direction, the last plane of calculation will be determined through linear extrapolation from the two contiguous planes. For example, assume a box with 3 x 3 x 4 grid elements. The following table describes how the value at each point is determined when Coarse is set.

**Table 1: Descriptions how value at each point is determined when Coarse is set.**

| i | j | k | Method | i | j | k | Method | i | j | k | Method | i | j | k | Method |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 0 | 0 | 0 | **Calculate** | 0 | 0 | 1 | Interpolate | 0 | 0 | 2 | **Calculate** | 0 | 0 | 3 | Extrapolate |
| 0 | 1 | 0 | Interpolate | 0 | 1 | 1 | Interpolate | 0 | 1 | 2 | Interpolate | 0 | 1 | 3 | Extrapolate |
| 0 | 2 | 0 | **Calculate** | 0 | 2 | 1 | Interpolate | 0 | 2 | 2 | **Calculate** | 0 | 2 | 3 | Extrapolate |
| 1 | 0 | 0 | Interpolate | 1 | 0 | 1 | Interpolate | 1 | 0 | 2 | Interpolate | 1 | 0 | 3 | Extrapolate |
| 1 | 1 | 0 | Interpolate | 1 | 1 | 1 | Interpolate | 1 | 1 | 2 | Interpolate | 1 | 1 | 3 | Extrapolate |
| 1 | 2 | 0 | Interpolate | 1 | 2 | 1 | Interpolate | 1 | 2 | 2 | Interpolate | 1 | 2 | 3 | Extrapolate |
| 2 | 0 | 0 | **Calculate** | 2 | 0 | 1 | Interpolate | 2 | 0 | 2 | **Calculate** | 2 | 0 | 3 | Extrapolate |
| 2 | 1 | 0 | Interpolate | 2 | 1 | 1 | Interpolate | 2 | 1 | 2 | Interpolate | 2 | 1 | 3 | Extrapolate |
| 2 | 2 | 0 | **Calculate** | 2 | 2 | 1 | Interpolate | 2 | 2 | 2 | **Calculate** | 2 | 2 | 3 | Extrapolate |

**NOTE:** The volume calculation is independent of whether Fine or Coarse is set for the dose calculation.

Maximum and minimum dose values are calculated from a combination of the dose calculation volume and a 64 x 64 x 64 grid that covers the entire CT study used for the plan. Therefore, if the maximum or minimum for the plan or for any region of interest lies outside the dose calculation volume, that maximum or minimum will be found to the accuracy of a 64 x 64 x 64 grid overlain on the entire CT study. The larger calculation volume is also calculated with the Fine or Coarse grid interpolation setting as the dose calculation volume.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



The theoretic error due to using grid elements is one-half the distance between calculated grid elements. So, for 1 mm grid elements and a Fine dose calculation, the theoretical dose error at any point may be as much as ½ mm * δ, where δ is the dose gradient in cGy/mm. For 1 mm grid elements and a Coarse dose calculation, the theoretic dose error at any point may as much as 1 mm * δ, where δ is the dose gradient in cGy/mm.

To minimize error due to interpolation and extrapolation of grid elements, use the smallest possible grid element size in each direction and calculate the dose with a FINE calculation grid before prescribing the treatment plan.

Though grid elements are used to determine the isodose curves, dose statistics, and DVH graphs, the dose can be more precisely calculated at any point using the point dose calculation capability described in *section, Point Dose, page 76*. With this method, the only source of error is interpolation of the beam table data discussed in *section, Standard Algorithm, page 98*.

## Density Compensation

The dose calculation algorithm has three methods for dealing with variable tissue density. Set the density correction algorithm with the interface. All three algorithms are relatively simple.

The default method is to treat all tissue as either air or water. If an area is defined as air, accumulated depth through this is 0 mm. If an area is defined as water, 1 mm of transmission is treated as 1 mm of depth. Most tissue has density close to water, so this introduces small errors for individual beams. The error is due to perturbations of the physical depth of the beams as opposed to the geometric depth. In general, this error is random. Therefore, the more beams the plan has, the less the total error introduced by this approximation.

The CT number can be selected to model areas that will be treated as lung tissue. Generally, these areas have density that is between air and water. The algorithm determines which voxels have CT number between two user-defined parameters. The default range is 100 – 800. Voxels that lie within this range have density values set by the user that may differ from 0.0 and 1.0. The default setting is 0.3 mm of depth/1 mm of beam transmission. For treatment plans in the thoracic region of the body, this method generally yields lower dose calculation errors than when treating all tissue as either water or air.

Lung regions can be manually drawn and treated as lung tissue. As in the method using CT number to differentiate lung from air and water, you can set density values between 0.0 and 1.0. The default setting is 0.3 mm of depth/1 mm of beam transmission. For treatment plans in the thoracic region of the body, this method generally yields lower dose calculation errors than when treating all tissue as either water or air.

**NOTE:** The dose calculation model does not ever consider the density effect of beam transmission through bone or the scatter effects that may occur at tissue/bone junctions.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

855

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



## Contour Correction

The default dose calculation algorithm calculates and uses depth for the central axis of the beam. Therefore, this calculation does not take into account the effect of variable surface contours of the patient. You can calculate the dose distribution with contour correction. Selection of this option is described in *section, Contour Correction, page 76.* A dose calculation that includes contour correction is significantly slower than the standard dose calculation algorithm. Therefore, you may not always want to use it. Typically, this algorithm provides significant error reduction only for larger diameter beams, treatments below the cervical spine, or treatments near the skin surface.

## Example Error Assessments

### Acceptance Test Error Evaluation

The error for the dose calculation is evaluated during installation of the CyberKnife System. The system must pass dose calculation accuracy tests detailed in **Acceptance Tests for the Accuray CyberKnife, 660-017551**. The tests are detailed in paragraphs 2.1.3.2, 2.1.3.3, and 2.1.3.4. These tests have allowable errors no greater than 1% of the maximum dose for any defined point outside the penumbra of a beam. Description of the test set-up and procedures to conduct these tests are given in that document. These tests involve small numbers of individual beams. Because the percent error will tend to be reduced for larger numbers of beams, the errors from these tests would be larger than expected for most calculations based on the calculated beam doses. These tests, however, do not consider errors resulting from incorrectly measured beam data, use of a finite dose calculation volume grid size, or modeling errors, such as ignoring beam scatter effects or use of simple density correction techniques.

### Film Test Study

The dose calculation of the standard algorithm described in *section, Standard Algorithm, page 98* has been analyzed for typical errors. The test used calibrated film to measure the delivered dose and compare it to the dose calculated with the treatment planning system.

The test analyzed dose delivered to a film cube loaded in an anthropomorphic phantom. A 31.75 mm sphere in the film cube marked the target for a single isocenter treatment sphere. The sphere was made of acrylic and placed in the center of the film cube. The film cube used standard radio-chromic film that had been calibrated to measure dose. Each cube had 10-14 film slices precision cut to 2.5inch squares. The films were oriented parallel to the CT slices and aligned with the left and anterior edges of the film cube.

A roughly 3000 cGy dose was delivered to the isocenter. Each plan used roughly 100 beams, with 25mm or 30mm collimator diameters. These collimator sizes give targets large areas compared to the CT slice thickness. The isocenter dose calculated by the treatment planning system was recorded. (*Figure 89 Plan used to Measure Dose Calculation Error, page 102* gives an example of the treatment plan used for this test.) The isodose curves were calculated using a coarse grid with unit size of 1mm in each direction. The dose at the centroid, however, was found using the point dose calculation. Therefore, most of the pixelation error is eliminated. The calculation did not include contour correction. The calculation used the simple air/water density model. This test uses the least sophisticated model available to you.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118 856

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



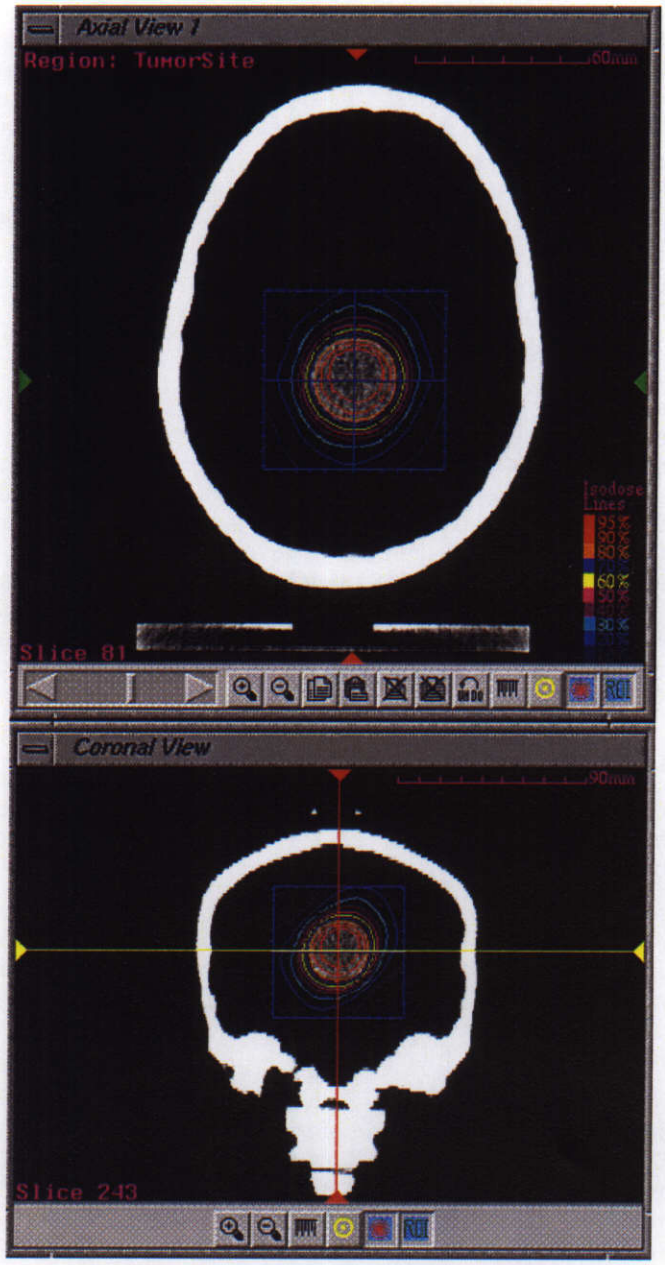



**Figure 89 Plan used to Measure Dose Calculation Error**

The films were exposed and then left to achieve equilibrium over 24 hours. The dose was measured by finding the centroid of the dose distribution based on the 70% of the maximum gray scale. The exposure of the film was measured at that centroid and converted to a dose value using the calibration coefficient for the film batch. Measurements were compared to expected dose measurements from the treatment planning system. Results for 23 tests are tabulated below. The maximum percent error is 6.0 percent and that the average percent error is 3.1 percent.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

857

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



**Table 2: Results for the 23 test.**

| Test | Slice Thickness (mm) | Measured Dose (cGy) | Calculated Dose (cGy) | Percent Error |
|---|---|---|---|---|
| 1. | 1.25 | 3095 | 3045 | 1.6 |
| 2. | 0.625 | 3369 | 3252 | 3.6 |
| 3. | 1.25 | 3107 | 3038 | 2.3 |
| 4. | 3.75 | 2973 | 2901 | 2.5 |
| 5. | 1.25 | 3007 | 2924 | 2.8 |
| 6. | 1.25 | 2976 | 2854 | 4.3 |
| 7. | 0.625 | 3084 | 3000 | 2.8 |
| 8. | 1.25 | 3110 | 3000 | 3.7 |
| 9. | 1.25 | 3019 | 3000 | 0.6 |
| 10. | 0.625 | 2871 | 3000 | 4.3 |
| 11. | 1.25 | 2926 | 3000 | 2.5 |
| 12. | 1.25 | 2820 | 3000 | 6.0 |
| 13. | 0.625 | 2889 | 3000 | 3.7 |
| 14. | 0.625 | 2856 | 3000 | 4.8 |
| 15. | 1.25 | 3140 | 3000 | 4.7 |
| 16. | 1.25 | 3140 | 3000 | 4.7 |
| 17. | 1.25 | 3047 | 3000 | 1.6 |
| 18. | 1.25 | 2880 | 3000 | 4.0 |
| 19. | 3.75 | 3056 | 3000 | 1.9 |
| 20. | 2.5 | 2874 | 3000 | 4.2 |
| 21. | 3.75 | 2941 | 3000 | 2.0 |
| 22. | 2.5 | 2992 | 3000 | 0.3 |
| 23. | 0.625 | 2926 | 3000 | 2.5 |
| **Maximum Error** | | | | **6.0** |
| **Average Error** | | | | **3.1** |



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

858

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



# Glossary

## Terms

The following terms and their definitions are used in this guide:

**Lucy phantom** — A box shaped phantom supplied by Accuray for quality assurance.

## Acronyms and Abbreviations

The following acronyms and abbreviations are used in this guide:

**CT** — Computed Tomography.

**DiCOM** – Digital Image Communication for Medicine

**DiCOM RTSS** – DiCOM Radiotherapy Structure Set

**DVH** — Dose Volume Histogram.

**HFS** — Head First Supine.

**MR** — Magnetic Resonance

**OAR** – off-axis ratio

**OCR** – off-center ratio

**PDD** – percent depth dose

**ROI** — Region Of Interest

**SAD** — source axis distance

**SSD** – source surface distance

**TMR** – tissue maximum ration

**TPS** — Treatment Planning System.

**Voxel** — volume pixel

**WRT** — with respect to



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

859

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



# GLOSSARY

## Definitions and Acronyms

### 6 degrees of freedom

A Cartesian coordinate system with 6 parameters: x, y, z, w (yaw), p (pitch), and r (roll). X, y, and z represent the three Cartesian axes, while w is the rotation about the z-axis, p is the rotation about the y-axis, and r is the rotation about the x-axis. This coordinate system is used by the robotic system and when aligning the patient on the treatment couch.

### CK-6™

The powerful tracking algorithm that identifies and corrects the patient position throughout the entire treatment enabling the CyberKnife® System to achieve total clinical sub-mm accuracy. This algorithm is able to perform this correction in all translations and rotations in real-time.

## A

### Accelerator

The portion of the Linac which accelerates electrons from a gun into a high-energy electron beam. See Linac and waveguide.

### Axial

An **axial plane** divides the body into upper and lower segments. Similar to "slicing" the body like a loaf of bread starting at the top of the head and working down.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118 860

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



# B

## Ball cube

The ball cube is a QA tool designed by Accuray for measuring stereotactic targeting accuracy. Physically it is an ABS plastic film cassette used for holding two pieces of radiochromic film. The notched films are placed orthogonally in the ball cube. The ball cube is 2.5" on each side and contains a 1.25 inch acrylic ball, which is visible in CT and used as a treatment target.

## Beam

The CyberKnife® System utilizes three X-ray beams, the high therapeutic energy (6MV) radiosurgical beam emanating from the Linac and two low diagnostic energy beams used for image generation. See Linac, XRS, and collimator.

## Beam selection

One of the primary algorithms of the Treatment Planning System (TPS). Beams are selected according to the given lesion size and shape. The selection uses a reachability model of the manipulator workspace. Multiple beam directions with a high degree of collimation are used to accurately target the lesion while sparing normal tissue.

# C

## Centigray (cGy)

A unit of radiation dose equal to the rad, 1/100 of a Gray. Radiation dose is a measure of radiation energy deposited per unit mass.

## CKS

CyberKnife System.

## Cold spot

A region being irradiated which receives an under-dose of radiation. See also under-dose.

## Collimator

X-rays radiate in all directions when an electron beam strikes the target. Since X-rays cannot be focused, heavy metal collimators are used to block the unwanted portion of the radiation to create a narrow beam.

The Linac has two collimators, a fixed primary collimator and a changeable secondary collimator. The primary collimator surrounds the X-ray target and limits the X-ray beam to a narrow cone in the forward direction. Secondary collimators of different sizes may be fitted to produce different beam sizes. The secondary collimator produces a beam with a circular cross section and a diameter ranging from 5 to 60 mm in 12 sizes (Defines at a distance from the source of 80 cm). Each secondary collimator has a different length in 1/16" steps based on its beam diameter. The Linac contains dual independent linear potentiometers to detect the length of the currently installed secondary collimator. Treatment cannot proceed with the wrong collimator installed.

A collimator is also used on each of the imaging X-ray sources to minimize patient exposure.



861 Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



## Conformal

The extent to which the radiosurgical treatment dose is restricted to the target volume, sparing surrounding healthy tissue, which may be critical and/or sensitive to radiation.

See also Dose.

## Coronal

A frontal image of the body. A **coronal plane** divides the body into front and back segments.

## Couch

See patient treatment table.

## Critical region

An important anatomical structure that is especially sensitive to radiation such as the eyes, optic nerve, or brain stem.

## CT

Computed Tomography is an imaging procedure in which many X-rays images are taken from different angles of a part of the body. These images are combined by a computer to produce cross-sectional pictures of internal organs. Except for the injection of a dye (needed in some but not all cases), this is a painless procedure that can be done in an outpatient clinic. CT images are used by the CyberKnife System for treatment planning and to produce the reference images (DRRs) for treatment simulation and delivery. CT images used in the CyberKnife System may be either of the patient or of a phantom. The images are generally created at a different site from treatment planning and delivery. They may be loaded to the CyberKnife System either from tape or Ethernet (TCP/IP).

## CyberKnife®

The CyberKnife System is a radiosurgery device used to treat cancer throughout the body by focusing many high energy beams precisely to the tumor delivering a very conformal dose. The CyberKnife System consists of three key components: 1) an advanced, lightweight linear accelerator (LINAC) (this device is used to produce a high energy (6MV) of radiation), 2) a robot, also called the manipulator, which can point the linear accelerator from a wide variety of angles, and 3) X-ray cameras (imaging devices) that are combined with powerful software to track patient position. The cameras obtain frequent pictures of the patient during treatment, and use this information to target the radiation beam emitted by the linear accelerator.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118 862

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



# D

## DICOM

A data standard used to transfer medical image and radiation therapy planning studies from the medical image scanner or contouring workstation to the CyberKnife System site via a network prior to treatment planning.

## Dmax

The depth at which the radiation dose reaches a maximum in water or water-equivalent material, such as soft tissue.

## DOF

Degrees of Freedom. The CyberKnife System manipulator has 6 degrees of freedom, three of translation (x, y, z) and three of rotation (yaw, pitch, and roll).

## Dose

A measure of accumulated radiation exposure. The region receiving the high radiation dose should match the target region. To protect healthy tissue, sharp dose drop-off should be achieved in the healthy tissue surrounding the tumor. Dose homogeneity for certain lesions is essential to prevent complications. The dose in the surrounding tissue should also be uniform. Certain structures (e.g. the optic nerves, arteries, and brain stem) are very critical and/or radiation sensitive. The dose in such critical regions should be very small. See also Hot spots, Cold spots, Conformal, Under-dose, and cGy.

## Dose Calculation

One of the primary algorithms of the Treatment Planning System (TPS).

The dose calculation algorithm, in the TPS, has two main purposes. The first is the calculation of Monitor Units (MUs) to be delivered by the Linac for each beam to irradiate the tumor with the prescribed isocentric dose (ID). The second is the calculation of dose distribution inside the head and body (including tumor, critical regions, and normal tissue) given the monitor units being delivered by the Linac.

## Dosimetry system

Dosimeters measure the energy carried by a beam over time. The dosimetry system in the Linac uses dual independent dosimeters (named A and B or primary and secondary) at the X-ray source to measure its output. They are configured in a redundant dose monitoring combination to safeguard against incorrect dose delivery. Irradiation at a node is terminated by the dosimeter hardware when the delivered dose at the node is equal to the planned dose. The first dosimeter to reach the desired dose causes the Linac to shut off. The software uses the dose from the primary dosimeter (dosimeter A) as the measure of delivered dose. The dosimetry software verifies that the two dosimeters differ by no more than +or- 5% at any node. If elapsed irradiation time at a node exceeds the planned time by more than 50%, a timer in the RCS terminates irradiation. If a dosimetry error occurs, this is considered an unrecoverable error and patient treatment is aborted.



863 Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



### DRR

Digitally Reconstructed Radiographs created from the patient's CT data. The DRRs are used as reference images by the Image Processing System for patient alignment during treatment or simulation. During simulation, the phantom does not move, but the initial position must be known.

### DVH

Dose Volume Histogram, a graph plotting structure tissue volume (in $mm^3$) receiving at least the dose plotted on the x-axis (i.e. a cumulative DVH).

## E

### E-Stop

Emergency Stop. E-Stop buttons (also referred to as pause buttons) are located on each piece of equipment, the treatment and control rooms. An emergency stop pauses the system. If a recoverable error has occurred, the system can be restarted from an E-Stop.

### Emergency Stop Control Chassis (ESCC)

The central unit responsible for handling emergency stops. See E-Stop.

### Error recoverable

An error condition that causes an E-Stop. Treatment can resume once the error condition is cleared.

### Error unrecoverable

An error condition that causes an E-Stop. Equipment power must be cycled to reset the E-Stop after the error condition has cleared.

## F

### Feet First Supine (FFS)

A patient orientation available for lower spine and abdomen area treatments.

### Fiducial markers

Artificial references (such as gold seeds or stainless steel screws) which are implanted in or near tissues undergoing radiosurgery or radiotherapy treatment. Where bone and other natural structures are not in the proximity of the tumor site, these markers are used as artificial landmarks by the imaging system. Usually three or more markers are used.

### Film Cube

The film cube is a QA tool designed by Accuray for measuring stereotactic targeting accuracy. Physically it is an HIPS plastic film cassette used for holding up to 14 pieces of radiochromatic film. The films are stacked parallel in the film cube separated by identical spacer plates. The film cube is 2.5" on each side.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118 864

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



### Forward planning

Treatment planning given beam selection and dosage. The computer finds the dose distribution. See also TPS.

### Fractionated Radiosurgery

Treatment that has been partitioned into several doses repeated over time (e.g. several days). Traditional treatments can be fractionated into a series of 2-30 doses. This may be necessary for large targets where a single treatment would deliver too much radiation to the healthy tissues at one time. In the past, fractionated treatment has been difficult due to the necessity of using a rigidly fixed frame attached to the skull to locate the tissue in space. Fractionated radiosurgery is only possible with the CyberKnife System and is done in 2-5 fractions. See staged.

### Frame

Frame is used in two different contexts in the CyberKnife System:

1. In one context frame refers to the various coordinate systems used to locate the robot, Linac, and patient. Coordinate frames used with the CyberKnife System are in general Cartesian 3D 6 degrees of freedom: 3 of translation (x, y, z) and 3 of rotation (yaw, pitch, roll or w, p, r). See Image frame, Tool frame, Uframe, and World frame.
2. In a different context, radiosurgery systems that do not use a target image location system must use a frame rigidly attached to the skull of the patient to immobilize the head during treatment delivery.

### Frameless

Radiosurgery systems such as the Gamma Knife use a frame rigidly attached to the skull to insure accurate radiation targeting and delivery. The CyberKnife System is considered frameless since only a non-intrusive restraint is used. The CyberKnife System targets off of bony landmarks and fudicials. The imaging system on the CyberKnife System allows the robot to correct for small movements of the patient or target during treatment delivery.

## G

### Gafchromic film

Self developing radiochromic film used to verify system targeting. Gafchromic film is manufactured by ISP. MD55 comes in 5" square sheets and MD22 is custom cut to fit in the film cube and ball cube. A pre-notched version of MD22 is available from Accuray for use in the ball cube. See also film cube and ball cube.

### Gamma rays

Photons in the energy band above ultraviolet light that have been produced by radioactive decay. Similar to X-rays except the source is different. The CyberKnife System uses an X-ray system rather than gamma rays. See also X-rays.

### Gray

A unit of radiation dose equal to 100 rad. Radiation dose is a measure of radiation energy deposited per unit mass (1 Gray = 1 Joule/Kg). See also Centigray.



865 Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



### Gun (Electron gun)

The unit in the Linac, which injects a low energy electron beam into the accelerator. The Gun is a vacuum tube that consists of the following:

- cathode with a filament heater to produce the electrons
- control grid to turn the electron beam on and off
- anode to provide initial acceleration for the beam.

The high voltage power supply provides a negative voltage to the cathode.

## H

### Headframe

A frame that rigidly immobilizes the patient's head during imaging and radiation treatment.

### HFS

Head First Supine. This is the normal patient orientation for CT scans.

### Hot spot

A region being irradiated which receives an abnormally high dose of radiation. Hot spots, even inside tumors, can cause complications.

## I

### IFCC (Interface Control Chassis)

The Interface Control Chassis is a subsystem that performs two functions: (1) Performs Linac On/off control, and monitors Linac status (2) Serves as a central hardware registry for all ESTOP's. The Linac on/off control is performed under commands from the host computer, and the status of the Linac and ESTOP's are reported back to the host computer.

### Image frame

One of the coordinate systems used by the CyberKnife.System. The Image Frame is a 3D Cartesian coordinate system with rotation (x, y, z, w, p, r) whose origin is at the center of the TLS image location system. Its position is fixed and is established during system installation. See also Tool Frame, Uframe, and World Frame.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118 866

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



## Imaging system

The imaging system locates the treatment center by comparing real-time radiographs of the patient with radiographs synthesized from CT data. Thus, patient positioning does not require mechanical fixation and lengthy alignment procedures.

The imaging system contains two nearly identical X-ray imaging units. Each unit has the following components:

- standard medical radiographic X-ray tube
- high voltage generator
- tungsten copper X-ray collimator
- X-ray detector

A patient needs to be aligned with respect to the Image Frame before treatment delivery may proceed. The best way to understand this process is to visualize the CT coordinate frame as being "attached" to the patient's head at the time the scan is made. In the CT data file, a precise connection exists between the patient's anatomical data and the CT coordinate frame.

Before alignment, digitally reconstructed radiographs (DRRs) are generated from the CT. The DRRs are generated using a technique that numerically simulates how an image would be taken by the orthogonal cameras. The origin of the CT becomes the origin of the DRRs.

During alignment, the patient's position is first set using a pair of images taken by the orthogonal X-ray detectors. These images are numerically overlaid with the appropriate DRRs. The treatment software calculates required adjustment to the patient's position. The operator performs the adjustment on the treatment table. This process aligns the origin of the CT coordinate frame, which in practice is the center of the patient's head, to the origin of the Image Frame, which is the imaging center.

After alignment, radiation treatment begins. Tracking adjustments are made by instructing the manipulator to modify its pointing angle at each node to compensate for any mismatch between the CT coordinate frame and the TLS image frame caused by misalignment or by patient motion.



867 Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



## Interlocks

The Linac displays the following safety interlocks and status information on the MCC. They are cleared (not illuminated) when the description shown is not satisfied.

| Interlock Name | Description |
|---|---|
| Door Interlock (Intlk) | All treatment room doors are closed |
| Water Flow Interlock | Cooling water or air flow is adequate |
| Magnetron Filament (Mag Fil) | Magnetron filament voltage is acceptable |
| Heater (Htr) Delay | CyberKnife System has completed an approximately 10 minute warm-up |
| Sulfur Hexafluoride (SF6) Gas | SF6 tank pressure is acceptable |
| Vacuum | No vacuum faults in accelerator waveguide or magnetron |
| Dose Power Supply (P.S.) | Dosimetry high voltage power supplies operating properly |
| Computer | Linac is in computer control mode |
| High Voltage Over-current (HVOC) | Excessive current is not being drawn from the high voltage power supply (to magnetron) |
| Inverse Current (I) | No excessive reverse current returning from X-ray head |
| Manual Override | When the CyberKnife System operates under computer control this light is illuminated |
| Grid Power Supply | Accelerator electron gun power supply working properly |
| E-Stop | E-Stop switch on the MCC is not pressed |
| Beam On | X-ray beam is on |
| Automatic Frequency Control (AFC)/Manual | Magnetron AFC is in automatic |
| Collimator Interlock | Both collimator sense potentiometers are reading the same value |
| Pulse Rate Frequency (PRF) Limit Interlock | No used |
| HV Enable | SGI has enabled high voltage when not in manual mode |
| DC Pwr | Monitors low voltages in the modulator |
| Diagnostic (Diag) Mode | Not used |



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



## Inverse Planning

Treatment planning devised by the software. The user specifies the following constraints:

- minimum lesion dose (in cGy)
- maximum lesion dose (in cGy)
- dose maximum of up to 10 critical regions (in cGy)
- maximum dose of soft tissue boundary that surrounds the lesion (in cGy)
- maximum beam weight (in MU)

The computer uses a linear programming algorithm to find a dose for each beam to satisfy the constraints, a feasible but not necessarily optimal solution. See also Treatment Planning (TPS).

## Ionizing radiation

A radiation beam that, when passing into a biological absorbing medium such as body tissue, transfers some of the energy carried in the beam to the medium sufficiently to ionize the tissue at the molecular level and therefore to disrupt cellular reproduction processes. The energy transferred may produce a biological effect in the medium. Use of the word "radiation" in this document will mean ionizing radiation.

## Isocenter

The point in space where the central axes of treatment beams intersect with the gantry axis or the machine center.

## Isocentric Planning

A model of treatment planning where the lesion is placed at isocenter and can be irradiated from different angles. In radiosurgery, this method typically results in a spherical dose distribution. For symmetrical, roughly spherical lesions, a single isocenter can be used. For asymmetrical lesions, multiple isocentric doses of varying sizes can be used to create a homogeneous dose distribution within the lesion.

## Isocrystal

Target located at the tip of the iso-post that is used with the laser in the linac to perform robot pointing calibration. Indicates the precise position of the system iso-center.

## Isopost

Calibration tool used to establish the machine center. See Isocrystal.



869 Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



# K

## Key switch

The radiation enable switch in the user control panel. When turned ON, it provides the "high voltage enable" to the Linac for treatment delivery, simulation, or calibration.

# L

## Linac

Acronym for linear accelerator. A linear accelerator is a device that uses high frequency electromagnetic waves to accelerate charged particles such as electrons to high energies through a linear tube. In the CyberKnife System, the Linac uses a Magnetron to produce X-band microwaves to accelerate an electron beam to a nominal energy of 6 MeV. The beam strikes tungsten target where X-rays are produced. Here the X-ray beam energy is measured by two dosimeters. The X-rays are reduced to a narrow beam by a fixed primary collimator and then by a secondary changeable collimator. The entire apparatus is mounted on the end of the robot arm that aims the X-ray beam at the treatment site in the patient. Radiation is only fired from the Linac when the manipulator is stopped and located at a node.

# M

## Magnetron

A magnetron is a vacuum tube device that produces microwaves. It functions as a high-power oscillator, generating microwave pulses of several microseconds duration and with a repetition rate of less than 200 pulses per second. The Linac uses a mechanically tunable magnetron to provide the energy necessary to accelerate the electron beam. See Linac and AFC.

## Makeup plan

A new treatment plan created when an executing plan is aborted during treatment delivery. The makeup plan contains the remaining dose to be delivered to the patient. If a treatment fraction has been terminated due to error or user request, a makeup fraction is created. It consists of all paths of the terminated fraction that was not executed. It contains the same set of nodes as the treatment plan except that the nodes already delivered are set to zero dose and the node where the termination occurred will contain only the amount of dose remaining.

## Menus

The SGI software displays a high level menu so that the users can select the function they wish to perform. The first nine options appear as buttons on the screen and the remaining six options appear as pull down menus under "ADMIN":

## MeV

One million electron volts, a unit of energy used to specify the energy of particles such as the electron beam in the Linac. One electron volt is the energy equivalent of an electron being accelerated in free space through a field of one volt. The Linac produces a nominal 6 MeV electron beam.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



## Modulator

Contains the pulse power modulator generator for the magnetron and the high voltage supply for the Linac gun.

Modulator Control Chassis (MCC)

A unitsubsystem of the Linac. It contains the control logic, fault logic and manual controls for the modulator.

## Monitor Unit

The Monitor Unit, commonly referred to as MU, is the measure of charge integrated by two independent dosimeters. The calibration of MU as a function of dose controls the dose delivery of the CyberKnife System.

Due to variations in linac calibration the MU is calibrated to be within about 5% of the true value. The precise dose calibration is achieved by an additional "calibration factor" measured each day and entered into CyberKnife System by the physicist. The calibration factor (in units of MU/cGy) sets the precise calibration of CyberKnife System.

## MRI

Magnetic Resonance Imaging, an alternate form of imaging not directly used with the CyberKnife System. MR uses magnetic energy and radio waves to create 2D or 3D images of the human body. This type of imaging is particularly useful for discriminating regions within soft tissue. The main component of most MR systems is a large tube shaped or cylindrical magnet. Also now available are MR systems with a C-shaped magnet or other type of open design. The strength of the MR systems magnetic field is measured in metric units called "Tesla". Most of the cylindrical magnets have a strength between 0.5 and 1.5 Tesla and most of the Open or C-shaped magnets have a magnetic strength between 0.01 and 0.35 Tesla. A 1.5 Tesla MR system has a magnetic field 30,000 times stronger than the pull of gravity on the earth's surface.

## MU

See Monitor Unit.

## MV

A medical radiation term that is a measure of the energy of a spectrum of X-ray photons. See MeV.



871 Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



# N

## Node

One of a set of predefined points at the end of the accelerator, from which radiation is delivered to the tumor target. The location of the set of treatment nodes is fixed at design and is not altered for individual treatment plans, though there will be variations in orientation to point at the current target center or position to compensate for patient motion. A set of nodes is selected at system design which provide useful coverage of the head, avoid physical objects in the treatment room, and avoid blocking the X-ray imaging system.

## Non-isocentric planning

A method of treatment unique to the CyberKnife System, in which the beams are directed to different points around the boundary of within the tumor and inverse planning is used to weight the beams and generate a conformal dose distribution.

# P

## Patient Coordinate Frame

Has its origin at the center of the CT volume with its axes along left-right (x), posterior-anterior (y), and inferior-superior (z) directions. The origin is in the center slice for an odd number of slices or between slices if the number is even. If the patient is supine, the positive x-axis is in the direction of patient right, the positive y-axis is in the anterior direction, and positive z-axis is in the superior direction.

## Patient alignment abbreviation

| | | | |
|---|---|---|---|
| POS – ANT | Posterior / Anterior | ROLL | Left / Right |
| SUP – INF | Superior / Inferior | PITCH | Heads up / Down |
| LFT – RGT | Left / Right | YAW | CW / CCW |

## Patient Treatment Table

The Patient Treatment Table is an X-ray transparent table that supports the patient during treatment. Moves in 5 DOF, x, y, z, roll, pitch.

## PDD

Percent Depth Dose. A measure of the energy, or the ability of a spectrum of radiation to penetrate a material such as water or soft tissue.

## PDP (Proximity Detection Process)

Its software program is used to check how close the robot is approaching stationary objects in the treatment room. It uses treatment room geometry files and real-time data from the robot encoders to detect and signal a proximity error when any part of the robot moves within 5 cm of any stationary object. When a proximity error occurs, robot motion is stopped. The robot is disabled when in manual mode.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



### Penumbra

The edge region surrounding a beam where the energy level drops from 80% to 20% of its maximum.

### Perch position

Rest position of the robot.

### Phantom

A 3D model of the skull or other target bearing portion of the body. A 3D photographic film cube is placed in the phantom in the particular volume. The exposed film shows the dose distribution applied during the simulation run. Upon inspection of the irradiated film, adjustments may be made to the treatment plan prior to its application to the patient.

The phantom with film cube is used to perform an end-to-end and QA test. In this test a CT is generated of a dosimetric phantom and a plan is created to treat a specified location in the film pack. After irradiating the phantom, the film pack is read and a comparison is made of the location of the planned treatment with the center of the delivered dose. In this way the total system accuracy is tested. See also film cube.

### Prescription

Dose to be delivered to the tumor.

## R

### Rad

A unit of radiation dose, replaced by the Centigray (cGy).

### Radiosurgery

The treatment of lesions using stereotactically directed convergent beams of external irradiation, usually in 1-2 fractions. Radiosurgery is usually confined to treating lesions of dimensions less than 3 to 5 cm because of the perceived limitation of normal tissue tolerance. See SRS.

### Robot Coordinate Frame

Same as the Uframe of the robot. The robot coordinate frame's origin is at the same place as the patient frame's origin however the robot coordinate frame is rotated 45 degrees.

### ROI

Region of Interest



873 Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



# S

## SAD

Source to Axis Distance. The distance from the X-ray source to the tumor target.

## Sagittal

A side image of the body. A **sagittal plane** divides the body into left and right segments.

## Simulation

One of the operational modes of the CyberKnife System, a physical execution of the treatment plan by the system with a dosimetric phantom instead of a patient. A treatment plan may be simulated prior to patient treatment. The primary purpose is to check for the accurate and safe delivery of a patient treatment plan. Simulation requires the use of a dosimetric phantom and a film cube. Treatment simulation is the same as treatment delivery except that the dose actually applied is not recorded in the database. After performing the simulated treatment delivery, the exposed film pack is examined and verified that the center of the dose distribution is at the intended location and that the shape is correct.

## Site

The location of a tumor or other lesion under treatment.

## SRS

Stereotactic Radiosurgery

## Stereotactic

Any device which accurately guides a surgical tool in space. Adjective form of stereotaxis (see).

## Stereotactic Radiotherapy

The treatment of larger lesions using stereotactically directed convergent beams of external irradiation, in several fractions. Radiotherapy is often used in treating lesions of dimensions greater than 5 cm because of the perceived limitation of normal tissue tolerance, whereas radiosurgery is often used for smaller lesions.

## Stereotaxis

Stereotaxis is a branch of neurosurgery that utilizes spatial information provided by neuroradiologic studies to treat certain disorders of the central nervous system with great accuracy.

## Sulfur Hexafluoride (SF 6)

A dielectric gas used to suppress ionization in the Linac waveguide between the magnetron and the accelerator. Also referred to as SF6.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118 874

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



### Synchrony™

Synchrony is Accuray's system for delivering dynamic radiosurgery to tumors that move with respiration. The Synchrony system precisely tracks tumors in or near the lungs as they move, enabling highly focused beams of radiation to destroy the tumors with minimal damage to adjacent normal tissue. Synchrony records the breathing movements of a patient's chest and combines that information with sequential X-ray pictures of tiny markers inserted inside the tumor to enable precise delivery of radiation during any point in the respiration cycle. CyberKnife System with Synchrony is the only radiosurgery device capable of targeting tumors in this manner.

### System Center

Sometimes referred to as the machine isocenter. The system center is a physical reference point chosen during system installation in the center of the patient treatment area. Under ideal conditions this point would coincide with the center of the image frame and also the Uframe. In reality these are three different reference frames that exist in close proximity and are used to compute the patient's location during treatment.

A second purpose for the system center is to provide a reference point for robot calibration. During system installation and at other times when system calibration is required, the system center is used as the reference to correct the computed node file to provide a precise isocenter, i.e. all beams from the linac are corrected to point at precisely the same point, the system center. The laser alignment unit (LAU) is used to perform this calibration.

## T

### Target

There are two different targets referred to in the CyberKnife System:

1. Inside the Linac, a 6 MeV electron beam is aimed at a tungsten target to generate 6 MV X-rays.
2. The X-ray beam is aimed at a second target, the tumor in the patient.

### Target Locating System (TLS)

The CyberKnife System subsystem that provides the capability to locate the treatment target.

### Teach Pendant

A hand held device used to manually control the manipulator or to program sequences of movements for it. In the CyberKnife System, the operator uses the teach pendant to position the manipulator for calibration or maintenance and to manually power up components such as the alignment lasers or imaging X-ray sources. Maintenance mode can only be accessed with a special key. The CyberKnife System is used for patient treatment only when the robot is under computer control.



875 Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



### Tool Frame

One of the coordinate systems used by the CyberKnife System. The Tool Frame is a coordinate system with 6 degrees of freedom (x, y, z, pitch, yaw, and roll). The tool frame location (x, y, and z) is defined relative to the faceplate of the robot with the z-axis perpendicular to it (positive pointing straight out). The tool frame orientation (pitch, yaw, and roll) is the same as the faceplate. The tool frame origin is called the tool center point (TCP). The TCP for the CyberKnife System is at the X-ray source of the Linac. Its position moves with the robot and is continually being recalculated during treatment delivery. See also Frame, Image Frame, Uframe, and World Frame.

### TPS

Treatment Planning System.

The main functionality of TPS is to:

- display the CT data
- delineate the tumor and the critical structures
- generate treatment plans
- evaluate and fine-tune plans.

### Treatment Path

The path which the Linac would follow in moving through a set or a subset of nodes. All defined nodes are visited during radiation treatment or simulation. No nodes are skipped even if radiation is not activated at all nodes. Normally radiation is only activated at a subset of the defined nodes. For the CyberKnife System, there are single or 3 path options available.

## U

### Uframe

One of the coordinate systems used by the CyberKnife System. The Uframe is a coordinate system (x, y, z) whose origin is at the center of the CT images. The location of the Uframe represents distances along the x, y, and z-axes of the world coordinate system; the orientation represents rotations around those axes (w, p, r). See also Frame, Image Frame, Tool Frame, and World Frame.

### UPS

Uninterruptible Power Supply used with the SGI to maintain power during power interruptions.

### User Control Panel

The purpose of the control panel is to allow the user to turn the high voltage on or off to the Linac. Once the high voltage is on, radiation can be generated and delivered.

See also **key switch**.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



# V

## Voxel

A 3-dimensional pixel, an atomic element of a 3D image.

# W

## Water cooling system

The linac uses a water cooling system to remove heat from the X-ray head. The water is cooled by a chiller located in the equipment room.

## Water phantom

A precise radiation measurement device used for characterization and calibration of the Linac beams. Every Linac is different. In the CyberKnife System, the beam from each collimator is characterized using a water phantom and the data collected is stored in a system file. This beam data is used in treatment planning to determine how much dose to deliver.

## Waveguide

The structure in the accelerator that develops the electric fields necessary to accelerate electrons. Utilizes microwaves of the appropriate frequency and power to provide the necessary energy

## Workspace

The workspace is the set of configurations that the robot (or manipulator) can assume without entering a forbidden region. A forbidden region is an obstacle plus any buffer around the obstacle. Defined obstacles in the treatment area include the patient, the couch, the camera stands, the floor, and the ceiling.

## World Frame

One of the coordinate systems used by the CyberKnife System. The World Frame is a Cartesian coordinate system (x, y, z expressed in millimeters) whose origin is predefined by the robot manufacturer for the particular model of robot. For the CyberKnife System, the World Frame origin is located 1 meter (1000 mm.) above the floor. See also Frame, Image Frame, Tool Frame, and Uframe.



877

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



# X

## X-band

A frequency spectrum in the microwave band. The Linac magnetron operates in the x-band. X-band microwaves are used in the CyberKnife System Linac because it allows for smaller robot-mounted Linac components than would a lower frequency band. Conventional linac accelerators typically use the lower-frequency S-band.

## X-rays

Photons in the energy band above ultraviolet light that have been produced by high energy particles colliding into a target. See also gamma rays.

## X-ray head

The portion of the linac that is mounted to the end of the robot arm and provides the radio-surgical X-ray beam.

## X-ray detectors

Amorphous silicon flat panel X-ray image detectors used in the TLS to obtain images of the patient for use in patient alignment and motion tracking.

## XRS

X-ray source used in the TLS to illuminate the X-ray detector.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015





879 Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015

K 062967



ACCURAY™

**Enabling Full-Body Radiosurgery Using Image-Guided Robotics**

**Accuray Worldwide Headquarters**

1310 Chesapeake Terrace
Sunnyvale, CA 94089 USA

**Accuray Worldwide Manufacturing**

1310 Orleans Drive
Sunnyvale, CA 94086 USA

**Accuray Europe**

Tour Atlantique
1, Place de la Pyramide
92911 PARIS La Défense cedex
Tel: +33-1-55-23-20-20 Fax: +33-1-55-23-20-39

**Accuray Asia**

Suites 1702-3
17th Floor, Tower 6, The Gateway
Harbor City, Kowloon, Hong Kong
Tel: +852-2247-8688 Fax: +852-2175-5799

**Authorized Representative**

MedNet GmbH
Borkstrasse 10
D-48163 Münster, GERMANY
Tel: +49 (251) 32266-0 Fax: +49 (251) 32266-22

**Customer Support +1 (877) 668-8667**

CE 0197

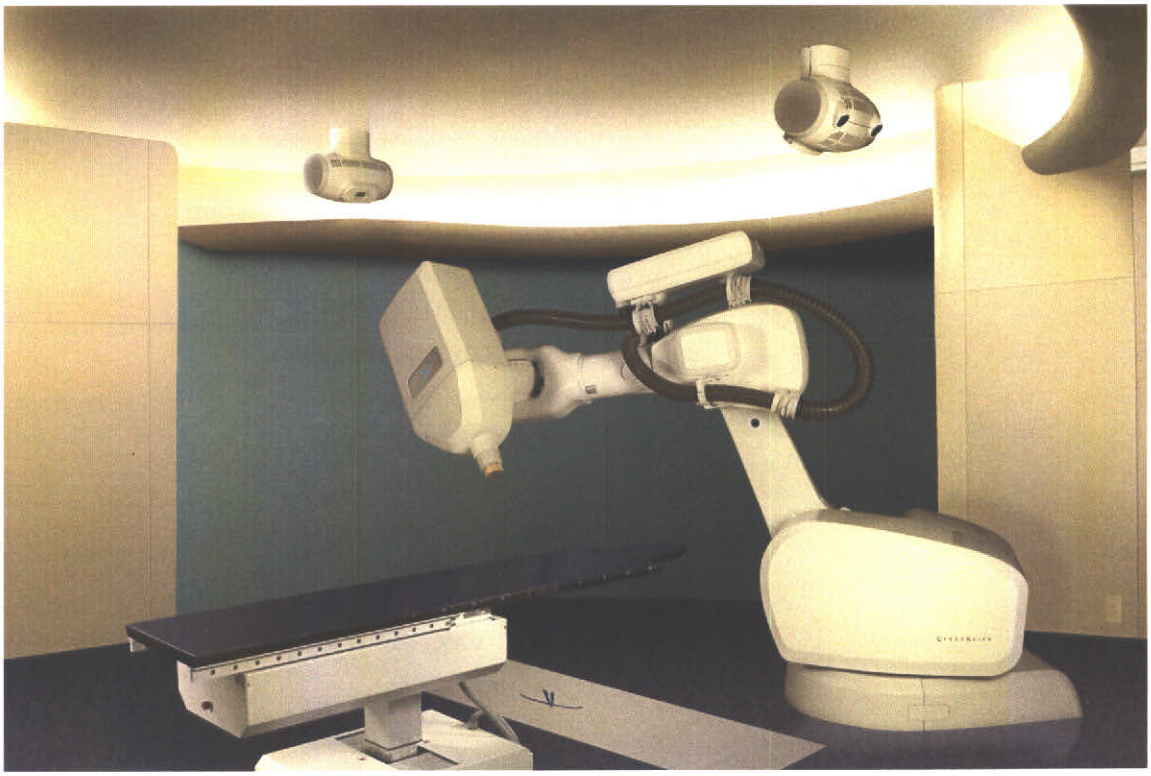


Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

880

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015





© 2006 Accuray Incorporated. All Rights Reserved. The Accuray stylized logo, Accuray, CyberKnife, Express, CyRIS, InView, MultiPlan, and Synchrony are trademarks and/or registered trademarks of Accuray Incorporated in the United States and other countries.

This document contains proprietary information that belongs exclusively to Accuray Incorporated and should not be distributed without prior written consent from Accuray.

The principals, officers, representatives, subsidiaries, employees, agents, heirs and assigns of Accuray Incorporated assume no responsibility or liability, either express or implied, for injury, death, or losses to consumers, users or service personnel resulting from improper handling of the CyberKnife® System by untrained or otherwise unqualified personnel.

Accuray Incorporated expressly denies any responsibility or liability for deliberate misuse or tampering with CyberKnife System components by persons not employed directly by Accuray Incorporated. This warranty voids all others to the contrary, either expressed or implied, regardless of form, content, or source.

The anticipated useful life of the CyberKnife System is seven to 10 years depending on utilization and proper performance of preventive and corrective maintenance.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

881

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



**WARNING: In the United States, law restricts this device to sale by or on the order of a physician.**

**Notice:**

**This User's Manual contains instructions for multiple features of the CyberKnife System. Since some features of the CyberKnife System are optional, some of the instructions in this manual may not apply to your system.**

**The availability of options is dependent on regulatory approvals in a particular country and varies from country to country.**

**The content of the User's Manual may vary since Accuray, the manufacturer, may modify them from time to time without giving notice to customers.**



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118 882

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



# REGULATORY COMPLIANCE

The CyberKnife System is classified by the following:

- Protection against electric shock: Class I, permanently connected
- Applied part: Patient treatment table only, Type B
- Protection against harmful ingress of water: IPXO - no protection against ingress of water
- Methods of sterilization or disinfection: Not required
- Degree of safety in the presence of flammable mixtures: Not suitable for use in the presence of flammable mixtures
- Mode of operation: Continuous

The CyberKnife System has been tested for compliance to the following standards:

| Standard Number | Standard Title |
|---|---|
| EN 60204-1:1997 | Safety of machinery - Electrical equipment of machines – Part 1: Specification for general requirements |
| EN 60601-1:1990 /A1:1993 /A2:1995 | Medical electrical equipment, Part 1: General requirements for safety |
| EN 60601-1-1:1993 | Medical electrical equipment, Part 1-1: General requirements for safety – Collateral standard: requirements for medical electrical systems |
| EN 60601-1-2:2001 | Collateral standard: Electromagnetic compatibility – requirements and tests |
| EN 60601-1-3:1994 | Collateral standard: General requirements for radiation protection in diagnostic X-ray equipment |
| EN 60601-1-4 1996 /A1:1999 | Collateral standard: Programmable electrical medical systems |
| EN 60601-2-1:1998 | Particular requirements for safety – Specification for electron accelerators in the range 1 mev to 50 mev |
| EN 60601-2-46:1998 | Particular requirements for safety – Specification for operating tables |
| EN 60825-1:1994/ A11:1996 /A2:2001 | Radiation safety of laser products, equipment classification, requirements and user's guide |
| EN 60950:2000 | Safety requirements for information technology equipment |
| EN 61010-1:2001 | Safety requirements for electrical equipment for measurement, control, and laboratory use – Part 1: General requirements |
| EN 62083:2001 | Medical electrical equipment – Requirements for the safety of radiotherapy treatment planning systems |
| EN 61508-1:1998 | Functional safety of electrical/electronic/programmable electronic safety-related systems – Part 1: General requirements |
| EN 60976:1998 | Medical electrical equipment – Medical electron accelerators – Functional performance characteristics |



883 Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



# TREATMENT DELIVERY USER'S MANUAL

## Table of Contents

1. Safety
2. Overview
3. System Startup
4. Equipment Checks
5. Patient Preparation
6. Patient Data & Image Administration
7. QA/Calibration
8. DRR & Prescription
9. Simulation of Treatment
10. Treatment Room Operations
11. Treatment
12. Synchrony™
13. Error Messages
14. System Shutdown
15. System Administration
16. Patient Archive and Restore System
17. Xsight™ Spine Tracking System (OPTION)
18. Glossary
19. Technical Bulletins
20. White Papers

P/N 023998A-ENG

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118 884

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015





Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

885

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



# Safety
## Table of Contents


Safety Precautions and Warnings ..... 1
- Warning, Caution and Note Symbols ..... 1

Overview ..... 2
- Equipment Symbols ..... 3

Emergency Procedures ..... 4
- Emergency Stop Procedure (E-Stop) ..... 4
  - Emergency Stop Failure ..... 6
  - E-Stop Button Failure ..... 6
- Emergency Power Off ..... 6
- Power Failure ..... 7
- Accelerator Malfunction ..... 7
- Fire or Fumes ..... 7
- Treatment Table Failure ..... 8
- Unexpected Manipulator Arm Motion ..... 8

Safety Precautions ..... 9
- X-ray Radiation ..... 9
- Pacemakers ..... 10
- Electromagnetic Interference ..... 10
- Laser Radiation ..... 11
  - Laser Warning Labels ..... 12
- Sulfur Hexafluoride ..... 12
- Implosion ..... 13
- Explosion ..... 13
- Electric Shock ..... 14
  - Observe the following precautions to avoid electric shock ..... 14
- Heavy Equipment ..... 15
- Hot Surfaces ..... 16

Facility Responsibilities ..... 17
- General Use ..... 17
- Safety Operations ..... 17
- Emergency and Safety Training ..... 18
- Radiation Overdose ..... 18




Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118 886

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015





Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



# SAFETY

## SAFETY PRECAUTIONS AND WARNINGS

Safe operation of the CyberKnife® System requires careful attention to the serious hazards associated with the use of the Linear Accelerator, ways to avoid or minimize the hazards and familiarity with emergency procedures. Additional hazards associated with movement of the robot are also present. Untrained or careless operation of the CyberKnife System can damage the system, its components or other property causing poor performance, or leading to serious bodily injury and possibly death. Anyone who operates, services, maintains, or is otherwise associated with the CyberKnife System must read, understand and be thoroughly familiar with the information in this manual and take precautions to protect themselves, patients, their associates and the equipment. Specific warnings and cautions are given with the instructions in this module.

**WARNING: The CyberKnife System can emit lethal doses of high energy radiation. The assemblies contain high voltage circuits that can deliver lethal electrical shocks. Always observe safety precautions when operating or working on or around the CyberKnife System.**

Address any questions regarding the safe and efficient use of the CyberKnife System directly to Accuray, Incorporated.

### Warning, Caution and Note Symbols

**WARNING: Describes actions or conditions that could result in injury or death to personnel.**

**CAUTION:** Describes actions or conditions that could result in damage to the equipment.

**NOTE:** Provides more information about a subject.

This module provides emergency procedures for the CyberKnife System. Anyone who uses the CyberKnife System should read this guide.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118 888

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



# OVERVIEW

This module provides information about the emergency procedures and safety features of the CyberKnife System and describes safe operating practices.

Review the following information before using the equipment.

**Emergency Procedures** Describes what to do in emergency situations.

**Safety Precautions** Describes how to avoid hazards.

**Facility Responsibilities** Describes user responsibilities for the training and safety of the staff and patients who come into contact with the CyberKnife System.

**WARNING: The CyberKnife System is a highly complex product. It is your responsibility to operate the equipment knowledgeably and safely and to ensure the service of each component that may be required. Improper operation or service can result in injury and even death.**

**WARNING: Do not alter the software or any of the components in the CyberKnife System. Results of these actions could cause injury or death.**



889

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



# Equipment Symbols

The CyberKnife System labeling includes several symbols designed to convey safety and usage information. Below are the symbols and their description.

| | |
|---|---|
| CE 0197 | CE mark |
| TÜV Rheinland of North America, Inc. C US | United States and Canada product safety certification mark (NRTL approval) |
| | WARNING: Alerts the user to potential serious outcomes (death, injury, or adverse events) to the patient or user. |
| | Electric shock hazard |
| | Caution, hot surfaces |
| | Read manual |
| | Caution, foot crush hazard |
| | Caution, hand crush hazard |
| 3 ~ | 3 Phase alternating current |
| IPX0 | Not protected against ingress of liquids |
| | Type B equipment |
| REF | Part number or reference number |
| SN | Serial number |
| | Date of manufacture |



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118 890

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



# EMERGENCY PROCEDURES

You are responsible for on-site procedures that follow the guidelines outlined here. The following emergencies are described:

- General emergency stop procedure.
- The emergency stop button does not work.
- The Linac X-ray beam does not shut off.
- Power failure.
- Fire or fumes are detected.
- The treatment table does not operate properly.
- The manipulator arm moves in an unexpected way.

Being prepared for an emergency is essential to operate this equipment safely.

## Emergency Stop Procedure (E-Stop)

If the CyberKnife System detects an error in its operation, it executes a system emergency stop (E-Stop). If any situation has the appearance of an emergency, immediately stop the equipment by pressing an E-Stop button. Pressing an E-Stop button stops motion and radiation, but does not turn off power to the equipment.

**To turn off power to all equipment in a non-urgent situation:**

**Step 1.** After pausing the operation, click **ABORT** on the display.

**Step 2.** Or in an emergency cut the power at the main circuit breaker by pressing the **EMERGENCY POWER OFF** (EPO) button or facility main breaker, as applicable. (*see section, Emergency Power Off, page 6*).

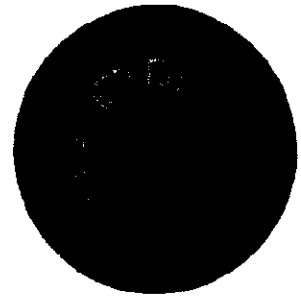


**Figure 1 System E-Stop Button**

Patient treatment table motions are disabled when an E-Stop is in effect. If the E-Stop is *not* caused by depressing one of the table E-Stop switches, manual controlled motion is possible by using the hand controller.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

891

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



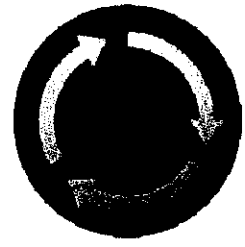


**Figure 2 EPO (Emergency Power Off) Button**

The CyberKnife System also has an emergency power off (EPO) system that uses a similar button. The appearance of the E-Stop and EPO buttons may differ from the above figures depending on the particular system.

**To cease operation immediately**

Press the nearest E-Stop button

E-Stop buttons are located on the following

- User control panel
- Linac control panel
- Robot teach pendant
- Additional locations chosen during installation.

Clicking **PAUSE** and pressing an E-Stop button have the same function.

When the pause button is selected the system goes to the following status:

- The Linac high voltage power shuts down so that **no radiation is emitted**.
- The Linac filament power remains on so that the Linac can resume operations without undue delay.
- The manipulator stops moving and remains in its current location. The power to the manipulator remains on.
- The imaging X-ray sources turn off so that **no radiation is emitted**.
- The user control console workstation remains on and receives status reports from the components.

When the status indicates that the radiation is off, you can enter the treatment room. The user control console monitor displays a window indicating that you may resume or abort the treatment. **ABORT** cancels the treatment at the incomplete stage and generates a "makeup" treatment plan, which enables you to resume treatment at any time (*see module, Makeup Fractions in the Treatment*). **RESUME** continues the treatment from the point when it stopped.

**NOTE:** You can easily reverse an E-Stop by clicking **RESUME** on the software menu. Do not hesitate to press the E-Stop or **PAUSE** even if you are unsure of the severity of the situation.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118 892

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



## Emergency Stop Failure

**Software E-Stop System Failure**

When any controller in the CyberKnife System detects an error, it sends a message to the system to execute an E-Stop. A message is displayed on the user control console monitor "Undergoing E-Stop Trip Sequence"

If this message is on the user control console monitor and the manipulator, Linac, or imaging system are still operating, the software emergency-off system has failed and you must manually stop the system.

**To execute the Emergency Off system manually:**

**Step 1.** Press the nearest physical E-Stop button.

**NOTE:** You must monitor the system at all times and manually initiate an E-Stop if an unsafe condition is imminent.

## E-Stop Button Failure

If you press the E-Stop button during an emergency and the manipulator is still moving, or the control console still indicates that the Linac beam or the imaging X-rays are on, the emergency off system has failed. You must manually stop the system.

**To manually stop the system:**

**Step 1.** Press an EPO button, or turn off the main circuit breaker in your facility.

**NOTE:** All users must know the location of the main circuit breaker.

# Emergency Power Off

CyberKnife Systems have an emergency power off (EPO) system that removes power from all non-computer-related equipment when actuated. Systems without power distribution units do not have an EPO system. Power must be removed by opening the main facility breaker through the means provided at the particular site. These sites should disregard references to the EPO button in this guide and use the site-specific means of removing power. The control button for the activating switch is shown in *Figure 2 EPO (Emergency Power Off) Button, page 5*. These switches are located by the user control computer, in the treatment room, on the power distribution unit and in additional locations chosen during installation.

**NOTE:** The computer equipment, e.g., user control computer, system PC, Synchrony™ computer and networking equipment, are powered from a UPS (uninterruptible power supply). To remove power from these items, the UPS must be turned off with its front panel power switch. After operating the EPO switch, follow the steps in *section, Power Failure, page 7* for loss of system power.



893

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



## Power Failure

The CyberKnife System operates from 3-phase electrical power. If the power fails, all treatment actions stop. In the event of a partial loss of power, resulting in abnormally low voltage on one or more phases of the input power, the system performs an emergency power off, (*see section, Emergency Power Off, page 6*). Use the following emergency shutdown procedure to protect the patient. For starting up after a power outage, *see module System Startup, section, Power-up Due to Power Interruption.*

**To recover from a power failure:**

**Step 1.** If necessary, turn on emergency lighting.

**Step 2.** Enter the treatment room and carefully help the patient off the treatment table.

**Step 3.** When power is restored, start the CyberKnife System using the normal start-up procedures as applicable to the specific situation.

**Step 4.** If power loss is likely to continue longer than approximately 30 minutes, shut down the system components powered from the UPS, (*see module, System Shutdown*).

## Accelerator Malfunction

If the dose in the Parameter Display window exceeds by 1% or 1 cGy the treatment dose at a node and an E-Stop was not automatic, the Linac has not functioned properly. You must turn off the Linac.

**To turn off the Linac:**

**Step 1.** Press the nearest E-Stop button.

## Fire or Fumes

If you smell smoke or fumes, or if you detect a fire, initiate the emergency shutdown procedure below.

**To shut down immediately:**

**Step 1.** Press the nearest EPO button.

**Step 2.** Activate the fire alarm in the facility.

**Step 3.** Attend to the patient.

**Step 4.** Evacuate everyone from the facility according to facility protocols.

**Step 5.** If in treatment mode, verify that the system has executed the abort sequence. All the treatment information is recorded automatically and the remaining undelivered dose will be saved into the "makeup" treatment plan for use later.

**Step 6.** If the smoke or fumes are coming from the computer equipment, manually turn off the uninterruptible power supply.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118 894

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



## Treatment Table Failure

The CyberKnife System treatment table uses a hand-held motor control and electro-mechanical actuators. These actuators have sufficient friction and mechanical stops to prevent a runaway condition.

**WARNING: If a malfunction occurs when a patient is on the table, do not attempt to use the control that malfunctioned (if possible), because the cause of the problem (e.g., an electrical malfunction) may endanger the patient and others.**

Instructions for operating the treatment table are found in the *module, Treatment Room Operations*.

## Unexpected Manipulator Arm Motion

If the manipulator arm moves in any unanticipated way, shut down the system by pressing the nearest E-Stop button and contact Accuray.



895

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



# SAFETY PRECAUTIONS

This section describes the hazards and safety precautions associated with the CyberKnife System. If the equipment is not operated safely, the following hazards could result in injury or death for patients and personnel.

- X-ray radiation
- Radio-frequency radiation
- Electromagnetic interference
- Laser radiation with power up to 1 mW at 632 nm (class II)
- Ozone
- Sulfur hexafluoride
- Implosion
- Explosion
- Electric shock
- Heavy equipment
- Hot surfaces

**WARNING: Many of these hazards are not visible.**

It is unsafe for anyone other than trained personnel to operate the CyberKnife System. Anyone working with the system must be aware of the hazards listed here. Only trained personnel should perform user functions.

**WARNING: You should NOT perform any maintenance not specifically listed as user functions.**

## X-ray Radiation

**WARNING: If the equipment is not operated properly, you can receive a harmful, even lethal, dose of radiation in a short time without knowing it is being received. Radiation exposure can damage some types of cardiac pacemakers.**

The CyberKnife System emits X-rays from both the Linac for treatment and the imaging system to determine the patient's real-time location.

**Protection from X-rays**

The following safety precautions are required:

- Radiation hazard warnings must be posted in appropriate locations.
- Only qualified personnel may operate and service the equipment.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118 896

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



- Radiation monitoring devices must be worn at all times while working with the CyberKnife System.
- When treatment is in progress, no one but the patient should be in the treatment room.
- Before entering the treatment room, be certain that the Linac and imaging system is not emitting radiation. Check and ensure that the HV ON light on the control console is off.
- Remove the safety interlock key from the console before leaving the console area to prevent unauthorized operation. Use this key, NOT a duplicate, to bypass the treatment room door interlock.
- Monitor the parameter display window during a treatment and commence emergency shut off procedures if the system does not terminate when the dose at a node exceeds the prescribed dose by 1% or 1 cGy.
- Pay attention to objects that may lie between the Linac and the patient. Such objects may attenuate and scatter radiation. Such objects may include shadow trays or blocks, side rails, spinal attachments, various panels and filters. If possible, remove these objects or make the necessary dose corrections.

## Pacemakers

Implement the following precautions when patients or personnel have cardiac pacemakers:

- Prominently display warnings regarding potential damage to pacemakers.
- If a patient or staff member has a pacemaker, contact the pacemaker manufacturer about the possibility of damage from radiation. The frequency of the microwaves used by the Linac in the CyberKnife System is approximately 9 GHz.
- Even after the manufacturer has indicated safe operation of a pacemaker when exposed to radiation, monitor their operation, particularly the pulse generators, when near an ongoing CyberKnife System treatment.

## Electromagnetic Interference

The low levels of electromagnetic radiation from the Linac may cause electromagnetic interference (EMI) to surrounding equipment and to patients and technical personnel who have cardiac pacemakers. In addition, EMI from other nearby equipment, such as microwave hypothermia and diathermy equipment, may interfere with the dose counter in the CyberKnife System, shielding by the walls of the treatment room may lessen this risk.

The following precautions further protect the CyberKnife System from electromagnetic interference from other equipment and protect other equipment from interference from the CyberKnife System components.

- Keep all doors, panels and covers in place while you are operating the CyberKnife System.
- Stop any treatment if you detect fluctuations in outputs, inputs and power or notice any obvious erroneous readings. These fluctuations indicate possible EMI between CyberKnife System components or from other nearby equipment.
- Follow the Pacemaker precautions from the *section, Pacemakers, page 10.*



897 Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



## Laser Radiation

The Linac uses laser radiation — narrow beams of bright red light. These Lasers are both in the Linac X-ray head and in some installations, on the X-ray sources (part of the imaging system). These lasers aid alignment of the patient for treatment and alignment of the manipulator for Linac calibration. Each laser consists of two components, the plasma tube and the power supply. The tubes used have a maximum of 1 mW output power, thus a Class 2 rating.

**WARNING: Use of controls, adjustments, or performance of procedures other than those specified herein, may result in hazardous laser radiation exposure.**

**WARNING: The light from a laser beam can damage the retinas of the eyes. Never look directly into the laser beam. Advise patients not to look into the laser beam.**

**WARNING: Replacement of the laser tube must be done only by Accuray service engineers.**



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

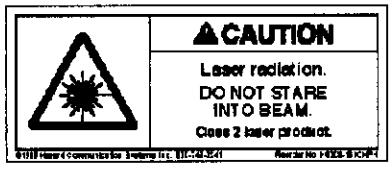
898

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015

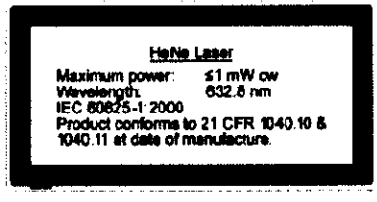


## Laser Warning Labels

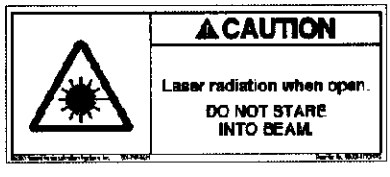
There are four types of laser warning labels used in the CyberKnife System:




**Warning Legend.** Indicates that the laser is Class 2 and to not stare into the beam. Affixed in the vicinity of each laser housing.




**Laser Information Label**. Affixed in the vicinity of each laser housing and describes the technical details of the lasers.




**Warning Legend.** Warning of exposure to laser light if covers are removed is affixed on each removable cover.

**Laser Aperture Label.** Is placed at apertures where laser light exits the equipment.

## Sulfur Hexafluoride

Sulfur hexafluoride ($SF_6$) is a colorless, odorless gas used in the CyberKnife System as an electrical insulator. It is stored in a metal container under high pressure. If the metal container ruptures, the gas or liquid will escape rapidly. Sulfur hexafluoride is nonflammable and is considered to be nontoxic, but it can act as a simple asphyxiate by displacing air. Contact with the liquefied gas may cause frostbite; $SF_6$ gas is denser than air and accumulates on the floor if released.

If the CyberKnife System detects a loss of $SF_6$ gas pressure, it will generate an E-Stop.

**WARNING: You can be asphyxiated from sulfur hexafluoride in high concentrations, or be injured by the escaping gas or liquid or by the container itself.**

- Handle the sulfur hexafluoride container carefully.
- Do not allow the temperature of the sulfur hexafluoride container to exceed 125° F (52° C).
- Store extra containers in a dry, well-ventilated location.
- Shut the valve on the gas bottle after filling the RF system.



899

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



**FIRST AID: If inhaled**, move the victim to fresh air. If not breathing, give artificial respiration, preferably mouth to mouth. If breathing is difficult, give oxygen. Call emergency. If **contact** with the liquefied gas occurs, treat for frostbite.

## Implosion

The windows that separate the vacuum in the Linac and magnetron from the waveguide, can shatter inwardly, if they are struck or jolted excessively. Damage may occur to the equipment because of the casing. Shattering glass should not harm the operator or patient.

The cathode ray tube (CRT) in the user control console monitor, system PC and the thyratron tubes in the Linac modulator could also implode.

**WARNING: You can be cut and injured by flying debris from an implosion.**

Only trained service personnel should service these or any part of the system.

## Explosion

The system must never be operated in the presence of flammable anesthetics or other flammable or explosive substances. Electrical arcs that can occur during the normal operation of switches, circuit breakers, push buttons and other circuit components can ignite vapors and gases.

**WARNING: You can be cut and injured from the pressure of an explosion or from flying debris caused by an explosion**

- If flammable substances are present before the system is turned on, do not turn it on.
- If flammable substances are detected after the system has been turned on, pause the system. **Do not turn the system off.**
- If flammable substances are detected during a treatment, open the treatment room door to cause an E-Stop. An E-Stop must be generated to evacuate the patient, but no other operations should be performed.

**If flammable substances are detected:**

**Step 1.** Evacuate all persons immediately.

**Step 2.** Ventilate the room to clear the air of the flammable vapor or gas.

**Step 3.** Remove any volatile liquids that are producing flammable vapors to a safe storage area.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118 900

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



# Electric Shock

Some CyberKnife System components operate with voltages up to 40,000 volts. Be cautious at all times during operation.

**WARNING: As with any equipment that uses high voltage, the residual voltage in the components can shock you after the equipment has been turned off. Only qualified service personnel should remove equipment covers.**

The following equipment may have residual high voltage:

- Power from the facility circuit breaker.
- Power lines to each component.
- User control console and system PC monitor CRT.
- Capacitors in various power supplies, several of which remain charged for long periods.
- When a laser is energized, the red wire from the laser power supply has a potential greater than 1 kV.

## Observe the following precautions to avoid electric shock

- Keep all equipment doors and covers closed during operation.
- Do not bypass any safety interlocks.
- Never attempt to tamper with instrumentation circuitry or disconnect a CyberKnife System cable at any time.
- Only authorized personnel shall service the high voltage components or any part of the system.
- Conductive fluids should not be spilled onto any part of the equipment.
- Discharge all high voltage storage components prior to servicing or disconnecting from the supply.



901 Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



## Heavy Equipment

Many CyberKnife System components are heavy, particularly the treatment table and manipulator. The motors that control the table and the manipulator are very powerful. When these components move, they have substantial inertia. Observe utmost care to prevent moving components from hitting you, the patient, other personnel, or other equipment.

**WARNING: Collision with the manipulator or any other heavy component can seriously injure or kill you or the patient.**

**CAUTION:** Collisions among components can damage equipment.

- Use caution when components are moving.
- During treatment, carefully watch while the manipulator is moving. If you see the manipulator moving too close (within 2 inches or 5 cm) to any object, press the nearest E-Stop button immediately.
- Observe the manipulator's safe movement envelope when you are in the treatment room and when adding objects to the treatment room. The safe movement envelope is the set of configurations the robot can assume without colliding with objects defined at installation. These objects include the floor, ceiling, treatment table/patient area and camera stands.
- Keep adequate clearance between you and the treatment table during table movements to avoid possible injury.
- If any equipment collides with the patient or another component, stop the treatment, attend to the patient, record the accumulated dosage and call Accuray to service the equipment before any further use.
- Use caution when handling the secondary collimators, dropping could cause serious injury to your feet. Never replace collimators where they could fall on any part of a patient.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118 902

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



## Hot Surfaces

Many components of the CyberKnife System operate at high temperatures. When equipment covers are removed, hot surfaces are accessible.

**WARNING: You can be seriously burned from touching high temperature surfaces.**

Take caution not to touch the following components when they are hot:

- Thyratron tubes
- Any light bulbs
- Transformers
- Resistors
- Magnetron
- Laser tubes
- Manipulator Motors

During operation of the CyberKnife System and during a reasonable cool-down period after turning the equipment off, avoid any bodily contact with these or other components that seem warm when approached. Be aware that the thyratron, magnetron and Linac filaments remain on while the equipment is in the stand-by mode.

Only qualified service personnel should remove any equipment covers.



903 Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



# FACILITY RESPONSIBILITIES

This section describes your responsibilities for setting up emergency and safety procedures for the CyberKnife System operations.

## General Use

Use the following guidelines for routine use of the CyberKnife System:

1. Keep a logbook of all unusual events related to system operation.
2. Always observe the standard start-up and shutdown procedures, being certain to disable the equipment by the documented procedures only.
3. Test emergency stop procedures monthly.

## Safety Operations

You must provide and train your technical, service and support staff in the following safety operations:

1. Fire extinguishers should be present in the treatment room and near the user control console.
2. The treatment room and user control console area must have emergency lighting. In addition, flashlights must be on site as a back-up during emergencies.
3. Hazard signs, regarding radiation exposure, high voltage, laser light hazards and pacemaker hazards, must be posted where appropriate, near the treatment room, near the user control console and on the system components.
4. Radiation monitoring badges should be worn at all times while in the treatment room.
5. Dangers to people with pacemakers must be ascertained by following the guidelines described earlier in this chapter.
6. Video and audio monitoring are mandatory whenever a patient is in the treatment room. This monitoring equipment is required in addition to the radiation monitoring equipment incorporated in the CyberKnife System.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118 904

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



## Emergency and Safety Training

All personnel who work with the CyberKnife System must have initial training and periodic refresher courses for the following:

1. Emergency off procedure (E-Stop).
2. Emergency power off (EPO) procedures
3. Location of the main circuit breaker as a backup for emergency power off.
4. Evacuation procedures and egress routes in case of fire, fumes, or other threatening situations.
5. Emergency procedures in case of earthquake or other natural disasters likely in the facility's location.
6. Emergency lighting system activation and the location of backup flashlights.
7. How to assist a patient to get down from the treatment table and out of the facility.
8. List of people to contact in case of a fire, medical, or technical emergency.
9. How to restart the CyberKnife System after an emergency shut down.

## Radiation Overdose

The CyberKnife System uses dual redundant dose monitoring systems, which stop treatment upon reaching the prescribed dose.

If the treatment is stopped manually because of a failure in the automatic shut-off by the dose monitoring system, the equipment must be checked and serviced by a qualified technician before any further treatments are performed.

**In the case of a radiation overexposure:**

**Step 1.** Seek emergency treatment for the victim.

**Step 2.** Contact local radiation safety officer according to facility protocols.

**Step 3.** Notify the local, state and federal authorities in accordance with your institutional procedures.

**Step 4.** Consult with medical experts in radiation treatment.

**Step 5.** Notify Accuray as quickly as possible.



905 Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



# Overview
## Table of Contents


**CyberKnife® Radiosurgery System** ..... 1

**CyberKnife System Overview** ..... 2

- **Indications for Use** ..... 2
- **The CyberKnife System Includes** ..... 2
  - Imaging and Computer Systems ..... 2
  - Treatment Planning and Operator Control Systems ..... 4
  - Linac and Control Systems ..... 4
  - Robotic Manipulator ..... 5
  - Power Distribution Unit (PDU) ..... 5
  - DICOM RT Open Architecture ..... 5
  - Express™ Throughput Solution ..... 5
  - User Control Console ..... 5

**CyberKnife System Components** ..... 7

- **Treatment Planning and Delivery Workstations** ..... 7
  - Main Treatment Planning and Delivery Workstation ..... 7
    - Main SGI Computer ..... 7
    - Linac Control Panel ..... 7
    - Main Intercom Box and Phone (supplied by customer) ..... 7
    - Closed Circuit TV (CCTV) Monitoring System (supplied by customer) ..... 7
    - Synchrony™ System (Optional) ..... 7
    - Xsight™ Spine Tracking System (Optional) ..... 7
    - Printer ..... 8
    - CyRIS™ InView™ Image Fusion and Contouring Station (Optional) ..... 8
- **Treatment Room** ..... 8
  - Robot (Manipulator) ..... 8
  - Linear Accelerator (Linac) ..... 8
  - Patient Alignment Couch ..... 8
  - Target Locating System (TLS) ..... 8
    - X-ray Sources and Generators ..... 8
  - Synchrony Respiratory Tracking System (Optional) ..... 9
  - Miscellaneous Equipment (Supplied by customer) ..... 9
- **Equipment Room** ..... 9
  - Power Distribution Unit (PDU) ..... 9
  - Chiller ..... 9
  - Robot Controller ..... 9
  - Modulator ..... 9




Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



Modulator Control Chassis (MCC) ..... 9
Interface Control Chassis (IFCC) ..... 10
Dual 19-inch Rack ..... 10
E-Stop Control Chassis (ESCC) ..... 10
Target Locating System Control Chassis (TLSCC) ..... 10
SMART Uninterruptible Power Supply (UPS) ..... 10
Target Locating System (TLS) Computer ..... 10
Synchrony Computer ..... 10
17" High Resolution CRT Monitor, Keyboard and Mouse ..... 10
Firewall ..... 10



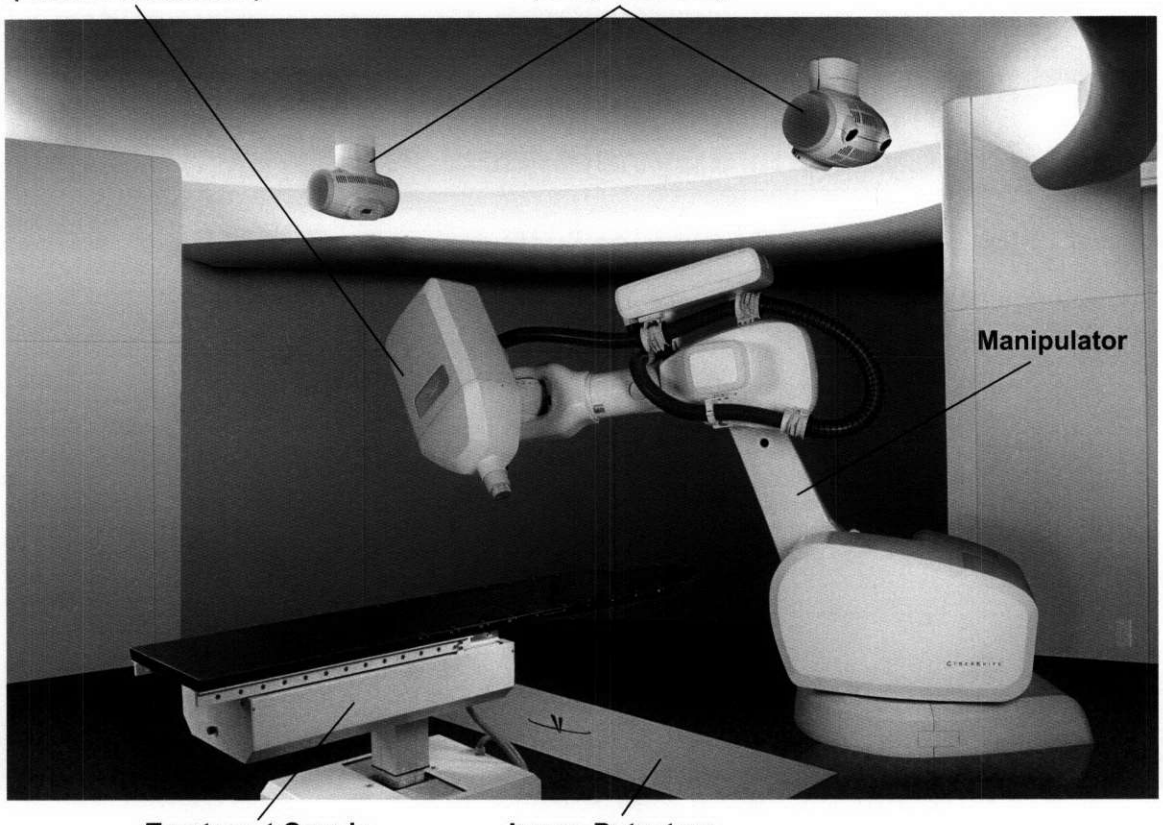
907 Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



# OVERVIEW

## CYBERKNIFE® RADIOSURGERY SYSTEM






Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



# CyberKnife System Overview

The CyberKnife System is an integrated turnkey radiosurgery system that combines continuous image-guidance technology with computer-controlled robotics to precisely deliver a prescribed dose of radiation. It utilizes a compact linear accelerator attached to a computer-controlled robotic arm to target a precise number of beams of radiation very accurately at a lesion from many different directions. The patented image-guidance technology correlates intra-operative X-rays with previously acquired CT images of the lesion and surrounding tissue to precisely target each beam of radiation. This approach results in a high dose of radiation concentrated within and conforming to the lesion, where the beams converge. In contrast, surrounding normal tissue receives a relatively minimal, less-injurious radiation dose from which it can quickly recover.

## Indications for Use

**The CyberKnife System is intended to provide treatment planning and image-guided stereotactic radiosurgery and precision radiotherapy for lesions, tumors and conditions anywhere in the body when radiation treatment is indicated.**

## The CyberKnife System Includes

### Imaging and Computer Systems

**Imaging System**- The imaging system includes the following hardware:

1. Two X-ray Sources
2. Two Digital X-ray Detectors
3. One Localizing Frame
4. One ISO Post Calibration Tool
5. Two Detector Windows (not shown in the image below)
6. Two Protective Window Coverings (not shown in the image below)

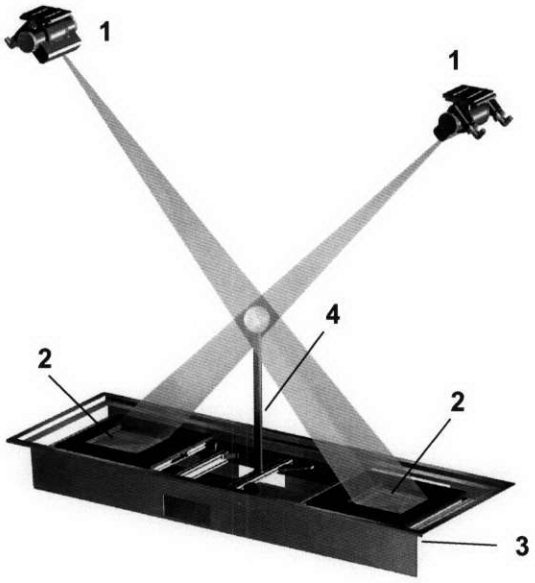


909 Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



**NOTE:** The imaging system is mounted either flush with or slightly above the treatment room floor.




**Target Locating Subsystem (TLS)** - Employs two X-ray sources mounted overhead, which provide orthogonal images. The images are digitized and compared to images synthesized from the patient's CT data (DRR's). The TLS system provides real-time precision information about the location of the treatment target.

All of these components are aligned within the imaging plane and are symmetric about the ISO post.

### X-ray Sources

The two X-ray sources are mounted over head and create the X-ray beams for imaging the patient.

### Digital X-ray Detectors

Two high sensitivity digital X-ray detectors are mounted within a localizing frame to ensure a high degree of alignment and accuracy between all of the imaging components.

### ISO Post Calibration Tool

The ISO Post calibration tool mounts directly into this localizing frame and is the reference point for calibrating the robot and imaging system.

### Detector Windows

The two detector windows are made of carbon graphite material to ensure X-ray translucency and high strength. They are designed to support up to a 500 lb. load and protect the detectors. There is a protective covering material that protects the detector windows and seals the imaging pit from fluid spills. The coverings can be replaced if they become too scratched or damaged.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



**CAUTION:** Care must be exercised not to drop any heavy or sharp objects onto the detector windows. For instance, secondary collimators should not be changed over the detector windows. If a heavy object has been dropped on the detector window an ACCURAY service call must be made to assess the structural damage.

**CAUTION:** Never jump onto the detector windows.

**CAUTION:** Do not operate the system without the detector windows in place.

**CAUTION:** Avoid walking on the detector windows. Do not slide heavy objects across detector windows.

**CAUTION:** Scratches can degrade the X-ray images to the point where skull or fiducial tracking may fail. If necessary, replace the protective film at regular maintenance intervals.

## Treatment Planning and Operator Control Systems

- **Operator Control Subsystem** - Provides treatment planning capability and automated control of the treatment process according to the treatment plan. It is a tightly coupled, symmetric, shared memory, multi-processing architecture design using RISC technology, custom VLSI and ASIC components to provide both high performance computing and high performance graphics.
- **Treatment Planning Subsystem** - State-of-the-Art treatment planning system. A highly interactive software package capable of developing inverse and forward treatment plans.

## Linac and Control Systems

- **Linear Accelerator (Linac)** - The Linac consists of an electron gun and a series of microwave cavities under vacuum. The X-band Linac provides a collimated beam of 6 MV X-rays. The compact size allows unique robotic manipulation that provides greater degrees of freedom.
- **X-Ray Head** - The assembly contains the Linac, magnetron, microwave wave-guide components, the pulse transformer, water circulating connections and a gas pressurizing connection for the wave-guide.
- **Secondary Collimators** - (in millimeters: 5,7.5,10,12.5,15,20,25,30,35,40,50,60, pinhole and blank) Interchangeable collimators allow for greater flexibility and conformability during the treatment planning process.
- **Modulator** - This assembly contains the HV pulse-generating circuits that drive the Radio Frequency (RF) system located in the X-ray head.
- **Chiller** - The chiller cools the Linac and consists of a re-circulating pump, a water reservoir and a refrigeration unit with chiller and temperature regulating control (used to maintain a stable operating temperature), water temperature indicator and status lamps. This is a closed loop system that does not require external facility connections.



911 Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



- **Target Locating System Control Console (TLSCC) and Computer** - This unit controls the diagnostic X-ray sources and imaging panels in acquiring images, as well as conducting image correlation to determine patient displacement during treatment.
- **Interface Control Chassis** - An interface control system, which provides near-real-time control of hardware components and relays status information to the multi-processing computer.

## Robotic Manipulator

- Accuray's robotic system (manipulator) carries and aims the Linac providing automated positioning in six-degrees of freedom.

## Power Distribution Unit (PDU)

- The PDU is the AC power source for the entire CyberKnife System. Uses a 208VAC, 3 phase, 150 amp input.

## DICOM RT Open Architecture

- Import DICOM RT image sets (CT, MR and PET) and RT structure sets.

## Express™ Throughput Solution

- Provides radiosurgery precision with greater throughput.

## User Control Console

The user control console equipment for the CyberKnife System, includes the following:

- Workstation monitor with keyboard and mouse.
- Treatment room monitoring equipment.
- Operator control console panel.
- Radiation generator controller used to calibrate the Linear Accelerator (Linac).



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015

**Figure 1 User Control Console Equipment**



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

913

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



# CyberKnife System Components

## Treatment Planning and Delivery Workstations

The treatment planning and delivery stations can be configured in many ways.

## Main Treatment Planning and Delivery Workstation

This station is used for operating and monitoring primary treatment delivery to the patient.

The station includes the following:

### Main SGI Computer

- CRT monitor (or optional flat panel monitor).
- One keyboard and mouse.
- The actual SGI computer itself, is usually located in the equipment room.

### Linac Control Panel

Control box.

### Main Intercom Box and Phone (supplied by customer)

### Closed Circuit TV (CCTV) Monitoring System (supplied by customer)

- Usually comprised of a Quad Multiplex Monitor, used for viewing the patient in the Treatment room.
- It is recommended that there be four CCTV cameras located in the Treatment room, two high and two low, with two of them capable of pan/zoom (one high and one low).

### Synchrony™ System (Optional)

When the Synchrony System is installed, then an additional flat panel monitor, keyboard and mouse are located next to the main treatment and planning system.

A physics conduit port should exist between the control room and the treatment room. It can also be used for remote patient monitoring.

### Xsight™ Spine Tracking System (Optional)

The Xsight Spine Tracking System enables tracking of skeletal structures in the body for accurate patient positioning and radiation beam delivery in the CyberKnife® System. Xsight provides the capability to deliver radiation treatments to the human body without the need for implanting fiducials. Xsight is capable of accurately and automatically tracking a wide range of skeletal structures, including the cervical spine, and most of the thoracic and lumbar spine. Xsight is capable of tracking non-rigid deformations typically observed in multiple vertebral structures.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118 914

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



### Printer

2550n HP Color Laser Printer (or comparable - normally located with the secondary treatment planning workstation).

### CyRIS™ InView™ Image Fusion and Contouring Station (Optional)

If the CyRIS InView option is selected, it may be located in any room. There may be more than one of these. Each system is comprised of a:

- Standard desktop computer system, with a computer, LCD flat panel monitor, keyboard and mouse.

### CyRIS™ MultiPlan™ Treatment Planning System

The CyRIS MultiPlan is a full purpose treatment planning system. It is specifically designed to optimize the flexible nature of the robotic treatment delivery system.

## Treatment Room

The treatment room contains the Robot, Linac, Patient Positioning Equipment and Target Locating System.

### Robot (Manipulator)

A six-axis robot used for positioning and pointing the Linear Accelerator for patient treatment.

### Linear Accelerator (Linac)

The Linac is attached to the end of the robot and delivers the radiation treatment to the patient.

### Patient Alignment Couch

- The couch is used to position the patient for treatment.
- The maximum capacity of the couch is 350 pounds (770 Kg).
- Includes a couch top, head base plate, hand control pad and readout display.
- Includes up to 2 indexed CT overlay kits (CT overlay + head base plate). Additional overlay kits can be purchased, as needed.

### Target Locating System (TLS)

#### X-ray Sources and Generators

- The X-ray sources are used to track patient positioning.
- They are attached to the ceiling on each side of the table.
- The X-ray generators, which supply high-voltage power to the X-ray sources, may be located in either the treatment room or the equipment room.



915 Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



### Synchrony Respiratory Tracking System (Optional)

Synchrony is used to monitor patient breathing and adjust the Linac position to match the motion of the target lesion.

- The Synchrony camera array is mounted to the ceiling near the foot of the treatment couch.
- The Synchrony Fiber Optic Interface Box, to which the Synchrony Tracking Markers are connected, is mounted on the couch.

### Miscellaneous Equipment (Supplied by customer)

- The treatment room also contains the following; phone, intercom system and patient monitoring cameras. It also includes the medical gas lines, if desired by the customer. All of these components are supplied by the customer.
- A physics conduit port should exist between the treatment room and the control room. It can also be used for remote patient monitoring.

## Equipment Room

The equipment room is located adjacent to the shielded walls of the treatment room and is intended to hold the bulk of support equipment needed for planning and treatment. This equipment includes the facility power interface, E-Stop assembly, primary and target locating computers and robot controller. The room is cooled with a customer-supplied A/C unit.

### Power Distribution Unit (PDU)

- The PDU supplies power to all components of the CyberKnife System.
- The customer supplies the power input to the PDU.

### Chiller

The chiller is a closed loop system that cools the Linac.

### Robot Controller

The robot controller controls the robot positioning.

### Modulator

The modulator provides a pulse to the magnetron so it can produce RT energy.

### Modulator Control Chassis (MCC)

The MCC contains the modulator and Linac control circuits, as well as the fault circuitry and an interface card allowing control by the CyberKnife System.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118 916

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



## Interface Control Chassis (IFCC)

The IFCC functions as an interface between the CyberKnife System and the Linac. The IFCC also handles most digital processing of the dosimetry signals as well as generating a variety of fault signals. It also monitors the sense potentiometers for the collimator.

## Dual 19-inch Rack

### E-Stop Control Chassis (ESCC)

The ESCC performs a wide variety of hardware functions, as well as functioning as a central point for E-Stop signals.

### Target Locating System Control Chassis (TLSCC)

This is an interface between the Target Locating System (TLS) PC and the imaging system.

### SMART Uninterruptible Power Supply (UPS)

Provides backup power to the system control computers.

### Target Locating System (TLS) Computer

Also known as the System PC, it is primarily used to control the TLS and interface between the TLS and the SGI.

### Synchrony Computer

### 17" High Resolution CRT Monitor, Keyboard and Mouse

### Firewall





Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



# System Startup
## Table of Contents


**Starting the CyberKnife® System ..... 1**

- **Pre-Startup Checklist ..... 1**
- **Logging-On ..... 5**
- **Powering Up the CyberKnife System ..... 7**
- **Post-Startup Checklist ..... 9**
- **Tube Warmup ..... 11**
- **Handling Errors ..... 14**
  - Power On Errors ..... 14
  - Errors Occurring After Power On ..... 15

**Equipment Operating Instructions ..... 16**

- **User Control Panel ..... 16**
  - Keyswitch ..... 16
  - Turning On-Off High Voltage ..... 16
- **TLS Imaging System Components ..... 17**
  - X-ray Source (XRS) Manual Power Switches ..... 17
  - Camera AC Power Switches ..... 18
- **Robot Operation ..... 21**
  - Controller Power-up ..... 21
  - Teach Pendant (KCP) ..... 21
    - Jogging ..... 22
    - Jog Coordinates ..... 23
    - Moving the Robot Manually ..... 24
    - Move the Robot to "PRCH" ..... 24
    - Turn Laser On Via the Teach Pendant ..... 25
    - Running Simulation Path Manually Via the Teach Pendant ..... 25

**Power-up Due to Power Interruption ..... 26**

- **Step 1 - Establish "Normal" CKS Power-Off Status ..... 26**
- **Step 2 – E-Stop Circuit Check ..... 27**
- **Step 3 – Reset All Subsystems ..... 28**
- **Step 4 – Communications Check ..... 29**
- **Step 5 – CyberKnife System Log-On ..... 29**
- **Step 6 – Hardware Power On ..... 30**




Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015





919

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



# SYSTEM STARTUP

## STARTING THE CYBERKNIFE® SYSTEM

### Pre-Startup Checklist

**WARNING: Only a qualified person operating the CyberKnife System should perform each item on the pre-startup checklist each time the system is to be used. It is also recommended that any discrepancy be corrected prior to logging-on (*see section, Logging-On, page 5*) and powering up the system (*see section, Powering Up the CyberKnife System, page 7*).**

It is recommended that each site develop a checklist that includes, at minimum, the tasks below. As each task is performed, you check it off. When all tasks are completed, initial the completed checklist and file it with the treatment records.

**Step 1.** Check that all E-Stop (Emergency Stop) buttons are in the pulled out position.

**Step 2.** Check that the robot teach pendent is in the proper mode.

- Check that the teach pendant is in External mode.

The display of the teach pendant should be dark indicating that the robot is powered down.

**Step 3.** Check the pressure (30 ± 2 psi) (2.1097 Kg/cm) of SF6 gas and recharge if needed.

**Step 4.** Verify that the E-Stop control chassis (ESCC) is **not** in the Service Mode. (*Figure 1 E-Stop Control Chassis (ESCC), page 2.*)



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118 926

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



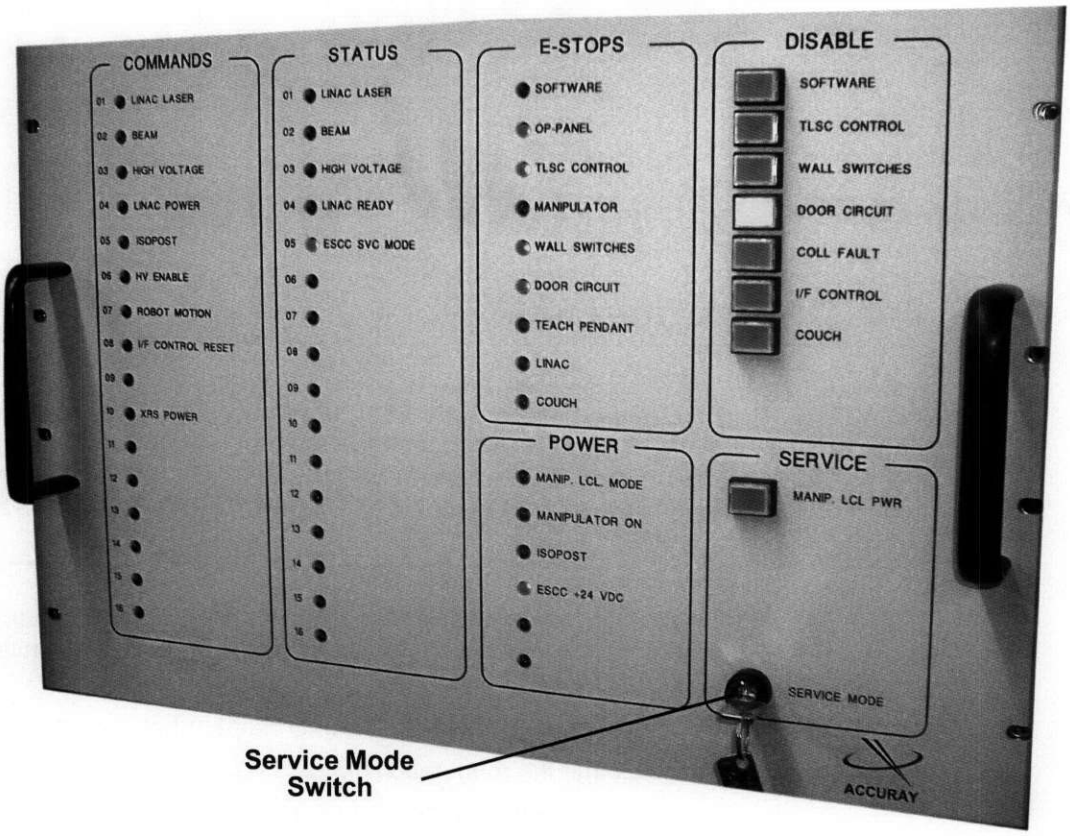



**Figure 1 E-Stop Control Chassis (ESCC)**

**Step 5.** Verify that the **MANIP LCL PWR** button is not depressed.

**Step 6.** Ensure that all breakers on the Power Distribution Unit (PDU) are closed. (*Figure 2 Power Distribution Unit (PDU), page 3*).



921

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



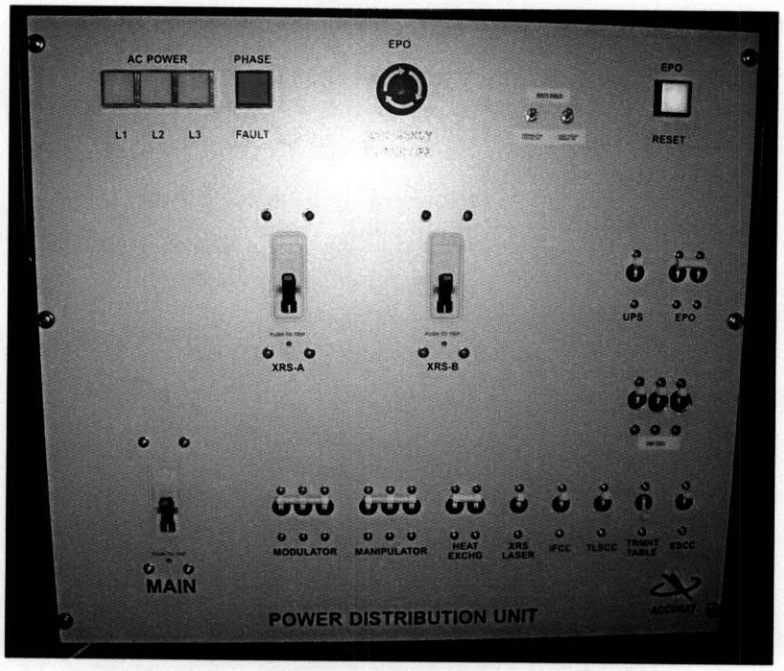



**Figure 2 Power Distribution Unit (PDU)**

**Step 7.** Check that the interface control chassis (IFCC) computer is powered on.

- Check that the manipulator controller is powered off.

**Step 8.** Check the uninterruptible power supply (UPS) battery charge level (*Figure 3 UPS, page 3*).

**UPS Power Switch**

**Battery Charge Level**

**Figure 3 UPS**



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



**Step 9.** Check that the target locating system (TLS) computer is powered on.

**Step 10.** Check the water level of the cooling system.

**Step 11.** Verify that the Modulator Control Chassis (MCC) manual power on key is in the off position. (*Figure 4 Modulator Control Chassis, page 4*).

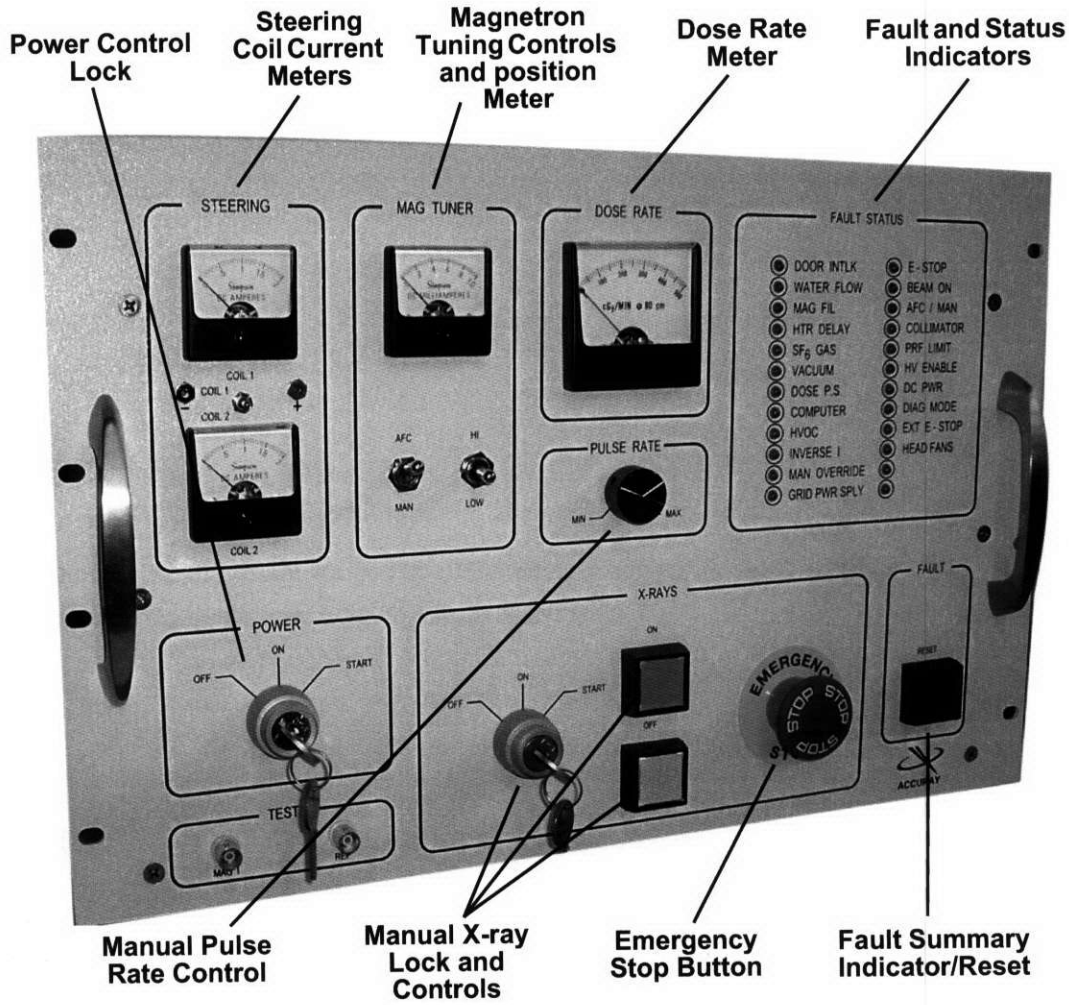



**Figure 4 Modulator Control Chassis**

**Step 12.** Check that the user panel key switch located at the control desk is turned to the right.

**Step 13.** Turn on the treatment room monitoring cameras and intercom system.

**Step 14.** Turn power on to the user control console monitor.

Continue with the log-on and power-up sequences described in *sections Logging-On, page 5 and Powering Up the CyberKnife System, page 7*.



923 Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



# Logging-On

Starting the CyberKnife System is a two-step process:

**Step 1.** Invoke the software.

**Step 2.** Access the features.

**Turn on the monitor and log-in.**

**Figure 5 Operator Control Console Monitor**

If the console is on, but the screen is dark, move the mouse and the log-in screen should appear. If the monitor remains dark, make sure it is plugged into an electrical outlet and turned on. After checking the electrical connection, if the monitor is still dark, refer to the SGI service manual or call Accuray.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



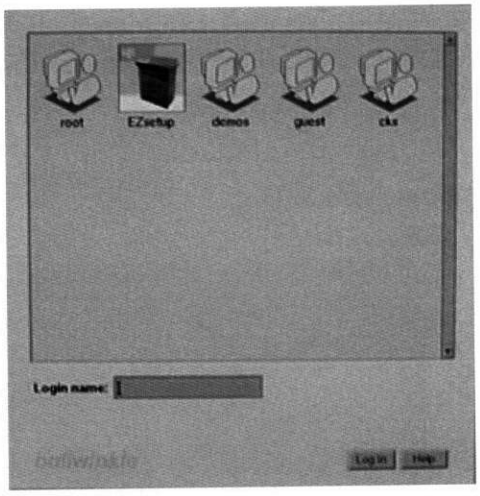



**Figure 6 Silicon Graphics Log-in**

To log into the CyberKnife System:

**Step 1.** Double-click the **CKS** icon

**Step 2.** Enter CKS as the username in the text box. Enter the password as assigned by the system administrator and press <Enter>.

If an error is made inputting the username or password, the next log-in screen will not appear, try to initiate the log-in again.

**Step 3.** Type Accuray into the Name text box. Press <Enter> or use the mouse to move the cursor to the **password** text box. Type in the password as provided by the system administrator into the text box and press <Enter>. If you type the wrong password, the cursor returns to the **name** field and you must start the log-in process again.

**Figure 7 CyberKnife Log-in**



925

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



After the final log-in, the CyberKnife System menu appears.

**Figure 8 CyberKnife System Menu**

**Step 4.** The CyberKnife System menu screen, also known as the **9 Button** window, is displayed.

## Powering Up the CyberKnife System

This section explains how to turn on the power to the CyberKnife System from the operator's control console. This should only be done after the pre-startup checklist is completed (*see sections, Logging-On, page 5 and Pre-Startup Checklist, page 1*). For instructions on powering up after a power outage, see section, *Power-up Due to Power Interruption, page 26*.

**NOTE:** A shorthand notation showing the basic sequence of software selections is given before detailed system instructions. For example: **CyberKnife System Menu → Equip Power → Power On**. Select the specified options from windows or menus as they appear.

**CyberKnife System Menu → Equip Power → Power On → Continue**

**Step 1.** From the system menu, click **EQUIP POWER** (*Figure 8 CyberKnife System Menu, page 7*). The Equipment Status window appears. This window shows that the electrical power of each piece of equipment is off and its status is NOT READY.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



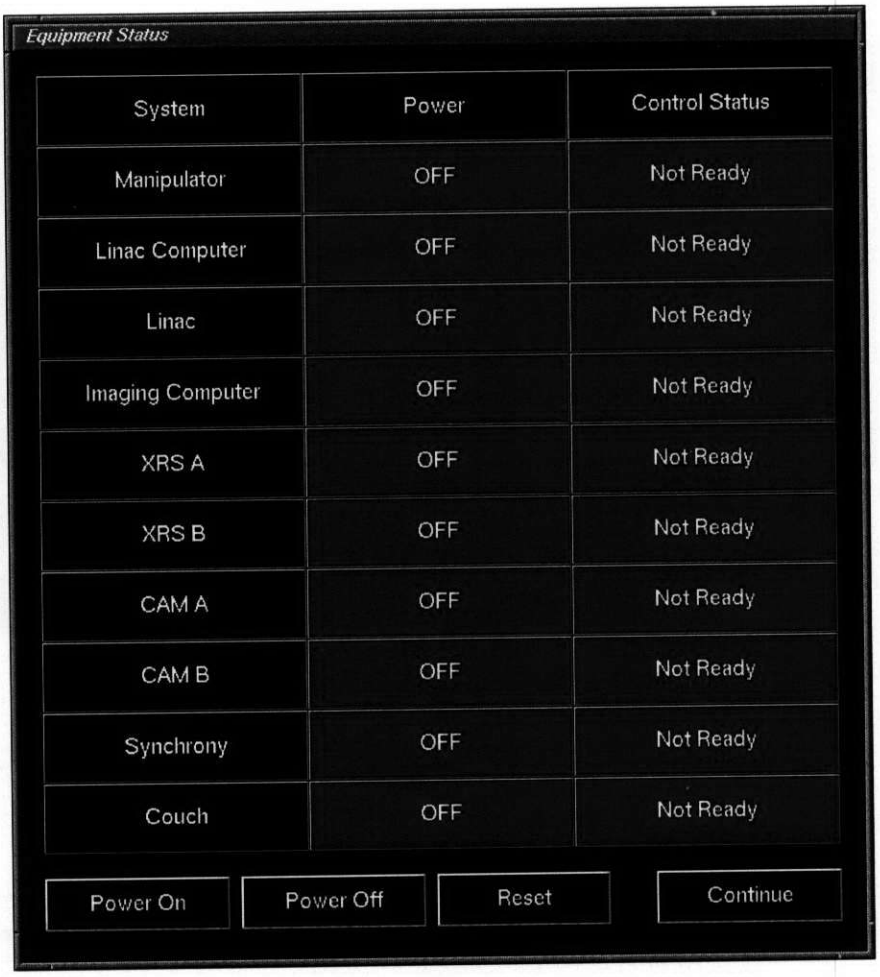



**Figure 9 Equipment Power Status "Not Ready"**

**Step 2.** Click **POWER ON**. The power for all of the equipment then turns on. The status of the manipulator, Linac, X-ray sources, X-ray cameras, couch, Motion Tracking System (MTS) and computer changes on the user control console monitor.

**Step 3.** When the electrical power of each unit is on and its status is ON STANDBY, the system is powered up. The power-up process usually takes approximately 20-25 minutes. (*Figure 10 Equipment Power Status "On", page 10*).

**NOTE:** The **POWER OFF** button is always active.

**Step 4.** Click **CONTINUE** to return the CyberKnife System menu window.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

927

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



# Post-Startup Checklist

**WARNING: When the power-up of the system is complete, perform each item on the post-startup checklist. Any discrepancy should be corrected prior to proceeding. If necessary power-off the system (*see module, 14. System Shutdown*), make the necessary corrections and restart the power-up procedure.**

It is recommended that each site develop a checklist that should include, at a minimum, the tasks below.

**Step 1.** Check that all mechanical interlocks are active by checking the ESCC. If illuminated, safety features are disabled and should be reset.

**Step 2.** Check that each X-ray imaging source (A and B) shows a green light on the ESCC.

**Step 3.** Check the Linac gun heater voltage (5.2 ± .5 V) on the MCC (*Figure 4 Modulator Control Chassis, page 4*).

**Step 4.** Check the Linac magnetic heater voltage (9.3 ± .5 V) on the MCC (*Figure 4 Modulator Control Chassis, page 4*).

**Step 5.** Check the Chiller water temperature (19 ± 1°C) on the Linac Chiller.

**Step 6.** Using the teach pendant, verify that the manipulator (Robot) is positioned in its perch position. Move the robot back to the perch position using the teach pendant as necessary.

**Step 7.** Verify door interlocks and E-Stops are enabled.

Each daily task should be performed, checked off, initialed and dated by the user.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

928

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



Equipment Status

| System | Power | Control Status |
|---|---|---|
| Manipulator | ON | On Standby |
| Linac Computer | ON | On Standby |
| Linac | ON | On Standby |
| Imaging Computer | ON | On Standby |
| XRS A | ON | On Standby |
| XRS B | ON | On Standby |
| CAM A | ON | On Standby |
| CAM B | ON | On Standby |
| Synchrony | ON | On Standby |
| Couch | ON | On Standby |

Power On | Power Off | Reset | Continue

**Figure 10 Equipment Power Status "On"**



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

929

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



# Tube Warmup

After powering up the CyberKnife System, the Tube Warmup procedure should be performed to ensure that the imaging system's X-ray tubes are adequately warmed up prior to being used for treatment.

**NOTE:** Tube warm up time takes less than 5 minutes.

**CAUTION:** Failure to perform the Tube Warmup procedure could damage the X-ray tubes.

**Step 1.** From the system menu, click **Physics**. The Calibration screen appears (*Figure 11 Calibration screen, page 11*). If the system is fully powered up, the **TUBE WARMUP** button is enabled.

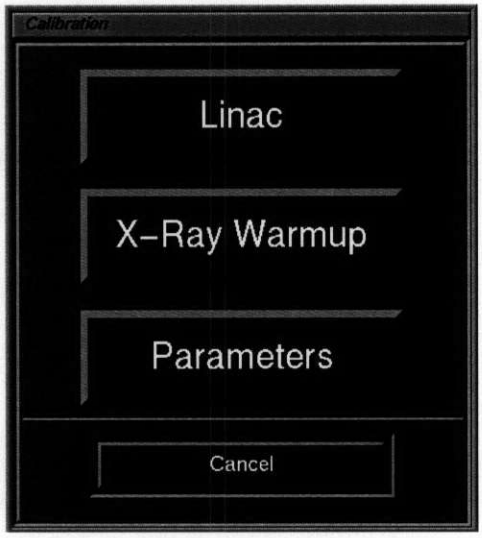



**Figure 11 Calibration screen**



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



**Step 2.** Click **TUBE WARMUP**. The Tube Warmup screen appears (*Figure 12 Tube Warmup screen "Not Started", page 12*). The text located in the upper right of the screen displays the date and time of the most recent tube warmup, which was performed on the system.

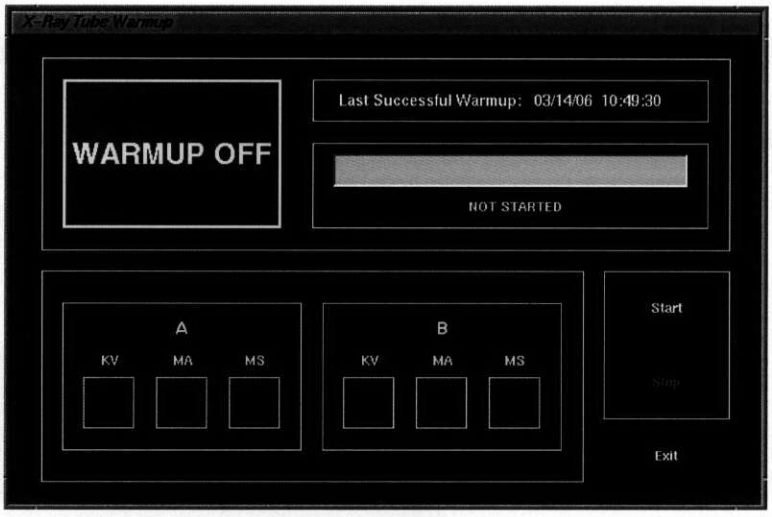



**Figure 12 Tube Warmup screen "Not Started"**

**Step 3.** Click **START** and the text located below the yellow progress bar displays IN PROGRESS, and the upper left graphic box will flash red, displaying the text WARMUP ON. As images are acquired, the X-ray setttings for the two camera/detector pairs are displayed in the 6 boxes located at the bottom of the screen (*Figure 13 Tube Warmup screen "Running", page 13*).

When warmup is complete, the upper left graphic box will change from red to green again, displaying the text WARMUP OFF. The progress bar will display 100%, and the text below will display COMPLETED. The Last Successful Warmup date/time text field is updated.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

931

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



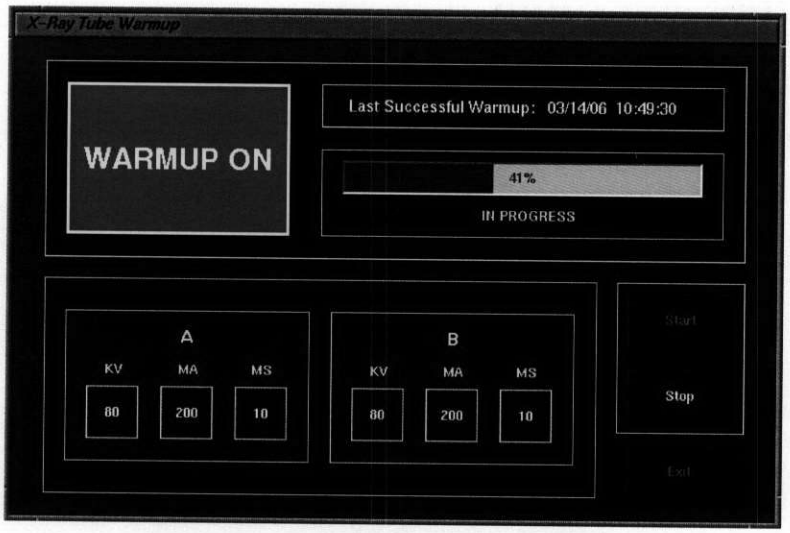



**Figure 13 Tube Warmup screen "Running"**

**Step 4.** Click the **EXIT** button to exit the Tube Warmup application.

**NOTE:** If the imaging system has been unused after 8 hours, it is recommended that you perform the Tube Warmup procedure again.

If the **STOP** button is pressed while warmup is in progress, warmup will be aborted, and a dialog will appear indicating that the warmup was interrupted. Clicking **RESET** will reset the system, and enable the **CONTINUE** button. Clicking **continue** will close the message dialog and allow Tube Warmup to be restarted by clicking the Tube Warmup **START** button.

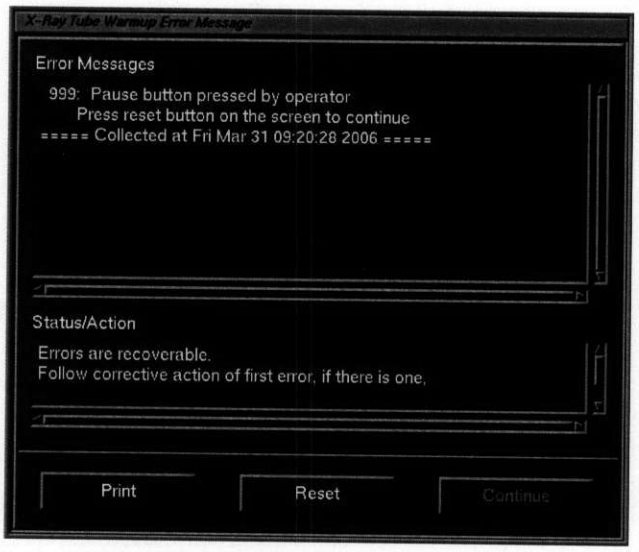



**Figure 14 Tube Warmup Error Message screen**



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



# Handling Errors

## Power On Errors

If an error in a subsystem is encountered during power on, a Power On Error Message appears.

**Figure 15 Power On Error Message**

If the error in the affected subsystem resolves itself, the error message box will disappear automatically and the normal power on sequence will complete. However, if the problem does not resolve automatically and you press **OK**, then a partial power down will be initiated. Only the treatment robot will stay powered on (*Figure 16 Manipulator and Couch Powered On, page 15*).

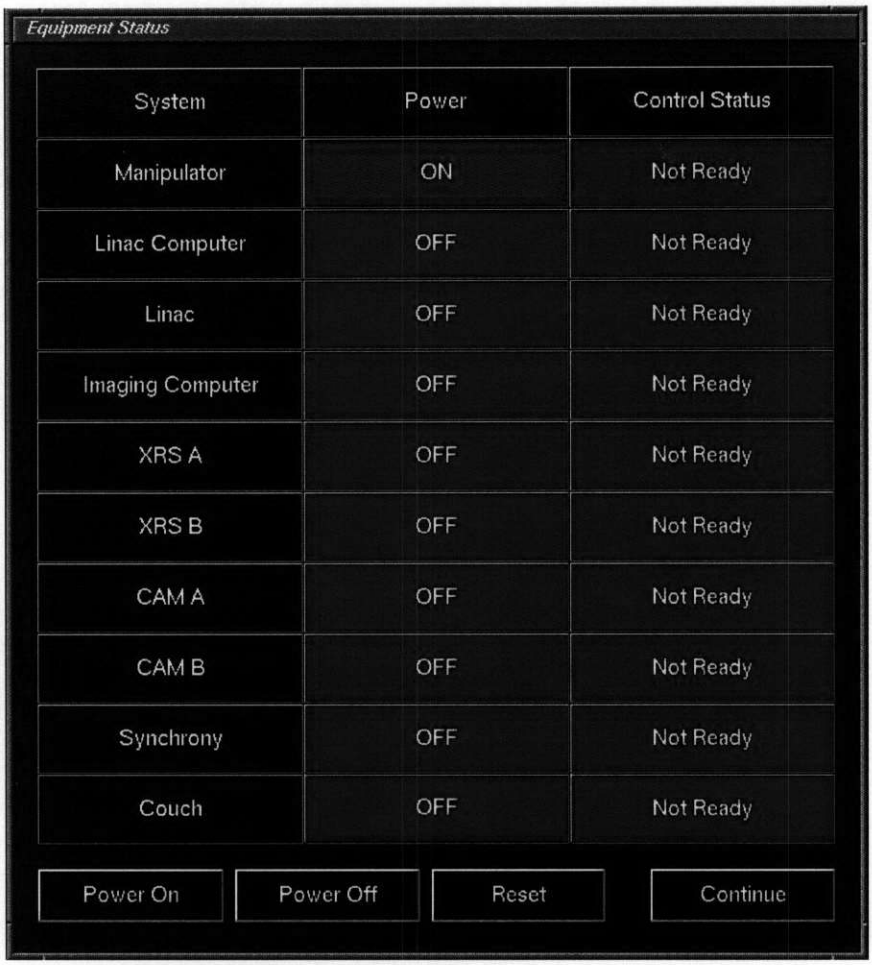
This partially powered state provides an opportunity to investigate and resolve the source of the power-on error without incurring the time penalty of a full equipment power-off followed by full power-on. However, if a full power-off is desired, it can always be accomplished by pressing the **POWER OFF** button on the main Equipment Status window.



933 Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015





Equipment Status

| System | Power | Control Status |
|---|---|---|
| Manipulator | ON | Not Ready |
| Linac Computer | OFF | Not Ready |
| Linac | OFF | Not Ready |
| Imaging Computer | OFF | Not Ready |
| XRS A | OFF | Not Ready |
| XRS B | OFF | Not Ready |
| CAM A | OFF | Not Ready |
| CAM B | OFF | Not Ready |
| Synchrony | OFF | Not Ready |
| Couch | OFF | Not Ready |

Power On | Power Off | Reset | Continue

**Figure 16 Manipulator and Couch Powered On**

## Errors Occurring After Power On

Unexpected loss of power to the treatment robot will trigger an E-Stop and result in automatic invocation of a full power down. However, a variety of lesser errors merely trigger a subsystem power reset. In this case, communication between the SGI and the equipment subsystems is shut down and then immediately restored, without performing a full power down of the robots. After successful reset, normal operation of the system resumes.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



# EQUIPMENT OPERATING INSTRUCTIONS

## User Control Panel

One of the functions of the user control panel (*Figure 17 Operator Control Panel, page 16*), is to enable the user to turn on/off the high voltage to the Linac. Once high voltage is on, radiation can be generated and delivered.

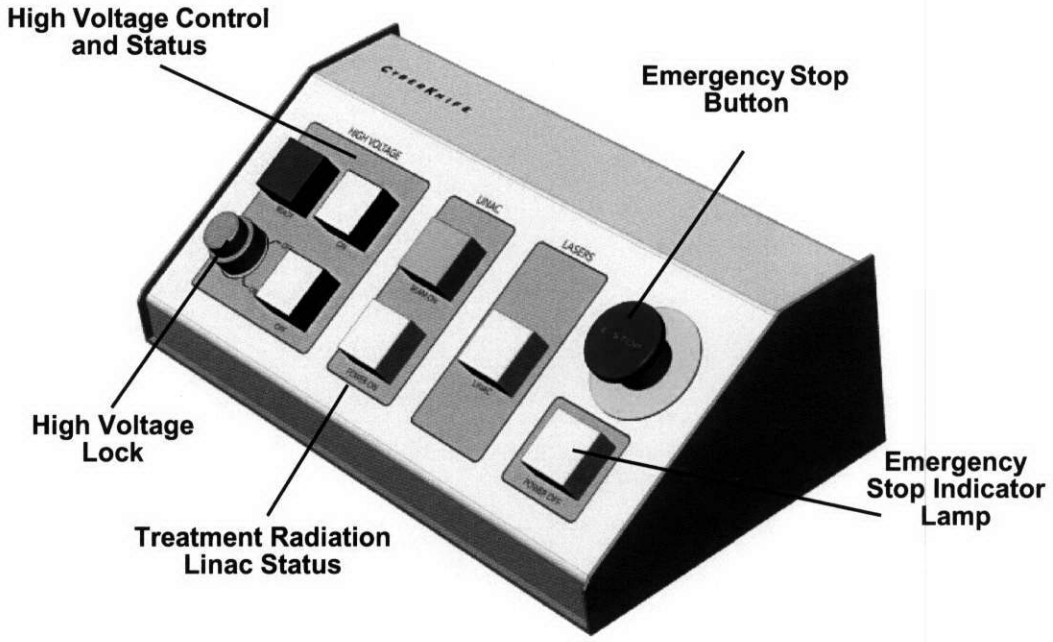



**Figure 17 Operator Control Panel**

## Keyswitch

Insert the safety interlock key into the switch and turn the key clockwise. This releases the safety and allows the high voltage to be turned on. The interlock key should be stored in a safe location at the end of use each day.

## Turning On-Off High Voltage

When the key is in the clockwise position and the "Turn High Voltage" message is displayed on the Treatment Delivery screen, pressing **HIGH VOLTAGE ON** turns on the high voltage to the Linac. Pressing **HIGH VOLTAGE OFF** turns the high voltage off. When radiation is being generated, the Beam on light will be on. When no radiation is being generated, the Beam on light will be off.

**WARNING: Depress the E-Stop button to terminate radiation delivery and cease manipulator motion if you suspect a problem.**



935

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



# TLS Imaging System Components

The imaging software and the associated imaging device hardware comprise the Target Locating Subsystem (TLS). The TLS controls the diagnostic X-ray sources and imaging panels to acquire images, as well as correlates images to determine patient displacements during treatment. The TLS software runs automatically upon startup of the TLS computer. Once the software is operational, it communicates with the CyberKnife User Control Console Computer. Digital control signals are sent from the TLS computer to the imaging hardware devices through the Target Locating Subsystem Control Chassis (TLSCC), shown in *Figure 18 Target Locating Subsystem Control Chassis (TLSCC), page 17*.

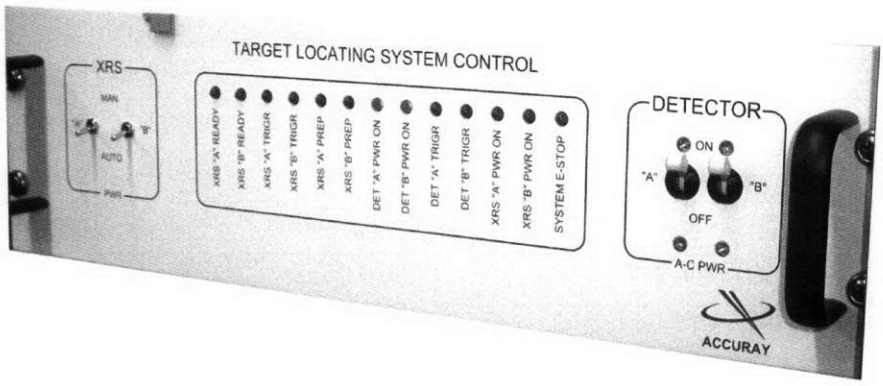



**Figure 18 Target Locating Subsystem Control Chassis (TLSCC)**

The proper switch settings for the TLSCC are described in *Figure 18 Target Locating Subsystem Control Chassis (TLSCC), page 17*).

## X-ray Source (XRS) Manual Power Switches

When the XRS switch is in the down position, the XRS "manual" power control is disabled (software power control is enabled). *The down switch position is required for normal system operation.* For maintenance, the switches may be placed in the up position to enable XRS manual power control. The up switch position allows the X-ray sources to be powered-up independently from the TLS software.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

936

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



## Camera AC Power Switches

These switches turn the power on/off to the TLS imaging camera devices. *For best imaging system performance, the imaging camera power should be kept on (switches up) at all times.* You may need to turn off camera power either for maintenance or to recover from a camera device fault. When ready to resume system operation, the cameras should be turned on and allowed to warm up for at least 15 minutes before resuming system operation.

The indicator lights on the TLSCC front panel are described in *Table 1: Description of TLSCC Front Panel Indicator Lights, page 18.*

**Table 1: Description of TLSCC Front Panel Indicator Lights**

| Indicator | Applicability | Description |
|---|---|---|
| XRS A/B READY | Not Used | Indicates XRS generator is powered up |
| XRS A/B TRIGGER | Not Used | Indicates X-rays on |
| XRS A/B PREP | Not Used | Indicates generator prep active |
| DETECTOR A/B POWER ON | All Configurations | Indicates camera AC power status |
| DETECTOR A/B TRIGGER | Not Used | Indicates external trigger signal sent from TLSC |
| XRS A/B POWER ON | All Configurations | Indicates power-on command from TLSC |
| SYSTEM E-Stop | All Configurations | Indicates that system E-Stop is cleared and Imaging Subsystem is ready to acquire images |

Turning on the TLS computer starts the TLS system software. After booting the TLS computer and before patient treatment, the TLS computer should remain at the Windows Login screen to ensure that only the TLS system software is operating.

**NOTE:** Using TLS software tools or other programs can interfere with the performance and proper functioning of the Target Locating Subsystem. For this reason, the TLS software tools should only be run by Accuray personnel for maintenance or calibration.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



Reboot the system if you experience problems with the TLS subsystem software such as:

- TLS communication failures that are reported on the CyberKnife user control console computer.
- Imaging hardware fails to power-on successfully (CYBERKNIFE EQUIPMENT STATUS screen)
- Other TLS-related errors.

Perform the following steps on the user control console computer:

**Step 1.** Navigate to the CyberKnife Equipment Status screen.

**Step 2.** Power down the system.

**Step 3.** Reboot the TLS computer (this is done in the equipment room).

1. Go to Start/Shutdown at the TLS PC.
2. Press the **POWER** button on the PC to power it down.
3. Wait 20 seconds, then turn it back on.
4. When this is complete, return to the SGI and power up the system again.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



If you encounter further problems, check the status of the TLS system software to ensure it is operational by performing the following steps:

**Step 5.** Open the Windows NT Control Panel Folder by navigating through: Start->Settings->Control Panel

**Step 6.** Double-click the services icon to bring up the Services dialog box

**Step 7.** Scroll down to the service named TLS Main Controller Service.

**Step 8.** Ensure that the Status is started and the Startup-Type is automatic.



939 Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



# Robot Operation

This section is a quick reference for operating the KUKA robot. For a more detailed information, *see the KUKA Robot operations manual.*

## Controller Power-up

The main disconnect switch is on the controller cabinet. When this handle is in the UP position, the switch is closed and if power is supplied to the cabinet, the controller will start. KUKA's boot-up usually takes about 2-3 minutes.

To power off the controller, put the handle in the DOWN position. It takes approximately 30-60 seconds for the controller to shut down. It is recommended to wait at least 60 seconds after powering off the robot before initial power up.

## Teach Pendant (KCP)

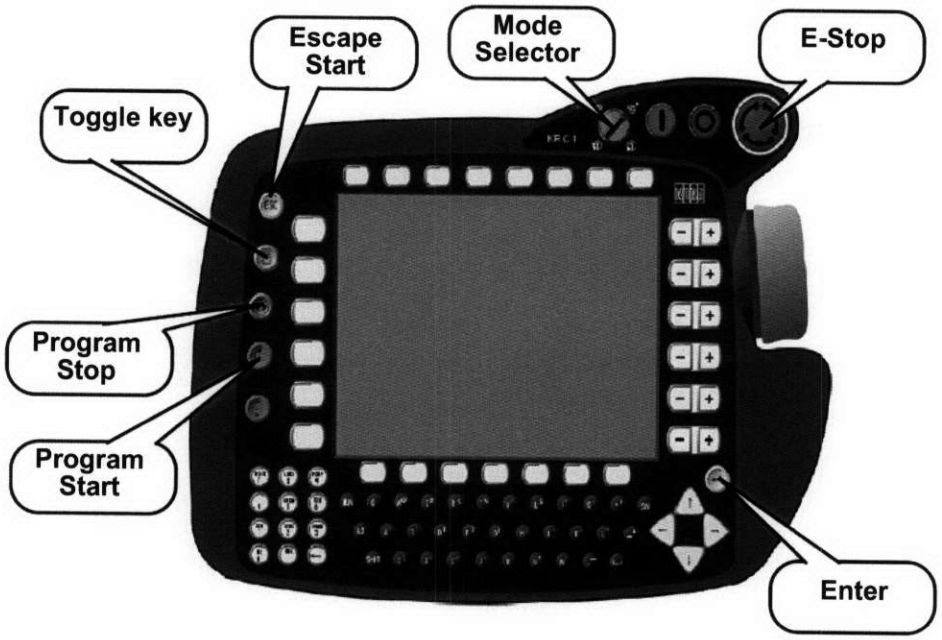



**Figure 19 Teach Pendant**



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



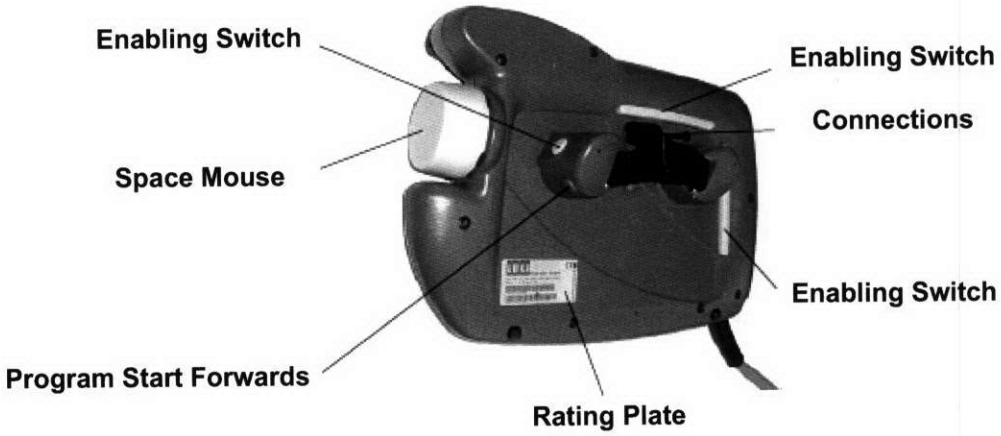



**Figure 20 KCP (View from behind)**

All enabling switches on the KCP are three-position switched. If they are released, the drives are disabled. If they are held too tightly, the drives are disabled as well. They should be held in the middle position for the drives to be enabled.

## Jogging

Jogging can only be performed in T1 or T2 mode.

### Jog Modes

Jog mode soft key is located on the left side of the display. Pressing it changes the Jog mode according to the following:

No Jogging allowed

Jog with space mouse

Jog using soft keys (right side of display)

**Figure 21 Jog Modes**



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

941

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



## Jog Coordinates

Jogging can be performed in one of the frames listed in *Figure 22 Jog Coordinate Frames, page 23*. Pressing the soft key on the left side of display can change the frame. All modes, except the first one, are Cartesian coordinate systems.

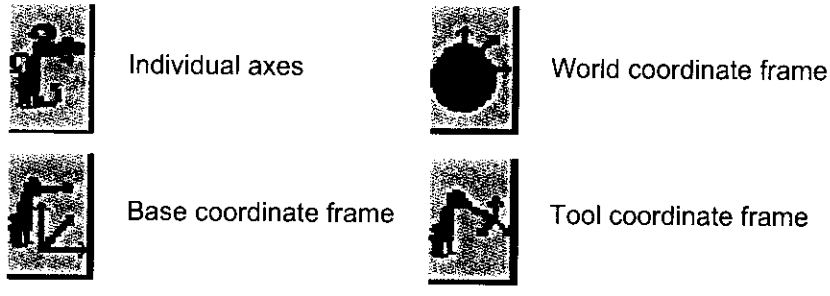



**Figure 22 Jog Coordinate Frames**

| | | |
|---|---|---|
| | **T1** | Low speed teach mode |
| | **T2** | High speed teach mode |
| | **Automatic** | Runs programs |
| | **External** | Runs programs from SGI computer |

**Figure 23 Mode Selection (Different Operating Modes)**

**WARNING: Maintain at least 3 ft. distance from robot when operating the robot manually. When moving the robot, focus on the robot rather than looking at the teach pendant. The PDP or safety zone parameters are not active when using the teach pendant.**

If the teach pendant system does not respond, check to see if the E-Stop button is depressed halfway



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



## Moving the Robot Manually

**Step 1.** Move key from automatic mode to manual mode (select either **T1** or **T2**).

**Step 2.** Select **ACKN** or **ACKN ALL** (soft key located at bottom right corner of display screen.

**Step 3.** Press the top left soft key until the following robot jog icon appears.

**Step 4.** Change the speed of the robot by selecting the soft key located at the lower right side of display screen (2nd from bottom).

**WARNING: Select 50% or less for the speed of robot travel to have enough time to avoid collision.**

**Step 5.** Depress and hold enable switch halfway to activate teach pendant. the middle status indicator turns green NUM INS (located at bottom left side of display screen) When enable switch is depressed, buttons along right hand side of screen will change to + / - corresponding to each of the 6 robot joints.

**Step 6.** Move robot as desired using the **+** / **-** buttons for each individual joint.

**WARNING: Keep your eyes on the robot at all times, not the teach pendant, when robot joints are in motion, to avoid collision.**

Reset the mode selection by moving the key from manual mode (**T1** or **T2**) to automatic external mode.

## Move the Robot to "PRCH"

**Step 1.** Move key from automatic mode to manual mode (**T2**). T

**Step 2.** Select **ACKN** or **ACKN ALL** (right bottom corner of display screen).

**Step 3.** Use blue toggle key to highlight top of screen.

**Step 4.** Select **CK MAIN** menu in left menu column (highlights in blue) by using the arrow keys.

**Step 5.** Open menu by selecting the **ENTER** key (**YELLOW** button).

**Step 6.** Use arrow keys to highlight the **prch** program.

**Step 7.** Launch the **prch** program by using the **ENTER** key.

**Step 8.** Depress and hold enable switch halfway until button turns green. NUM INS

**Step 9.** Press **GREEN +** button once and release after message "programmed path reached (BCO)" appears in message window.

**Step 10.** Press **GREEN +** button a second time. Hold until robot returns to perch position as indicated by black button.



943 Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



**Step 11.** Reset the mode selection by moving the key from manual mode automatic external mode.

## Turn Laser On Via the Teach Pendant

**Step 1.** Switch key to manual mode (**T2**).

**Step 2.** Select **MONITOR** soft key above display screen.

**Step 3.** Use arrow keys to select **I/O**, then press <Enter>.

**Step 4.** Use arrow keys to select **DIGITAL OUTPUTS**, then press <Enter>.

**Step 5.** Depress and hold enable switch halfway until red button changes to a green button.

**Step 6.** Wait for the "Change" option on the menu at bottom of screen to become active then select **CHANGE**; wait a few seconds to verify laser has turned on.

**Step 7.** Switch key back to automatic mode.

Repeat sequence outlined above to turn the laser off.

## Running Simulation Path Manually Via the Teach Pendant

**Step 1.** From Imaging Parameters on the console – Select **B.B. TEST MODE**, then **OK**.

**Step 2.** Select **START** to receive message "Use Teach Pendant to Continue BB Test".

**Step 3.** Enter treatment room; bypass door interlock by inserting key into wall panel.

**Step 4.** Maintain key position in external automatic mode.

**Step 5.** Press the **ACKN ALL** button on the bottom right, if applicable. Press **SIM NODE** (simulate one node at a time in the path) or **SIM ALL** (simulates all nodes in path automatically) on the bottom left. When the simulation path finishes, robot will return to perch.

**Step 6.** Be prepared to press the E-Stop button to halt movement of the robot if necessary.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118 

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



# POWER-UP DUE TO POWER INTERRUPTION

This procedure describes taking the CyberKnife System from a shutdown state, typical of how the system would be left for the weekend, up to a Powered-On condition where it is ready to perform a treatment or be operated in physics mode.

**NOTE:** This procedure is most often used when a power interruption or some other disruptive event has occurred, usually when the system was unattended (during the night or over a weekend).

It insures all sub-systems and computers are in the proper condition for power-up and that communications between various sub-systems are working correctly.

## Step 1 - Establish "Normal" CKS Power-Off Status

This step ensures that the CyberKnife System is powered down properly and in the correct standby state, thereby establishing a dependable starting point.

**To achieve normal power-off status:**

1. The SGI (Primary workstation) should be at the UNIX log-on screen. This is the screen where the login is cks.
2. The TLSPC should be at the Desktop. This can be seen on the monitor in the equipment room.
3. The robot should be in the perch position and powered off.
4. The PDU (Power Distribution Unit) and UPS (Uninterruptible Power Supply) should be set properly.

   **To do this check the following:**

   - Verify the three lights on the upper left-hand side of the PDU, labeled **AC POWER**, **L1**, **L2** and **L3** are illuminated. If the lights are not on, press to engage.
   - Press the **EPO RESET** button on the upper right–hand side to insure the EPO circuit is latched on.
   - Verify all circuit breakers on the PDU except the XRS LASER (optional) are on. Reset if necessary by turning them off, then on again.



945 Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



## Step 2 – E-Stop Circuit Check

If any system E-Stop conditions exist, the CyberKnife System may not power up without generating a fault condition.

**To check out E-Stop issues:**

**Step 1.** Turn the ESCC key switch to the **SERVICE MODE** (CW).

**Step 2.** Power on the robot by depressing the **MANIP. LCL PWR** button on the ESCC.

- Insure the robot is completely booted up before proceeding. This can be confirmed by monitoring the display on the robot pendant.
- The robot can also be monitored in the equipment room by selecting it with the KVM switch. The KVM switch toggles the Keyboard, Video and Mouse controls between the TLS PC and the Robot PC.

**NOTE:** Do not attempt to turn the robot on or off while it is going through a boot up or power down sequence!

**Step 3.** Verify the **System E-Stop LED** on the right-hand side of the TLSCC is illuminated.

- If the **System E-Stop LED** is not illuminated this means there is an E-Stop engaged. Troubleshoot by checking E-Stop buttons, Collimator, door, etc.or call Accuray Customer Service.

**Step 4.** Power down the robot by releasing the **MANIP. LCL PWR** button on the ESCC.

- Ensure the robot is completely off before proceeding. This can be confirmed by observing the robot display or Teach Pendant and ensuring it is blank.

**Step 5.** Turn the ESCC key switch out of the Service Mode (CCW).



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118 946

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



## Step 3 – Reset All Subsystems

There are several computers and microprocessors included in the CyberKnife System. Resetting, or rebooting them before powering up will usually eliminate them as a cause of operational problems.

**To reset/reboot all sub-systems:**

**Step 1.** Disconnect the Network connection between the Hospital and the CyberKnife System by pulling the network cable from the network wall jack.

**Step 2.** Turn off the IFCC for 20 seconds and then turn it back on.

- This will cause the IFCC computer to reboot and request initialization information from the SGI.
- This step can be performed by using the rocker power switch on the rear of the 19 inch rack mounted chassis (in the MCC rack). The front of this chassis is plain with only a set of handles on each side. Do not confuse this with the display power switch on the rear of the display that rests on top of the MCC.

**Step 3.** Perform a hard (power down) reboot of the TLSPC. Leave the TLSPC off for 20 seconds before turning back on.

- The reason for a power-down reboot is that the two frame grabber PCBs use microprocessors. These microprocessors reboot only when power is removed.

**Step 4.** Reconnect the network connection between the Hospital and the CyberKnife System.

- This step is not necessary for powering up the CyberKnife System and may be deferred until later. This must be done once power is re-established in order to receive planning studies from CT, MR, etc.



947 Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



## Step 4 – Communications Check

Several of the CyberKnife System sub-systems communicate with each other through Ethernet connections.

**To ping the appropriate sub-systems:**

**Step 1.** From the SGI, log on at the UNIX log-on screen.

**Step 2.** Open a shell. (Right mouse click in the blue area of the screen and select "Shell").

**Step 3.** Type cat /etc/hosts, press <Enter>.

**NOTE:** View the IP addresses of the IFCC and TLSPC.
The IFCC is typically identified as IFCC.
The TLS PC is typically identified as System PC.

**Step 4.** Ping the noted IP addresses from the SGI.

- To ping, type: ping<space><IP Address> and press <Enter>.
- If a proper ping response is not received, troubleshoot or call Customer Accuray service.

## Step 5 – CyberKnife System Log-On

**To view status details or the sub-systems after log-on:**

**Step 1.** Log-on at the CyberKnife System screen.

**Step 2.** The CyberKnife System menu should now be presented and the hardware status should be:

- Robot is off and in the perch position.
- Linac is off.
- PDU circuit breakers are in their correct positions and the EPO circuit is on.
- UPS is on.
- TLSPC at the NT desktop.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118 948

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



## Step 6 – Hardware Power On

**To power up the CyberKnife System:**

**Step 1.** From the CyberKnife System menu screen, click **EQUIP POWER**.

**Step 2.** From the Equipment Status screen, click **POWER ON**.

- If at any time an error message appears, troubleshoot using the fault message as a guide or call Accuray service.

**Step 3.** When all equipment sub-systems show electrical power "ON" and status "ON STANDBY," click **CONTINUE**.

- If any subsystems are listed that are not part of the current CyberKnife System, disregard.

**Step 4.** The CyberKnife System should now be fully powered up and the CyberKnife System menu screen showing.



949 Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



# Equipment Checks
## Table of Contents


Battery Replacement ..... 1
Annual QA System Checks ..... 2
- Treatment Planning System ..... 2
- Robot ..... 2
- Image Processing ..... 2
- Linac ..... 2
- Safety System ..... 2

Monthly QA System Checks ..... 3
- Laser Alignment ..... 3
- Beam Symmetry Test ..... 3
- Robot ..... 4
- Imaging ..... 4
- Film/Phantom Targeting Test ..... 4

Daily QA System Checks ..... 5
- Linac System Check ..... 5
- Linac Dose Calibration ..... 5
- Safety Interlock Tests ..... 6
- Manipulator Mastering, Simple Check ..... 7
- Linac Dosimeter Calibration ..... 7
- Primary/Secondary Dosimeter Check ..... 9
- Output Spot Check 9 .....

Disinfection Instructions ..... 9




Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118 950

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015







Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



# EQUIPMENT CHECKS

This section suggests daily, monthly and annual equipment quality assurance checks that should be undertaken for the CyberKnife® System. It also describes the optional treatment simulation, or "end-to-end test", that Accuray suggests using to confirm dose distribution for individual cases at the discretion of your staff.

**NOTE:** Electro Static Discharge: If access to the equipment room is required during system operation, personnel entering the space should observe standard ESD precautions, such as:

Dissipate static electricity before handling any system components by touching a grounded metal object.

If possible, use antistatic devices, such as wrist straps and floor mats.

## BATTERY REPLACEMENT

The modulator control chassis (MCC) back up dose counter batteries must be changed every 5 years. Battery disposal should be made according to local codes. Most local codes consider batteries to be a hazardous material and do not allow their disposal with other waste. Contact your local agency.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



# ANNUAL QA SYSTEM CHECKS

Annually and whenever the system has undergone changes that may affect calibration, you, with the help of Accuray staff, should repeat the *Acceptance Tests* (*see Accuray document 017751*) performed at original installation. Use the results from these tests to make any necessary adjustments to the system.

## Treatment Planning System

Spot check the display, measurements and calculations.

## Robot

Check targeting corrections for each node by running SEARCH2.

## Image Processing

Perform motion test with anthropomorphic phantom.

## Linac

Check beams with water phantom, measure leakage and check dosimetry with rotation of the Linac.

## Safety System

Test all interlocks and spot check proximity detection system.



953

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



# MONTHLY QA SYSTEM CHECKS

The following procedures should be performed monthly or when service on the Linac or its collimator may affect laser or beam alignment.

## Laser Alignment

Perform this procedure to assure that the laser accurately coincides with the beam axis. It is assumed that the rotational bearing of the collimator assembly coincides with the beam axis.

This test may be done in conjunction with the Linac spot check. Use the laser collimator with the beam vertical and source surface distance (SSD) at 80 cm. Turn the laser on and pull the pin prior to rotating the collimator through its range of motion. Mark the locus of the laser spot on a sheet of paper. Repeat this test with SSD at 60 cm. A diameter exceeding 2 mm indicates the laser needs realignment.

## Beam Symmetry Test

This test provides a record of the laser location with respect to the beam and a check of the symmetry of the beam.

Therapy verification film such as Kodak XV-2 film may be used. Ensure that the surface upon which the film will be irradiated is normal to the beam by placing a piece of reflective material such as a sheet of clear plastic on the surface and verifying that the reflection of the laser at the laser collimator coincides with the collimator aperture. If it does not, adjust the beam orientation and set the desired distance.

Inscribe a cross on the envelope containing the film with a fine ball-point pen (or use an alternative method for localizing the laser in the beam spot) and clearly mark the film so its orientation to the beam will be known. Align the cross with the laser spot. Replace the laser collimator with the 40 mm collimator. Place material on the film. Irradiate with sufficient monitor units to produce a maximum optical density of 1.0 on the film. This density is achieved with 25 to 35 MU for verification film.

Develop and scan the film. Compare the center of the irradiation spot with the location of the laser, represented by cross lines in the developed film. Scientific software may be used to facilitate the comparison. A displacement > 1 mm indicates a need to adjust the laser or beam (if not symmetrical).

Use commercially related software, such as RIT 113, or DP-systems to determine beam symmetry.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118 954

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



## Robot

Visually check simple test path that targets iso-crystal (5-10 nodes). (This path can be setup by Accuray at your request).

## Imaging

Acquire image of isopost. Verify iso-crystal is at center pixel (+/- x). This checks that cameras have not moved.

## Film/Phantom Targeting Test

Measure clinical accuracy of CyberKnife System by performing treatment to an anthropomorphic phantom loaded with film/TLD for each mode used for treatment (skull, fiducial, ...).



955 Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



# DAILY QA SYSTEM CHECKS

The following tests should be performed prior to using the CyberKnife System for patient treatment **each day**. Only persons adequately trained in CyberKnife System operation should perform these tests.

## Linac System Check

Daily Startup Log measurements provide a check and a record of Linac performance.

Log on to the CyberKnife System. Start equipment power. As the Linac is warming up, record readings per the form, (*Figure 1 CyberKnife Daily Startup Log, page 8*) and verify that tolerances are not exceeded. Report readings out of range to Accuray prior to clinical use.

## Linac Dose Calibration

Daily Startup Log measurements provide a check and a record of Linac performance.

Log on to the CyberKnife System. Calibrate the Linac dose output, record readings per the form, (*Figure 1 CyberKnife Daily Startup Log, page 8*) and verify that tolerances are not exceeded. Report readings out of range to Accuray prior to clinical use.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118 956

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



## Safety Interlock Tests

The safe operation of the CyberKnife depends on the proper functioning of all safety interlocks. (*Table 1: Interlock Safety Test, page 6*)

Once all equipment is on, check that no one is in the treatment room; then close the treatment room door and correct any fault condition. Load the calibration process and program the Linac to deliver 100 MU. Check the door interlock and pause buttons on the operator console. The unit may not be used clinically unless all interlocks are functional. Report problems to Accuray.

**Table 1: Interlock Safety Test**

| No. | Test | Pass Result |
|---|---|---|
| 1 | With the operator control console key switch in the off position, press the **HIGH VOLTAGE ON** button when the message to do so comes on the screen. | High Voltage will not come on. |
| 2 | With the key switch in the on position, start the High Voltage. Note the condition of warning light over treatment room door. | Light is on |
| 3 | Note the condition of warning light in the treatment room. | Light is on |
| 4 | When the beam comes on, note the condition of the warning light on the operator control console. | Light is on |
| 5 | With the beam on, open the treatment room door **taking care to avoid exposure to radiation if the beam does not go off**. Close the door. Attempt to restart the High Voltage before resetting the interlock at the console screen. | Beam goes off and stays off until reset at the console screen. |
| 6 | With the beam on, press the **STOP** button on the operator control console. Release the button. Attempt to restart the High Voltage before resetting the interlock at the console screen. | Beam goes off and stays off until reset at the console screen. |





Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



# Manipulator Mastering, Simple Check

Mark the manipulator joints in their standard perch position, check that the marks are aligned.

# Linac Dosimeter Calibration

The CyberKnife monitor chambers are open to the atmosphere. For this reason it is imperative that you measure the calibration factor on each treatment day and periodically during the treatment day, if the weather changes significantly and enter the calibration factor into the CyberKnife System. Before doing the daily Linac calibration deliver 2000 MU of radiation to warm up the Linac. This will minimize the drift of the ion chambers. If the system has high voltage off for over two hours, deliver another 1000 MU warm-up.

**CAUTION:** The calibration factor entered affects the dose delivered to the patient in a way that will not be obvious during treatment. It is imperative that the following procedure is done **only** under the direct supervision of a qualified medical physicist or other suitably qualified and responsible individual in accordance with national or regional quality standards.

**Linac Readings**

| METER | EXPECTED | READING | ☑ | COMMENT |
|---|---|---|---|---|
| GUN HTR | 5.2 ± 0.5 V | | ☐ | |
| MAG HTR | 9.3 ± 0.5 V | | ☐ | |
| Steering coil 1 | 1.03 ± .03 A | | ☐ | |
| Steering coil 2 | 0.22 ± .03 A | | ☐ | |
| ION PUMP | < 2 μA | | ☐ | |
| Water temp. | 19 ± 1 °C | | ☐ | |
| Water level | low level light off | | ☐ | |
| $SF_6$ pressure | 28 < p < 32 psi (193 < p 221 kPa) | | ☐ | |

**Linac/Robot Safety Checks**

| INTERLOCK | TEST (Calibration) | EFFECT | ☑ |
|---|---|---|---|
| Key switch | Key off (beam off) | High voltage will not come on | ☐ |
| Warning lights | Turn HV on | Door light illuminated | ☐ |
| | | Room light illuminated | ☐ |
| | Beam on | Beam on light is illuminated | ☐ |
| Door | Open door | Beam goes off and stays off until reset | ☐ |
| Console E-stop | Depress | Beam goes off and stays off until reset | ☐ |



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



**Primary/Secondary Dosimeter Check**

| | | | |
|---|---|---|---|
| Dose A | Set cal f A:B:1:1.2 | A stops beam at 5000±15 counts | ☐ |
| Dose B | Set cal f A:B:1.2:1 | B stops beam at 5000±15 counts | ☐ |

**Output Spot Check**

| Chamber | | Electrometer | | |
|---|---|---|---|---|
| Temperature | °C | Pressure (temp) | mm ( °C) | |
| Collimator | mm | Pressure corrected | mm Hg | |
| R (readings) | NC | SSD | cm | |
| M = Dose A/100 | MU | Dose B/100 | MU | |
| Output for 100 MU set | $R_{avg} \times C_{T,p} \times F / M$ = = | | cGy/MU | ☐ |
| Calibration factor entered | | | MU/cGy | ☐ |
| (Dose A – Dose B) / (Dose A) | | | [< 0.03] | ☐ |
| Date | | Signature | | |

*F = factor depending on setup that is determined at time of annual calibration.*

**Figure 1 CyberKnife Daily Startup Log**



959

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



## Primary/Secondary Dosimeter Check

The CyberKnife System is fitted with dual redundant monitor chambers. The primary chamber is calibrated to turn the beam off when the desired dose has been delivered and the secondary chamber checks the proper operation of the primary. Test that each of the two dosimeters will turn the beam OFF within the acceptable number of counts. (*Figure 1 CyberKnife Daily Startup Log, page 8*). If the test fails, notify Accuray and do not use the CyberKnife System for patient treatment.

## Output Spot Check

Set up a field chamber under conditions identical to those used during initial installation or annual calibration. A Farmer field chamber is suitable. If a Farmer field chamber is used, select the largest collimator (60 mm) for the spot check. Record data in the CyberKnife System daily startup log. Recommended conditions are SSD 80 cm and 5 cm depth in a solid phantom set up on the floor of the treatment room. Note the room temperature and pressure.

With the treatment room door closed and bias voltage to the ion chamber on, expose to 100 MU and record the collected charge. Any variation of monitor chamber reading of greater than 4% from the historical mean should be investigated. Record the dosimeter counts for both primary and secondary as well. Calculate the calibration factor in MU/cGy correcting for temperature and pressure. Enter the factor in the CyberKnife System for both primary and secondary dosimeters. Verify that the secondary (Dose B) is less than the primary (Dose A) and that the two do not differ by more than 3%.

# Disinfection Instructions

The only part of the CyberKnife System that should come in contact with the patient is the carbon fiber treatment tabletop. This surface is not intended to be sterile. It can be cleaned with normal cleaning solutions.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015





961

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



# Patient Preparation
## Table of Contents


**Patient Setup** ..... 1
- **Patient Setup Safety Considerations** ..... 3
- **Immobilization** ..... 5
  - Head and Neck Immobilization ..... 5
    - Head and Neck Immobilization Without Fiducials ..... 5
    - Head and Neck Immobilization for Fiducial Tracking/Xsight™ Treatments ..... 6
  - Body Immobilization ..... 6
  - Using the Synchrony™ Vest (Optional) ..... 8
    - CT/MR/PET Acquisition ..... 9
    - Treatment Delivery Setup ..... 10
  - Reassess Patient Positioning ..... 11
- **Acquire Treatment Planning Image Studies** ..... 11
  - CT Imaging Guidelines ..... 11
  - MRI Imaging Guidelines ..... 13
- **Attaching the Headrest to the CT Machine** ..... 14
- **Setting the CT Scanning Parameters** ..... 14
- **Key DICOM Identifiers** ..... 14

**Fiducial Placement Principles** ..... 15
- **Supplies** ..... 16
  - Soft Tissue Supplies ..... 16
  - Spine and Bone Supplies ..... 16
    - Fiducial Kit for Spine ..... 17
- **Fiducial Placement Procedure** ..... 18
  - Post Placement Guidelines ..... 18
  - Lung ..... 18
    - Outline of Procedure ..... 18
    - Potential Complications ..... 20
    - Points To Consider ..... 20
    - Conclusion ..... 20
  - Pancreas/Liver ..... 21
    - Outline of Procedure ..... 21
    - Potential Complications ..... 22
    - Points To Consider ..... 23
    - Conclusion ..... 23
- **Cleaning and Sterilization** ..... 23
  - Sterility ..... 23




Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

962

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015





963 Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



# PATIENT PREPARATION

## PATIENT SETUP

To treat a patient with the CyberKnife® System, Accuray recommends following the procedure as shown in *Figure 1 Treatment Process, page 2*.

**Important steps to take before treating a patient with the CyberKnife System:**

**Step 1.** Log into the console and power up the CyberKnife System.

**Step 2.** Load the imaging studies (i.e., CT, MRI) which will enter patient information.

**Step 3.** Check CT center and move as needed.

**Step 4.** Fuse images as required.

**Step 5.** Generate one or more treatment plans.

**Step 6.** Generate DRR's (Digital Reconstructed Radiographs) any time after treatment plan has been created and prior to beginning treatment. Generation of DRR's requires approximately 3 minutes for extracranial plans and 20 minutes for intracranial plans. Be sure to allow sufficient time before treatment to generate DRR's.

**Step 7.** Load and recalculate final plan on Treatment Delivery System.

**Step 8.** Prescribe treatment plan.

**Step 9.** Calibrate and enter appropriate dosimeter factors as described in *module, QA/Calibration, section, Calibrating the Linac*.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



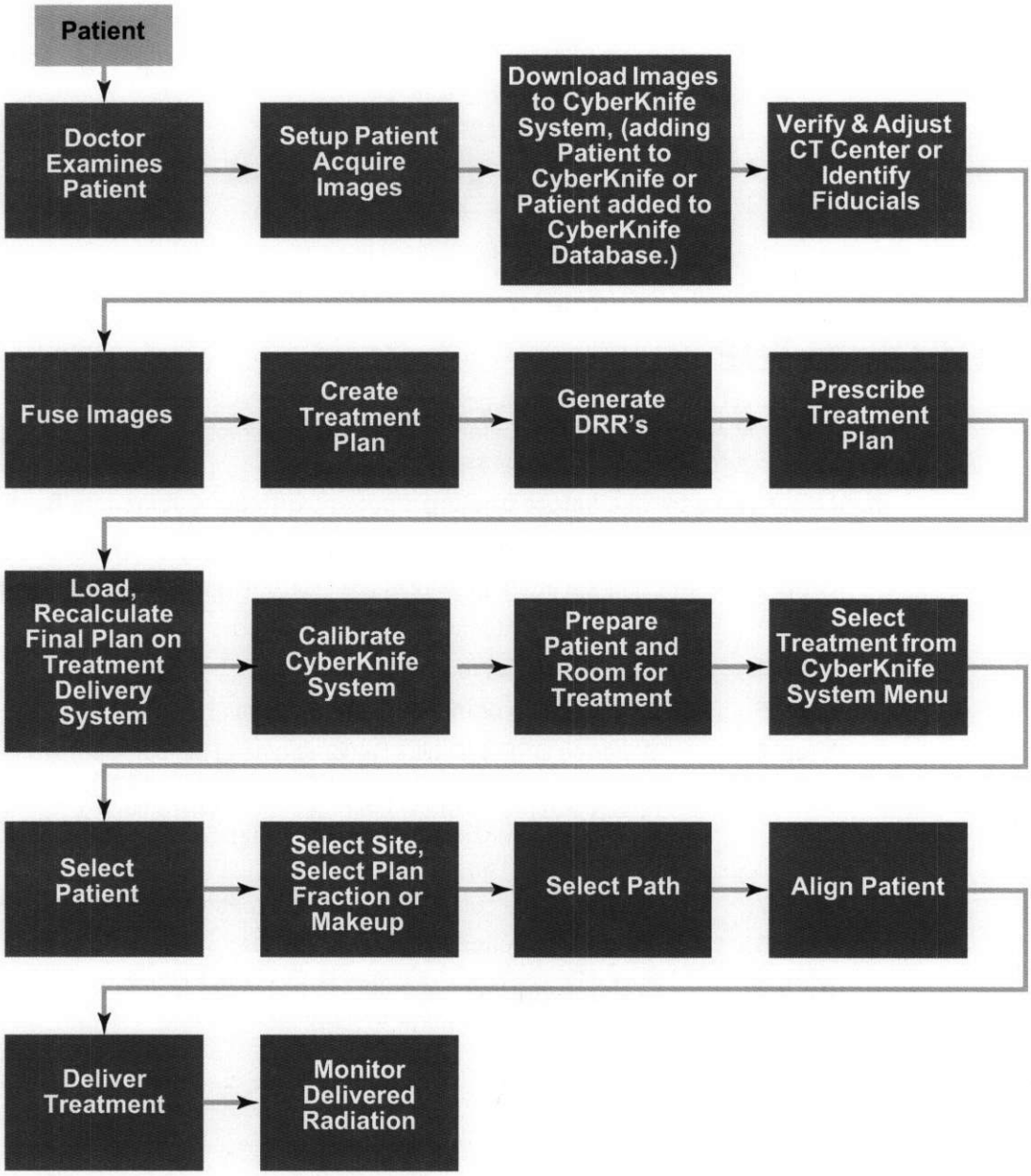



**Figure 1 Treatment Process**

**NOTE:** It is essential to have patients in the same position for treatment as they were during CT scanning. A reproducible patient position is the primary requirement during preparation of a patient for the CT scan.



965

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



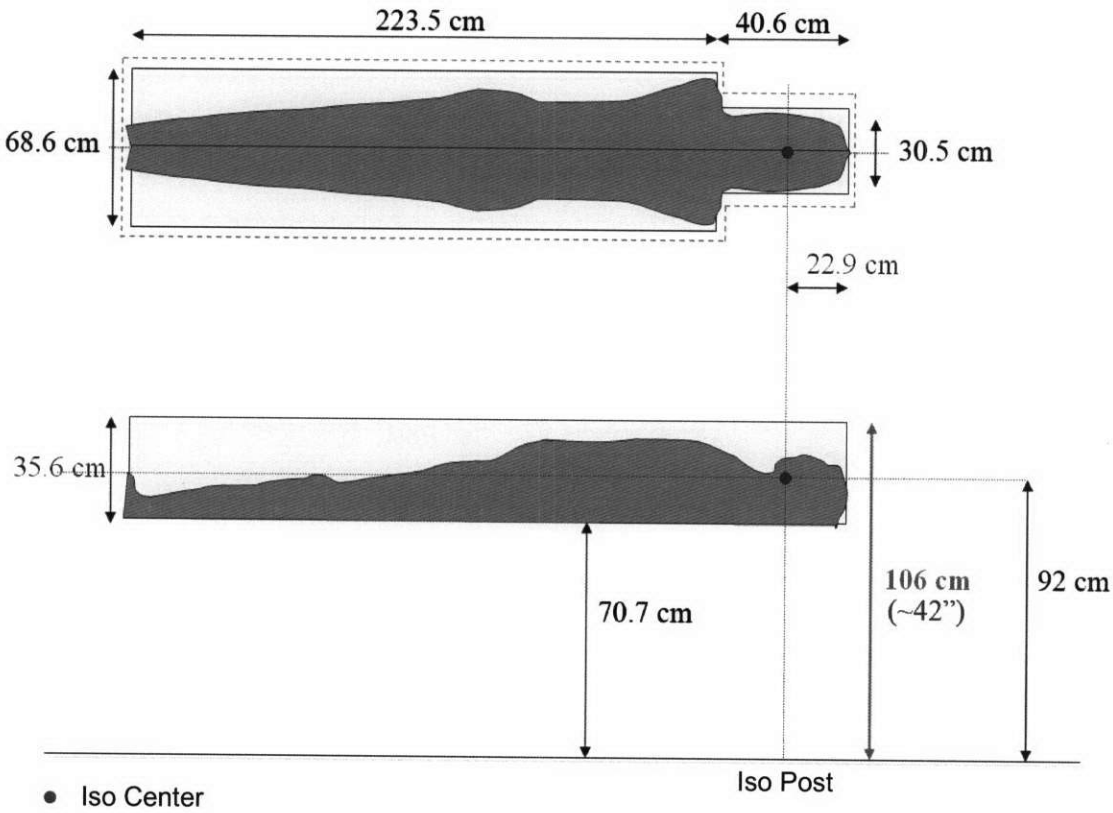
**WARNING: Position the patient and all devices within the PDP Model. Anything extending outside the boundaries of the PDP model increases the risk of collision with the manipulator.**

## Patient Setup Safety Considerations

With patient in treatment position, verify that patient does not violate the safe zone as specified below:

1. No part of the patient or couch may extend >111 cm (~44 inches) from the floor (*Figure 2 Patient Safety Setup Dimensions for Head Treatment, page 3*).

**PDP Model: Head Treatments**




PDP program adds 5 cm to the boundary of the head model. If any part of the manipulator enters the boundary zone, an error will be triggered and manipulator motion will cease.

**Figure 2 Patient Safety Setup Dimensions for Head Treatment**



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

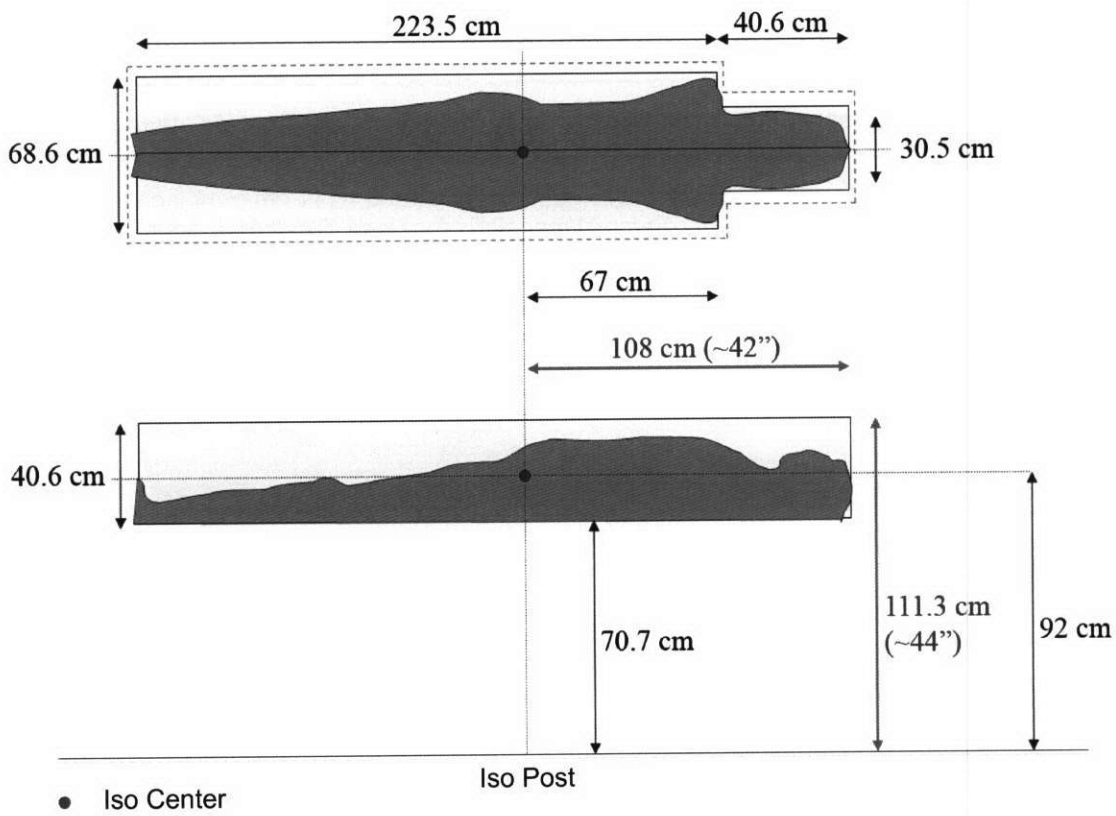
9160

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



2. No part of the patient or couch may extend >108 cm (~42 inches) superior from the nominal isocenter (*Figure 3 Patient Safety Setup Dimensions for Body Treatment, page 4*).

**PDP Model: Body Treatments**




PDP program adds 10 cm to the boundary of the body model.

**Figure 3 Patient Safety Setup Dimensions for Body Treatment**

**WARNING: Do NOT place pillows and/or objects in area, common errors can occur that cause safe zone violations.**

1. Pillows under the patient's head may raise head above the 111 cm height limit.
2. Positioning patient with arms raised above head can cause elbows to exceed the 111 cm height limit or the 108 cm superior limit.
3. Using too large a wedge under the patient's knees may elevate them above the 111 cm height limit.
4. Treating lesions below L-4 head first supine (HFS) may cause the patient's head to extend >108 cm from the nominal isocenter.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

967

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



# Immobilization

**WARNING: Head and neck treatments require that the neck of the patient is immobilized. There are some techniques that help with immobilization, however, it should be recognized by the user that complete immobilization is not achievable. Therefore all users should understand that it is never completely possible to immobilize a person's neck, therefore Accuray strongly recommends that the user use caution and visually check for patient movement throughout treatment. It is the user's responsibility to decide what is best for their patient.**

If pre-CT immobilization is done on the Cyberknife treatment couch it is important to be sure the couch pitch and roll is at zero (0) during the immobilization process.

## Head and Neck Immobilization

### Head and Neck Immobilization Without Fiducials

**Step 1.** Thermoplastic mask should fit snugly to minimize movement. (Mask thickness of 2.4 mm is recommended)

- **a** Mask should extend below patient's chin.
- **b** Mold bridge of nose to reduce lateral movement.
- **c** Bubble wrap over headrest can increase patient comfort.
- **d** Using shims under mask flange can accommodate for future shrinkage.
- **e** Mark laser lines to assist in setup reproduction.

**Figure 4 Thermoplastic Mask**



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



## Head and Neck Immobilization for Fiducial Tracking/Xsight™ Treatments

**Step 1.** Make aquaplast mask as above.

**Step 2.** A C-spine collar can be used in conjunction with a mask for better immobilization of the neck. Ensure that the C-Spine collar does not contain any metal or radiopaque material which may interfere with the visualization of the fiducials or the spine.

**Step 3.** Conduct an imaging test to evaluate visualization of fiducials or spine prior to CT.

## Body Immobilization

**Step 1.** Set up patient for treatment.

- **a** Use knee sponge, bolster or other means to stabilize legs and feet; re-evaluate position for patient comfort and safety.
- **b** Consider placement of arms:
  - Upper body treatment site - placed at sides.
  - Lower body treatment site - holding sternum ring, crossed at chest, overhead.
- **c** Position the patient Feet First Supine (FFS) if superior limit of 106 cm is exceeded.

**WARNING: Verify that placement of patient extremities does not violate the PDP zone (see section, *Patient Setup Safety Considerations, page 3*).**

**Step 2.** Make immobilization device to replicate setup position (alpha cradle or vacuum bag can be used).

- **a** Upper body immobilization (bottom of sternum and superior):
  - Include patient head and shoulders extending inferior toward pelvis.
  - Include arm position and imprint of fingers when possible.



969 Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015

**Figure 5 Alpha Cradle for Upper Body**

**b** Lower body immobilization (bottom of sternum and inferior):

- Extend device below patient knees and include heel imprint.
- Place knee sponge or bolster under immobilization device for patient.

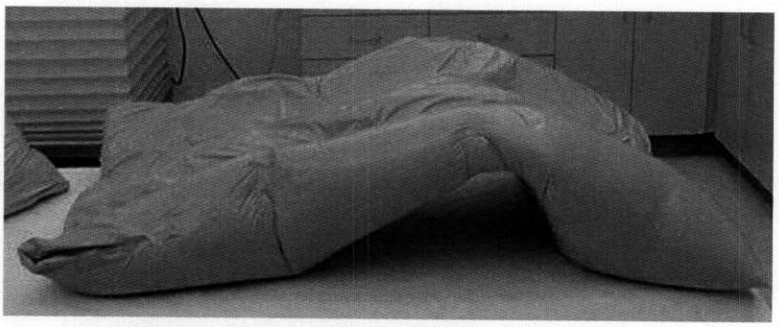


**Figure 6 Alpha Cradle for Lower Body**

**NOTE:** For patients with fiducials, evaluate patient position and fiducial visualization by acquiring a treatment image:

**Step 1.** Set up patient in treatment position using newly created immobilization device.

**Step 2.** Position patient's treatment area into image detector field.

**Step 3.** On the treatment workstation, open a phantom plan designed using fiducial tracking.

**Step 4.** Acquire live treatment image.

**a** Ignore fiducial errors. These occur due to difference between patient and phantom fiducials.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



**Step 5.** Verify number and location of fiducials against details from physician op notes and films.

- **a** Reposition patient as needed to bring fiducials into imaging field.
- **b** Check for obscured, overlapping or unusable fiducials.

**Step 6.** Repeat steps 4 and 5 as necessary to determine quality of fiducial placement and patient setup.

**Step 7.** Using room lasers for reference, mark patient position on immobilization device.

## Using the Synchrony™ Vest (Optional)

**Step 1.** Select the appropriate Synchrony Tracking Vest size for the patient.

**Table 1: General Guidelines**

| | |
|---|---|
| **Small Vest** | Height < 5'5" (1.68 m) |
| | Weight < 130 lbs (59 Kg) |
| **Medium Vest** | Height 5'5" – 6'0" (1.68 – 1.83 m) |
| | Weight 130 – 180 lbs (59 – 81.6 Kg) |
| **Large Vest** | Height > 6'0" (1.83 m) |
| | Weight > 180 lbs (81.6 Kg) |

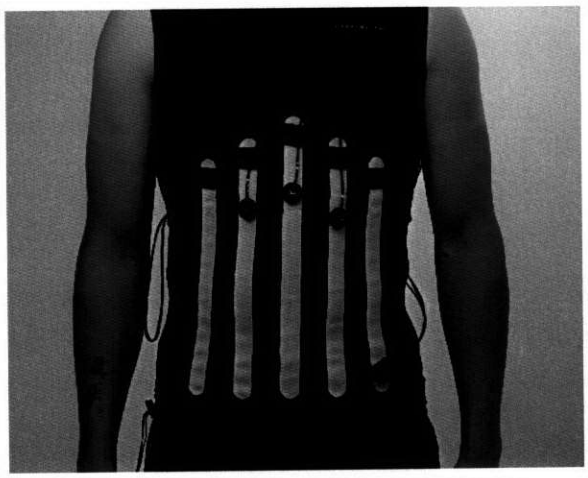


**Figure 7 Synchrony Tracking Vest**



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

971

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



**Step 2.** Take the Vest out of the pouch.

**Step 3.** Instruct the patient to put on the Synchrony Vest or, if unable, assist the patient to put on the Vest:

1. Unzip the back of the Vest and detach the Velcro tab at the bottom, back of the Vest.
2. Ensure the two drawstrings are in the loosest position.
3. Remove all clothes from upper body. (Jog bra with no metal inserts or fasteners is permissible if necessary for large breasted patients.)
4. Slip Vest over head of patient.
5. Slip arms into arm holes of the Vest.
6. Fasten Velcro tab at the bottom, back of the Vest.
7. Pull the string attached to the zipper or the zipper itself down to the bottom of the Vest.
8. Detach the Velcro tab at the bottom of the Vest to ensure the zipper has been pulled all the way to the bottom and re-fasten the Velcro tab.
9. Pull the whole Vest down as far as possible and cinch the bottom drawstring for a snug fit – this will aid in preventing the Synchrony Vest from riding up.

**Step 4.** Create an immobilization device using an alpha cradle or vacuum bag following standard procedure. Use of the indexing table will facilitate patient setup.

**Step 5.** With the patient lying down on the table (supine or prone), cinch the mid-thoracic drawstring for a snug fit – this will prevent "tenting" of the Vest ensuring it follows the contour of the patient's body.

## CT/MR/PET Acquisition

Patients must wear the Synchrony Tracking Vest during pre-treatment scanning. Follow standard protocol guidelines for the appropriate pre-treatment scan for extracranial applications. Instruct the patient to breathe normally until acquiring the scan, at which time the patient must hold their breath at end of normal expiration. If the patient cannot hold their breath for the entire scan, ensure that one of the scan segments includes the entire target and the fiducials.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118 972

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



## Treatment Delivery Setup

**Step 1.** Mount the Fiber-Optic Interface Box under the head portion of the table top.

**Step 2.** Position the patient on the immobilization device in the approximate treatment position.

**Step 3.** Instruct the patient to relax and breathe normally.

**Step 4.** Evaluate the patient's breathing to identify the location of maximum body motion during respiration.

- In the supine position this is most typically the diaphragm area, but possibly the lower thoracic (for "chest breathers") area or the abdominal area (for "stomach breathers.")
- In the prone position this is most typically the thoracic area but can also be in the lumbar area.

**Step 5.** Apply the 3 Tracking Markers onto the white Velcro strips on the Synchrony Vest at the location of maximum body motion due to respiration.

**Step 6.** Connect the Tracking Marker Harness connector to Fiber-Optic Interface Box.

**Step 7.** Lower the camera so that it is directly in-line with the patient (not angled from the side of the patient) and is approximately 6-7 feet (2 meters) from the floor.

**Step 8.** Continue to adjust the position of the Tracking Markers and Camera Array until the Tracking Markers are visible by the Camera Array which is confirmed by very fast blinking action from each of the Markers. This can best be viewed by standing directly under the Camera Array looking at the Markers. (A good test is to place your hand in front of one of the three cameras in the Camera Array and compare the beams emanating from the Markers. When not seen by the Camera Array, the beams are steadily lit, when seen by the Camera Array the beams blink rapidly.) This can also be confirmed by reviewing the breathing waveforms displayed on the Synchrony PC (*see module, Synchrony.*)

**NOTE:** Keeping the camera low will reduce the incidence of the robot obscuring the Tracking Markers from the Camera Array.

**CAUTION:** Moving the Camera Array forward can increase the risk of potential robot collisions with the Camera Array.

**Step 9.** Evaluate the application of the Tracking Markers by reviewing the waveforms displayed and the correlation error values from the model created. (*see module, Synchrony.*)

- If the correlation error is close to 5 mm consider turning off a Marker or repositioning the Markers and/or Camera Array, rebuild the model and evaluate the correlation error maintaining it as close to 0 mm as possible.
- Watch the Markers through a couple of breathing cycles to ensure the Markers stay within view throughout the breathing cycle.

**Now the patient set-up is complete and fiducial identification can occur.**



973 Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



## Reassess Patient Positioning

**Step 1.** Reassess patient position after localization of the implanted fiducials on the acquired images.

**Step 2.** Ensure that the patient's anatomy does not exceed the anterior or superior limits as stated under Patient Setup Safety Considerations (*see section, Patient Setup Safety Considerations, page 3*). If the patient's anatomy exceeds the superior limit of 106 cm, consider scanning and treating FFS. If the patient's anatomy exceeds the anterior limit of 112 cm, every attempt should be made to reposition the patient so as not to exceed this limit. If this is not possible, it is recommended that the treatment paths are simulated using the teach pendant prior to treatment delivery.

# Acquire Treatment Planning Image Studies

**WARNING: Some scanners may orient patient data differently when the patient position is other than HFS. Image studies from scanners should not be used unless the correct orientation of the patient in the Treatment Planning System has been verified. Treatments based on incorrect oriented patient data can lead to death or injury of the patient.**

## CT Imaging Guidelines

1. Bring immobilization devices to CT to replicate setup for the CT scan
2. Basic CT parameters:
   - **a** IV Contrast may be used when indicated.
   - **b** Gantry angle = 0.
   - **c** Maximum 300 slices.
   - **d** kVp = 120 mAs = scanner maximum (minimum 400).
   - **e** Contiguous 1.0 - 1.5 mm slice thickness.

**NOTE:** Variable slice thickness is not supported.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



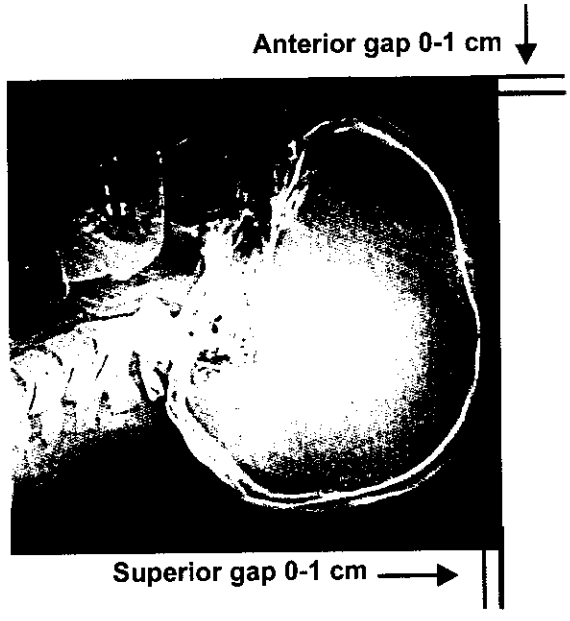



**Figure 8 Treatment Image**

3. CT rules for skull tracking studies:
   - **a** Set windows to soft tissue levels.
   - **b** Set Field of View (*Figure 8 Treatment Image, page 12*).
     - Patient must be centered laterally in the FOV.
     - FOV must include the chin and extend 0-1 cm superior past top of skull.
     - FOV must include the headrest and extend 0-1 cm anterior past the tip of nose.
4. CT rules for fiducial tracking:
   - **a** Set windows to bone levels.
   - **b** Set Field of View.
     - Patient must be centered L/R and ANT/POST in the FOV.
     - Tumor should be centered in the INF/SUP direction with a minimum 10-15 cm scanned in either direction.
     - FOV should include the entire patient circumference (use the largest field of view possible) - anatomy left out of scan will cause beams to be excluded by the TPS.
5. Push images to the Treatment Planning System:
   - **a** Send only AXIAL slices.
   - **b** Patient ID on CT must match the ID used in the CyberKnife System exactly.
     - Spaces and punctuation (dashes, slashes, commas, etc.) may not be used in the patient ID.



975 Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



## MRI Imaging Guidelines

1. Immobilization devices are not necessary
2. Basic MRI parameters:
   - **a** IV Contrast may be used when indicated.
   - **b** True AXIAL scan plane only (angle = 0).
   - **c** Maximum 300 slices.
   - **d** 512 x 512 square acquisition.
   - **e** Contiguous 1.0 - 3.0 mm slice thickness or volume scan.

   **NOTE:** Variable slice thickness is not supported.

3. MRI rules for intracranial studies:
   - **a** Set windows to visualize anatomy.
   - **b** Set Field of View to replicate CT.
     - Patient must be centered laterally in the FOV.
     - FOV must include the chin and extend 0-1 cm superior past top of skull.
     - FOV must include the headrest and extend 0-1 cm anterior past the tip of nose.
4. MRI rules for extracranial studies:
   - **a** Set windows to visualize anatomy.
   - **b** Set Field of View.
     - Patient must be centered L/R and ANT/POST in the FOV.
     - Tumor should be centered in the INF/SUP direction.
     - FOV should include the entire patient circumference.
5. Push images to the Treatment Planning System:
   - **a** Send only AXIAL slices.
   - **b** Patient ID on MRI must match the ID used in the CyberKnife® system exactly.
     - Spaces and punctuation (dashes, slashes, commas, etc.) may not be used in the patient ID.

   **NOTE:** When collecting images from more than one series, it is necessary to push the scans separately (Not necessary with SW Version 4.3.0.1 or later). The first scan must be imported prior to pushing the second scan to avoid combining the scans as one series.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118 976

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



## Attaching the Headrest to the CT Machine

Headrest orientation is critical to patient alignment and must be reproduced as closely as possible. You must record the orientation of the headrest after it is attached to the CT table and the patient, with head restraint, is securely positioned. Use the digital level to measure the orientation of both the long and short sides of the headrest.

Record the headrest orientation and duplicate it when you position the patient for treatment.

## Setting the CT Scanning Parameters

When CT scanning, place the patient in the supine position and scan head-first or feet-first. The position that the patient is scanned should be the same as the position you will use to treat the patient. The CyberKnife System does not support scans of patients positioned prone or on their sides. It supports Head-First Supine (HFS) and Feet-First Supine (FFS).

## Key DICOM Identifiers

You should refer to the CyberKnife DICOM Conformance Statement (Accuray P/N 19055) to understand fully how the CyberKnife System handles the import of DICOM images. One key identifier is used to classify imported DICOM data. All patient data is linked by a unique Medical ID. To maintain all image studies under one patient in the database, the images should all have the same Medical ID. If this is not possible, the AccuFusion program does allow you to fuse image studies assigned to different patient Medical IDs.

**NOTE:** Multiple series from the same image study will be linked together in the CyberKnife System database. If a study is to be done in multiple segments and then combined, they should have the same Image Study UID. Each segment can have a different Image Series UID.



977 Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



# FIDUCIAL PLACEMENT PRINCIPLES

In order to treat the patient with ease and accuracy, there are a few key principles that need to be taken into consideration when implanting the fiducial markers for patient treatments with the CyberKnife System. Sample fiducial configuration can be seen in *Figure 9 Example Configuration of 5 Fiducials, page 15.*

- Minimum of 2.0 cm distance between fiducials (max. distance 5-6 cm from lesion).
- Non-collinear placement (X-ray plane); Right Anterior Oblique (RAO)/Left Anterior Oblique (LAO) or Right Post-anterior Oblique (RPO)/Right Left-anterior Oblique (LPO) images acquired during patient treatments.
- A minimum 15 degree angle between any grouping of 3 fiducials should be used.

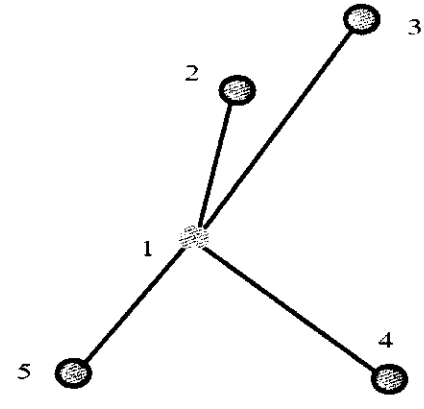



**Figure 9 Example Configuration of 5 Fiducials**

**NOTE:** You may find that some of the fiducials are unusable, for example due to any of the following reasons: (i) migration, (ii) close placement of fiducials - closer than 2.0 cm, i.e. fiducials 1,2, (iii) less than 15 degree angle between any set of 3 fiducials, i.e. fiducials 2,1,3. This type of fiducial placement adversely affects tumor localization and treatment accuracy. Fiducial placements that meet the requirements listed above are recommended so that the CyberKnife System can track and treat tumors with sub-millimetric accuracy.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118 

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



# Supplies

## Soft Tissue Supplies

**Figure 10 Gold Seeds, Biopsy Needle**

4 - 6 Gold seed fiducial markers (3 options)

- **Option 1**: Alpha Omega P/N SMG0242-025. 25 gold seeds/vial, 0.8 mm x 5 mm, packaged non-sterile. 19G thin walled biopsy needle, 10-11 or 15 cm length (*Figure 10 Gold Seeds, Biopsy Needle, page 16*)
- **Option 2**: Med-Tec P/N MT-NW-887-816. 3 gold seeds/package, 1.6 mm x 5 mm, packaged non-sterile.
- **Option 3**: Med-Tec P/N MT-NW-887-825. 3 - 17G needles preloaded with 1 gold seed marker per needle, 1.2 mm x 5 mm, sterile.

Needle aspiration kit and/or chest tube insertion kit (optional)

## Spine and Bone Supplies

- 4 - 6 stainless steel fiducial markers (*Figure 11 Stainless Steel Fiducial Markers, page 16*).

**Figure 11 Stainless Steel Fiducial Markers**



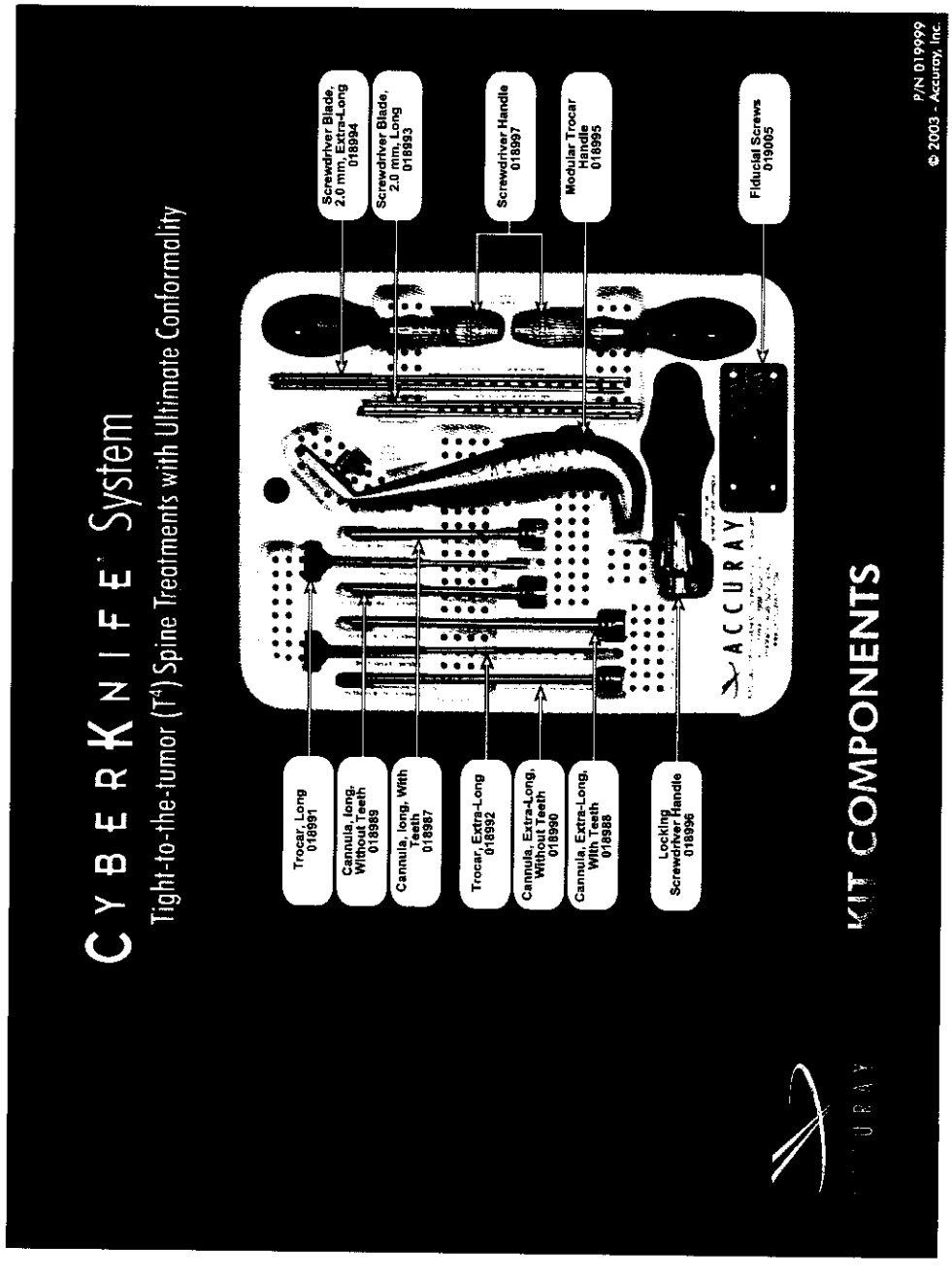
979 Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



- Accuray P/N 019005. Single screw/pk, 2.0 mm x 5 mm, packaged non-sterile.
- Accuray P/N 019006. 5 screws/pk, 2.0 mm x 5 mm, packaged non-sterile.
- Accuray P/N 019007. 10 screws/pk, 2.0 mm x 5 mm, packaged non-sterile.
- Fiducial instrument kit. Accuray P/N 018985. Non-sterile.

## Fiducial Kit for Spine






Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118 980

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



# Fiducial Placement Procedure

**NOTE:** Accuray does not make recommendations as to any particular fiducial placement procedure. The fiducial placement procedures presented here are developed by the medical professionals listed and are only presented here as guidelines.

## Post Placement Guidelines

For fiducials implanted for the treatment of spinal lesions, it is advised to wait 24-48 hours before acquiring the CT scan therefore enabling resolution of any localized pain or swelling. For soft tissue lesions, 1 week is recommended to allow adequate time thereby minimizing fiducial migration.

**NOTE:** It is imperative that the time between CT scanning and treatment delivery is kept to a minimum for soft tissue lesions; recommend time span is 24-48 hours. This will aid in reducing the incidence of fiducial extraction errors related to fiducial migration during treatment delivery.

## Lung

The treatment of lung lesions using the CyberKnife System requires the implantation of gold seeds referred to as fiducial markers. This outline reviews the procedure for placement of fiducial markers using a percutaneous approach with CT guidance. In order to track lesions in 6D (translational and rotational movements), a minimum of 3 fiducials are required for the software to track the lesion. It is recommended to place a minimum of 4 fiducials, 1 more then is required for tracking in 6D and no more than 6. This recommendation is based on a study of the tracking accuracy possible in the presence of uncertainties in fiducial localization both in the CT scan and live radiographic images. (*Murphy MJ Fiducial-based targeting accuracy for external-beam radiotherapy Med Phys 29(3) 334-344 (2002).*)

### Outline of Procedure

*Lung information provided by Stephen T. Kee M.D., Associate Professor of Interventional Radiology, Stanford University Medical Center.*

The fiducial placement procedure is very similar to a CT guided lung biopsy. Anyone who has experience with CT guided lung biopsies should be well aware of the methods employed and potential complications of the placement of needles in lung tissue. Perform the procedure utilizing the exact same methods used for a CT guided lung biopsy; the main difference being that once the needle is placed in the lesion, fiducials are implanted rather than taking tissue out. The complications and challenges are almost identical.

The first step is to obtain a detailed informed consent during which the patient is made aware of complications pertinent to placement of any needle within the lung, namely pneumothorax and hemorrhage. The incidence of pneumothorax with a single visceral pleural puncture is approximately 15-30%; this increases if multiple visceral punctures need to be performed. Hemorrhage can occur any time a needle is placed within the lung tissue resulting in hemoptysis.



981 Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



The patient is placed on the CT table in either the supine or prone position depending on the best approach to be used to access the lesion. The procedure is performed using conscious sedation and the patient should be monitored following hospital protocol for such a procedure. Images are acquired to locate the lesion and assess the approach and puncture site. The area is prepped using sterile technique and local anesthetic is injected at the intended puncture site. Under CT fluoroscopic guidance, the biopsy needle is advanced into the target lesion. The smallest gauge biopsy needle through which the gold seeds will fit should be used.

**NOTE:** The 19-gauge thin-wall needle is recommended for the Alpha Omega gold seeds. In our practice, an increased incidence of a pneumothorax using the larger gauge needle has been noted.

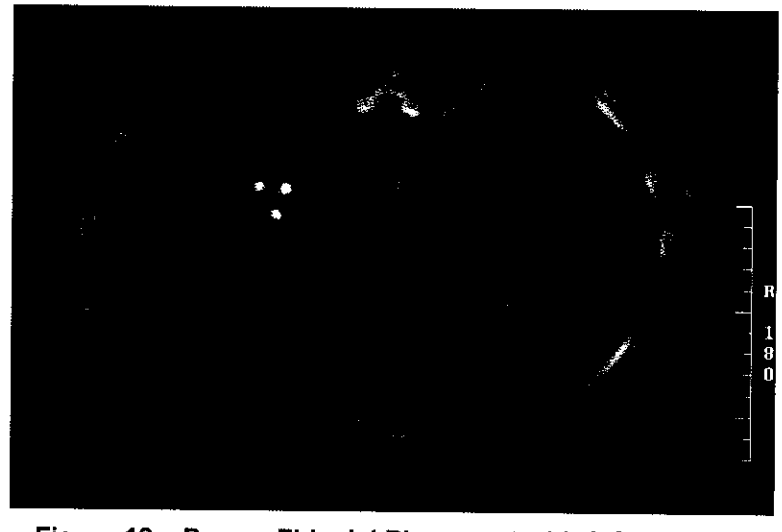



**Figure 12 Proper Fiducial Placement with 3 Gold Seeds**

When deciding what trajectory to use in order to place the needle within the lesion, the ideal route allows for placement of multiple fiducials within the lesion without having to puncture the visceral pleural multiple times. There is a significantly lower incidence of pneumothorax should the visceral pleura be transversed once rather than multiple times. When placing the needle within the lesion attempt to advance the needle to the back wall of the lesion and place the first fiducial in this location. Withdraw the needle from the initial fiducial placed, verify with imaging then implant the second fiducial. Angle the needle medial or lateral for placement of the other fiducials repeating the process described above on the opposing side of the lesion. Whenever possible, every attempt should be used to place the fiducials within the lesion as long as the fiducial placement guidelines are met (*Figure 12 Proper Fiducial Placement with 3 Gold Seeds, page 19*). CT scanning can be used to verify proper fiducial placement. Image patient at the end of the procedure to assess for complications. Obtain a chest X-ray 3 hours after the procedure to ensure no late onset of pneumothorax.

**NOTE:** Most lung lesions measure 3-5 cm in diameter making it possible to place 4-6 fiducials within the lesion with a single visceral puncture. In an extremely large lesion, it may be necessary to place multiple needles within the lesion to achieve adequate positioning of the fiducials.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118 982

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



## Potential Complications

Pneumothorax - occurs in approximately a 30% of all biopsy cases; less than 10% require treatment. A small pneumothorax can be observed and if stable in size requires no further treatment. A pneumothorax greater than 20-30% requires either aspiration or placement of a chest tube. Aspiration of air from a pneumothorax can be done through a sheathed needle while the patient is still on the CT table. Placement of a chest tube usually requires the patient to be supine and is often performed after the post-procedure chest X-ray. In our experience at Stanford, placement of a chest tube has been required in a minimum of cases, less than 5%. Should a chest tube be required, this usually requires an overnight admission to a step down unit with continuous wall suction. A chest X-ray is performed the next day. If the pneumothorax be resolved and stable, the patient is discharged.

Hemoptysis - occurs in approximately 10-50% of cases whenever a needle is introduced into the lung. It is less common in patients who do not have a biopsy, therefore, it is rarely observed with fiducial placement procedures. Prior to the procedure evaluate if the patient is taking anti-coagulants. Should hemoptysis occur, the major concern is the patient's alarm at seeing that they are coughing up blood. Typically this complication ceases spontaneously due to the low blood pressure within the pulmonary arteries. It is usually not life threatening. It is important to adequately inform the patient during consent and remain calm while rendering the appropriate supportive care.

## Points To Consider

The major downside with performing fiducial placement in the lung is the difficulty of obtaining a good trajectory to place the needle within the lesion while taking into consideration the surrounding anatomy, i.e. ribcage. Anyone who has performed multiple lung biopsies should be able to adequately guide the placement of a needle into the lesion without great difficulty. CT and CT fluoroscopic guidance is recommended for the placement of fiducials as it allows for better visualization of the entire lung and lesion and enables the operator to rapidly identify complications during the procedure.

If a pneumothorax should develop during the procedure attempt to complete the fiducial placement procedure if at all possible. It may be necessary to place a chest tube during the procedure to re-inflate the lung. If the patient is stable and can tolerate it, the procedure should be resumed and completed. Should a pneumothorax develop during the placement of the first needle consider leaving it in place and introduce a second needle into the lesion to complete the procedure.

Another point to consider is the often used statement that "the enemy of good is perfect". During the procedure the goal is to get multiple fiducials placed into the lesion in the best locations. It is not absolutely necessary to get 5 fiducials in the most perfect place within the lesion to treat the patient. Placement of 3 fiducials within or adjacent to a tumor will be sufficient to track and treat the patient. Therefore, should the procedure become more complicated than expected, or should the patient become unable to tolerate a long procedure rapidly placing 3 fiducials, adhering to the fiducial placement principles, in and around the tumor should be adequate in most cases.

There is always the possibility of placing a fiducial within a significant sized pulmonary vein which could become a serious complication as it may travel and become lodged in the heart, lungs or brain. This has not occurred but is possible therefore, it is mentioned in this section. It is important to include this as a potential complication when obtaining patient consent. Documentation of the discussion between the physician, patient and preferably a relative is recommended.

## Conclusion

The key to success is to adequately inform the patient, perform the procedure with caution using the standard approach for needle biopsies, be prepared for potential complications and be familiarized with the fiducial placement principles.



983 Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



# Pancreas/Liver

*Pancreas and Liver information provided by Stephen T. Kee M.D., Associate Professor of Interventional Radiology, Stanford University Medical Center.*

## Outline of Procedure

The risks of the procedure are essentially identical to those of an image guided biopsy, however, depending upon the number of needle repositions required in order to adequately place the fiducials these risks may be somewhat higher. Most of the risks associated with placement of needles in soft tissues is hemorrhage, these risks are kept to a minimum if a single needle puncture can be used in order to place multiple fiducials and if adequate imaging is obtained prior to the procedure in order to identify potential hazards. A detailed informed consent outlining the potential complications to the patient should be the first step.

The diagnostic imaging technique of choice is CT or CT-fluoroscopy, however, other operators have performed this procedure using ultrasound guidance and this is quite feasible particularly for large lesions. If the patient is considered a candidate for treatment with the CyberKnife System while in the operating room, placement of the fiducial markers using direct visualization could be an option.

The patient is placed on the CT table in either the supine or prone position depending on the best approach to be used to access the lesion. The procedure is performed using conscious sedation and the patient should be monitored following hospital protocol for such a procedure. Images are acquired to locate the lesion and assess the approach and puncture site. The area is prepped using sterile technique and local anesthetic is injected at the intended puncture site. Under CT guidance, the biopsy needle is advanced into the target lesion. The smallest gauge biopsy needle through which the gold seeds will fit should be used.

**NOTE:** The 19-gauge thin-wall needle is recommended for the Alpha Omega gold seeds. When deciding what trajectory to use in order to place the needle within the lesion, the ideal route allows for placement of multiple fiducials within the lesion without having to reposition the needle multiple times. There is a significantly lower incidence of hemorrhage should the organ involved be transversed once rather than multiple times. When placing the needle within the lesion attempt to advance the needle to the back wall of the lesion and place the first fiducial in this location. Withdraw the needle from the initial fiducial placed, verify with imaging then implant the second fiducial.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118 984

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015

**Figure 13 Proper Fiducial Placement with 4 Gold Seeds**

Angle the needle medial or lateral for placement of the other fiducials repeating the process described above on the opposing side (or wall) of the lesion. Whenever possible, every attempt should be used to 4-6 fiducials within the lesion as long as the fiducial placement guidelines are met (*Figure 13 Proper Fiducial Placement with 4 Gold Seeds, page 22*). This can prove to be challenging with lesions less than 3 cm in diameter. With smaller lesions, it is acceptable to place fiducials in the organ tissue surrounding the lesion. CT scanning should be used frequently to verify proper fiducial placement.

## Potential Complications

Hemorrhage is the most likely complication when puncturing the liver, pancreas and other soft tissue regions in the body. Use of a small, gauge needle and knowledge of critical structures surrounding the lesion should minimize this complication. Should the concern of hemorrhage be present for whatever reason following placement of the last fiducial, a small amount of gel-foam slurry can be injected into the needle as it is being removed to immobilize the track. The gel-foam slurry is created by cutting up small amounts of gel-foam, mixing with either saline or lidocaine.

Transgression of a section of bowel when advancing the needle towards a lesion particularly for pancreatic lesions is a possibility. There are usually no necessary precautions to be taken if the stomach or small bowel is to be transgressed, however, if the large bowel is transgressed then it is recommended to place the patient on broad spectrum antibiotics for one week. Every attempt should be made to avoid puncturing these structures especially the large bowel.

Another potential complication is immobilization of fiducials to a distal site. In theory, placement of a fiducial in a significant artery could result in distal immobilization. This has not occurred in our practice but warrants mention in this paper. If there is significant arterial flow through the needle upon removal of the stylet placement of a fiducial at this location is not recommended instead, remove the needle, assess the patient's condition and if stable proceed by selecting another location to place the fiducial.



985 Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



### Points To Consider

Typically, during placement of fiducials in pancreatic lesions the imaging does not include administration of intravenous contrast. Therefore, the contrast study from the patient's previous imaging should be studied to ensure that no significant vessels will be transgressed with the placement of the needle and fiducials. If there are any doubts, a contrast CT study should be performed during placement. There are some situations in which structures must be transgressed to access the lesion for fiducial placement. In our practice, the preference is to cross "nothing" first, stomach second, liver third, small bowel fourth and large bowel as an extreme last resort. As stated above, if the large bowel is punctured the patient should be administered antibiotics.

### Conclusion

The fiducial placement procedure is very similar and only slightly more elaborate than a standard image guided biopsy. Anyone who has experience with CT guided biopsies should be well aware of the methods employed and potential complications of the placement of needles in soft tissue organs such as the pancreas and liver. Perform the procedure utilizing the same methods used for an image guided biopsy, the main difference being that once the needle is placed in the lesion, fiducials are implanted rather than taking tissue out. The complications and challenges are almost identical. The key to success is to adequately inform the patient, perform the procedure with caution using the standard approach for needle biopsies, be prepared for potential complications and be familiarized with the fiducial placement principle.

## Cleaning and Sterilization

### Sterility

Implantable screw radiographic markers are supplied non-sterile and must be sterilized prior to use.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015





987

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



# Patient Data & Image Administration

## Table of Contents

**Patient Data Administration** ..... 1
- Add New Patient Data ..... 1
- Discontinue Patient Data ..... 4
- Review Patient Treatment ..... 5
- Discontinue Treatment Plan ..... 8
- Archive Patient Database ..... 9
  - Errors ..... 13
- Restore Patient Database ..... 14

**Patient Image Administration** ..... 17
- Medical Image Review and Import Tool ..... 17
- Adding New Images ..... 18
- Review and Load Images to the Database ..... 19
  - Couch Position ..... 20
  - Patient Image ..... 21
  - Phantom Image ..... 23
  - Load Images from Tape ..... 23
  - Delete Image Before Import to Patient Database ..... 23
- Export Data from the CyberKnife User Control Console ..... 24
  - CT Image Study ..... 24
  - Other Studies ..... 25
- Deleting Images ..... 25
- Reloading Images for Incomplete Loaded Images ..... 26



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118 988

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015





989

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



# PATIENT DATA AND IMAGE ADMINISTRATION

## PATIENT DATA ADMINISTRATION

This section describes how to do the following:

1. Add new patient data
2. Discontinue the use of patient data
3. Review patient data

### Add New Patient Data

**NOTE:** New patients are automatically added to the patient database when the patient's first medical image is loaded. Manual creation of a patient is optional and usually unnecessary.

**CyberKnife® System Menu -> Patients -> Add New Patient ->Patient**

**To add new patient data:**

**Step 1.** Click the **PATIENTS** button from the CyberKnife System menu, the Patients window appears (*Figure 1 Patient List, page 2*).



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118 990

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015

**Figure 1 Patient List**

**Step 2.** Click **ADD PATIENT** in the patients window. The Add New Patient window (*Figure 2 Add New Patient, page 2*) appears.

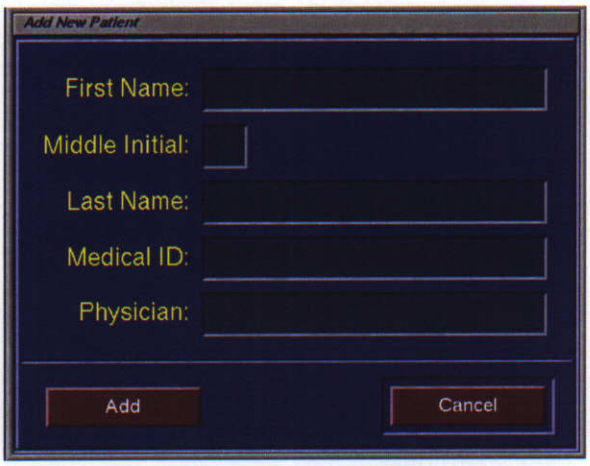



**Figure 2 Add New Patient**

**Step 3.** Move the cursor to the text fields and fill in the appropriate information. The patient's **Medical ID** must match that used for the CT.

To move back to any previously entered field, press <Enter> several times until the desired field is highlighted with the yellow box. Data entered with leading, embedded, or trailing blanks is stripped by the CyberKnife software and stored in the system without the extra blank spaces. For example: Type: 12 34 56 in the **Medical ID** field. When stripped and stored, **Medical ID** becomes 123456.

**Step 4.** After you type the text and check for accuracy, click **ADD**. The message "Updating database. Please wait" is displayed in a Status Message window (*Figure 3 Updating Database Wait Message, page 3*).



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

991

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015

**Figure 3 Updating Database Wait Message**

**Step 5.** When the information is stored in the database, the message, "A new entry has been added to the database." is displayed (*Figure 4 New Patient Added Status Message, page 3*). To continue, click **OK** in the message window and the Add New Patient window reappears.

**Figure 4 New Patient Added Status Message**

**Step 6.** Repeat the steps to add more patients.

**Step 7.** To return to the CyberKnife System menu, click **CANCEL**.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

992 pp

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



# Discontinue Patient Data

Patient data can be discontinued or deleted when the patient does not need more treatment. Discontinued patient data is handled differently depending on the status of the patient. If a patient was never treated with the CyberKnife System, the patient data is completely deleted from the database. If a patient was treated, the patient data is marked as *discontinued* in the database, which means no one can work on this patient anymore, but the data is not deleted from the database. To reclaim the disk space of this discontinued patient data, you must archive it to tape (*see section, Archive Patient Database, page 9*).

**CyberKnife System Menu -> Patients -> Confirmation Message**

**To discontinue patient data:**

**Step 1.** Click **PATIENTS** from the CyberKnife System menu. The Patients window appears.

**Step 2.** Select the patient's name from the list and the **DISCONTINUE** button becomes active.

**Step 3.** Click **DISCONTINUE**. The Confirmation Message (*Figure 5 Discontinue Patient Confirmation Message, page 4*) appears. The Confirmation Message asks you to confirm discontinuance of the patient data.

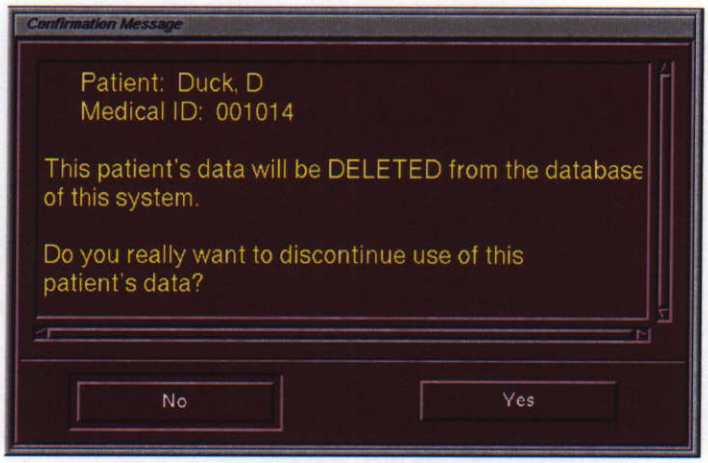



**Figure 5 Discontinue Patient Confirmation Message**

**Step 4.** Click **YES** to discontinue the patient data. The confirmation message disappears and the message "Updating database. Please wait." appears.

**CAUTION:** Once the patient is discontinued, the patient cannot be used again.

**Step 5.** Click **OK** in the Status Message, when the message "Database update successful. Patient data can no longer be used." appears and the Patient window returns.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

993

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



# Review Patient Treatment

The CyberKnife System allows you to review the patient's treatment history of each site, plan and plan fractions.

**CyberKnife System Menu -> Patients -> Review Treatment Sites -> Review Treatment Plans -> Review Plan Usage**

**To review patient treatment:**

**Step 1.** Click the **PATIENTS** button from the CyberKnife System menu. The Patients window appears.

**Step 2.** Select the desired patient's name from the patients list. The **REVIEW** button becomes activated.

**Step 3.** Click the **REVIEW** button. If data is available, the Review Treatment Sites window appears (*Figure 6 Review Treatment Sites, page 5*). If no data is available, a status message (*Figure 7 No Treatment Data Status Message, page 5*) appears informing you that the selected patient has no data. Click **OK** to return to the Patients window.

The Review Treatment Sites window displays a list of the patient's sites. The name of the site, indication of the treatment status, date last treated, amount of radiation delivered and the prescribed dose appear in the window.

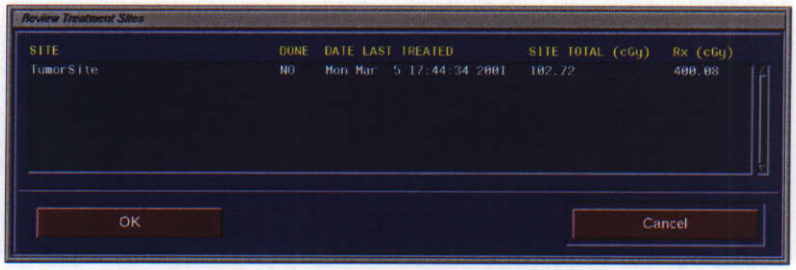



**Figure 6 Review Treatment Sites**

**Figure 7 No Treatment Data Status Message**



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

994

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



### To review the treatment plan history

Select the site name in the Review Treatment Sites window. The Review Treatment Sites window disappears and the Review Treatment Plans window (*Figure 8 Review Treatment Plans, page 6*) appears. Click **CANCEL** to return the Patients window.

The Review Treatment Plans window displays a list of the patient's plans. The name of the plan, plan treatment status, date last used and prescription radiation dose are given. If the plan is not complete, you can discontinue the plan in the Review Plan Usage window (*Figure 9 Review Plan Usage, page 7*).

**Figure 8 Review Treatment Plans**

### To review plan fraction history

Select the treatment plan name in Review Treatment Plans. The Review Plan Usage window appears. Click **CANCEL** to redisplay the Review Treatment Sites window.

The Review Plan Usage window shows the treatment history of the specified plan. The text areas in this display show plan information. The **DISCONTINUE PLAN** button is active if the plan has not gone through the full course of treatment. The **DISCONTINUE PLAN** button allows you to discontinue use of the selected plan.

Each text area of the Review Plan Usage window is explained below.

- **Plan Selected**: Name of the treatment plan.
- **Rx (cGy)**: Total prescribed dose of this plan in cGy.
- **Number of Fractions**: The number of fractions for this plan.
- **Dose Per Fraction**: Dose for a fraction in cGy.
- **Plan Dose (cGy) Delivered**: Total radiation delivered using this plan in cGy.
- **Plan Dose (cGy) Remaining**: Total remaining radiation to be delivered for this plan in cGy.
- **Fractions Remaining Full**: The number of remaining full fractions.
- **Fractions Remaining Makeup**: The number of remaining makeup fractions (*see module, Treatment, section, Makeup Fractions*).



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

995

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015

**Figure 9 Review Plan Usage**

The following is a list of information shown in the plan's Fraction History:

- **Fraction No.**: The fraction number.
- **Date Used**: The date and time this fraction was delivered.
- **Aborted**: The status of the fraction. If it has been aborted, YES is displayed; if not, NO is displayed.
- **Delivered**: Dose delivered for this fraction.

The following is a list of information shown in the plan's Makeup Fraction History:

- **Makeup Fraction**: The name of the makeup plan.
- **Date Made or Used**: The date and time this makeup fraction was created, if the dose delivered is zero. If the makeup fraction were used, the dose delivered would be greater than zero and the date and time would indicate when the makeup was last used.
- **Delivered**: Dose delivered for this makeup fraction.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

996

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



# Discontinue Treatment Plan

At the review plan usage window, you can discontinue use of a plan that has not finished the full course of treatment.

**CyberKnife System Menu -> Patients -> Review Treatment Sites -> Review Treatment Plans -> Review Plan Usage**

**To discontinue the treatment plan:**

**Step 1.** Follow the sequence to get to the Review Plan Usage window (*Figure 9 Review Plan Usage, page 7*).

**Step 2.** Click **DISCONTINUE PLAN** the confirmation message (*Figure 10 Discontinue Plan Confirmation Message, page 8*) appears. It displays the Plan, Site, Patient name, Medical ID information and the message "Do you really want to discontinue the use of this plan?"

**Step 3.** Click **YES** to discontinue the plan.

**CAUTION:** Once you discontinue the plan, the plan cannot be used again.

**Step 4.** Click **NO** to cancel discontinuation. The Review Plan Usage window is redisplayed and the confirmation message disappears.

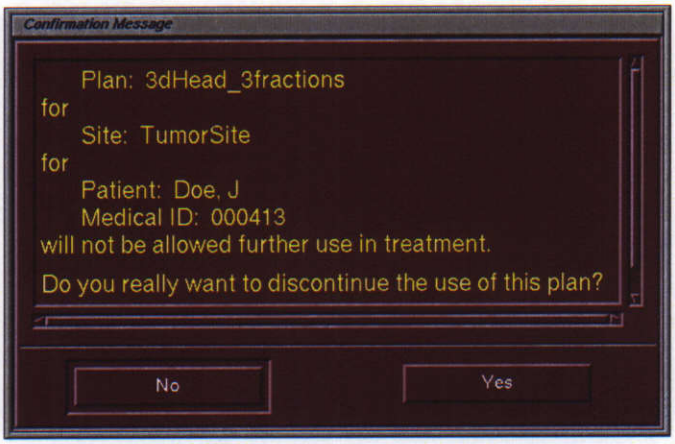



**Figure 10 Discontinue Plan Confirmation Message**



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

997

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



# Archive Patient Database

You can archive selected patient database to a 12 GB 4mm digital audio tape (DAT). If the database exceeds 12 GB, use several tapes. The patient database includes image sets, digitally reconstructed radiographs, treatment plans and treatment history data. Archiving unused data frees disk space by transferring a single patient's data to the archive tape. The archived data can be restored (*see section, Restore Patient Database, page 14*).

**CyberKnife System Menu -> Administration -> Archive -> Patients -> Patient Verification -> Archive Status Message**

**To archive the patient's database:**

**Step 1.** Pull down the **Administration** menu bar from the CyberKnife System menu (*Figure 11 CyberKnife System Menu, Administrative Submenu, page 9*).

**Step 2.** Click **ARCHIVE** from the menu bar. The Loading Process window is displayed with the message "Loading process. Please wait."

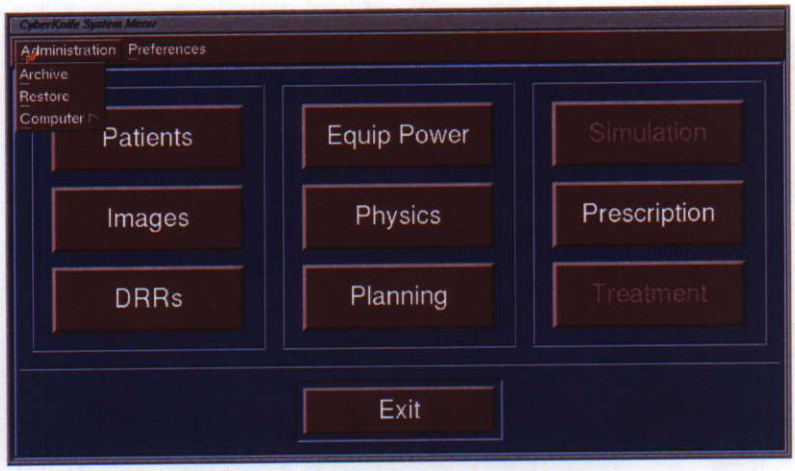



**Figure 11 CyberKnife System Menu, Administrative Submenu**

**Step 3.** When the archiving process is ready, the Patients window (*Figure 12 Archive Patients, page 10*) appears. Click **CANCEL** to return to the CyberKnife System menu.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



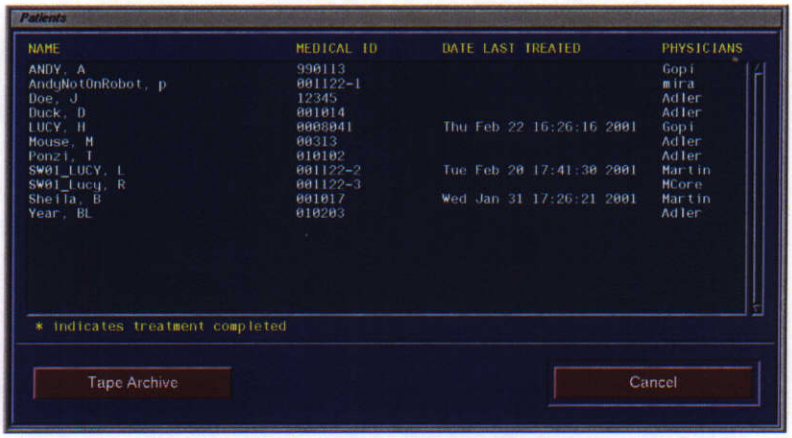



**Figure 12 Archive Patients**

**Step 4.** The Patients window shows a list of patients whose data can be archived. An "*" by a patient's name indicates that the patient record has been discontinued.

**Step 5.** Select the patient to be archived. The selected names will be highlighted.

**Step 6.** Click **TAPE ARCHIVE**. The Patient Verification window (*Figure 13 Archive Patient Verification, page 10*) appears.

**Figure 13 Archive Patient Verification**

**Step 7.** Review the patient information.

**Step 8.** If it is correct and you want to archive the patient's database, select the **PATIENT NAME CONFIRMATION** button. This action activates the **MEDICAL ID** button and deactivates the **Patient Name**.

**Step 9.** Confirm that the **Medical ID** is correct. When selected, the **MEDICAL ID** button becomes inactive and the **CONTINUE** button becomes active.

**Step 10.** Click **CONTINUE** to archive. The Archive Status Message appears. Clicking **CANCEL** discontinues the archive process. The Patients window appears.

**NOTE:** Cancel is always active.



999

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



### Write to the tape

**Step 1.** When the Archive Status message (*Figure 14 Archive Patient Tape Status Message, page 11*) appears, a message instructs you to insert a blank 12 GB 4mm DAT into the tape drive.

**NOTE:** Any data on the tape will be overwritten.

**Step 2.** Make sure the write protect feature of the tape is in the off position. Consult the tape manufacturer's instructions for turning off the write protect feature.

**Figure 14 Archive Patient Tape Status Message**

**Step 3.** After the tape is in the tape drive, select CONTINUE. The Archive Message (*Figure 15 Checking Tape Archive Status Message, page 11*) appears. CANCEL discontinues the archiving. The Patient Verification window returns.

When the Archive Message appears, the archiving has started. The archiving process checks if the tape is in the tape drive and if there is any data on it, including other patients' archived data.

**Figure 15 Checking Tape Archive Status Message**

**CAUTION:** Make sure you want to discard any data already on the tape. Once a decision is made to write over existing data, you cannot recover that data

When the tape has been checked, the Tape Status message appears (*Figure 16 Initial Archive Tape Status, page 12 and Figure 17 Continue Archive Tape Status Message, page 12*). The archiving process is now writing to the tape.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

1000

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015

**Figure 16 Initial Archive Tape Status**

**Figure 17 Continue Archive Tape Status Message**

**Step 4.** A message in the Archive Status message window informs you that archiving is complete (*Figure 18 Archive Completion Message, page 13*). The selected patient's database is removed from the main disk of the console computer.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

1001

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



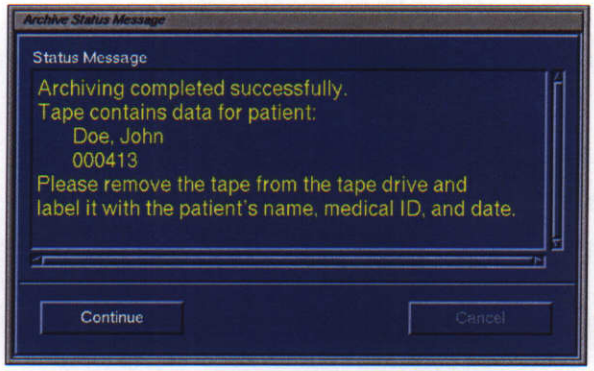



**Figure 18 Archive Completion Message**

**Step 5.** Click **CONTINUE** to return to the Archive Patients window.

**Step 6.** After successful archiving, remove the tape from the tape drive. Set the write protect tab and clearly label the tape. Do not subject tapes to extremes of temperature and humidity and keep tapes away from strong electromagnetic fields. For long-term storage, you should re-copy magnetic tapes every year to year-and-a-half to prevent data loss through deterioration.

**NOTE:** If problems occur while transferring data to tape, clean the tape drive head with a standard cleaning tape. To avoid problems due to a dirty tape drive head, clean the tape drive once a month.

## Errors

If there are any discrepancies during the archive process, the Archive Error Message (*Figure 19 Archive Error Message, page 13*) appears. Self-explanatory messages are displayed in the Archive Error Message to help you correct the problem and **CONTINUE** or **CANCEL** the archive.

**Figure 19 Archive Error Message**



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

1002

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



# Restore Patient Database

Restores archived patient data to the CyberKnife System Main database from tape.

**CyberKnife System Menu -> Administration -> Restore -> Patients -> Patient Verification -> Restore Status**

**To restore the patient's database:**

**Step 1.** Pull down the Administration menu from the CyberKnife System menu (*Figure 11 CyberKnife System Menu, Administrative Submenu, page 9*).

**Step 2.** Click **RESTORE**. The Loading Process window displays the message "Loading process. Please wait."

**Step 3.** When the restoring process is ready, the Archived Patients window (*Figure 20 Restore Archived Patients, page 14*) appears.

**Step 4.** **CANCEL** displays the CyberKnife System menu.

The Archived Patients window lists patients whose data can be restored. An "*" by a patient's name indicates that the patient record has been discontinued.

**Figure 20 Restore Archived Patients**



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

1003

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



**To accept patient data for restoring:**

1. Select the desired patient's name in the Archived Patients list.
2. Click **RESTORE FROM TAPE**. The Patient Verification window (*Figure 20 Restore Archived Patients, page 14*) appears.

**Figure 21 Restore Patient Verification**

3. Review the patient information. The **PATIENT NAME** button is active.
4. Confirm that the **Patient Name** is correct. The **MEDICAL ID** button becomes active and the **PATIENT NAME** button becomes inactive.
5. Confirm that the **Medical ID** is correct. The **MEDICAL ID** button becomes inactive and the **CONTINUE** button becomes active.
6. Click **CONTINUE** to continue with the restoration procedure. The Restore Status window (*Figure 22 Restore Status Message, page 15*) appears.
7. Click **CANCEL** to discontinue. The Patients window appears.

**NOTE:** The **CANCEL** button is always active.

**Figure 22 Restore Status Message**



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



**To restore patient's database:**

**Step 1.** When the Restore Status window appears (*Figure 22 Restore Status Message, page 15*), a message instructs you to insert an archived patient tape into the tape drive. Make sure the write protect feature of the tape is off. Consult the tape manufacturer's instruction for turning off the write protect feature.

**Step 2.** Click **CONTINUE** to restore the patient's database to the console computer's main hard disk.

**Step 3.** Click **CANCEL** to discontinue restoring. The Patient Verification window returns.

**Step 4.** When restoration is complete, the "Restore completed successfully" message appears.

**Step 5.** Click **CONTINUE** to return to the Archived Patients window.

**Errors**

If the restoration process has discrepancies, the Restore Error message appears (*Figure 19 Archive Error Message, page 13*). Self-explanatory messages in this window help you correct the problem and continue or completely cancel the archive.

**NOTE:** After restoring the patient data, remove the tape from the tape drive and remove the patient labeling from the tape. The tape is reusable.



1005 Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



# PATIENT IMAGE ADMINISTRATION

This section shows you how to add new patient and phantom images, remove an image and reload an existing patient's image.

The CyberKnife System recognizes two input image sources in DICOM standard format. The first one is a digital audio tape (DAT) and the other is a DICOM network communication.

If the user site has a network system, a customized network version must be installed. Contact Accuray to discuss specifications. The recommended format of image that will be transferred via network is DICOM standard format.

## Medical Image Review and Import Tool

Click **IMAGES** from the CyberKnife Systems menu (*Figure 11 CyberKnife System Menu, Administrative Submenu, page 9*). The Medical Image Review and Import Tool (*Figure 23 MIRIT Main Screen, page 17*) will open. If a medical image has been exported to the CyberKnife System since the last time MIRIT was opened, the timer (*Figure 24 Import Images to CyberKnife, page 18*) will appear, while the imported images are sorted by patient and modality.

**NOTE:** If two or more image studies for the same patient with the same modality are going to be imported, you must import one image study to the database first. Then exit MIRIT and restart Images to load each study one at a time.

**Figure 23 MIRIT Main Screen**



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

1006

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015

**Figure 24 Import Images to CyberKnife**

## Adding New Images

Use MIRIT to add Medical Images to the patient database. You can add images as either a patient or a phantom. Each phantom image in the database must be associated with a specific patient image. A patient, on the other hand, does not need an associated phantom image.

**NOTE:** The patient image must be entered first. A phantom image must be associated with a patient.

Click **SELECTION**. The Patient Selection Dialog (*Figure 25 Load Image Selection, page 18*) will appear. This interface has four options:

1. **OK** load an image into the user interface.
2. **DELETE** highlight an image and delete the image from the CyberKnife System.
3. **SPLIT** highlight an image with multiple series and split them into multiple studies.
4. **LOAD TAPE** load an image transferred to the system via tape media.
5. **CANCEL** cancel the selection.

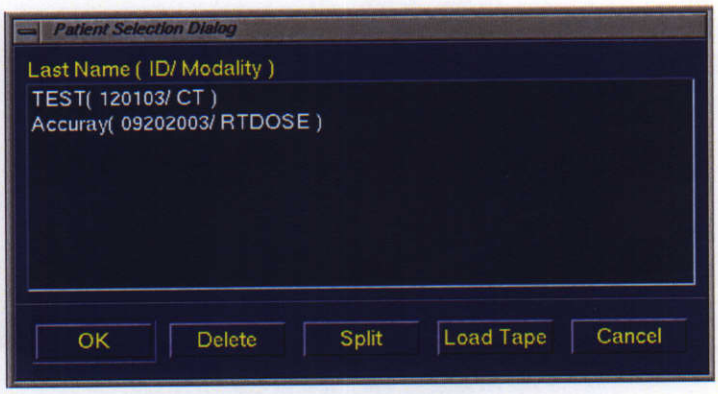



**Figure 25 Load Image Selection**

**NOTE:** If an image study has multiple series, the default import operation will combine these multiple series as one case (study) in the patient database. Using **SPLIT** allows you the option to import multiple seeries as multiple cases (studies) in the patient database.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

1007

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



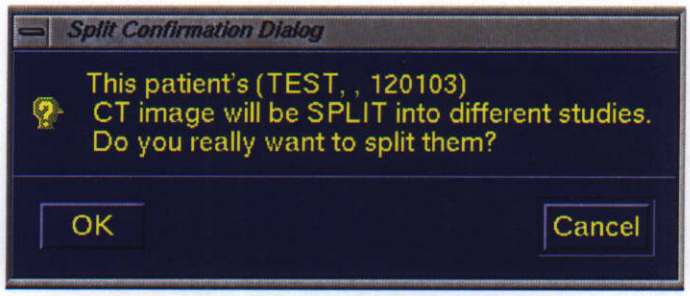



**Figure 26 Split Confirmation Dialog**

Typically, multiple series from the time the study is combined can be split into multiple studies if they represent non-contiguous anatomy.

## Review and Load Images to the Database

After the patient image is loaded, you can review the image. Images are sorted to preselect images to import and delete before importing into the database. Images are deleted if they are repeated positions or if they are scout images. Lists of images to import and images to delete are on the bottom of the display. The lists sort the image by the z-position of the slice. You can scan through the images to determine what to delete and what to import. Highlight the scan to move and use the arrow buttons to delete or retain image. The display has two image windows to help you review the image study.

The image window on the left has the axial slice data. A sagittal or coronal reconstruction of the patient image appears in the window on the right. You can toggle between sagittal and coronal with the buttons between the two image windows. In each window, you can change the view plane by dragging the cursor up or down in the window. You can select the axial slice to display by clicking the cursor in the reconstructed image, dragging the cursor left or right through the reconstructed image or highlighting the slice in the Image Import or Image Delete list.

If this is the first image imported for the patient, you can edit the patient name. You can modify the physician name anytime an image is loaded. Each patient must have a first name, last name and physician.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



## Couch Position

The average couch position separation is used to determine the distance between slices for planning and DRR generation.

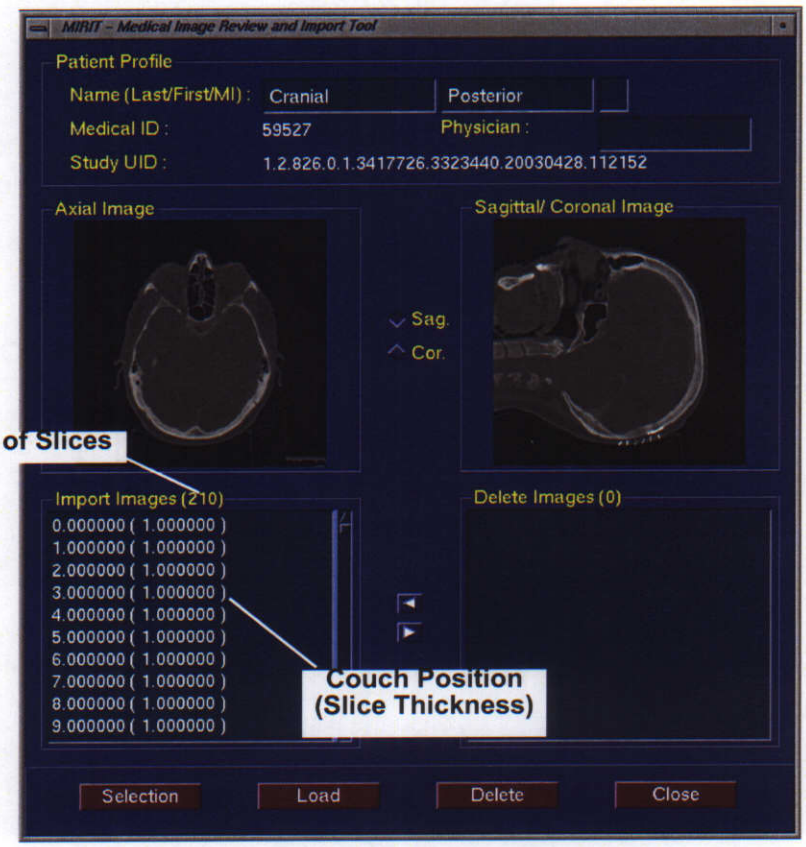



**Figure 27 Image Review**



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

1009

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



Once you are satisfied that the Image Study is correct, click on **LOAD** Button to load the image. The confirmation (*Figure 28 Image Import Confirmation, page 21*) will appear. Select whether the image should be loaded as a phantom or a patient. Click **OK** to load or **CANCEL**.

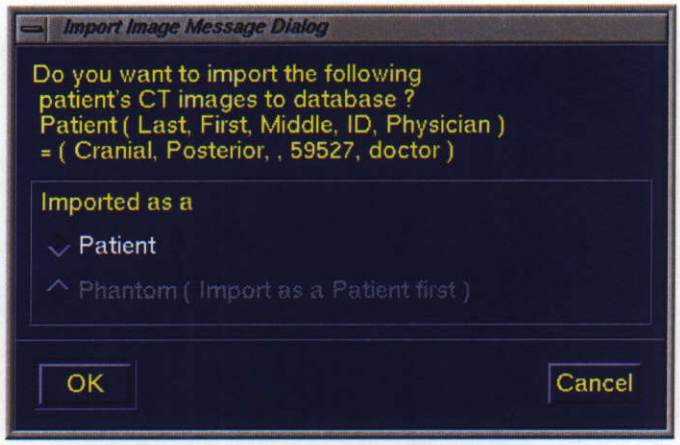



**Figure 28 Image Import Confirmation**

## Patient Image

The system will attempt to load the image to the patient database. A confirmation (*Figure 30 Successful Image Load, page 22*) or an error message (*Figure 31 Image Import Error Message, page 22*) will appear. Images will fail to load due to the following errors.

- Unacceptable patient or physician name
- Variable slice thickness, pixel size
- Study has skipped slices
- Essential DICOM header information is missing, such as patient position, rescale intercept/ slope for CT and PET
- A CT Study has a tilt angle other than zero
- Image with the same Study UID already loaded
- New scanner for CyberKnife System
- Repeated couch position
- Number of slices is over 300
- Slice thickness is not in the range, i.e, max (6 mm) and min (0.5 mm)
- Scout image

**NOTE:** The corresponding DICOM RT Structure Set is imported.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

1010

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



**NOTE:** If no image series have the same study UID, you must split those series in order to import both to the patient database.

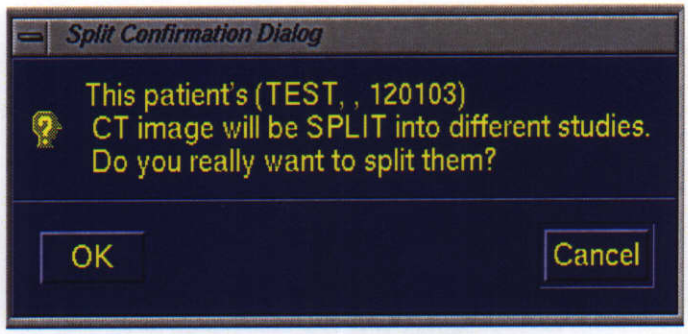



**Figure 29 Split Confirmation**

**NOTE:** Image studies are automatically named. The name is based on a time stamp of when the image was loaded to the CyberKnife patient database. The convention for names of an image study is: caseYYYY.MM.DD.HH.MM.SS, where YYYY is the year, MM is the month, DD is the day, HH is the hour, MM is the minute and SS is seconds.

**Figure 30 Successful Image Load**

**Figure 31 Image Import Error Message**



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

1011

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



## Phantom Image

A phantom image must be associated with a previously loaded patient image. Therefore, when the image to load is a phantom, you will have to select an associated patient image from the list in the case selection dialog (*Figure 32 Case Selection for Phantom Image Load, page 23*) before the phantom image is loaded to the database. The image load will then proceed in the same way as patient image load.

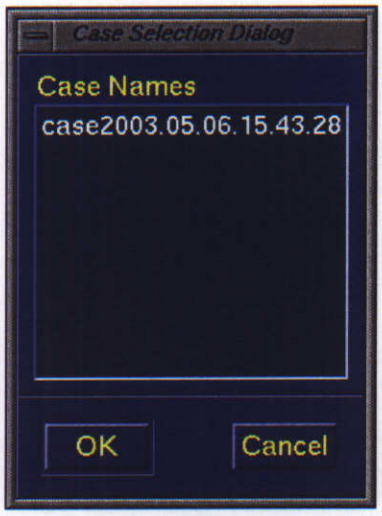



**Figure 32 Case Selection for Phantom Image Load**

## Load Images from Tape

If you have transferred the image via tape rather than a local area network. Click **LOAD TAPE**. The computer will transfer the images on tape to the temporary database and sort them by Medical ID and modality. The exported image will then appear (*Figure 25 Load Image Selection, page 18*). Continue to load the image as described in *section, Review and Load Images to the Database, page 19*.

## Delete Image Before Import to Patient Database

If you cannot or do not want load an image study listed (*Figure 25 Load Image Selection, page 18*), highlight the study and click **DELETE**.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

1012

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



# Export Data from the CyberKnife User Control Console

**NOTE:** CyRIS™ InView™ must be turned on in order for DICOM data to be transmitted to it.

One disadvantage of importing data directly from the scanner to CyRIS InView is that the image editing tools are not as sophisticated as on the CyberKnife User's Control Console (UCC). It may be easier for you to import the medical images to the UCC and then push those images to the CyRIS InView workstation.

## CT Image Study

If you have already imported a CT image study into the CyberKnife patient database, you can export the CT image by opening the Treatment Planning System and loading the CT image.

**Step 1.** Click **PLAN->EXPORT DICOM DATA**. *Figure 33 Export DICOM Data from the UCC, page 24* will appear.

**Step 2.** Select the CT Image Study to export.

**Step 3.** Choose to Export to Host.

**Step 4.** Select CyRIS InView as the host to export to.

**Step 5.** Click **OK**.

The UCC will export the CT image to CyRIS InView.

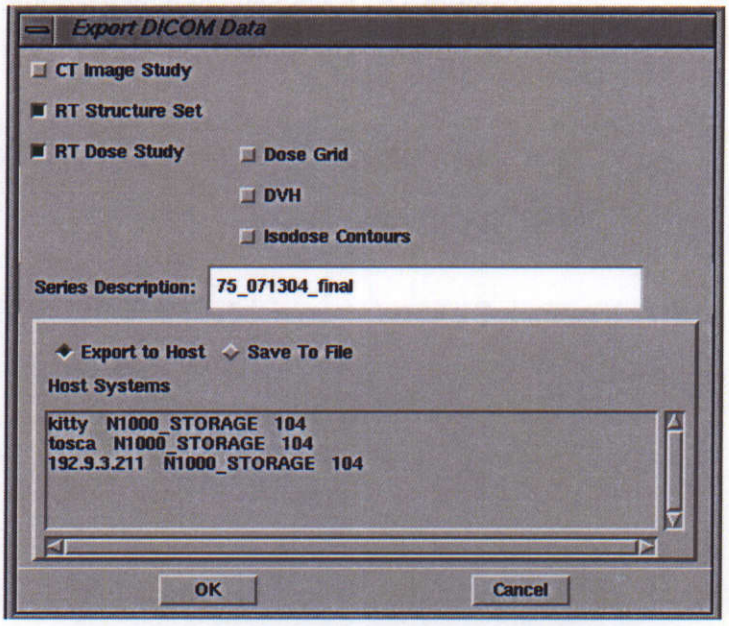



**Figure 33 Export DICOM Data from the UCC**



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

1013

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



## Other Studies

To export a medical image that is not a CT study is a little more difficult, because you cannot use the treatment planning system to perform this operation. Instead you need to use the command-line controls.

**Step 1.** On the UCC, log in as cks and open a shell using the right mouse-click in the dark blue background.

**Step 2.** Go to the patient database directory by typing pats

```
>> pats
```

**Step 3.** Go to the desired medical image directory.

```
>> cd <patient_name>_<med_id>/ct/patient/<image_name>/
<image_modality>
```

The *image modality* can be CT, MR, XA, or PT.

**Step 4.** Type the command to send to the image. For example, if the AE_TITLE of CyRIS InView is *TPS*, the command is:

```
>> /accuray/tools/dicom/send_image -a N1000_STORAGE -c
<TPS_PW_ae_title> <TPS_PW_ip_address> 104 n*
```

*CKS_PW_ip_address* is the TP address of CyRIS InView and TPS_PW_ae_title is the AE_TITLE of the DICOM server on the CyRIS InView and that n is the first number in the listed image instance UID's and that the * is a character that tells the computer to push all images that begin with the alphanumeric *n*.

# Deleting Images

To delete a case from the patient database, click **DELETE** from the MIRIT main screen. The delete image dialog (*Figure 34 Select Case to Delete, page 26*) will appear. Select the patient case you want to delete. A list of image studies will appear. Highlight the case to delete and click **OK**. The Delete Confirmation window will appear (*Figure 35 Delete Case Confirmation, page 26*) to prompt you to confirm the deletion. Click **OK** and everything listed under this case will be deleted. If the case is deleted, a window will appear that informs you of the successful deletion. If the case could not be deleted, an error message will appear. Image studies cannot be deleted if the CT study was used to create a deliverable treatment plan or to generate DRRs.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118 1014

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



**NOTE:** Multiple modalities, such as CT, MR and RTSS, with the same study UID could exist as part of the same case. Thus, when you delete a case, it is possible that you will delete CT and MR images as well as RTSS instances.

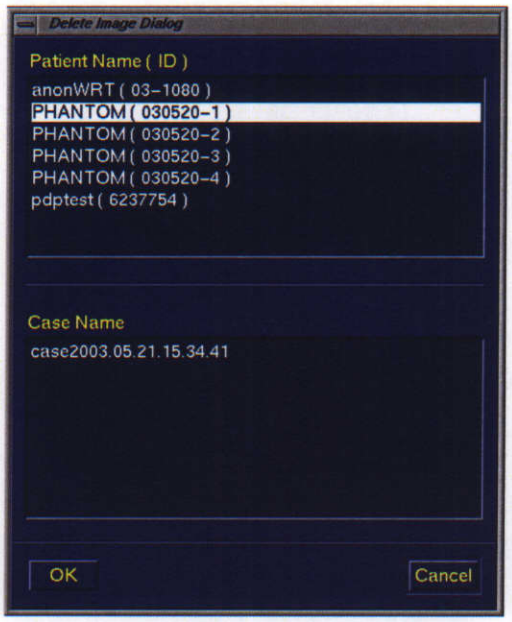



**Figure 34 Select Case to Delete**

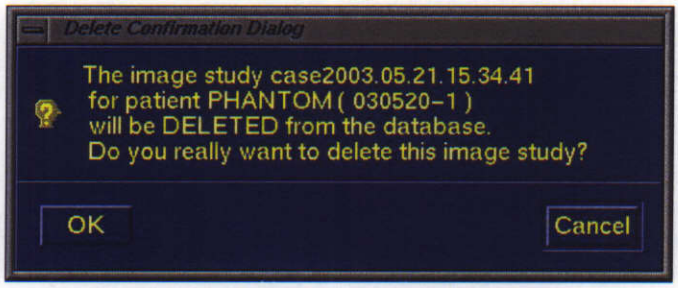



**Figure 35 Delete Case Confirmation**

## Reloading Images for Incomplete Loaded Images

To reload an image, you must first delete the image (see *section, Deleting Images, page 25*). Then you can reload the image using the method described in *section, Adding New Images, page 18*.

**NOTE:** Case name will be different because the image case name is based on a time stamp of when the image was loaded to the CyberKnife patient database.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

1015

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



# QA/Calibration
## Table of Contents

**Quality Assurance Program** ..... 2
- **Periodic Quality Assurance** ..... 2
  - Daily: ..... 2
  - Monthly: ..... 2
  - Quarterly: ..... 3
  - Annually: ..... 3
    - Environmental factors ..... 3
  - Contact Detection Sensor Check ..... 4
    - Changing Collimators ..... 4
- **Annual Quality Assurance** ..... 5
  - Annual Testing Requirements ..... 5



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118 1016

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015





Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

1017

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



# QA/CALIBRATION

Many professional guidelines and regulatory standards exist which govern the use of high energy radiation devices for the treatment of medical conditions.

A complete description of the quality assurance (QA) tests, the procedures used to perform these tests, and their recommended frequency is presented in the Physics Essentials Guide which is first utilized by the clinical physicists when they begin their training at Accuray, Incorporated. The owner of the CyberKnife System is responsible for ensuring that the system is correctly calibrated according to local and Federal regulations governing the use of medical radiation linear accelerators.

Commissioning of the CyberKnife radiosurgery system, including the linear accelerator and the treatment planning system, along with maintaining the proper documentation of that commissioning, is typically performed by a qualified Medical Physicist.

Because the CyberKnife introduces several new technologies not commonly encountered in radiosurgery, several periodic QA procedures must be performed to ensure continued precision and accuracy of the CyberKnife System.

QA tests are used for two primary reasons. The first is to document the on-going correct performance of the system. The second is to identify any non-compliance with critical performance criteria as soon as possible. Recommended QA tests for the CyberKnife System and the frequency that they should be performed are presented in Table 1.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



# QUALITY ASSURANCE PROGRAM

## Periodic Quality Assurance

The following summarizes Accuray's recommendation for a Quality Assurance Program:

### Daily:

- System Status Check
- Linac Output Constancy Check
- Contact Detection Sensor Check
- Linac Calibration
- Safety Interlock Check
- Targeting Accuracy, visual check with AQA (expose film weekly and analyze.)

### Monthly:

- Beam Parameters Check
- Robot Mastering Check (visual)
- Visual Targeting Check
- Imaging Alignment (Image isopost with treatment software)
- Ball Cube Targeting Test (rotate fiducial tracking, 6D Skull, Xsight, and Synchrony delivery modes, so that each test will be done three times per year.)
- Beam Energy ($TPR^{20}_{10}$ or $PDD^{20}_{10}$)
- Positioning Accuracy Checks



109 Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



## Quarterly:

- Target Locating System Tracking Test (or after significant change due to maintenance or repair).
- Linac Laser Mechanical alignment check

## Annually:

- Beam Commissioning Spot Checks
- Treatment Planning System Tests
- Beam Calibration Check
- Safety Systems Tests
- Robot Mastering (electronic)
- Linac Laser/Radiation Field Axis Congruence check (Done after every laser change.)

To support your comprehensive QA program, service engineers will request your records to assist them in evaluating the current performance status of your system. They will provide a written record of all work completed, along with the results of any relevant testing they have completed at the time of that visit.

**A more comprehensive description of the tests and procedures can be found in the Physics Essentials Guide.**

### Environmental factors

**Table 1: Environmental factors**

| Parameter | Location | Acceptable Range |
|---|---|---|
| Humidity | globally | 30% - 80% |

For measurement of environmental factors including humidity we recommend the CNMC model 4195 Digital Barometer, which comes with a traceable certificate of calibration for pressure temperature and humidity.



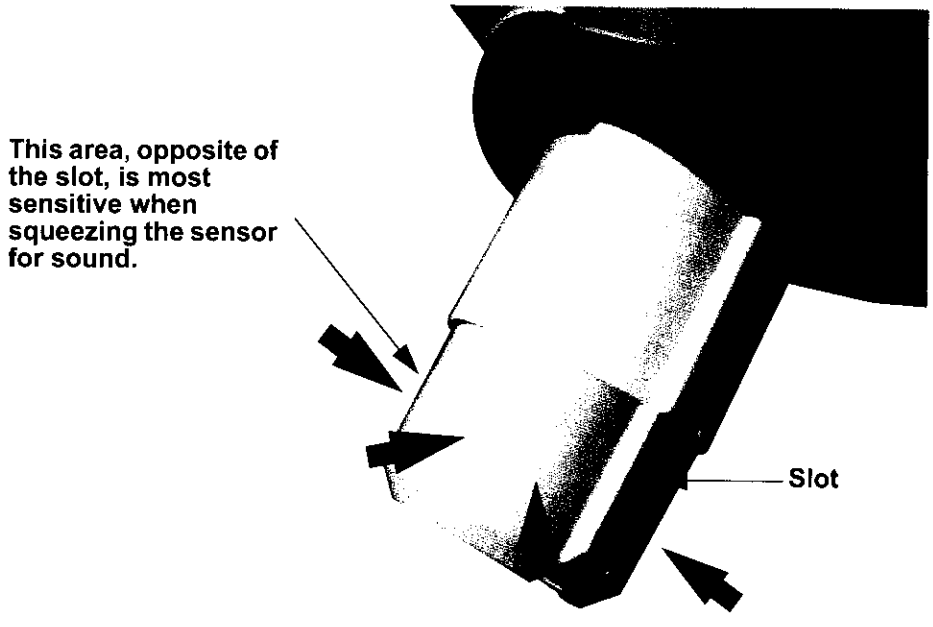
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118 1020

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



## Contact Detection Sensor Check

**Step 1.** Squeeze firmly around in different areas of the sensor (see image below).




**Step 2.** Verify that the clicking noise can be heard. This test can be performed as frequently as you want.

**CAUTION:** If the sensor malfunctions (no clicking sound) contact Accuray customer support.

## Changing Collimators

Refer to the module, Treatment Room Operations pages 1-3, for detailed instructions on how to change a collimator.



1021

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



# Annual Quality Assurance

## Annual Testing Requirements

The CyberKnife program is readily incorporated into the institutional Radiation Safety and Quality Management Programs. It is recommended that the results of the quarterly and annual testing be presented as part of the quarterly and Annual Radiation Safety Reports so that the results are available for administrative review.

- Evaluate monthly and quarterly trends for compliance with system performance specifications.
- Robot mastering check using Search 1 and Search 2 to quantitatively document robot targeting accuracy.
- Perfom End to End Tests by acquiring new CT studies, generating new treatment plans, deliver the treatments for each modality and document treatment delivery accuracy results for all Treatment Modes. Plans generated at this time can be delivered on a monthly basis to document system targeting accuracy during treatment delivery.
- CT geometric accuracy must be documented for the new phantom CT studies.
- TPS:beam data check with single beam plan & measurement
- TPS (calculation check)
- Safety system tests



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015





1023 Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



# DRR and Description
## Table of Contents

**Generate Digitally Reconstructed Radiographs (DRR)** ..... 1
- Select patient information for DRR generation ..... 2
- Select a treatment site for DRR generation ..... 2
- Select a plan for DRR generation ..... 3
- Cancel DRR generation ..... 5
- Errors ..... 6

**Prescription** ..... 7
- Select a patient identifier ..... 7
- Select a site identifier ..... 8
- Select a plan for treatment ..... 9
- Prescribe selected plan for treatment ..... 11



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118 1024

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015





1025 Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



# DRR AND PRESCRIPTION

## GENERATE DIGITALLY RECONSTRUCTED RADIOGRAPHS (DRR)

DRR's are images constructed from the CT's. Each DRR image represents an X-ray view of the patient showing a possible displacement of the patient and the target. By comparing the real-time images taken of the patient during treatment with the set of DRR's, the position of the target can be determined (3D/6D only). The manipulator can then adjust its position to properly point to the radiation source. The CyberKnife® System provides the means to generate DRR's for 6D and Fiducial plans.

**NOTE:** If you have purchased the Xsight™ Spine Tracking System option, refer to the Xsight Spine Tracking System module located in tab "16" in this manual.

Generate DRR function allows you to generate DRR's for a given patient. The patient information, CT's and treatment plan must first be present within the patient database before DRR's can be generated.

**CyberKnife System Menu -> Patient List -> Site List -> Plan List -> DRR Generation Status**



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118 1026

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



## Select patient information for DRR generation

**Step 1.** From the CyberKnife System menu, click **DRR**. The "Please wait" message appears. When the DRR process is ready, the Patients window (*Figure 1 Patients Selection, page 2*) appears. The **OK** button is inactive (grayed out) until a patient is selected.

**Step 2.** Select a patient from the list in the Patients window. The patient's name is highlighted and **OK** becomes active. Click **OK**. The Sites List window (*Figure 2 Generate DRR Sites List, page 2*) appears.

**Step 3.** Click **CANCEL** to redisplay the CyberKnife System menu.

**Figure 1 Patients Selection**

## Select a treatment site for DRR generation

**Step 1.** Select a site from the list in the Sites window. The site name (e.g., "TumorSite") is highlighted and **OK** becomes active. Click **OK** and the Plan List window (*Figure 3 Plan List, page 3*) appears.

**Step 2.** Click **CANCEL** to redisplay the Patients window.

**Figure 2 Generate DRR Sites List**



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

1027

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



# Select a plan for DRR generation

When the Plan List window appears, the **PATIENT** and **PHANTOM** buttons are inactive. This window displays the plan name followed by three flags indicating the presence of Patient DRR's, Phantom CT and Phantom DRR's.

**Step 1.** In the Plan List window, select the applicable plan to generate DRR's.

**Step 2.** If the DRR's are for patient treatment, click the **PATIENT** button. If the DRR's are for phantom simulation, click **PHANTOM**. The Plan List window disappears and the drr generation status message (*Figure 4 DRR Generation Status, page 4*) appears.

**Step 3.** Click **CANCEL** to redisplay the Patients window.

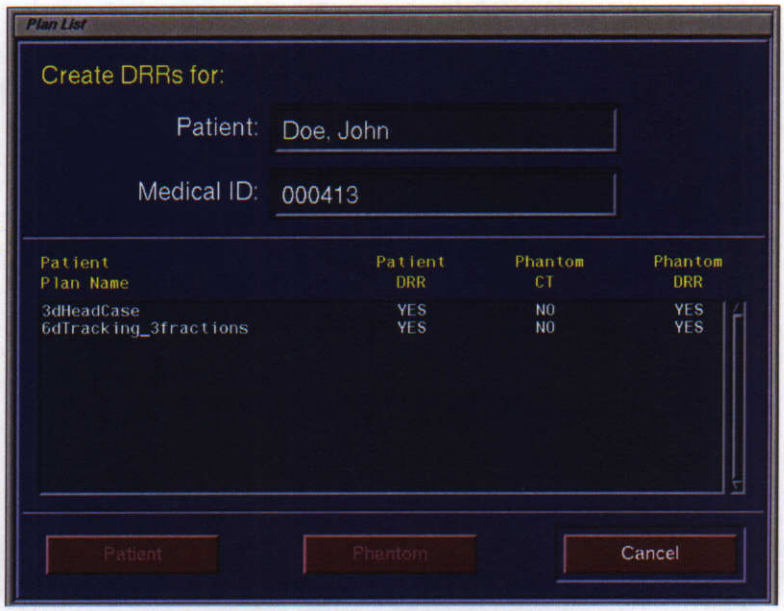



**Figure 3 Plan List**



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



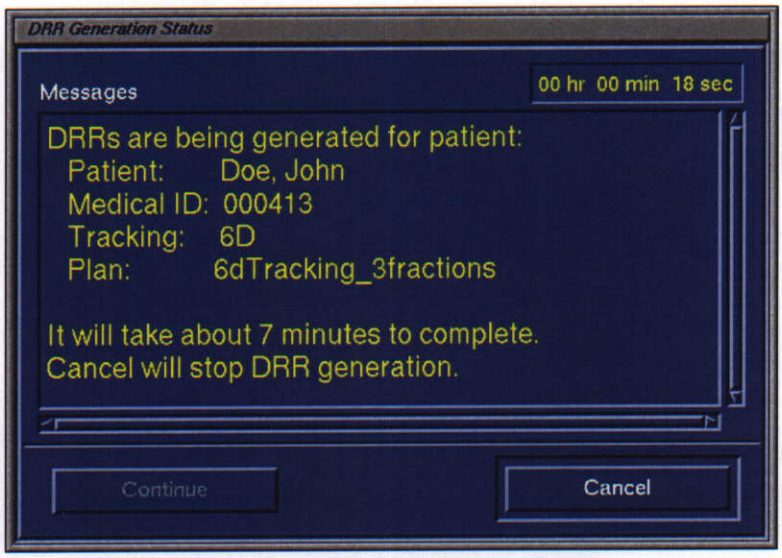



**Figure 4 DRR Generation Status**

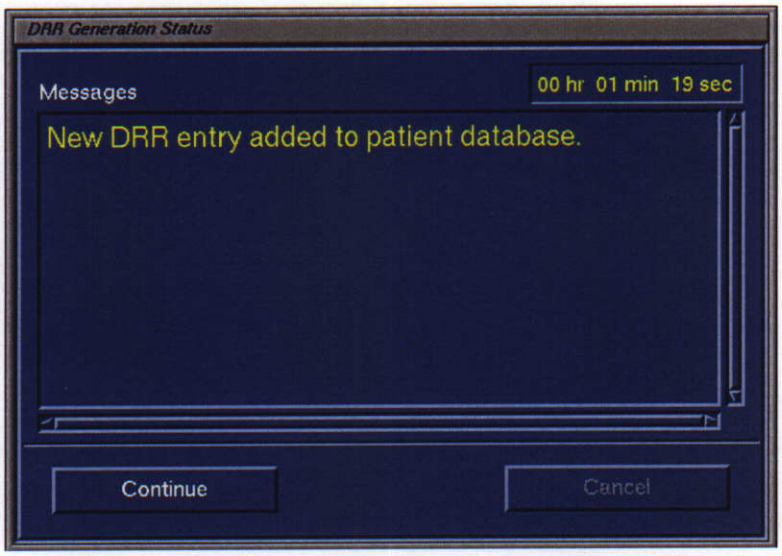



**Figure 5 DRR Generation Status: New Entry Added**



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

1029

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



# Cancel DRR generation

**Step 1.** Click **CANCEL**. The DRR Generation Status disappears and the Confirmation Message (*Figure 6 Confirmation Message, page 5*) appears.

**Step 2.** Click **YES** and the DRR Generation Status (*Figure 7 DRR Generation Cancelled Status Message, page 5*) appears.

**Step 3.** Click **CONTINUE**. The Patients window is redisplayed.

**Step 4.** If **NO** is selected, the DRR generation continues.

**Figure 6 Confirmation Message**

**Figure 7 DRR Generation Cancelled Status Message**



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



## Errors

If errors occur during the DRR selection and generation process, the DRR Error Message (*Figure 8 DRR Generation Error Message, page 6*) appears and the previous window disappears. Follow the instructions in the DRR Error Message and click **CONTINUE**.

**Figure 8 DRR Generation Error Message**



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

1031

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



# PRESCRIPTION

The physician or radiation physicist may create a number of treatment plans for the treatment of the patient. The prescription feature of the CyberKnife System allows the physician to choose one or a number of those plans for the treatment of a patient.

**NOTE:** For CyberKnife Systems with multiple workstations, only plans generated on the User Control Console Workstation can be simulated, prescribed, or treated.

**CyberKnife System Menu -> Patients -> Sites for Treatment -> Plans for Treatment -> Patient and Treatment Verification**

## Select a patient identifier

**Step 1.** From the CyberKnife System menu (*See module, System Startup*), click **PRESCRIPTION**. The Patients window (*Figure 9 Prescription Patients, page 7*) appears.

**Step 2.** Click the applicable patient name in the patient identifier list.

**Step 3.** Click **OK**. The patient's treatment sites are shown in the Sites For Treatment window (*Figure 10 Prescribe for Treatment Site, page 8*).

**Step 4.** To return to the CyberKnife System menu, click **CANCEL**.

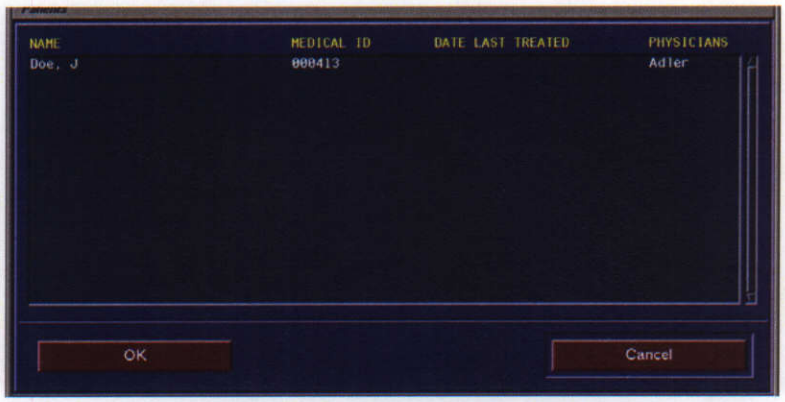



**Figure 9 Prescription Patients**



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015

**Figure 10 Prescribe for Treatment Site**

## Select a site identifier

**Step 1.** Click the applicable site name in the site identifier list of the Sites For Treatment (*Figure 10 Prescribe for Treatment Site, page 8*) window.

**Step 2.** Click **OK**. The patient's treatment plans are shown in the Plans For Treatment window (*Figure 11 Prescribe a Treatment Plan, page 8*).

**Step 3.** To return to the Patients window, click **CANCEL**.

**Figure 11 Prescribe a Treatment Plan**



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

1033

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



# Select a plan for treatment

**Step 1.** Click the applicable plan name in the plan identifier list of the Plans For Treatment window.

**Step 2.** Click **OK**. If the plan has not been simulated, a Warning message (*Figure 12 Simulation Warning Message During Prescription, page 9*) is shown.

**Step 3.** If the plan has been simulated, the Patient And Treatment Verification window (*Figure 13 Patient and Treatment Verification Menu, page 10*) appears.

**Step 4.** To return to the Sites For Treatment window, click **CANCEL**.

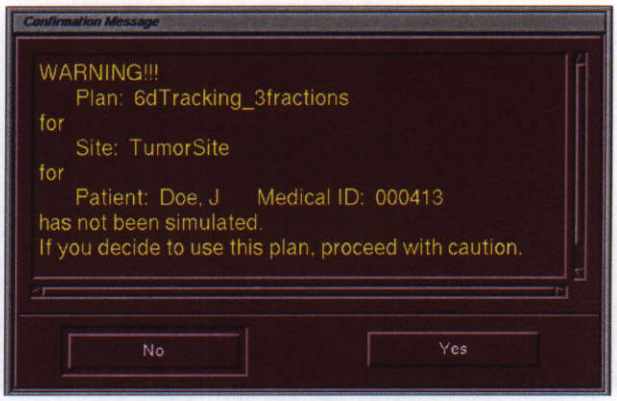



**Figure 12 Simulation Warning Message During Prescription**



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



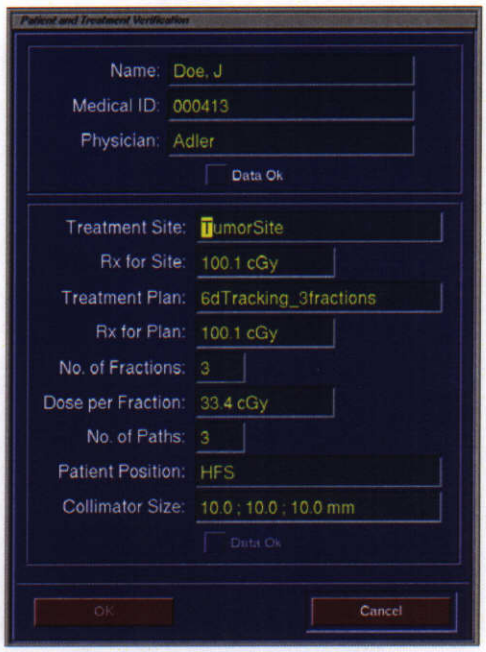



**Figure 13 Patient and Treatment Verification Menu**

The Patient And Treatment Verification window has three sections:

1. The **patient** information, which contains the patient's name, medical ID, physician's name and the **DATA OK** button.
2. The **treatment** information, which contains the name of the treatment site, prescription dose for the site, name of treatment plan, prescription dose for the plan, number of fractions for the plan, dose per fraction, treatment position of patient, collimator size for each treatment path and the **DATA OK** button. This button is inactive until the **DATA OK** button in the patient information section is clicked.
3. The **command** area, which contains the **OK** button (inactive until both **DATA OK** buttons are selected) and **CANCEL**.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

1035

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



# Prescribe selected plan for treatment

**WARNING: Follow hospital procedures for verifying the patient information and treatment plan. If there is any discrepancy, do not prescribe the plan for treatment of the patient.**

**Step 1.** Review the data in the Patient information area. If the data is correct, click **DATA OK**. The Patient information **DATA OK** button becomes inactive (grayed out) and the Treatment information **DATA OK** becomes active.

**Step 2.** Review the data in the Treatment information area. If the data is correct, click **DATA**. The treatment information **DATA OK** button becomes inactive and **OK** becomes active (turns green).

**Step 3.** If the data is correct, click **OK**. The Patient And Treatment Verification window disappears and "Please wait" appears. It informs you that the database is being updated to allow the selected plan for treatment, then the Status Message appears. The Status Message (*Figure 14 Treatment Prescription Status, page 11*) informs you that a treatment database has been created, allowing the plan for treatment.

**Step 4.** By clicking **OK** of the Status Message, the Plans For Treatment window is displayed. To return to the plans for treatment window from the patient and treatment verification window, click **CANCEL**.

**Step 5.** To return to the CyberKnife System Menu, click **CANCEL** on the Plans For Treatment window, the Sites For Treatment window and the Patients For Treatment window.

**Figure 14 Treatment Prescription Status**

**NOTE:** If you selected a plan that already is being used for treatment, the CyberKnife System will not allow that plan to be prescribed again. The Status Message window, appearing after the Patient And Treatment Verification window, informs you that the plan already is being used in treatment. In addition, the window informs you that another plan should be selected.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

1036

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



**NOTE:** If a plan has been prescribed and has **not** been used in treatment (i.e., no dose delivery has been recorded), the plan can be prescribed again.

**WARNING: Do not attempt to modify a treatment file. Improperly changed data could result in death or injury of the patient.**



1037 Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



# Simulation of Treatment
## Table of Contents

**BB Test Procedure** ..... 1



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118 1038

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015





1039 Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



# SIMULATION OF TREATMENT

## BB TEST PROCEDURE

The simulation procedure is similar to the treatment procedure. Its primary purpose is to check for the accurate and safe delivery of a patient treatment plan. Two additional windows are present in the simulation procedure. One (*Figure 1 Simulation Type Options, page 1*) allows you to choose the type of simulation, that is, either to expose the film cube or to verify the treatment dose of the treatment plan.

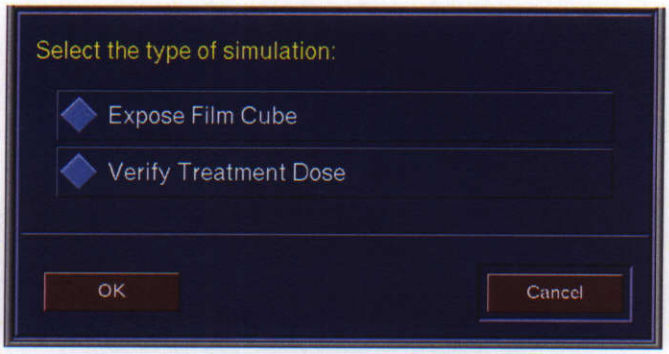



**Figure 1 Simulation Type Options**

When a film cube is exposed, it generates a treatment dose of 30 cGy. This dose should be sufficient to expose and evaluate the film. Treatment dose verification should be done with another sensor, such as an ion chamber or TLD array.

The other window (*Figure 2 Post Simulation Options, page 2*), appearing at the end of the simulation, allows you to retry the simulation, delete the treatment plan, or save the plan for prescription.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

1040

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



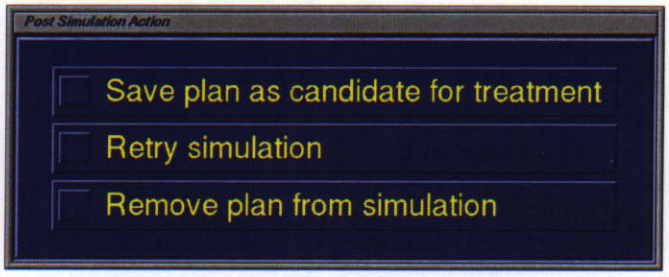



**Figure 2 Post Simulation Options**

Simulation of a treatment plan is optional. It is useful for validation that the Linac beam is pointing at the right spot. This reassurance of accuracy may be especially useful for small targets with narrow margins and tumors in extreme anatomical positions (such as far superior, inferior, posterior or anterior). The procedure is given in *module, Equipment Checks*. If a plan is not simulated, warnings will appear when the plan is prescribed and treated.

The BB Test or Pointing Test is used for simulation. BB Test is applied only for Automatic Mode and not for Manual Mode. Similar to end-to-end test, the BB test should be repeated for each of the following combinations, or as required by the test plan:

- 6D Skull Tracking.
- Fiducial Tracking with 3 or more fiducials (6D Fiducial Tracking), Automatic Mode

The following describes the steps and the procedure of the BB test.

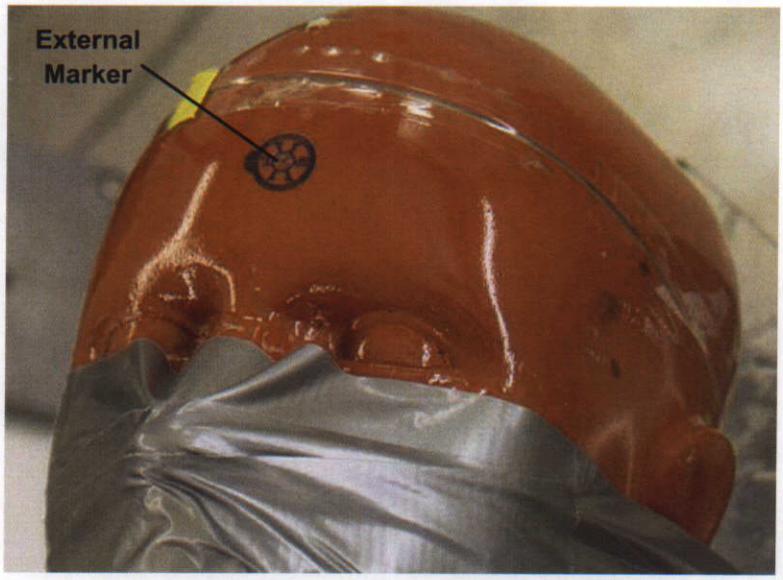



**Figure 3 External Marker (BB) on Surface of Phantom**



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

1041

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



**In test preparation, the following phantoms are required for these tests:**

- Skull phantom with external markers or BB's on the surface of the phantom for 6D skull tracking. The external marker (BB) on the surface of the phantom is shown in *Figure 3 External Marker (BB) on Surface of Phantom, page 2.*

A skull or body phantom with 3 or more fiducials and external markers or BB's on the surface of the phantom are for fiducial tracking.

**NOTE:** For systems with multiple workstations, only plans saved from the User Control Console workstation can be simulated, prescribed and treated.

**In Treatment Plan and DRR Generation, perform the following steps:**

**Step 1.** Select the appropriate phantom for the test.

**Step 2.** Obtain a CT scan of the phantom and load in as a patient CT image into the CyberKnife System.

**Step 3.** Start the treatment planning system, select the patient and CT scans for this test and select the tracking mode. Mark fiducials if necessary.

**Step 4.** Select the unnamed menu to the right of Paths. Move the mouse down to the CpyImage2Phm option and release the button. This will generate a phantom CT image set.

**Step 5.** Choose a 5 mm collimator and locate the target as the one of the identifiable markers (BB's) on the external surface of the phantom.

**Step 6.** Generate a simple, forward plan.

**Step 7.** Generate phantom DRR's

**In Patient, Plan and Path Selection, perform the following steps:**

**Step 1.** From the CyberKnife main menu, select **SIMULATION**.

**Step 2.** Observe that the Patient List appears.

**Step 3.** Select the Patient ID for the phantom used for this test and select **OK**.

**Step 4.** Observe that the Site List window appears.

**Step 5.** Select the site used in the Treatment Plan for this test. (This is typically the Tumor Site).

**Step 6.** Observe that the Plan list appears. Observe that the Treatment Plan generated for this test is in the list. Select this Treatment Plan and click **OK**.

**Step 7.** Observe that the Treatment Dose in the window appears.

**Step 8.** Observe that the Path List window appears. Select one of the paths.

**Step 9.** Observe the data in the Data Verification window appears. click **DATA OK** in the upper and lower portions of the window and select **OK**.

**Step 10.** Observe that the Treatment Files are being loaded message appears.

**Step 11.** Observe that when the file transfer is completed, the Patient Alignment screen appears.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118 

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



**In Patient Alignment, perform the following steps:**

**Step 1.** Position the phantom on the couch or the headrest, close to the required position by visual inspection.

**Step 2.** In the Control Window of the Patient Alignment screen, select Acquire to acquire an image of the phantom.

**Step 3.** Acquire an image. Adjust the couch or the phantom, as directed by the Couch Corrections.

**Step 4.** If no Couch Corrections are available, visually assess the position of the Synthetic and Live image windows in the Patient Alignment screen.

**Step 5.** Repeat the process until the Couch Corrections are within 1 mm for translations and 1 degree for rotations.



1043 Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



**Then select BB Test Mode and start the BB test (Pointing Test):**

**Step 1.** Ensure that the couch corrections are within 1 mm for translations and rotations (if available) are within 1 degree.

**Step 2.** Select the **START** button in the Control window of the Patient Alignment screen.

**Step 3.** Observe that the Equipment Ready window appears.

**Step 4.** When all the equipment is ready, observe that the **START** button in the Equipment Ready window becomes active.

**Step 5.** Select the BB Test Mode on the Equipment Readiness as shown in *Figure 4 BB Test Mode in Equipment Readiness, page 5*

**Step 6.** Click the **START** button. (Continue to Perform the BB Test)

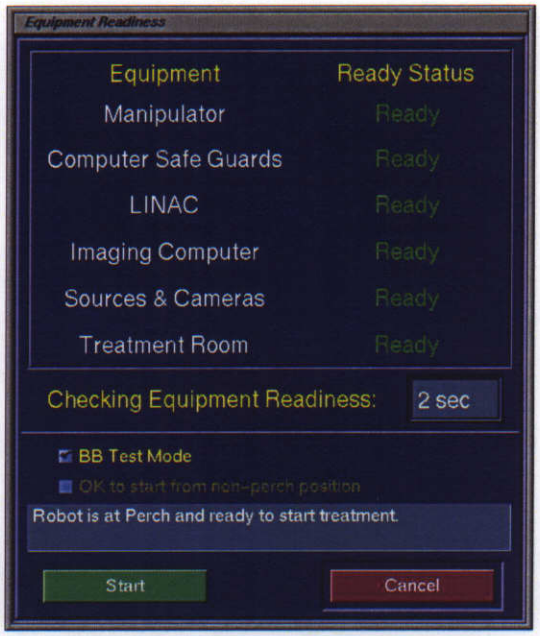



**Figure 4 BB Test Mode in Equipment Readiness**



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



### Alternative BB Test Selection Option

**Step 1.** Ensure that the couch corrections are within 1 mm for translations and rotations (if available) are within 1 degree.

**Step 2.** Select Imaging Parameters from the Patient Alignment screen.

**Step 3.** Observe that an Imaging Parameters window (*Figure 5 BB Test Mode in the Imaging Parameters Window, page 6*) appears.

**Step 4.** Select the BB Test Mode in the Imaging Parameters window as shown in *Figure 5 BB Test Mode in the Imaging Parameters Window, page 6* and select **OK**.

**Step 5.** Observe that the Imaging Parameters window closes.

**Step 6.** Select the **START** button in the Control Window of the Patient Alignment screen.

**Step 7.** Observe that the Equipment Ready window appears and that BB Test Mode is selected as shown in *Figure 5 BB Test Mode in the Imaging Parameters Window, page 6*.

**Step 8.** When all the equipment is ready, observe that the **start** button in the Equipment Ready window becomes active.

**Step 9.** Click the **START** button.

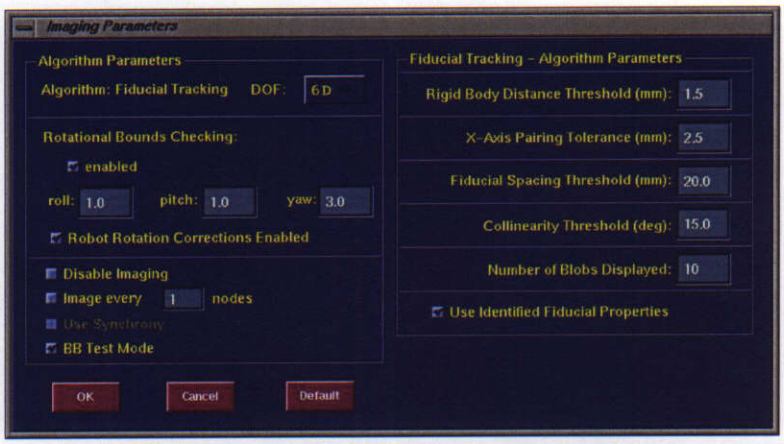



**Figure 5 BB Test Mode in the Imaging Parameters Window**

### Perform the BB Test (Pointing Test) – Automatic Mode: (Kuka Only)

**Step 1.** Once the Start is selected on the Equipment Ready window, Observe that the Treatment Delivery screen appears.

**Step 2.** Observe that a window with the message, "Use Tech Pendant to Continue BB Test" pops up, as shown in *Figure 6 Treatment Messages, page 8*.

**Step 3.** By pass the Door E-Stop and enter the Treatment room.

**Step 4.** On the teach pendant select the **SIM NODE** button to move to the first node.

**Step 5.** Observe that the robot moves to the first node.

**Step 6.** Verify that the laser is pointing at the external marker (BB) targeted in the treatment plan within 1mm.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

1045

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



**Step 7.** On the teach pendant select the **SIM NODE** button to move to the next node.

**Step 8.** Verify that the robot stops at the next node and the laser points to the external marker (BB) within 1 mm.

Adjust the phantom position a few times during the pointing test and continue the test.

**Step 1.** On the Treatment window, select **PAUSE** in the Control bar at the bottom.

**Step 2.** Verify that the system goes through E-Stop tripped sequence and an Error Message box appears. Verify that the robot stops motion through further nodes.

**Step 3.** Click **RESET**. Verify that a window with the **ABORT** and **RESUME** buttons pop up.

**Step 4.** Click **RESUME**. Verify that TMT enters Patient Re-Alignment screen.

**Step 5.** Enter the treatment room and adjust the patient position by about +5 mm along X axes in the Imaging Co-ordinate System. (X - Inf, Y - Left, Z - Ant).

**Step 6.** Exit the treatment room.

**Step 7.** From the Patient Re-Alignment screen, in the Control Window select **ACQUIRE**.

**Step 8.** Verify that an image is acquired and new couch corrections are computed. Verify that the couch corrections change by approximately the amount that the couch position was adjusted.

**Step 9.** Select **RESUME** from the Control Window.

**Step 10.** Observe that a window with the message, "Use Tech Pendant to Continue BB Test" pops up, as shown in *Figure 6 Treatment Messages, page 8*.

**Step 11.** Re-enter the treatment room.

**Step 12.** On the teach pendant select the **SIM NODE** button to move to the next node.

**Step 13.** Verify that the robot moves to the next node, the laser points to the external marker (BB) within 1mm.

Repeat the test with following patient position adjustments:

- +/- 5 mm along X
- +/- 5 mm along Y
- +/- 5 mm along Z
- +5 mm along X, +5 mm along Y, +5 mm along Z
- -5 mm along X, -5 mm along Y, -5 mm along Z



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



When sufficient nodes are observed for pointing accuracy, select the button "Sim All" on the teach pendant. Observe that the robot moves through the rest the nodes in the path and finally to perch, without stopping for operator intervention.

**Figure 6 Treatment Messages**

**NOTE:** For systems with multiple workstations, only plans saved from the User Control Console workstation can be simulated, prescribed and treated.

**WARNING: Pay close attention to the robot while it is moving to ensure the safety of the observers. Use the teach pendant ESTOP to stop the robot motion if necessary.**



1047 Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



# Treatment Room Operations
## Table of Contents

**Preparing the Treatment Room** ..... 1
- Patient Monitoring System ..... 1
- Collimator Installation ..... 1
  - Remove Collimator ..... 3
  - Insert Collimator ..... 4
- Manipulator Starting Position ..... 4

**Restraining the Patient** ..... 5
- Head Restraint ..... 5
- Body Restraint ..... 5

**Preparing the Treatment Table** ..... 5

**Aligning the Treatment Table** ..... 6
- Automatic Patient Positioning System ..... 6
  - AutoCouch Alignment ..... 6
- Powering Up the CyberKnife System with the Couch and Imaging System ..... 7
- Couch Hand Controller and Display Units ..... 10
  - Couch Hand Controller ..... 10
  - Read-Out Display Unit ..... 12



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

1048

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015





Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



# TREATMENT ROOM OPERATIONS

The CyberKnife® System uses an X-ray guided tracking system to align the patient prior to treatment and to compensate for small patient movements during treatment. This module instructs you on how to initially position the patient on the treatment table.

Powering up the system takes between 15 and 30 minutes. It is recommended that the system be completely powered up before the patient is brought into the treatment room (*see module, System Startup*).

When the CyberKnife System is installed, the positions of all permanent objects in the treatment room are taken into account when creating the PDP zone (Proximity detection Process).

**WARNING: Do NOT leave temporary objects in the PDP zone during treatment delivery.**

## PREPARING THE TREATMENT ROOM

The treatment room can be prepared any time before treatment begins as the patient need not be present during preparation. Standard hospital housekeeping practices should be used in the CyberKnife treatment room. The *CyberKnife System Maintenance Manual* (Accuray part number 017089) provides instructions for maintaining all major components and subassemblies of the CyberKnife System.

### Patient Monitoring System

Turn on the closed circuit TV monitoring system and intercom and ensure that it functions properly. The patient should be monitored directly by personnel or unobscured closed circuit TV view at all times while in the treatment room.

### Collimator Installation

Install the correct collimator in the X-ray head. A CyberKnife System has a variety of collimators that range between 5 mm and 60 mm in diameter and the system senses which collimator is installed (*Figure 1 Interchangeable Secondary Collimators, page 2*). The field size is stamped on the front of the collimator and each collimator is a different length.

The collimator must be completely inserted into the X-ray head, using the spring-loaded retaining pin and a brass retaining ring, to avoid generating an error.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118 1050

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



**WARNING: Each CyberKnife collimator weighs more than 12 lb. (5 kg). Be sure no one, other than the person removing or installing the collimator, is directly underneath the X-ray head when a collimator is removed or installed. Do not try to replace the collimator when the X-ray head is above the treatment table and the patient is on the table.**

**WARNING: Use only Accuray supplied collimators in the CyberKnife.**

**WARNING: When you remove or install the collimator, securely hold it with your palm underneath the front face and be careful not to drop on your foot or other part of your body.**

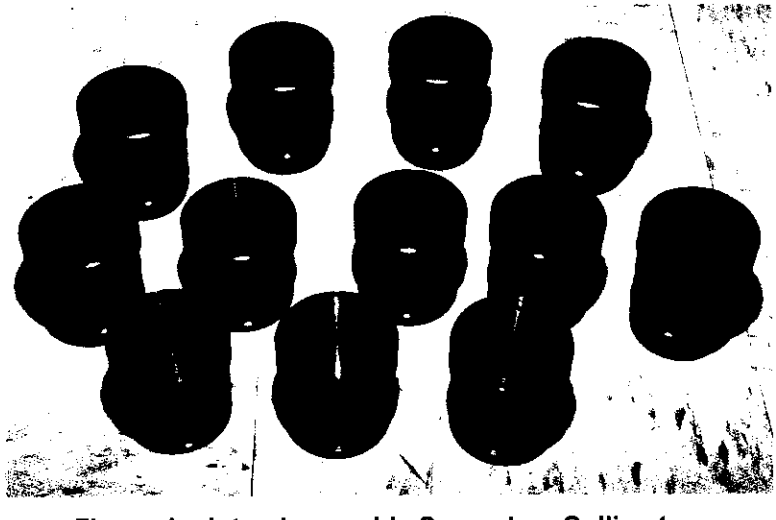


**Figure 1 Interchangeable Secondary Collimators**



1051

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



## Remove Collimator

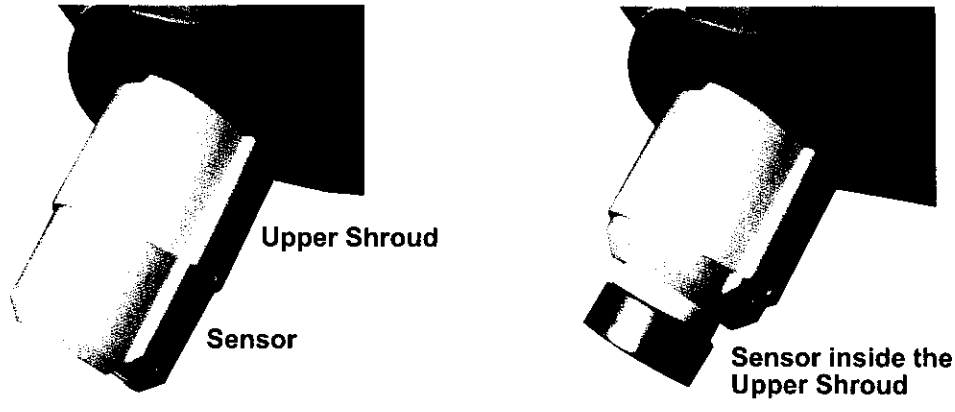



**Figure 2 Contact Detection System**

If your system has the Contact Detection System installed, you will need to perform the following before changing the collimator.

**Step 1.** Slide the sensor up until it seats firmly on the magnets located inside the secondary collimator housing, and until the collimator release pull-pin emerges from the end of the sensor.

**Step 2.** Unscrew the brass retaining ring.

**Step 3.** Hold the collimator firmly with one hand.

**Step 4.** With the other hand, pull the collimator-retaining pin.

**Step 5.** Slowly slide the collimator out of the X-ray head housing.

**NOTE:** If you notice significant friction between the collimator and the X-ray head housing, contact Accuray.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118 1052

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



## Insert Collimator

**Step 1.** Securely hold the collimator so that the palm of your hand is below the stamped front face.

**Step 2.** Slide the collimator into the X-ray head housing until the retaining pin latches and holds the collimator in place.

**Step 3.** Screw the brass retaining ring over the end of the collimator. The collimator should move approximately 3 mm as the retaining ring is screwed in.

**Step 4.** Slide the sensor down the secondary collimator housing until the notch aligns with the pull pin shoulder and it locks in.

**Step 5.** Squeeze the sensor firmly to test. Verify that the clicking sound can be heard.

**Step 6.** Resume treatment.

**WARNING: Never leave the collimator hanging by only the retaining pin over the patient or yourself. Hold it with your hand until the retaining ring further secures the collimator to the X-ray head.**

## Manipulator Starting Position

After the collimator is installed, use the teach pendant to position the robot near the perch starting position for the manipulator.

Use the program called "prch" in the **CKmain** folder on the controller to place the robot at the perch position

**WARNING: Do not remove the teach pendant from the treatment room during treatment.**



1053 Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



# RESTRAINING THE PATIENT

**WARNING: The patient must be mechanically restrained whenever the manipulator moves. This restraint prevents the patient from accidentally moving from a safe location and colliding with the manipulator. Such a collision could result in death or serious injury to the patient.**

## Head Restraint

Proper initial patient alignment should replicate as closely as possible the patient position during the CT scan. Therefore, use the same head restraint for treatment that the patient wore during the CT scan.

Place the head restraint on the patient following the procedure in the head restraint vendor's manual.

## Body Restraint

Secure the patient in the restraint that was used during CT imaging. In some instances, the restraint needs to be attached to the table before the patient can be properly placed in the restraint.

# PREPARING THE TREATMENT TABLE

Verify that the treatment table is free of unnecessary objects.

Secure the immobilization system to the table. Adjust the orientation of the table so that the alignment is the same as that recorded during the CT scan.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118 1054

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



# ALIGNING THE TREATMENT TABLE

Using the couch hand controller, the treatment table can be translated in three directions and rotated in the pitch and roll directions. Yaw is adjusted manually.

Move the treatment table so that the area to be treated is in the field of view of the imaging system. If alignment lasers or a position measurement device is available, these can help initially align the patient.

On the CyberKnife System main computer, begin treatment as described in *module, Treatment, section, Initiating Treatment* and proceed through the operations up to *section, Patient Alignment*.

**NOTE:** You can complete these procedures before bringing the patient into the treatment room.

Follow the procedure to align the patient given in *module, Treatment, section, Patient Alignment*. It is recommended that treatment start only after the total detected alignment error is 2 mm or less and rotational error should be less than 1 degree when 6D information is provided by treatment.

## Automatic Patient Positioning System

The automatic patient positioning system adjusts the patient position under computer control, based on the displacements and rotations reported by the imaging system.

### AutoCouch Alignment

**Step 1.** Open the AutoCouch window.

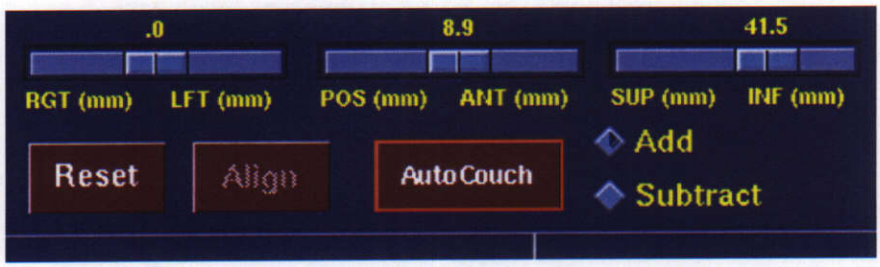



**Figure 3 AutoCouch**

**Step 2.** Input the patient shift from the graphic sliders.

**Step 3.** Click the **MOVE** button to align the patient.

**Step 4.** After this initial alignment, the patient position should be within the tracking range.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

1055

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



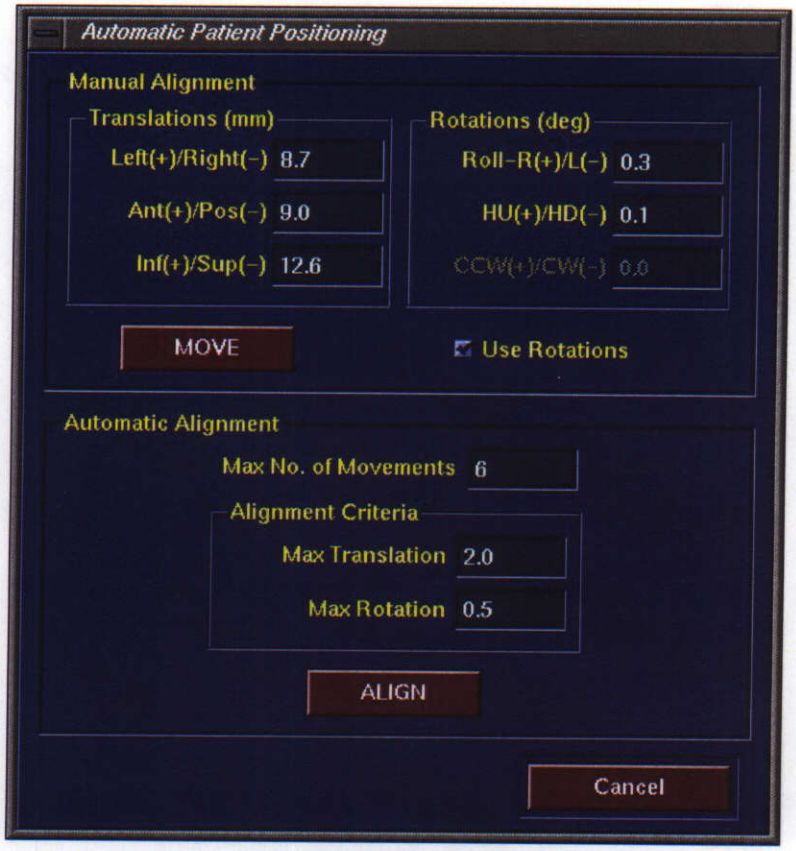



**Figure 4 Automatic Patient Positioning**

# Powering Up the CyberKnife System with the Couch and Imaging System

This section explains how to turn on the power to the CyberKnife® System from the operator's control console.

### CyberKnife System Menu -> Equip Power -> Power On -> Exit

**Step 1.** From the system menu, click **EQUIP POWER**. The Equipment Status window appears (*Figure 5 Equipment Power Status "Not Ready", page 8*). This window shows that the electrical power of each piece of equipment is off and its status is NOT READY.

**Step 2.** Click **POWER ON**. The power for all of the equipment turns on. The user control console monitor displays the status for the manipulator, Linac, X-ray sources, X-ray cameras, Synchrony, and couch.

**Step 3.** When the electrical power of each unit is on and its status is ON STANDBY, the system is powered on (*Figure 6 Equipment Power Status "On", page 9*). The power on process typically requires approximately 20-25 minutes.

**Step 4.** Click **CONTINUE** to return to the CyberKnife System menu window.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

1056

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



**NOTE:** The **RESET** button quickly resets communication between the SGI and the equipment subsystems, while avoiding a full power-off and power-on of the treatment and couch robots. Under normal conditions, you do not need to press **RESET**.

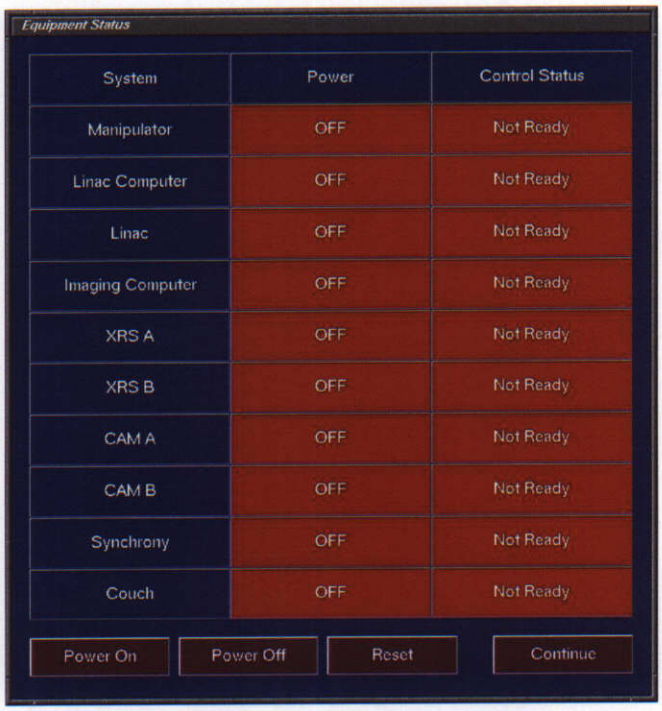



**Figure 5 Equipment Power Status "Not Ready"**



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

1057

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



Equipment Status

| System | Power | Control Status |
|---|---|---|
| Manipulator | ON | On Standby |
| Linac Computer | ON | On Standby |
| Linac | ON | On Standby |
| Imaging Computer | ON | On Standby |
| XRS A | ON | On Standby |
| XRS B | ON | On Standby |
| CAM A | ON | On Standby |
| CAM B | ON | On Standby |
| Synchrony | ON | On Standby |
| Couch | ON | On Standby |

Power On | Power Off | Reset | Continue

**Figure 6 Equipment Power Status "On"**

| Equipment | Electrical Power | Status |
|---|---|---|
| Manipulator | On | On Standby |
| LINAC Computer | On | On Standby |
| LINAC | On | On Standby |
| Imaging Computer | On | On Standby |
| Xray Source A | On | On Standby |
| Xray Source B | On | On Standby |
| Camera A | On | On Standby |
| Camera B | On | On Standby |
| Synchrony | On | On Standby |
| Couch Control | Off | FAULT |

Power On | Power Off | Continue

**Figure 7 Equipment Power Status "Couch Disabled"**



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



# Couch Hand Controller and Display Units

## Couch Hand Controller

The Couch Hand Controller (*Figure 8 Couch Hand Controller, page 10*) can be used for adjusting motions of the couch under manual control. Table 1 lists button descriptions on the hand controller.

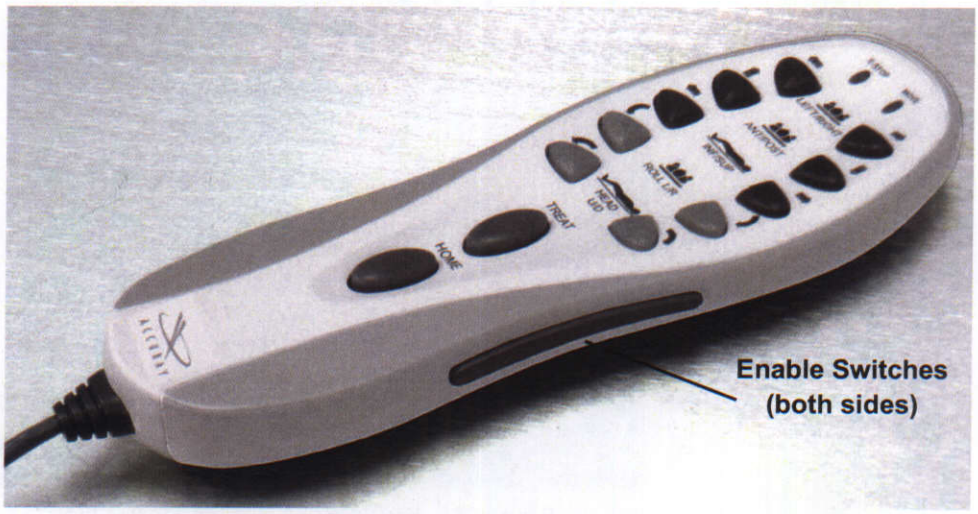



**Figure 8 Couch Hand Controller**



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

1059

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015

**WARNING: The Couch does not detect collisions with surrounding objects. Release the ENABLE button to stop motion when you see a potential collision.**

**Table 1: Button descriptions**

| | |
|---|---|
| **Head up** | Rotates the couch in a direction to bring the patient head up. |
| **Head down** | Rotates the couch in a direction to bring the patient head down. |
| **Roll left** | Rotates the couch about the inferior-superior axis towards patient left. |
| **Roll left** | Rotates the couch about the inferior-superior axis towards patient right. |
| **Inf** | Moves (translates) the couch towards the patient inferior direction. |
| **Sup** | Moves (translates) the couch towards the patient superior direction. |
| **Left** | Moves (translates) the couch towards the patient left. |
| **Right** | Moves (translates) the couch towards the patient right. |
| **Ant** | Moves (translates) the couch towards the patient anterior direction. |
| **Post** | Moves (translates) the couch towards the patient posterior direction. |
| **HOME** | Moves the couch to the home position. This position is programmed as a convenient position of the couch for the patient get on or off the table. |
| **TREAT** | Moves the couch to the nominal treatment position. The nominal treatment position for the first treatment session for a plan is obtained from a stored position for the type of anatomy being treated (head or body). For subsequent sessions, the treatment position used in the previous treatment session is used. |
| **ENABLE** | Both Enable buttons need to be activated in order before any couch movements can occur. |

**E-STOP LED** The E-STOP LED has three possible states:

1. **OFF** Indicates that there are no E-Stop's engaged in the system. The couch can be moved in manual or computer control (from SGI) in this state.
2. **GREEN** Indicates that there is a CyberKnife System E-Stop. In this state, the couch can be moved in manual control only. All computer-controlled motions from SGI are disabled.
3. **YELLOW** Indicates that the couch E-Stop is engaged. In this state, both manual and computer-controlled motions are disabled.

**MOVE LED** The MOVE LED is Green whenever any button that performs a move is depressed.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118 1060

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



## Read-Out Display Unit

The Read-Out Display Unit (*Figure 9 Read-Out Display Unit, page 12*) displays the couch position at all times. Couch positions can be displayed in two co-ordinate systems:

1. **ABSOLUTE**: Absolute co-ordinates are with respect to a native co-ordinate system of the couch. The couch is at zero in all five axes when it is centered, level and at the lowest, most inferior position.
2. **RELATIVE**: Relative co-ordinates are with respect to a previous reference in absolute co-ordinate systems. The reference can be reset to the current couch position by pressing the **ZERO** button.

Pressing the **ABS/REL** button toggles the display between ABSOLUTE and RELATIVE modes. Pressing the **ZERO** button changes the display to RELATIVE mode, if it is not already in that mode and resets the current couch position as the reference for calculating the relative co-ordinates.

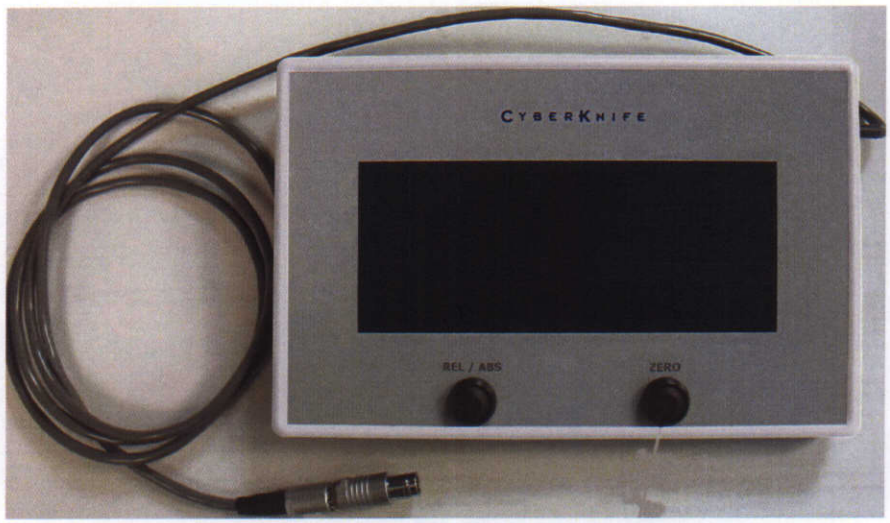



**Figure 9 Read-Out Display Unit**

**NOTE:** The relative positions on the Display Unit do not correspond to the imaging center. Numbers are different from the Couch Corrections on the Patient Alignment window, which do correspond to the imaging center.

If a motion button is held (depressed) for more than 5 seconds without the enable button depressed, then the couch enters a calibration mode for that axis with the message, "press zero to Calibrate <axis name> axis". This mode should only be used for re-calibrating the zero position of each axis. Wait for a brief period to return to normal mode of operation.

**WARNING: DO NOT press the ZERO button when the read-out display reads "Press ZERO to Calibrate <axis name> axis" and the couch is not in the correct location for re-calibrating the zero position for that axis. Doing so will compromise the calibration of the couch and will affect the system's ability to detect potential collisions between robot and the couch or the patient.**



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

1061

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



# Treatment
## Table of Contents


**Initiating Treatment** ..... 1
- Select Treatment Feature ..... 1
- Patient Selection ..... 1
- Site Selection ..... 2
- Plan Selection ..... 3
- Plan Fractions Selection ..... 5
  - Information Section ..... 5
  - Selection Section ..... 5
- Path Selection ..... 6
- Plan Verification ..... 8

**Path Downloading** ..... 10

**Patient Alignment** ..... 11
- Patient Alignment: General Operation ..... 11
  - Automatic Patient Alignment ..... 12
    - Manual Alignment Area ..... 14
  - Alignment Window ..... 15
    - Image Area ..... 15
    - Patient Adjustment Area ..... 16
    - Zoom drop-down Box ..... 16
    - Imaging X-ray Parameters Area ..... 17
    - Overlay Image Format Area ..... 18
    - Fiducial Location Control Area ..... 18
- Multi-Purpose Imaging Window ..... 18
  - Couch Display Window ..... 18
  - Enlarged Image View Window ..... 19
  - Image Data Log Window ..... 20
  - Pause Control Window ..... 21
  - Treatment Data Screen ..... 21
  - Controls Window ..... 22
  - Initial Condition of the Align Patient Window ..... 22
  - Acquiring Live Images ..... 22
  - Results After Acquiring Live Images ..... 23
    - Moving the Crosshairs ..... 23
    - Moving the Sliders ..... 23
- Patient Alignment: Automatic Couch Positioning ..... 24
  - Out of Bounds Error ..... 25




Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118 1062

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



Automatic Patient Alignment ..... 26
Manual Alignment Mode ..... 26
Automatic Alignment Mode ..... 28
Pausing Couch Movement ..... 29
Patient Safety Guidelines ..... 29
Manual Alignment Mode ..... 30
Treatment Delivery ..... 30
Patient Re-Alignment ..... 31
Corrections for Patient Rotations ..... 32
Imaging Parameters Area ..... 32
**Patient Alignment: Fiducial Tracking ..... 35**
Fiducial Display Control ..... 35
View Mode Drop-down Box ..... 35
Zoom drop-down Box ..... 35
Display Fiducial Markers Checkbox ..... 36
Display Blobs ..... 36
Display ROI Checkbox ..... 36
Threshold Checkbox ..... 36
Fiducial Parameters Control ..... 36
Fiducial Area Selection Drop-down box ..... 36
Tracking Mode Button ..... 36
Search Parameters Button ..... 36
Track Parameters Button ..... 37
Enable Offset ..... 37
Search Parameters Window ..... 37
Pixel Area Range ..... 37
Threshold Range ..... 38
Search Window ..... 38
Fiducial Contrast ..... 38
Track Parameters Window ..... 38
Pixel Area Range ..... 39
Threshold Range ..... 39
Tracking Window ..... 39
Fiducial Contrast ..... 39
Use For Tracking Checkbox ..... 39
Fiducial Type Drop-down Box ..... 39
Aligning the Patient in Fiducial Tracking Mode ..... 40
Ensuring Proper Fiducial Identification ..... 40
Adjusting Patient Position ..... 41
**System Check ..... 42**
**Start Treatment ..... 43**



1063

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



**Treatment Delivery** ..... **44**
**Treatment Delivery Window** ..... **44**
Treatment Data ..... 44
Alignment Monitor ..... 44
Beam Data Window ..... 45
Graph Display Window ..... 46
Controls Window ..... 47
**Treatment Control: Automatic Mode** ..... **48**
**Treatment Control: Manual Mode** ..... **50**
**Treatment Control: Path Completion** ..... **52**
Return to the Treatment Sites Window ..... 53
Return to the Treatment Plans Window ..... 53
Return to the Treatment Paths Window ..... 53
Return to the CyberKnife System Menu ..... 53
**Pausing Treatment** ..... **54**
Reset or Continue ..... 55
Manipulator Pause ..... 55
Abort ..... 57
**Unrecoverable Error** ..... **57**
**Recoverable Error** ..... **57**
**Errors** ..... **58**
**Contact Detection Sensor** ..... **58**
Error 221 ..... 58
**Patient Re-Alignment** ..... **59**
**Makeup Fractions** ..... **60**



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118 1064

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015





1065 Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



# TREATMENT

This section gives the instructions for starting the CyberKnife® System to deliver radiation to treat a patient.

**CyberKnife System Menu -> Treatment -> Patients -> Treatment Sites -> Treatment Plans -> Plan Fractions -> Treatment Paths -> Patient and Treatment Verification -> Loading Treatment Files -> Align Patient -> Equipment Readiness -> Treatment Delivery**

## INITIATING TREATMENT

### Select Treatment Feature

After logging on to the main computer and powering up the CyberKnife System, click **TREATMENT** in the CyberKnife System menu. The treatment Patients window appears.

### Patient Selection

The Patients window (*Figure 1 Treatment Patient, page 1*) displays a list of patients who have prescribed treatments. The Date Treated field in the Patients window indicates the last date and time the patient was treated.

**Figure 1 Treatment Patient**



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

1066

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



**Step 1.** Select patient from list and click **OK**.

**Step 2.** The Treatment Sites (*Figure 2 Treatment Sites Menu, page 2*) and Treatment Data
(*Figure 3 Treatment Data, page 2*) windows appear.

**Step 3.** The Menu Selection window appears when **CANCEL** is clicked.

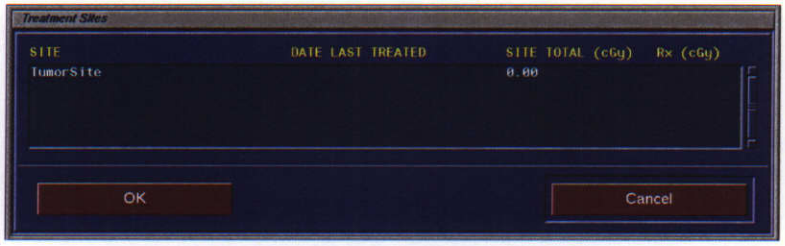



**Figure 2 Treatment Sites Menu**

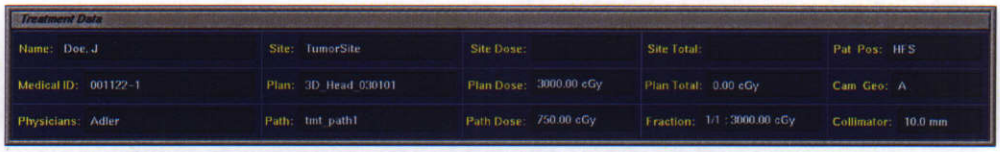



**Figure 3 Treatment Data**

## Site Selection

After a patient has been selected from the Patients window, the Treatment Sites window (*Figure 2 Treatment Sites Menu, page 2*) appears. It contains a list of the treatable sites of the selected patient, with the site name, the date the site was last treated, the cumulative site dose in cGy and the prescribed dose.

**Step 1.** Double-click the applicable site.

**Step 2.** The Treatment Plans window appears (*Figure 4 Treatment Plans, page 3*). The Patients window appears when **CANCEL** is clicked.

**NOTE:** The Treatment Data screen (*Figure 3 Treatment Data, page 2*) contains the selected patient's name, medical ID and physician's name. Information about the selected site appears in the Treatment Data window when the Treatment Plans window appears.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

1067

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



# Plan Selection

After a site has been selected from the Treatment Sites window, the Treatment Plans window (*Figure 4 Treatment Plans, page 3*) appears. The window contains two sections.

- The top section contains a list of the treatment plans for the selected site. It shows the plan name, whether the plan was simulated, the date the plan was last used and the prescribed dose of the plan in cGy.
- The lower section contains a list of the completed treatment plans for that site. It shows the plan name, the date the plan was last used and the prescribed dose of the plan in cGy. This section provides information only.

**Figure 4 Treatment Plans**

**Step 1.** Double-click the applicable plan. If the plan has not yet been simulated, the system displays a warning message (*Figure 5 Simulation Warning Message During Treatment, page 4*). Simulation of the plan is optional (*see module, Simulation Of Treatment*).

**Step 2.** If the treatment has been simulated, then the Plan Fractions window appears (*Figure 6 Treatment Fractions Menu, page 4*). The Treatment Sites window appears when **CANCEL** is clicked.

**NOTE:** The Treatment Data window contains the selected site name. Information on the selected plan appears in the Treatment Data window when the Plan Fractions window (*Figure 6 Treatment Fractions Menu, page 4*) appears.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



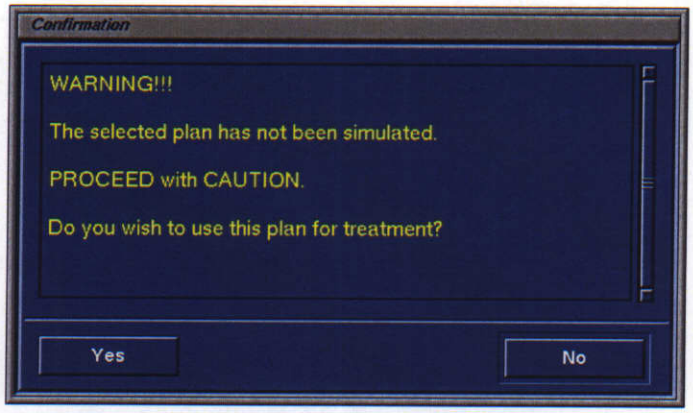



**Figure 5 Simulation Warning Message During Treatment**

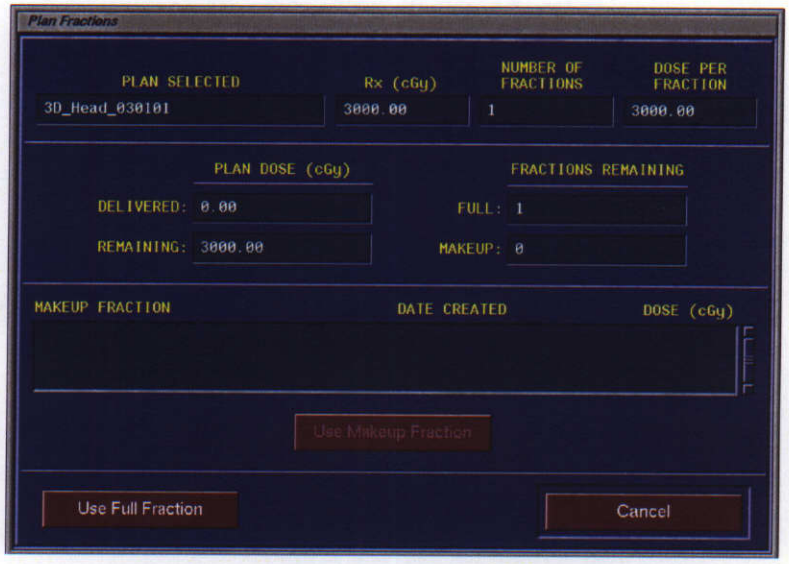



**Figure 6 Treatment Fractions Menu**



1069

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



# Plan Fractions Selection

After a plan has been selected from the Treatment Plans window, the Plan Fractions window appears. The window contains an information and a selection section.

## Information Section

The top section contains information on the selected treatment plan. It shows the plan name, the prescribed dose of the plan in cGy, the total number of fractions prescribed for the plan and the dose per fraction.

- In the Plan Dose area, the dose delivered (an increasing value) appears in the Delivered text area and the dose remaining (a decreasing value) appears in the Remaining text area. The sum of the dose delivered and the dose remaining should equal the prescribed dose.
- In the Fractions Remaining area, the number of fractions remaining for the plan is shown in the full text area. Each fraction whose dose is equal to the dose per fraction is referred to as a full fraction. The number of makeups for a plan is shown in the Makeup text area. A makeup is the remainder of a fraction that was not completed. The sum of the makeup fractions and full fractions should equal the total number of fractions for the plan.

## Selection Section

The lower section contains a list of the makeup fractions for the selected treatment plan. It shows the name of the makeup fraction, the date the plan was created and the dose remaining for the makeup fraction.

**To select a makeup fraction:**

**Step 1.** Highlight the desired makeup fraction.

**Step 2.** The **USE MAKEUP FRACTION** button becomes active. The **USE FULL FRACTION** button becomes inactive (grayed out).

**Step 3.** Click the **USE MAKEUP FRACTION** button. The Treatment Paths window appears.

The name of the makeup plan has the following format: "**plan-name_fYYY_ mkupZZZ_plan**", where "*plan-name*" is the name of the plan for which a makeup plan was created, "*YYY*" is the number of the fraction of the plan that was being executed when a makeup plan was created, "*ZZZ*" is the number of times in which a makeup plan was created for the plan and fraction.

For example, "ellipse_shape_f2_mkup3_plan" means the third makeup plan for the second fraction of the plan "ellipse_shape." *See section Patient Re-Alignment, page 59* on Makeup Plans for more details.

The Treatment Data window now contains the selected plan's name in the Plan text area, the prescribed dose in the Plan Dose text area and the cumulative dose in the Plan Total. Information about the plan fractions appears in the Treatment Data window when the Treatment Paths window appears.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118 1070

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



**To deselect a makeup fraction:**

**Step 1:** Click the highlighted makeup fraction. This fraction is deselected.

**Step 2.** The **USE MAKEUP FRACTION** button becomes inactive. The **USE FULL FRACTION** button becomes active.

**To select a full fraction:**

**Step 1.** Click the **USE FULL FRACTION** button, if active. The Treatment Paths window (*Figure 7 Treatment Paths, page 7*) appears. The Treatment Plans window appears when **CANCEL** is clicked.

**NOTE:** The **USE FULL FRACTION** button is inactive (grayed out) if there are no more full fractions to select (i.e., the Full text area shows 0), or if a makeup fraction was selected.

## Path Selection

After selecting a plan fraction from the Plan Fractions window, the Treatment Paths window (*Figure 7 Treatment Paths, page 7*) appears. The window contains a selection and information section.

- The top section contains a list of the treatment paths of the treatment plan. It shows the path name, the path dose in cGy, the treatment position of the patient and the type of geometry of the camera system.
- The lower section contains a list of the paths completed for the selected fraction of the treatment plan. It shows the name of the completed path fraction, the date the path was completed and the dose delivered.

**To select a treatment path:**

**Step 1.** Select the desired treatment path and click **OK**.

**Step 2.** The Patient And Treatment Verification window (*Figure 8 Patient and Treatment Verification, page 9*) will appear.

**Step 3.** The Plan Fractions window appears when **CANCEL** is clicked.



1071 Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



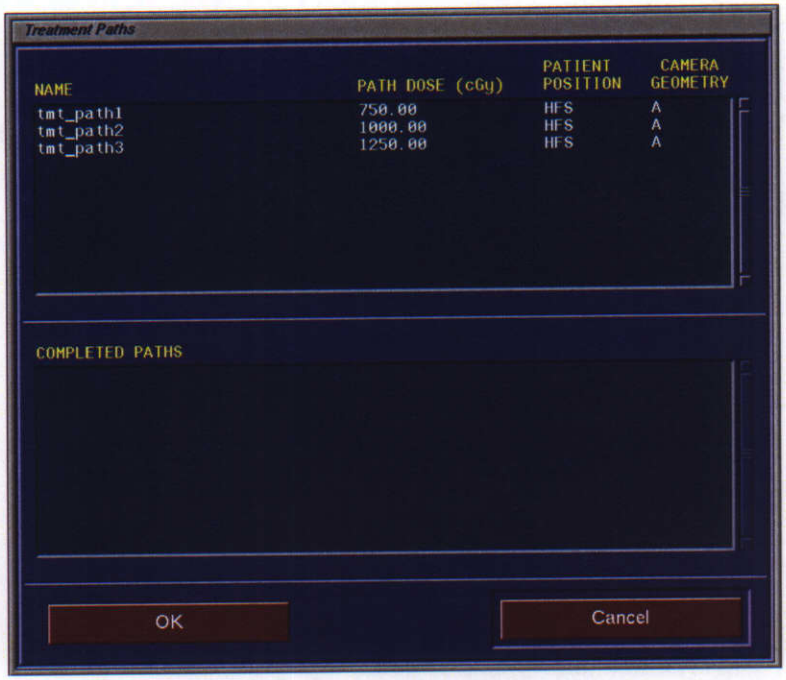



**Figure 7 Treatment Paths**

The Treatment Data window will now contain information in the Fraction text area. The information is in the form "(number of fractions executed) / (total number of fractions allowed): dose per fraction." The "*number of fractions executed*" is the total number of full fractions completed after this chosen fraction is executed. For example, "3/10 : 1000" means that 2 out of 10 fractions have been executed and, when this fraction is completed, 3 out of 10 fractions will have been executed. The fraction dose is 1000 cGy.

Information about the path appears in the Treatment Data window when the Loading Treatment Files window appears.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



# Plan Verification

After a path has been selected from the Treatment Paths window, the Patient And Treatment Verification window (*Figure 8 Patient and Treatment Verification, page 9*) appears. The window contains a patient information verification section and a treatment information section.

The patient information section contains the name of the patient, the medical ID and the name of the physician. The treatment information section shows:

- Name of the plan to be treated
- Name of site to be treated
- Control mode of the plan
- Tracking mode of the plan
- Motion tracking enabled
- Dose per fraction
- Current fraction of the plan being executed
- Name of the path
- Path dose
- Patient treatment position
- Type of anatomy being treated
- Camera layout geometry
- Collimator size

**WARNING: It is important that you verify that this patient is in fact the one to be treated and the plan is the correct one to use.**

Notice that the only buttons active when the Patient And Treatment Verification window appears are the patient information **DATA OK** button and **CANCEL**.



1073 Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



To indicate that the patient and treatment information are correct:

**Step 1.** If the data is correct, click **DATA OK** in the **patient** information section. If the information is not correct, click **CANCEL**. The treatment information **DATA OK** button becomes active and highlighted.

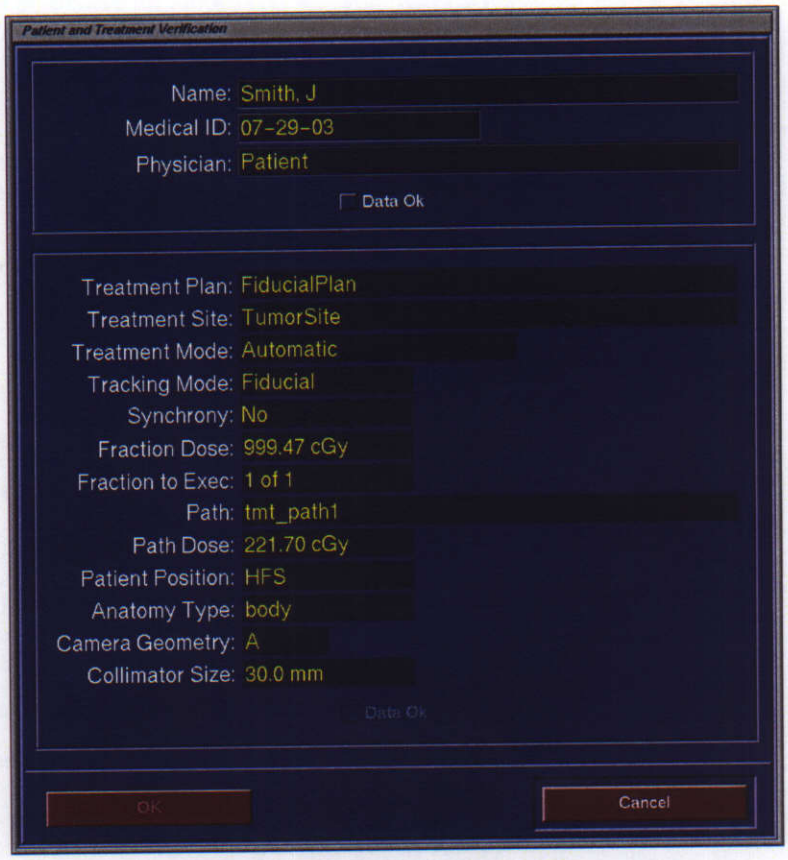



**Figure 8 Patient and Treatment Verification**

**Step 2.** If the data is correct, click the **DATA OK** button in the **treatment** information section. If the information is not correct, click **CANCEL**. The **OK** button becomes active (turns green).

**Step 3.** Click **OK**. The Loading Treatment Files window appears.

**Step 4.** The Treatment Paths window appears when **CANCEL** is clicked.

**NOTE:** The Treatment Data window does not appear with the Patient And Treatment Verification window. It appears again when the loading Treatment Files window appears. All text areas in the Treatment Data window contain information on the patient and treatment plan.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



# PATH DOWNLOADING

Patient alignment begins with path downloading (*Figure 9 Loading Treatment Files Message, page 10*). During the path download, the couch is loaded with the alignment position from the treatment plan's previous session. If there is not an existing couch position stored for the treatment plan, then a default position associated with the plan' anatomy type, is loaded into the controller. The couch can be moved to this nominal treatment position using the **TREAT** button on the Couch Hand Controller.

After verifying the patient and treatment data, the Loading Treatment Files window appears. Treatment files are being downloaded to the manipulator computer and the TLS computer. The time display text area shows the elapsed time during the download. When the files have been downloaded, the Align Patient window automatically appears.

To cancel a download, click **CANCEL**. The Treatment Paths window appears.

**CANCEL** is only available after files have been successfully downloaded to the TLS computer. If the file transfer to the TLS computer fails, treatment file download automatically cancels after three minutes.

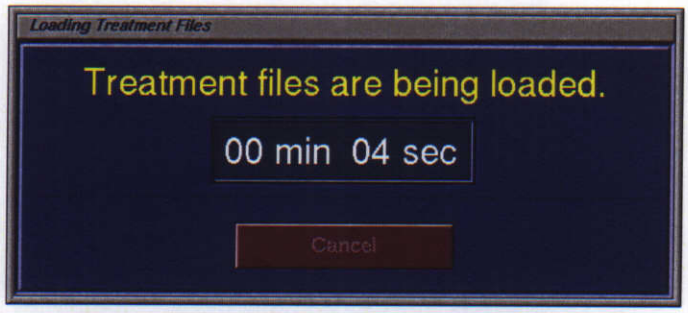



**Figure 9 Loading Treatment Files Message**

If downloading files takes more than three minutes, an error message appears. The download can be canceled any time before the timed-out error occurs. The text areas of the Treatment Data window (*Figure 3 Treatment Data, page 2*) display the patient and treatment information.



1075

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



# PATIENT ALIGNMENT

## Patient Alignment: General Operation

There are three tracking modes that can be performed during treatment:

1. 6D-Skull Tracking
2. Fiducial Tracking
3. Xsight™ Spine Tracking System - OPTION

**NOTE:** If you have purchased the Xsight Spine Tracking System option, refer to the Xsight Spine Tracking System module located in tab "16" in this manual.

After the Treatment Files have been downloaded to the manipulator computer and the imaging computer, the Align Patient window (*Figure 10 Initial Align Patient, page 12*) automatically appears.

The Align Patient window has four different areas:

1. Alignment window (*Figure 14 Alignment, page 15*)
2. Pause Control window (*Figure 19 Pause Control, page 21*)
3. Treatment Data screen (*Figure 3 Treatment Data, page 2*)
4. Controls window (*Figure 21 Controls, page 22*)



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

1076

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015

**Figure 10 Initial Align Patient**

## Automatic Patient Alignment

The automatic patient positioning functions are accessible through the **AUTOCOUCH** button located in the Patient Adjustment Area. Click **AUTOCOUCH** to display the Autocouch Alignment window (*Figure 11 AutoCouch Alignment Window, page 13*).



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

1077

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



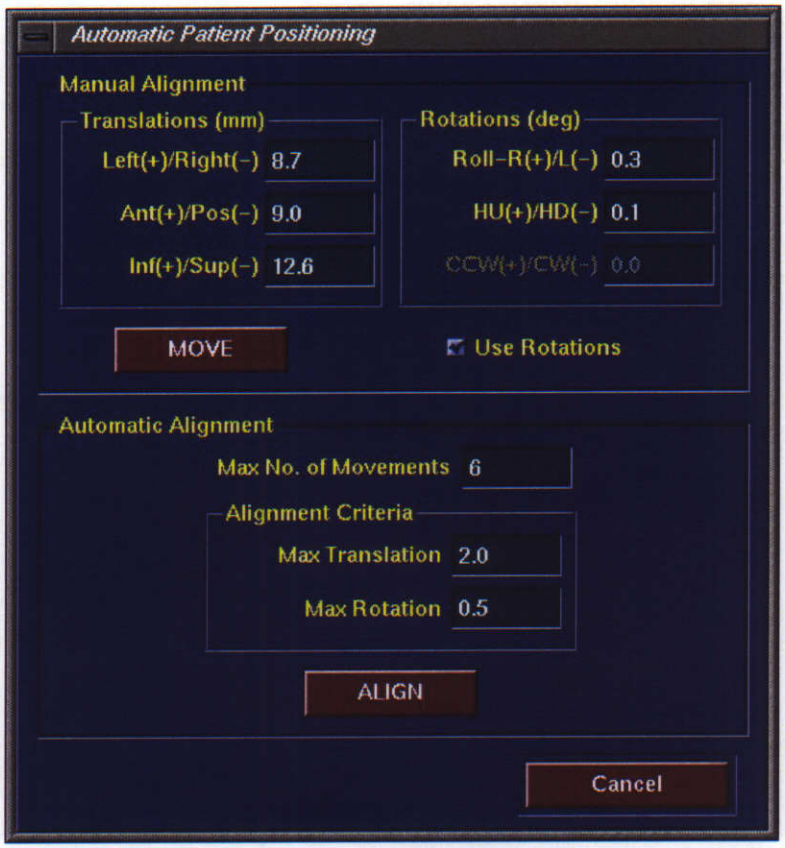



**Figure 11 AutoCouch Alignment Window**

The Autocouch Alignment window contains two sections that aide in placing the patient into a treatable position.

**Manual Alignment** (top section): controls movement of the couch by a fixed number.

**Auto Alignment** (bottom section): automatically aligns the patient based on section parameters.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118 1078

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



## Manual Alignment Area

The Manual Alignment area contains six editable text boxes, loaded with the current couch corrections computed by the imaging system. Click **MOVE** to displace the couch by the values displayed in the translation correction text boxes. If a correction value is beyond the couch movement range the couch movement failed message will appear (*Figure 12 Couch Movement Failed Message, page 14*). Click **USE ROTATIONS** to incorporate the rotational corrections into the couch displacement. On activation of the **MOVE** button, the Autocouch Alignment window will disappear and the couch movement message will appear (*Figure 29 Couch Movement Message, page 28*). When couch movement is complete, the couch movement message will disappear. Click **ACQUIRE** in the Controls window (*Figure 13 Control Window, page 14*) to reestablish the displacement of the patient.

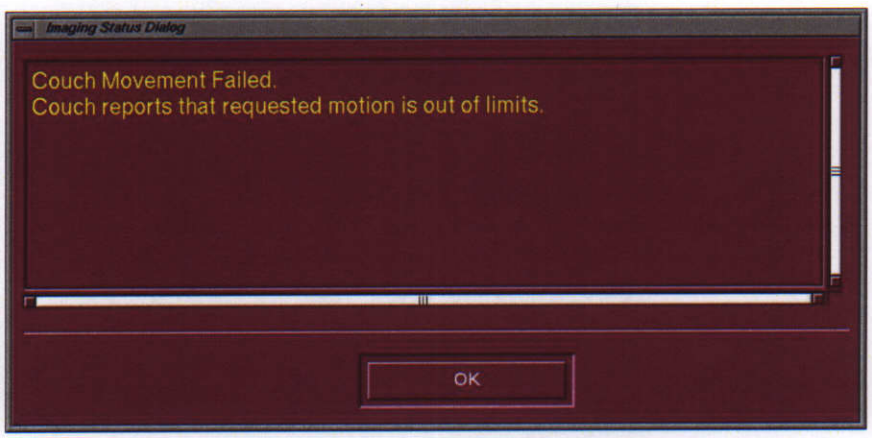



**Figure 12 Couch Movement Failed Message**

**Figure 13 Control Window**



1079

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



# Alignment Window

The Alignment window (*Figure 14 Alignment, page 15*) has a number of different areas.

## Image Area

The Image Area consists of six image displays, three each for both cameras. A digital reconstructed radiograph (DRR) reference image is displayed in each of the Synthetic Image (A or B) windows. The live image captured by the imaging system is displayed in the Camera Image (A or B) window.

Each of the Synthetic and Camera Image windows contains a set of crosshairs. The crosshairs are available to aid in alignment of the synthetic and live images. The crosshairs in each of the synthetic images move independently. Crosshairs for pairs of Synthetic and Camera Image windows move in unison.

**Figure 14 Alignment**

Each of the Overlay Image (A or B) displays contains the live image overlaid on the synthetic reference image. The overlaid images can be viewed as either the sum or the difference between the real and synthetic images.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

1080

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



Below the six image displays at the bottom of the Alignment window are the image display controls. Two slider bars and their corresponding text boxes control the Window and Level of the image displays. The top slider bar controls the Window setting and the bottom bar controls the Level setting. These bars affect only the window currently selected (denoted by a yellow outline) unless the **APPLY W/L TO ALL** box is checked, in which case the bars affect all six windows. The **INVERT** button inverts all images. The **MAX CONTRAST** button maximizes the contrast of the live image data based on the current ROI drawn in the window.

## Patient Adjustment Area

The Patient Adjustment area contains three sliders for moving the live images to match with the reference images in the Overlay of Images windows. The coordinate system of the sliders is based on anatomical coordinates, that is, patient's left-right, superior-inferior and anterior-posterior, as defined for the human body. Additionally, the six text boxes to the left contain the calculated offset of the patient from the patient nominal position. The boxes display, in order from top to bottom, the correction required in the left-right, anterior-posterior, superior-inferior, left-right roll, head-up—head-down and clockwise-counterclockwise axes.

**NOTE:** The above anatomical coordinate positions are based on a head first supine position.

In fiducial tracking with two or fewer fiducials, only the first three boxes are used. With 6-D skull tracking or fiducial tracking with three or more fiducials, all six boxes are used. A three-dimensional cartoon represents a patient lying on the treatment table with the anatomical coordinates. It aids you in determining the direction the treatment table must move to position the patient within the range of the imaging system.

## View Mode Drop-down Box

View Mode drop-down box sets the action of the mouse over the images. In X-Hairs mode, clicking the mouse in either a live or reference image, positions the red and green lines to intersect over the mouse click. This is the standard mode of operation in 6-D Skull Alignment. In Pan mode, click-drag pans the image in the Image window. In ROI mode (available for fiducial tracking only), click-drag draws a yellow box indicating a desired Region of Interest in which the Fiducial Location Algorithm searches for fiducials. In Offset mode (available for fiducial tracking only), click-drag moves all Fiducial ROI's simultaneously. You should line up the green dots displayed in the Offset view mode with the fiducials as seen in the live images.

**NOTE:** Moving the offsets automatically clicks the Enable Offset checkbox located in the Fiducial Area.

## Zoom drop-down Box

Zoom drop-down box sets the zoom level of the image. Smaller zoom levels show more of the image in the Image window. The Auto option zooms the image just enough so all of it appears in the image window. Any change in zoom affects all image windows.



1081 Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



## Imaging X-ray Parameters Area

**NOTE:** If you have purchased the Xsight Spine Tracking System option, refer to section, X-ray Parameters in the Xsight Spine Tracking System module located in this manual.

The Imaging X-Ray Parameters area has text blocks that show the X-ray parameters and a button (to the right above the text blocks) that allows you to adjust those parameters. The numbers represent the kVp (KV), current (MA) and X-ray exposure time (EX) in milliseconds. Clicking the **X-RAY PARAMETERS** button brings up the Set X-Ray Parameters window (*Figure 15 Set X-ray Parameters, page 17*).

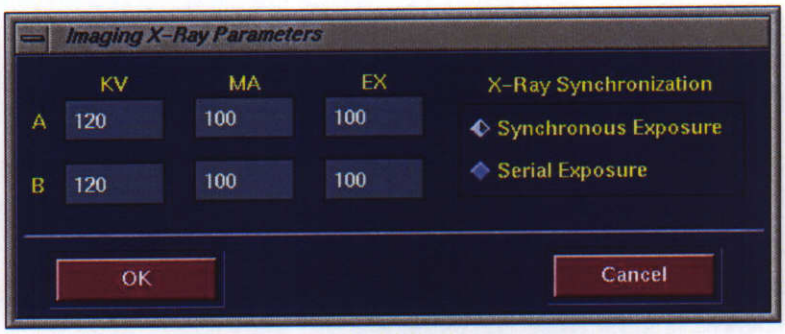



**Figure 15 Set X-ray Parameters**

Synchronous mode instructs the TLS to create/capture images on camera A and B simultaneously. Serial mode captures images one at a time.

After selecting parameters and clicking **OK**, the parameters are set and the Review X-Ray Parameters window (*Figure 16 Imaging Status Message, page 17*) appears. Clicking **CANCEL** in the Imaging X-ray Parameters window or **OK** in the Review X-ray Parameters window returns you to the Patient Alignment window. With 6-D tracking treatment, set the parameters to achieve live images that look similar to the DRR's. For fiducial tracking treatments, set X-ray parameters so that fiducials can be clearly seen against the background.

**Figure 16 Imaging Status Message**



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



### Overlay Image Format Area

The Overlay Image Format area has four buttons that you may use to set the image comparison format. The images in the Overlay image boxes can be set to either be additions or subtractions of the live and DRR images. The **ALIGN** button shifts the live images to overlay with the DRR images as if the patient were aligned with the current couch corrections. For Fiducial Tracking mode, the images are automatically aligned after each image acquisition based on the tracking results. The **RESET** button resets any shifting that may have been done on the live images, showing them exactly as they are taken by the imaging system.

### Fiducial Location Control Area

The Fiducial Location Control area contains several controls specific to Fiducial Tracking mode. This area is dimmed out when the tracking mode is not fiducial tracking. For more on these controls, *see section, Patient Alignment: Fiducial Tracking, page 35.*

## Multi-Purpose Imaging Window

The screen area on the right of Alignment window (*Figure 14 Alignment, page 15*), is a Multi-Purpose Imaging window (*Figure 17 Multi-Purpose Imaging, page 19*). Three display modes Couch, Image and Imaging Log, can be selected by "right-clicking" in the window area. The different modes are described below.

### Couch Display Window

The coordinate directions are displayed next to a graphical depiction of the patient and couch. This display will shift as you move the offset slider controls. The coordinate directions are displayed along with an animated depiction of the patient displacement on the couch as you move the offset slider controls.



1083 Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



## Enlarged Image View Window

This window (*Figure 17 Multi-Purpose Imaging, page 19*) displays an enlarged view of the selected image view window. Any one of the six 200 x 200 or smaller image display windows can be selected by clicking in the window area. The currently selected window is indicated with a yellow box surrounding the image area. All available image display functions are available in the Enlarged Image View window.

**Figure 17 Multi-Purpose Imaging**



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

1084

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



## Image Data Log Window

This window (*Figure 18 Imaging Data Log Window, page 20*) is a scrollable read-only text window, which displays imaging data pertinent to each acquisition. In addition to the correction values that are computed, there may be relevant textual information displayed in this window.

**Figure 18 Imaging Data Log Window**



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

1085

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



## Pause Control Window

The Pause Control window (*Figure 19 Pause Control, page 21*) contains six buttons. The **SITES**, **PLANS** and **PATHS** buttons are not used in the Align Patient window. **PAUSE** can be clicked at any time, other than during error recovery, to pause system operation (*see section, Pausing Treatment, page 54*).

**Figure 19 Pause Control**

Clicking the **CONTROLS** button brings up the Controls window (*Figure 21 Controls, page 22*) when it is available. The **EXIT** button removes the Align Patient window and returns you to the Treatment Paths window.

## Treatment Data Screen

The Treatment Data window displays information about the current patient, plan and path. *See section, Site Selection, page 2* for more information.

**Figure 20 Treatment Data Window**



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

1086

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



## Controls Window

The Controls window has four buttons used to control image acquisition and treatment delivery.

- **ACQUIRE** button, when clicked, causes the system to acquire new radiographic images and determine the patient location.
- **START** button, when clicked, removes the Align Patient window and brings up the Equipment Readiness window (*Figure 36 Equipment Readiness, page 42*). The **START** button is not active until after the patient has been aligned within acceptable bounds ( *Patient Alignment: Fiducial Tracking, page 35*).
- **CORRELATE** button, redetermines patient location based on the current images. It is only active when images have been acquired.
- **CURRENT/PREVIOUS** button, bypasses current image data and allows treatment to start with the patient position from the last node's delivery. This button should be used very carefully and only when it is not feasible to acquire new images for patient positioning.

**Figure 21 Controls**

## Initial Condition of the Align Patient Window

When the Align Patient window appears after the Loading Treatment Files window, the **START** button is inactive. The Synthetic Image display windows show digitally constructed radiograph images of the optimal patient position. The Live Image display windows are blank. The **ACQUIRE**, **PAUSE** and **EXIT** buttons are active.

## Acquiring Live Images

Click the button **ACQUIRE** to capture live images. Within a few seconds, the system responds either with new images and suggested couch corrections or with an error signifying the patient is out of bounds.

**WARNING: Make sure no person other than the patient is in the treatment room when images are generated. Follow hospital procedures.**



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

1087

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



## Results After Acquiring Live Images

When the images have been acquired and correlated, the Alignment window shows six images, three active sliders and the X-ray image parameters (*Figure 22 Align Patient Window with Acquired Images, page 23*). The green and red crosshairs are active in the Synthetic Image windows.

The six text boxes to the right of the images show the amount the treatment table needs to move to position the patient into range of the imaging system.

A green rectangular outline is shown in the three-dimensional patient drawing. This represents the position where the treatment table needs to move relative to the original position.

**Figure 22 Align Patient Window with Acquired Images**

### Moving the Crosshairs

Crosshairs are used for visual verification, intensity and the x and y position. Click in **SYNTHETIC IMAGE A** to move the crosshairs. The corresponding center of the crosshairs in Camera Image A also move to the same relative position as those in the Synthetic Image A. Repeat this procedure for the crosshairs in the Image B window. To rotate the crosshairs, hold down the left and middle mouse buttons simultaneously.

### Moving the Sliders

Moving the sliders moves the live images to simulate patient motion. Click to move the pointer over the desired slider.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



# Patient Alignment: Automatic Couch Positioning

On completion of the Path Download, the Align Patient window (*Figure 23 Align Patient, page 24 or Figure 24 Align Patient, page 25*) will automatically appear. If the couch does not power on, an error message (*Figure 25 Couch Power On Error Message, page 25*) appears to remind you that the couch automatic patient positioning functions are disabled. Clicking **OK** in the Couch Disabled Message window will return control to the Align Patient window.

**Figure 23 Align Patient**



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

1089

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



## Out of Bounds Error

Move each slider until the overlaid images appear as one. Adjust Patient Alignment as necessary, using the numbers under the sliders instead of the couch correction numbers. Negative left-right numbers indicate movements right, negative posterior-anterior numbers indicate movements posterior and negative inferior-superior numbers indicate movements superior.

The slider and three-dimensional cartoon move synchronously.

**Figure 24 Align Patient**

**Figure 25 Couch Power On Error Message**



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

1090

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



## Automatic Patient Alignment

The automatic patient positioning functions are accessible through the **AUTOCOUCH** button located in the Patient Adjustment Area. Clicking the **AUTOCOUCH** button will display the Couch Automatic Patient Positioning window (*Figure 26 Automatic Patient Positioning, page 26*).

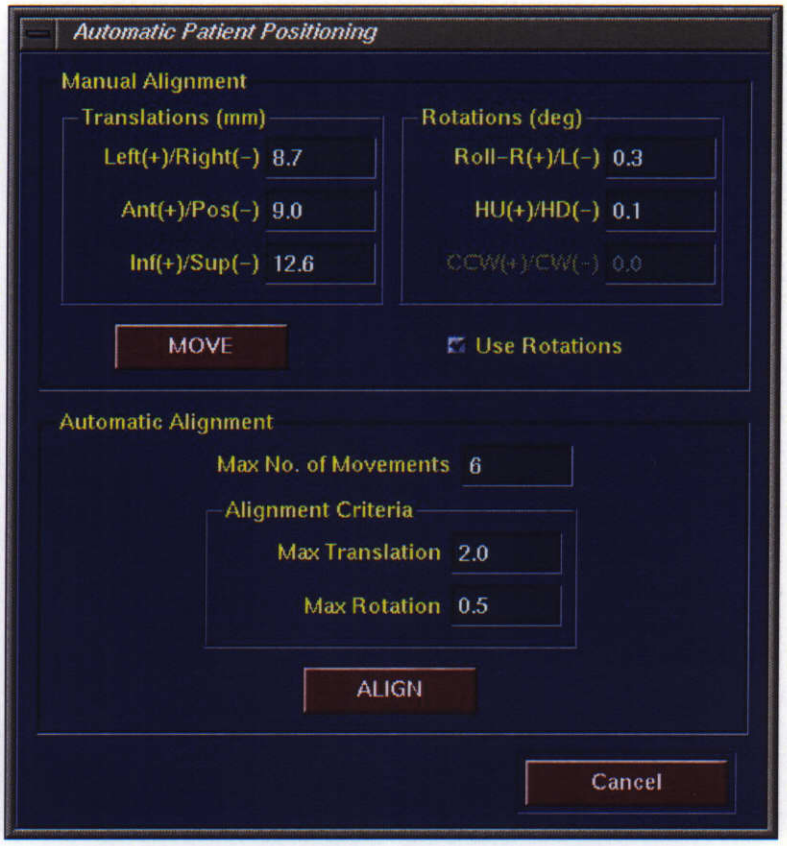



**Figure 26 Automatic Patient Positioning**

The Automatic Patient Positioning window contains two alignment modes that aid in placing the patient into the treatment position. The Manual Alignment mode in the top section of the window only moves the couch by the values specified. No image acquisition or repeated couch movements will occur. The Automatic Alignment mode in the bottom section of the window acquires an image, moves the couch and repeats these steps until either both the translation and rotational values are below the maximum values specified, or until the maximum number of movements has been reached.

Manual Alignment and Auto Alignment modes are mutually exclusive. Only one mode can be used at any given time. Clicking the **CANCEL** button will close the Automatic Patient Positioning window and revert all updated parameter values back to their initial values.

### Manual Alignment Mode

The Manual Alignment mode contains editable text boxes, loaded with the current couch corrections computed by the imaging system.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

1091

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



- **MOVE** button: Displaces the couch by the values displayed in the translation correction text boxes. If a correction value is beyond the couch movement range the Couch Movement Failed message will appear (*Figure 27 Couch Movement Failed Message, page 27*).
- **USE ROTATIONS** button: Incorporates the rotational corrections into the couch displacement.
- On activation of the **MOVE** button, the Automatic Patient Positioning window will disappear and the couch movement message will appear (*Figure 29 Couch Movement Message, page 28*). Upon completion of the couch movement, the couch movement message will disappear.
- **ACQUIRE** button: The Controls window (*Figure 28 Control, page 27*) will re-establish the displacement of the patient.
- Repeat this process for as many times as necessary.
- **CCW(+)/CW(-)**: Type in a numeric value to rotate the couch (in degrees) clockwise or counter-clockwise.

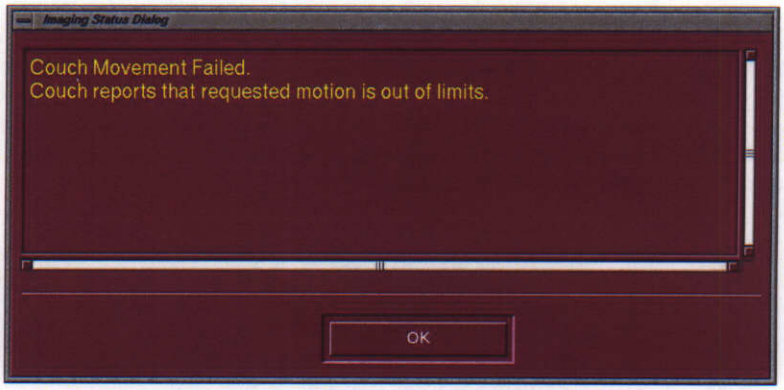



**Figure 27 Couch Movement Failed Message**

**Figure 28 Control**



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

1092

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



## Automatic Alignment Mode

The Automatic Alignment mode contains conditions used by the alignment algorithm to determine the completion of the alignment sequence.

- Clicking the **ALIGN** button in the Automatic Patient Positioning window will activate the automated alignment sequence. Each cycle of the alignment sequence consists of both a couch movement and an image acquisition. Alignment will complete when either the Max No. of Movements has occurred or both the translation and rotation corrections are below the Max Translation and Max Rotation text box values.
- On activation of the **ALIGN** button, the Automatic Patient Positioning window will disappear and the couch movement message will appear (*Figure 29 Couch Movement Message, page 28*).
- Following each couch movement, the couch movement message will switch to the image acquisition message (*Figure 30 Image Acquisition Message, page 28*).
- This sequence will continue until the completion of the alignment process, when the alignment report message will appear (*Figure 31 Alignment Report Message , page 29*).

**WARNING: The Automatic Couch Motion Subsystem does not detect when the patient or the couch is outside the nominal patient setup boundaries. At the end of patient alignment or re-alignment, ensure that the patient is within the nominal alignment boundaries. (These limits are 42" for skull from the ground and 44" for extra-cranial superior from isocenter, when performing body treatments.)**

**Figure 29 Couch Movement Message**

**Figure 30 Image Acquisition Message**



1093 D1
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015

**Figure 31 Alignment Report Message**

## Pausing Couch Movement

Couch movement is not monitored by the CyberKnife System collision detection system. It is important to monitor all patient table movement to prevent potential collisions. Couch movement can be terminated at anytime by clicking the **PAUSE** button located in the Pause Control window (*Figure 19 Pause Control, page 21*). Clicking the **ALIGN** button in the Autocouch Alignment window will resume the automated patient alignment.

## Patient Safety Guidelines

Once the patient is aligned and before you start treatment delivery, enter the treatment room and do a visual check of the patient's position. This check should be done in accordance with the following patient safety guidelines. In particular,

- For cranial treatments, two measurements must be made to ensure the patient is located within the safety zone:
  - a. Measuring upward from the floor, verify that the entire patient is inferior to the 42" line
  - b. Measuring 10" superior from the isocenter, verify that the patient is inferior to this 10" line
- For extracranial treatments, measure upward from the floor to verify that the entire patient is inferior to the 44"line
- If you are treating a lateral lesion, measure to verify that the lateral borders of the entire patient do not exceed 14" either to the left or right of the isocenter.

Always visually scan the patient to confirm measurements. If you need to re-align the patient during the treatment process, it is recommended you enter the treatment room and perform a visual check of the patient's position, following the patient safety guidelines.

**NOTE:** If the patient's position exceeds the safety limits described above, there are limited changes that can be done to the patient's position at the time of treatment. We recommend you simulate the treatment plan prior to treatment delivery to ensure patient safety. To prevent this situation from occurring again in future cases, follow the patient safety guidelines during the initial patient setup and immobilization process.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



## Manual Alignment Mode

**NOTE:** Manual Alignment Mode is for use when automatic alignment is not possible due to couch hardware limitations.

**To move the patient into better alignment, follow these steps:**

**Step 1.** Record the number from the Couch Correction text areas to the right of the images and their direction (that is, left-right, superior-inferior, posterior-anterior). Use these numbers to realign the patient, if necessary.

**Step 2.** Remove the "radiation enable" key from the user control panel. Use it to disable the door interlock.

**Step 3.** Using the controls on the treatment table, move it by the amount and in the direction indicated by the patient alignment form.

**Step 4.** Remove the key from the treatment room door. Return it into the user console panel.

**WARNING: Make sure no person other than the patient is in the treatment room when images are generated. Follow hospital procedures.**

**Step 5.** Click **ACQUIRE IMAGES** to acquire another set of images.

**Step 6.** Repeat the previous five steps, if necessary. When you are satisfied, click **OK** to display the Equipment Readiness window.

## Treatment Delivery

No alignment operations are allowed during treatment delivery. During treatment delivery, the robot corrects the beam directions for the patient displacement for both translations and rotations. The robot corrects for beam directions up to ±10mm along each translation axes, ±3 degrees of couch clockwise and counter-clockwise rotation and ±1 degree of head up/down and roll left/right rotations. The limits for rotation corrections can be changed to values below these limits using the Imaging Parameters interface during Patient Alignment or Re-alignment. Corrections for rotations can be also disabled from this interface.



1095 Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



## Patient Re-Alignment

If the patient displacements during treatment are larger than the maximum allowed values, then the system will be paused automatically. The automatic patient positioning functions can be used to re-align the patient.

Before start of treatment delivery, perform a visual check of the patient's position in the treatment room, following the patient safety guidelines.

**WARNING: The Automatic Couch Motion Subsystem does not detect when the patient or the couch is outside the nominal patient setup boundaries. At the end of patient alignment or re-alignment, ensure that the patient is within the nominal alignment boundaries. (These limits are 42" for skull from the ground and 44" for extra-cranial superior from isocenter, when performing body treatments.)**



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118 1096

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



## Corrections for Patient Rotations

The CyberKnife Software includes the ability to correct for patient rotations up to ±3° yaw, ±1° pitch and ±1° roll. During treatment delivery, the robot repositions the Linac to correct for the patient rotations up to these limits.

The automatic patient positioning couch can adjust the patient position for all translations and for roll, pitch.

The following should be noted for these corrections for rotation:

- The Treatment Planning System simulates the motions of the robot for these corrections and ensures the safety of the generated treatment plan.
- During treatment delivery, corrections for rotations can be disabled using the Imaging Parameters Interface in the Patient Alignment window, during patient alignment or re-alignment.

During treatment delivery, corrections for rotations can be disabled using the Imaging Parameters interface in the Patient Alignment Window (*Figure 23 Align Patient, page 24 or Figure 24 Align Patient, page 25*) during patient alignment or re-alignment.

### Imaging Parameters Area

**NOTE:** If you have purchased the Xsight Spine Tracking System option, refer to section, Imaging Parameters in the Xsight Spine Tracking System module located in tab "16" in this manual.

The Imaging Parameters area has a button that allows you to adjust imaging and algorithm parameters. Clicking the button **IMAGING PARAMETERS** displays the Imaging Parameters window (*Figure 32 Imaging Parameters Area – Fiducial Tracking, page 32 or Figure 33 Imaging Parameters Area – 6D Skull Tracking, page 33*).

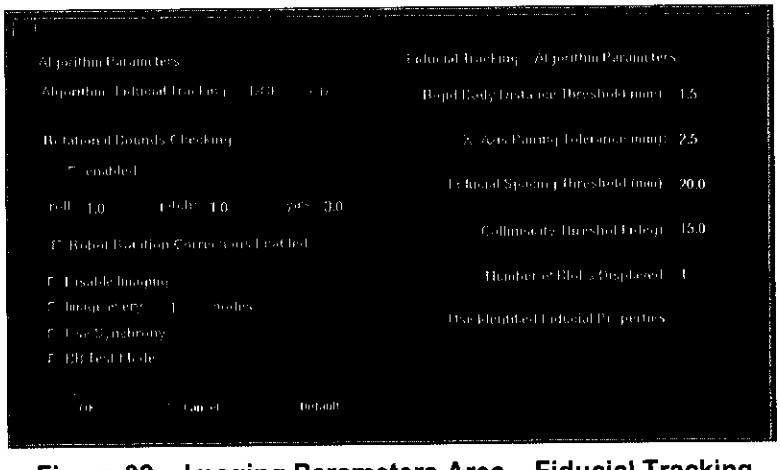


**Figure 32 Imaging Parameters Area – Fiducial Tracking**



1097 Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



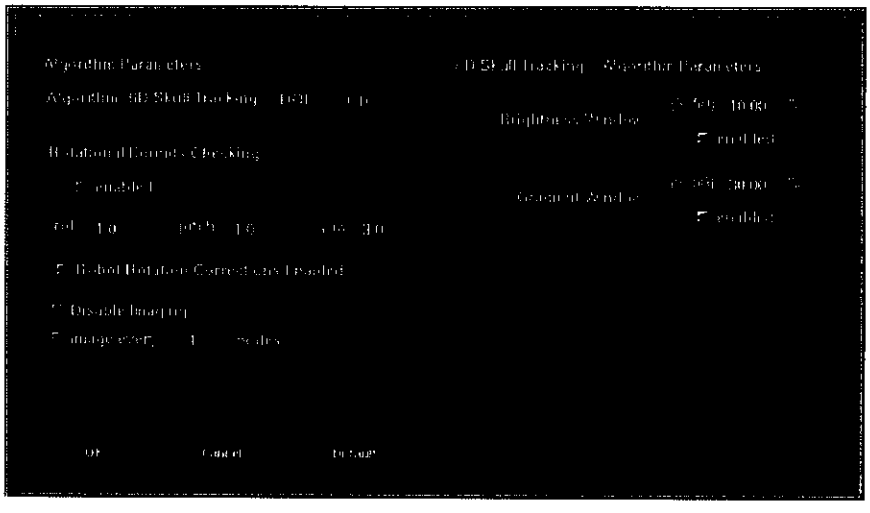


**Figure 33 Imaging Parameters Area – 6D Skull Tracking**

The general algorithm parameters are specified in the left part of the window. Below is a brief explanation of the parameters in the general algorithm parameters area:

The dof (6D) can be chosen for fiducial tracking in the drop-down box. Typically, fiducial tracking will compute all six degrees of freedom of displacement (three translations and three rotations).

Enabling Robot Rotation Corrections allows the robot to correct for user defined rotation angles during treatment delivery. The robot can correct for roll and pitch rotations of up 1 degree and yaw rotations of up to 3 degrees.

Enabling the Rotational Bounds Checking allows you to define the bounds of the rotation angles of roll, pitch and yaw within the range of 1 to 5 degrees. If the Robot Rotation Corrections are enabled, then the range is reduced to the robot rotation correction range. If this box is unchecked, the rotation bounds are ignored and the Robot Rotation Corrections are disabled.

Selecting the **DISABLE IMAGING** button inhibits all imaging past node 0.

When the **IMAGING EVERY N NODES** button is selected, the nodes 0, N, 2N etc., are used for imaging, provided these nodes are not blocked and not marked as non-imaging in Treatment Planning System.

Clicking the **BB TEST MODE ENABLED** button allows you to perform the BB test (*see module, Simulation of Treatment*).



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118 1098

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



Some algorithm-specific parameters are available in the right half of the window. The list of parameters displayed here depends upon the tracking method (algorithm) chosen for the plan. The following parameters can be modified by you for fiducial tracking:

**Rigid body distance threshold** is the maximum deviation of the fiducial configuration from the reference configuration. If the distance between live fiducials differ from the corresponding distance between reference fiducials by more than this distance, then a Rigid Body Constraint error is flagged by the tracking algorithm. The default value of 1.5mm ensures that the error due to rigid body deformation is below 1mm. Increasing the value above 1.5mm, reduces or eliminates rigid body errors at the expense of allowing larger errors in targeting.

**X-axis pairing tolerance** is the maximum relative distance between candidate fiducials in the inferior-superior axes, to consider them as projection from the same fiducial. The default value is designed to eliminate false identification of fiducials. However, in some cases such as abnormally long fiducials (>5mm), or fiducials in close proximity to another bright object in the projected image, the displacement estimate in the inferior superior direction from one camera differs more than this limit from the other camera. Such cases can be handled by increasing this limit.

**Fiducial spacing threshold** is the minimum distance between fiducials required for accurate estimation of rotations. The algorithm will compute rotations if the fiducial configuration should contain a minimum of three fiducials whose distance between each other exceed this threshold. Otherwise, only translations are computed. You can force the computation of rotations by reducing this threshold. However, the accuracy of rotations is not guaranteed for such fiducial configurations.

**Collinearity threshold** is the minimum angle between lines joining a triplet of fiducials required for accurate estimation of rotations. The parameter is a measure of the closeness of a triplet of fiducials to a straight line. The algorithm will compute rotations if the fiducial configuration should contain at least one triplet of fiducials which meet this condition. Otherwise, only translations are computed. You can force the computation of rotations by reducing this threshold. However, the accuracy of rotations is not guaranteed for such fiducial configurations.

**Number of blobs displayed** is the number of blobs or candidate fiducials that will be displayed in the live image window, when **DISPLAY BLOBS** is selected in the Patient Alignment window. The feature is used to display candidate fiducials and get their distinguishing properties, in order to differentiate them from other fiducial-like features in the images.

When the **USE IDENTIFIED FIDUCIAL PROPERTIES** button is selected, the TLS will be automatically instructed to use actual computed fiducial properties when performing target acquisition and localization during treatment. The actual fiducial properties are identified during patient alignment or re-alignment. By default, the button is always checked so that the identified fiducial properties are automatically used during treatment. When the identified fiducial properties are not good during treatment, then you can uncheck the button to use the nominal fiducial properties instead.



1099 Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



The following parameters can be modified by you for 6D skull tracking:

**Brightness window** is the range of the average brightness of live image with respect to the DRR's allowed. The algorithm computes a **Brightness Gain** as the ratio of the average brightness of the live image to that of the DRR image (after correcting for coarse translations). This ratio should be 1.0± Brightness window value (specified as a percentage), otherwise a **Brightness Error** will be flagged by the algorithm. The Brightness window check can be disabled by un-checking the **ENABLED** checkbox next to this parameter.

**Gradient window** is the range of the average variance of live image with respect to the DRR's allowed. The algorithm computes a **Gradient Gain** as the ratio of the variance of the live image to that of the DRR image (after correcting for coarse translations). This ratio should be 1.0± Gradient window value (specified as a percentage), otherwise a **Gradient Window Error** will be flagged by the algorithm. The Gradient window check can be disabled by un-checking the **ENABLED** checkbox next to this parameter.

# Patient Alignment: Fiducial Tracking

The Fiducial Location Control area has two sections:

1. **Fiducial Display Control** section, located on the left
2. **Fiducial Parameters Control** section, located on the right

Each area contains five controls.

## Fiducial Display Control

### View Mode Drop-down Box

View Mode drop-down box sets the action of the mouse over the images. In X-Hairs mode, clicking the mouse in either a live or reference image, positions the red and green lines to intersect over the mouse click. This is the standard mode of operation in 6-D Skull Alignment. In Pan mode, click-drag pans the image in the Image window. In ROI mode (available for fiducial tracking only), click-drag draws a yellow box indicating a desired Region of Interest in which the Fiducial Location Algorithm searches for fiducials. In Offset mode (available for fiducial tracking only), click-drag moves all Fiducial ROI's simultaneously. You should line up the green dots displayed in the Offset view mode with the fiducials as seen in the live images.

**NOTE:** Moving the offsets automatically clicks the Enable Offset checkbox located in the Fiducial Area.

### Zoom drop-down Box

Zoom drop-down box sets the zoom level of the image. Smaller zoom levels show more of the image in the Image window. The Auto option zooms the image just enough so all of it appears in the image window. Any change in zoom affects all image windows.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

1100

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



### Display Fiducial Markers Checkbox

When Display Fiducial Markers Checkbox is selected, fiducial markers (plus shape and diamond shapes) are displayed on the images. Diamond shapes are placed in the Synthetic and Overlay images to show where fiducials are expected to be found and plus shapes are placed in the Live and Overlay images to show where fiducials are actually found. Uncheck this box to remove the markers to verify that the plus shapes are lined up over fiducials in the live images.

### Display Blobs

When Display BLOBS checkbox is selected, all blobs (fiducial candidates) will be displayed in the live images and overlay images.

### Display ROI Checkbox

When Display ROI checkbox is selected, the ROI boxes are displayed on reference and live images. These boxes indicate where in the image the Fiducial Location algorithm is looking to find fiducials. Yellow boxes indicate ROI's that have not yet been set for use, green boxes indicate ROI's that will be used on the next Acquire or Correlate function.

### Threshold Checkbox

When the Threshold checkbox is selected, the live images are binary based on thresholds returned by the target locating system. This feature is used for enhanced user visualization only. For Track mode, the threshold used is that of the currently selected fiducial area. For Search mode, the threshold used is the lowest threshold associated with the set of fiducials found.

## Fiducial Parameters Control

To the right is the Fiducial Parameters Control section. It contains the following controls.

### Fiducial Area Selection Drop-down box

Fiducial Area Selection drop-down box selects which fiducials to display ROI information for in the images. In Search mode, only the search ROI information is available, but in Track mode, any individual fiducial can be selected.

### Tracking Mode Button

Tracking mode button allows you to select whether to track fiducials in Search mode or Track mode. Use Search mode during patient alignment to search large areas of the image (usually the entire image) for the fiducials. The Fiducial Algorithm may take longer to execute and may be less reliable while in Search mode. When search mode is selected, the button below will be the **SEARCH PARAMETERS** button.

Once fiducials have been located and the patient has been aligned, the Tracking mode should be set to Track. This automatically sets smaller ROI's around each located fiducial and searches for each fiducial only in its own ROI. When the track mode is selected, the button below will be the **TRACK PARAMETERS** button.

### Search Parameters Button

**SEARCH PARAMETERS** button brings up the Search Parameters window. See the Search Parameters Window section below for more information. This button is only sensitive when the **TRACKING MODE** button is set to **SEARCH**.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

1101

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



### Track Parameters Button

Clicking the **TRACK PARAMETERS** button brings up the Track Parameters window. *See, Track Parameters Window , page 38*, for more information. This button is only sensitive when the **TRACKING MODE** button is set to **TRACK**.

### Enable Offset

Clicking the **ENABLE OFFSET** button applies Fiducial ROI changes made in the Offset mode. Moving the offsets automatically clicks the Enable Offset checkbox located in the Fiducial Area.

## Search Parameters Window

The Search Parameters window (*Figure 34 Search Parameters, page 37*) allows for fine-tuning the Fiducial Location Algorithm in Search mode. Various properties can be fine-tuned.

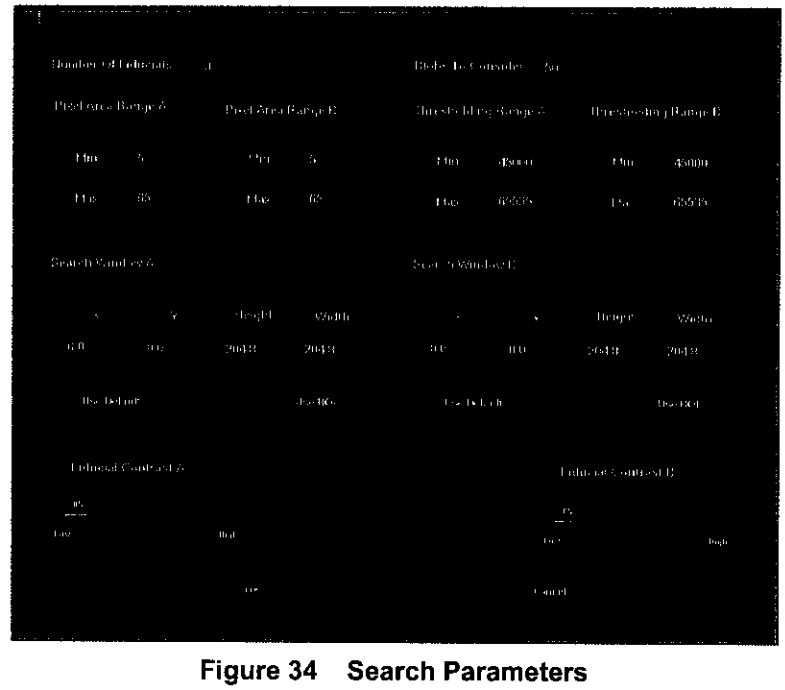


**Figure 34 Search Parameters**

### Pixel Area Range

This feature allows you to enter the min/max pixel area ranges for each image (A, B). Only blobs that have an area in pixels, which fall within the specified range, will be considered candidate fiducials by the TLS fiducial algorithm. In most cases, the defaults set based on the fiducial type are sufficient to track the fiducials reliably. This feature allows you to better handle some difficult tracking scenarios. One example scenario that this feature can help with is the case when the cylindrical gold fiducials is imaged "end-on" (shows up as a small dot in the image). In this case, you may want to decrease the min. and max. area values for the specific fiducial projection that is problematic.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

1102

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



### Threshold Range

Search Threshold Range sets the range of values over which fiducials are searched in the image. These correspond to the Window and Level settings in the image area of the Alignment window, where:

**minimum** = **level**

**maximum** = the lesser of 65535 or the sum of **window + level**.

If different WINDOW/LEVEL settings allow for more visibility of the fiducial, changing the threshold range to match them can improve the performance of the Fiducial Location Algorithm. If fiducials are not clearly visible for any WINDOW/LEVEL setting, X-ray parameters should be modified to either increase or decrease the exposure and setting a new threshold should be re-attempted.

**NOTE:** Different values can be set for image A and image B.

### Search Window

Search Window Location allows you to set the size and location of the area that the Fiducial Location Algorithm searches for the fiducials. The values can be set by either manually entering values, clicking the **USE DEFAULT** button (which sets the window to the entire image), or clicking the **USE ROI** button (which sets the window to the ROI that has been drawn on the images using the ROI View Mode in the Fiducial Display Control section).

### Fiducial Contrast

This feature allows the algorithm to better take advantage of high contrast fiducials. For most cases the default values are sufficient. Features with a contrast value below this setting are excluded from consideration as a fiducial. This generally results in more reliable tracking. For low contrast situations, you can decrease the value significantly for better tracking results.

**NOTE:** Different values can be set for image A and image B.

ROI's drawn on the imaging windows appear yellow until they have been committed to the Fiducial Algorithm by clicking the **USE ROI** button and then clicking **OK**, then they appear green.

Clicking **OK** commits changes that have just been made in the Search Threshold Range and Search Window Location boxes and sends the information to the Fiducial Location Algorithm on the TLS computer. Clicking **CANCEL** returns the values to the state they were in when you clicked **SEARCH PARAMETERS**.

## Track Parameters Window

The Track Parameters window (*Figure 35 Tracking Parameters, page 39*) allows for fine-tuning the Fiducial Location Algorithm in Track mode. Various properties can be fine-tuned. The properties are set independently for each fiducial, based on the current fiducial selected by the Fiducial Area Selection drop-down box in the Fiducial Parameters Control section. The fiducial whose properties are currently being set is displayed in the top left of the window.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015

**Figure 35 Tracking Parameters**

## Pixel Area Range

Tracking Pixel Area Range is identical to the function of the Search Threshold Range described above, except that it applies only for the selected fiducial.

## Threshold Range

Tracking Threshold Range is identical to the function of the Search Threshold Range described above, except that it applies only for the selected fiducial.

## Tracking Window

Tracking Window Location Values is identical to the function of the Search Window Location Values described above, except that it applies only for the selected fiducial.

## Fiducial Contrast

Tracking Fiducial Contrast is identical to the function of the Search Fiducial Contrast described above, except that it applies only for the selected fiducial.

## Use For Tracking Checkbox

When this checkbox is unchecked, the currently selected fiducial is not used for patient alignment calculations. If there seems to be excessive migration of a fiducial, use this button to disregard it.

## Fiducial Type Drop-down Box

Fiducial Type drop-down box displays the type of the selected fiducial.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118 1104

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



# Aligning the Patient in Fiducial Tracking Mode

After the acquisition of live images the synthetic image windows show the reference DRR images, the Camera Image Windows show the live images and the Overlay of Images show the live image overlaid on the synthetic image. If the correlation performed during acquisition found candidates for all fiducials, the Couch Corrections box will display the couch movements necessary to align the patient.

Aligning the patient in Fiducial Tracking mode consists of two steps:

**Step 1.** Ensure that the proper fiducials have been identified by the fiducial tracking algorithm.

**Step 2.** Adjust the patient position until proper alignment is reached.

## Ensuring Proper Fiducial Identification

Once images have been acquired, the fiducial location algorithm attempts to locate the fiducials in the images. Once located, fiducials are marked in the live image with a plus sign. If the fiducials have been found correctly, the plus signs and the diamond shapes should overlap in the overlay images, indicating that the correct fiducial configuration was found. If this is the case, verify that the plus signs in the live image are actually marking fiducials by deselecting the Display Fiducial Markers checkbox and visually noting the fiducials under each marker. You may need to modify the window and level settings for the live images to see the fiducials. Once you verify that each fiducial has been located with a marker and that the fiducials are in the correct configuration, proceed to alignment.

If the fiducials are not properly located, there will either be an E-Stop or an error generated and the fiducial markers in the live image will not mark the fiducials. To correctly locate the fiducials, you can attempt one or more of the following:

- Modify the X-ray parameters to improve the quality of the image. If there is too little detail in the images, try increasing the MA and EX to increase the exposure. If the image is too dark, try decreasing the MA and EX to decrease the exposure. For fiducial location, it is best to maximize the contrast between the fiducials and the surrounding tissue. Once the X-ray parameters are modified, reacquire the images to reattempt fiducial location.
- Set as appropriate...

  Whenever possible, use the offset feature to shift ROI's over the fiducials. Do this by selecting **OFFSET** from the View Mode window and dragging the fiducial pattern over the fiducials. This will automatically check the Use Offsets checkbox.

  If it is not possible to drag the ROI's correctly, redraw or redefine the ROI's around their fiducials. (Do this by selecting ROI area of the fiducials.)

  (If in Search mode, draw the box around the entire fiducial area. If in Track mode, draw the box around only the location of the currently selected fiducial. After the boxes are drawn in both image A and image B, enter the Search Parameters or Track Parameters window, depending on current Tracking mode and click the **USE ROI** button for both window A and window B. Then click **OK**.)

  **NOTE:** The fiducial pattern displayed in Offset mode reflects the centers current ROI regions. Re-drawing Track ROI's will change the pattern.



1105

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



**NOTE:** DO NOT attempt to modify the Offsets and Redraw ROI's for the same acquisition/correlation.

**NOTE:** After redrawing or redefining ROI's, the settings must be applied in the Tracking Parameters box before changing the currently selected fiducial in the Fiducial Area Selection drop-down box. If they are not applied prior to changing the currently selected fiducial, ROI settings will be lost.

After attempting one or more of the above, you must attempt to find the fiducials again. If the X-ray parameters have been changed, you must acquire new images by clicking the **ACQUIRE** button on the Controls window to get new images with the new X-ray parameters. If only the threshold range and/or ROI have been changed, you can attempt to correlate in the current image by clicking the **CORRELATE** button on the Controls window. New images will not be acquired, but the fiducial location algorithm will attempt to find fiducials using the new settings in the most recently acquired image.

Once the new acquisition or correlation is complete, you should once again attempt to ensure that the fiducials have been correctly located. If they have not, repeat the above steps and try again.

## Adjusting Patient Position

**NOTE:** When aligning the patient after finding the fiducials by re-drawing specific ROI's, the patient will often be moved so that the fiducial is no longer imaged within the area of the ROI. New ROI's will often need to be drawn after such alignment.

**WARNING: Visually verify that the fiducials have been correctly identified throughout treatment.**

**WARNING: Change tracking mode from search to track prior to beginning treatment delivery.**

**CAUTION:** During treatment delivery in Fiducial Tracking mode it is important to monitor the fiducial locations throughout the treatment to ensure that fiducials are being properly located. This is especially important when entering Treatment Delivery in Search mode instead of Track mode or when using a single fiducial. If at any time it appears the fiducials have not been correctly located, click **PAUSE** on the Parameter Display window or push the nearest E-Stop button. Then use the Patient Re-Alignment window to properly locate the fiducials and proceed.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118 1106

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



# SYSTEM CHECK

After aligning the patient with the information provided from the Align Patient window, the Equipment Readiness window (*Figure 36 Equipment Readiness, page 42*) appears. The window displays a list of the equipment in the CyberKnife System. While the system is checking that the equipment is operational, the **START** button is inactive. When each piece of equipment is ready for treatment, the **START** button becomes active (green).

A timer displayed in the Checking Equipment Readiness text area indicates that the CyberKnife System is checking equipment. If any components have not replied within 30 seconds, an error message appears. This error is an unrecoverable E-Stop.

The Treatment Paths window appears when **CANCEL** is clicked.

**Figure 36 Equipment Readiness**



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

1107

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



# START TREATMENT

If the **START** button on the Equipment Readiness window is active, the CyberKnife System is ready to start treatment. *Refer to section, System Check, page 42.*

**WARNING: While the treatment is in progress, at least one user should watch robot motion using the video monitors.**

**WARNING: When the START button is selected, the manipulator starts to move. The manipulator moves toward its perch position. If the manipulator was not in a safe location, it should fail the perch check. Use the teach pendant to move the manipulator near the perch position (Refer to module, Treatment Room Operations).**

**Figure 37 Treatment Delivery**



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

1108

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



# TREATMENT DELIVERY

## Treatment Delivery Window

When the **START** button of the Equipment Readiness window is activated, the Treatment Delivery window appears (*Figure 37 Treatment Delivery, page 43*). The Treatment Delivery window consists of five separate windows: the Treatment Data area, Alignment monitor, Beam Data window, Graph display and the Controls window.

### Treatment Data

The Treatment Data area displays pertinent data about the current patient, plan and path (*see section, Site Selection, page 2*). It appears across the top of the screen. (*Figure 3 Treatment Data, page 2*)

### Alignment Monitor

The Alignment Monitor window displays information regarding the current images and patient position. It is a section of the Patient Alignment window seen during patient alignment and patient realignment (*see sections, Patient Alignment, page 11 and Patient Re-Alignment, page 59*). It appears to the left of the screen (*Figure 38 Alignment Monitor, page 44*).

**Figure 38 Alignment Monitor**



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

1109

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



## Beam Data Window

The Beam Data window displays information regarding the dose delivery. It is to the right of the screen. (*Figure 39 Beam Data Window, page 45*). The Beam Data window displays whether the beam is on or off, the number of nodes of the path, the desired MU's for the path, the current node number, the desired dose for the node, the dose being delivered for the node, the total dose for the path (all doses in cGys and MU's), the current dose rate and the elapsed time since the Parameter Display has appeared.

The beam on/off display is green when the beam is off and is red when the beam is on. When the beam is on, the dose being delivered for the node and the cumulative dose will count up.

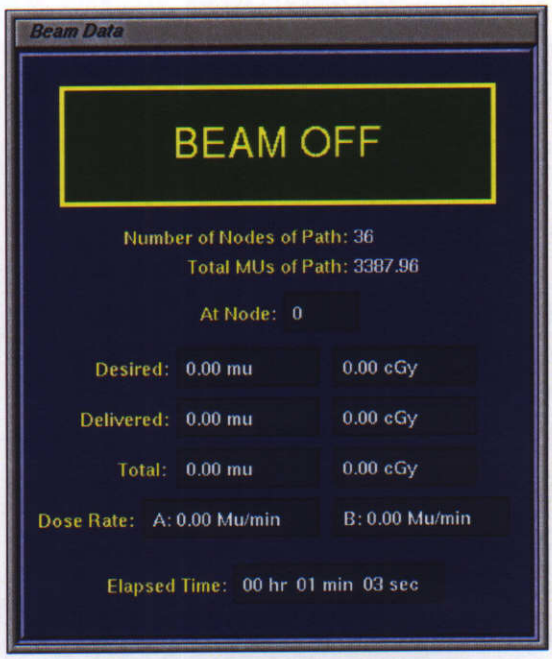



**Figure 39 Beam Data Window**



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

1110

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



## Graph Display Window

The Graph Display window graphs Patient Position delta and Monitor Units delta data over the course of a path. It also contains primary Treatment control buttons.

The graph area displays two graphs.

1. The default right graph shows the difference between the desired and actual dose delivered to the node number. The text area above this graph shows the numerical value of the difference (in MU's) at the present node.
2. The default left graph shows the distance of the target relative to the origin of an imaging coordinate system at the node number. The text area above this graph shows the distance in millimeters at the present node.

Either graph window can be configured to show any of five treatment data graphs by right-clicking in the window area and selecting the desired graph.

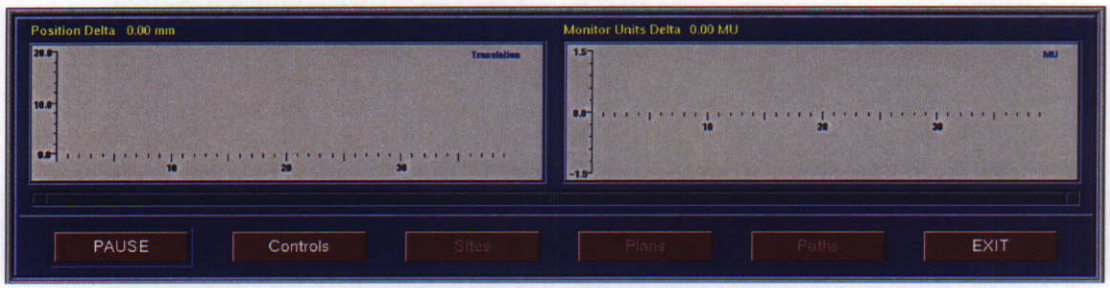



**Figure 40 Graph Display**

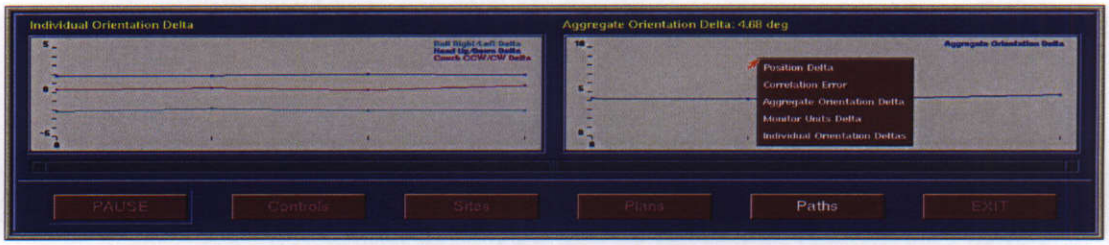



**Figure 41 Graph Display (Graph Selection)**

There are six function buttons located at the bottom of the Graph Display window. Patient movement is displayed in the left screen of the Graph Display window during treatment. The three lines in the left window show the x, y and z coordinates and will change If patient movement is detected during treatment. The right screen shows a collection of the x, y and z coordinates. Click the right mouse button in the right screen to display the menu for selecting five different display graphs.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



**Table 1: Graph Display Button Functions**

| Button | Function |
|---|---|
| **Pause** | Pauses treatment, stopping the manipulator and turning off the beam. After the pause, you can resume the treatment. This button is inactive when an error occurs. |
| **Controls** | Pops up the Controls window (*Figure 28 Control, page 27*). If the Controls window is hidden behind another window, clicking this button brings it to the front. This button is only active when the CyberKnife System is requesting user action. |
| **Sites** | Allows you to return to the Treatment Sites window to select another treatment site. This button is only active when all paths of a plan fraction are completed. |
| **Plans** | Allows you to return to the Treatment Plans window to select another plan for the same treatment site. This button is only active when all paths of a plan fraction are completed. |
| **Paths** | Allows you to return to the Treatment Paths window to select another path of the plan being used for treatment. This button is only active when a path of a plan fraction is completed. |
| **Exit** | Allows you to leave treatment and return to the CyberKnife System menu. This button is available when a plan is completed or after an error sequence. |

## Controls Window

The Controls window holds buttons to control treatment flow (*Figure 42 Controls, page 48*). It appears at the top of the screen, over the Treatment Data window.

**Table 2: Controls Window Button Functions**

| Button | Function |
|---|---|
| **Acquire** | Acquires radiographic images and determine patient location |
| **Correlate** | Redetermines patient location based on the current images. It is only active when images have been acquired. |
| **Current/Previous** | The selection of this option specifies the patient position information to be used for correcting the treatment position.<br>**CURRENT** indicates that the system should use the most current position information. This usually means the system will acquire a new image prior to the next beam delivery.<br>**PREVIOUS** indicates that the system should use the position information from the last modes delivery. This option should be used very carefully and only when it is not feasible to acquire new images for patient positioning. |
| **Treat** | Commences delivery of treatment radiation. When you click **TREAT**, it uses the current patient offset, unless the **PREVIOUS** button was pressed to specify that the offset for the previous treatment node should be used. |



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118 1112

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



**WARNING: Selecting the PREVIOUS option and then clicking TREAT causes a radiation dose to be delivered based on the patient's position at the last dose delivery. Use PREVIOUS option only when the manipulator or some other obstruction prevents successful acquisition of new radiographic images. Misuse of the PREVIOUS option can lead to incorrect radiation dose delivery.**

**WARNING: In Manual Mode (*see section, Treatment Control: Manual Mode, page 50*) treatment dose delivery commences when you click the TREAT button. Be sure to monitor the manipulator and patient positions at all times. If at any time it appears that the manipulator is moving too close to the patient or any object in the treatment room, or that dose is being delivered incorrectly, click PAUSE of the Graph Display Window or push the nearest E-Stop button.**

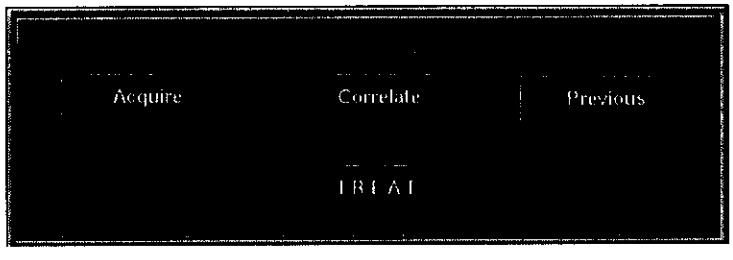



**Figure 42 Controls**

## Treatment Control: Automatic Mode

If treatment is being controlled in Automatic mode, the CyberKnife System begins the treatment plan when you click the **START** button on the Controls window.

**WARNING: The manipulator starts to move from its perch position to the first node of the treatment path. If the manipulator appears to be moving too close to the patient or any other object in the treatment room, click PAUSE of the Parameter Display window or push the nearest E-Stop button.**

**WARNING: When the manipulator is at the first node, the system prompts you to turn on the high voltage. To turn on high voltage:**

**Make sure the radiation enabling key is in the HIGH VOLTAGE key switch of the user control panel and turned clockwise. (*Figure 43 Operator Control Panel, page 49*).**

**Push the ON button in the HIGH VOLTAGE section of the user control panel. The high voltage is now on and radiation can now be generated.**



1113 Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



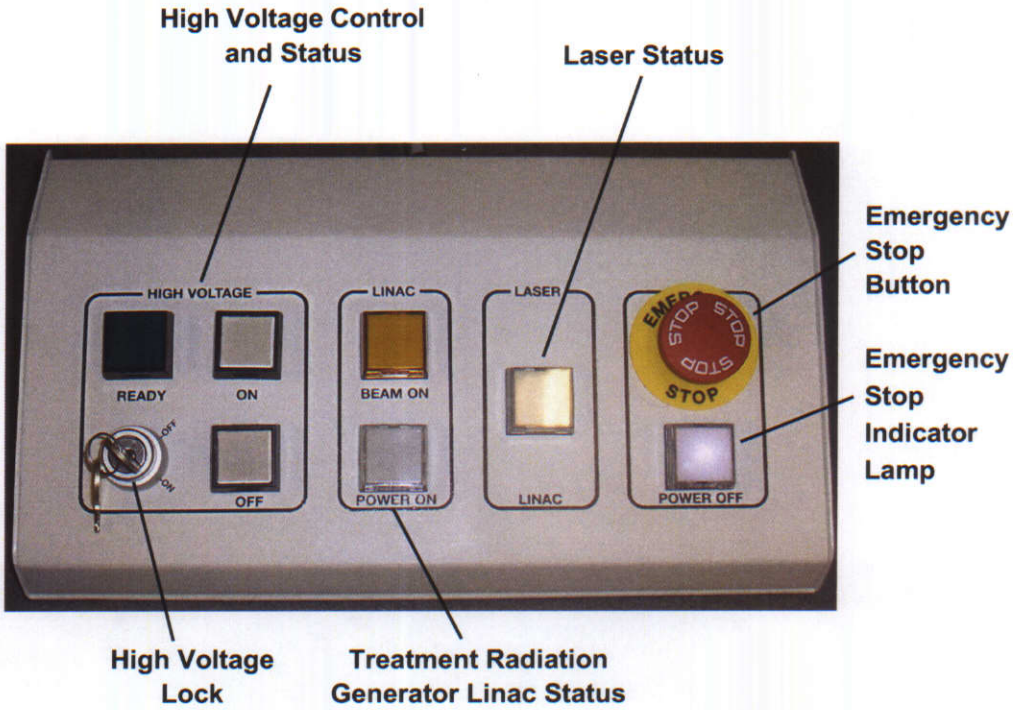



**Figure 43 Operator Control Panel**

**WARNING: Once the high voltage is on, treatment radiation can be generated. The manipulator moves from node to node. At each node, the CyberKnife acquires an image, corrects the manipulator pointing and delivers radiation. If at any time the manipulator appears to be too close to the patient or any other object, or it appears that the correct dose is not being delivered, click PAUSE on the Parameter Display window or push the nearest E-Stop button.**

**CAUTION:** After the image acquisition at each node in fiducial tracking mode, it is important that you visually verify the patient position and/or the positions of the located fiducials. If at any time it appears that the patient or fiducials are not correctly located in the image, click **PAUSE** on the Parameter Display window or push the nearest E-Stop button

**CAUTION:** The treatment room must be continuously monitored during treatment via video cameras and microphones.

**WARNING: During treatment, you should not move the manipulator with the teach pendant unless the operator control console monitor instructs you to move the manipulator. Never remove the teach pendant from the treatment room.**



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

1114

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



# Treatment Control: Manual Mode

If treatment is being controlled in Manual mode, the CyberKnife System enters the Treatment Display window and prompts you for action with the Control Panel window. When you press either the **ACQUIRE** or the **TREAT** button on the Control Panel window, a confirmation message (*Figure 44 Confirm Acquire Message , page 50 or Figure 45 Confirm Treat Message , page 50*) asks you to confirm the action.

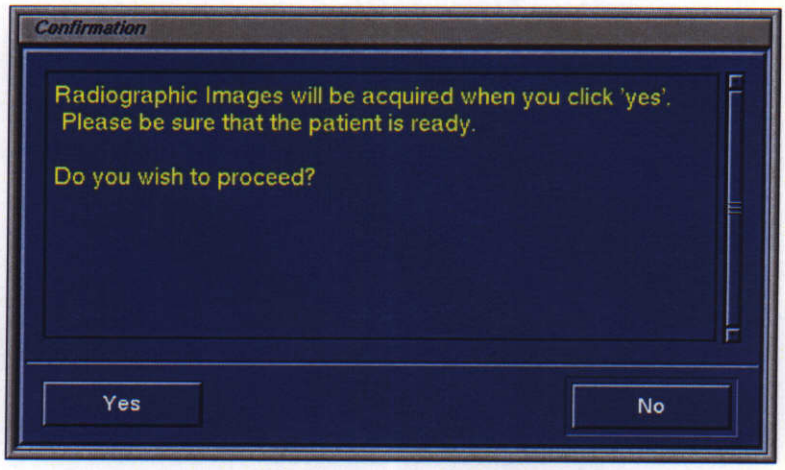



**Figure 44 Confirm Acquire Message**

**WARNING: Radiographic images are acquired when YES is clicked in the Confirm Acquire message. The patient must be properly positioned and prepared for this acquisition at the time that YES is clicked.**

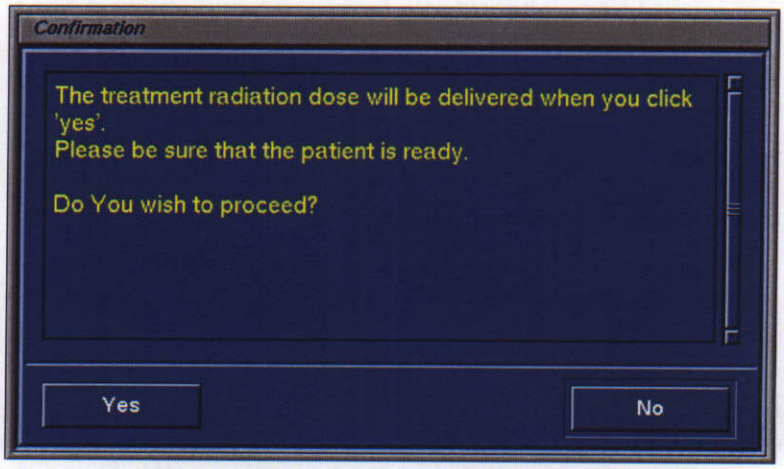



**Figure 45 Confirm Treat Message**



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

1115

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



**WARNING: Radiation is delivered when YES is clicked in the Confirm Treat message. The patient must be properly positioned and prepared for this delivery at the time YES is clicked.**

When radiographic images have been acquired or a radiation dose has been delivered, you will once again be prompted for action.

**NOTE:** No radiation, either for imaging or treatment dosage, is delivered to the patient in Manual mode without the request and confirmation of the user.

**WARNING: The manipulator starts to move from its perch position to the first node of the treatment path after dose delivery at each node and immediately at the beginning of the path. If the manipulator appears to be moving too close to the patient or any other object in the treatment room, click PAUSE of the Parameter Display window or push the nearest E-Stop button**

**CAUTION:** After the image acquisition at each node in fiducial tracking mode, you must visually verify the patient position and/or the positions of the located fiducials. If at any time it appears that the patient or fiducials are not correctly located in the image, re-acquire the image or modify fiducial parameters until a location is successful and shows that the patient is within alignment bounds.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



**WARNING: At every node of delivery in Manual mode, the PREVIOUS button on the Controls window is active. Clicking this button and then clicking TREAT causes a radiation dose to be delivered based on the patient's position at the last dose delivery. Use the PREVIOUS button only when the manipulator or some other obstruction prevents successful acquisition of new radiographic images. Misuse of the PREVIOUS button can lead to incorrect radiation dose delivery.**

## Treatment Control: Path Completion

**When a path is completed, the following sequence of events occurs:**

1. A message (*Figure 46 Path Completion Message, page 52*) is shown. The database is updated after each path.
2. The patient treatment summary for the path is automatically printed.
3. When the database update is completed, a number of different messages could appear, depending on the number of completed paths of the treatment plan.

- If there are paths not yet completed, a message tells you the number of paths remaining. You are asked to select the **PATHS** button. The **SITE**, **PLANS and EXIT** buttons are inactive.
- If all paths are completed, the message, Fraction completed. For further treatment select "Plans". is displayed. The **SITE**, **PLANS and EXIT** buttons are active.
- If a plan is completed, the message, Treatment Successfully Completed. For further Treatment select "Plans" or "Site" button if active. (*Figure 47 Plan Completion Message, page 53*) is displayed. The **SITE**, **PLANS** and **EXIT** buttons are active.

**Figure 46 Path Completion Message**



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

1117

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015

**Figure 47 Plan Completion Message**

## Return to the Treatment Sites Window

Click the **SITE** button. The Parameter Display window disappears and the Treatment Sites window appears.

**NOTE:** The Treatment Data window contains only patient information.

## Return to the Treatment Plans Window

Click the **PLANS** button. The Parameter Display window disappears and the Treatment Plans window (*Figure 4 Treatment Plans, page 3*re) appears. The Treatment Data window contains only patient and site information.

## Return to the Treatment Paths Window

Click the **PATHS** button. The Parameter Display window disappears and the Treatment Paths window appears. Note that the Treatment Data window contains only patient, site and plan information.

## Return to the CyberKnife System Menu

Click the **EXIT** button. The Parameter Display and the Treatment Data window disappear and the CyberKnife System menu appears.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



# PAUSING TREATMENT

**While the Treatment Delivery window is displayed, patient treatment can be paused in the following way:**

- You can pause the patient treatment by clicking **PAUSE** in the Graph Display window. When **PAUSE** is activated, an E-Stop is triggered and the button becomes inactive.
- You can push in the nearest E-Stop button.
- The CyberKnife System detects an error and pauses the system.

Pausing treatment results in stopping the motion of the manipulator and terminating all radiation. You have the option to resume or abort the treatment.

**Treatment Delivery Window -> Treatment Message -> Treatment Error Message -> Manipulator Paused -> Treatment Message**

or

**Manipulator Paused -> Treatment Status Message -> Treatment Error Summary**

The Treatment Message displays the message "Undergoing E-Stop tripped sequence."

When the sequence that was stopped by tripping the E-Stop is complete, the Treatment Error Message (*Figure 48 Sample Treatment Error Message, page 54*) appears. This window displays which E-Stops were tripped in the E-Stop on text area and lists the causes for the E-Stops in the Error Messages text area. In general, the first cause is usually the reason for the E-Stop.

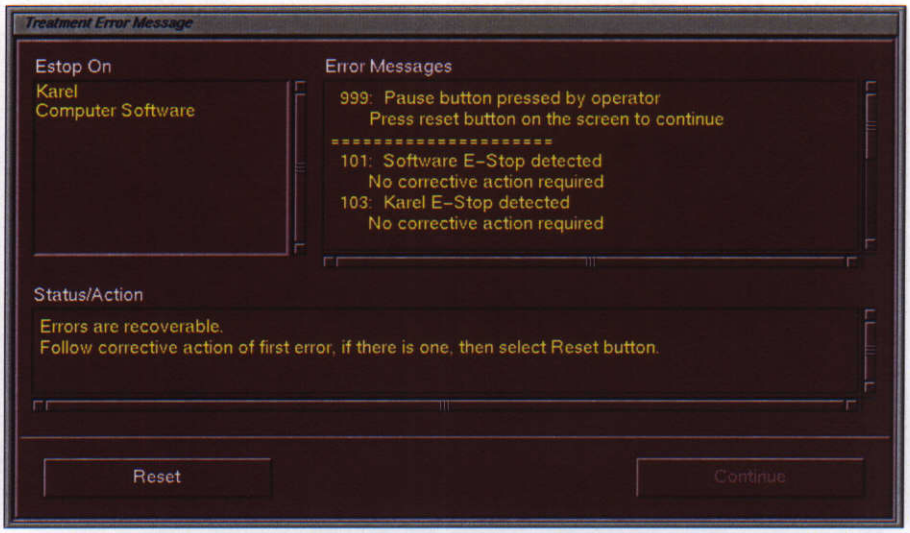



**Figure 48 Sample Treatment Error Message**

In the Status/Action text area, an instruction is given for resolving the first cause of the E-Stop.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

1119

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



## Reset or Continue

The **RESET** button allows you to clear the E-Stops. If the E-Stop is unrecoverable, the **RESET** button is inactive. If recoverable, the **RESET** button is active.

If you select **RESET**, the Treatment Error Message remains on the display while the system is resetting. The message "E-Stops are being cleared and Linac being reset. Please wait." or "TLS is being Reset. Please wait" appears in the Treatment Message window, depending on the error.

When the reset is complete, the Manipulator Pause appears on top of the Parameter Display windows. The Treatment Error Message disappears.

If the **RESET** failed to complete correctly, the treatment error message is re-displayed with an indication that the error could not be reset. This is most commonly caused by a failure to clear the E-Stop circuitry. Check the status of the E-Stop buttons, the door and the Robot teach Pendant before attempting to reset again.

**NOTE:** After three failures to reset, the system assumes that the error is unrecoverable.

If the E-Stop was unrecoverable, **CONTINUE** is active. For more information about unrecoverable errors, *see section, Abort, page 57*.

## Manipulator Pause

Manipulator Pause (*Figure 49 Manipulator Pause Options, page 55*) allows you to either resume or abort the patient treatment. If a recoverable situation occurred in the CyberKnife System, both the **RESUME** and **ABORT** buttons are active. If an unrecoverable situation occurred in the CyberKnife System, only the **ABORT** button is active. Click to activate the **RESUME** or **ABORT** buttons.

When **RESUME** is activated, the system resumes treatment from where it was paused. The following message is displayed: "System undergoing resume sequence." The **PAUSE** button becomes active and Manipulator Pause disappears. When the resume sequence is completed, treatment delivery resumes, based on the chosen control mode (automatic or manual). For more information about Abort, *see section, Abort, page 57*.

**Figure 49 Manipulator Pause Options**



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

1120

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



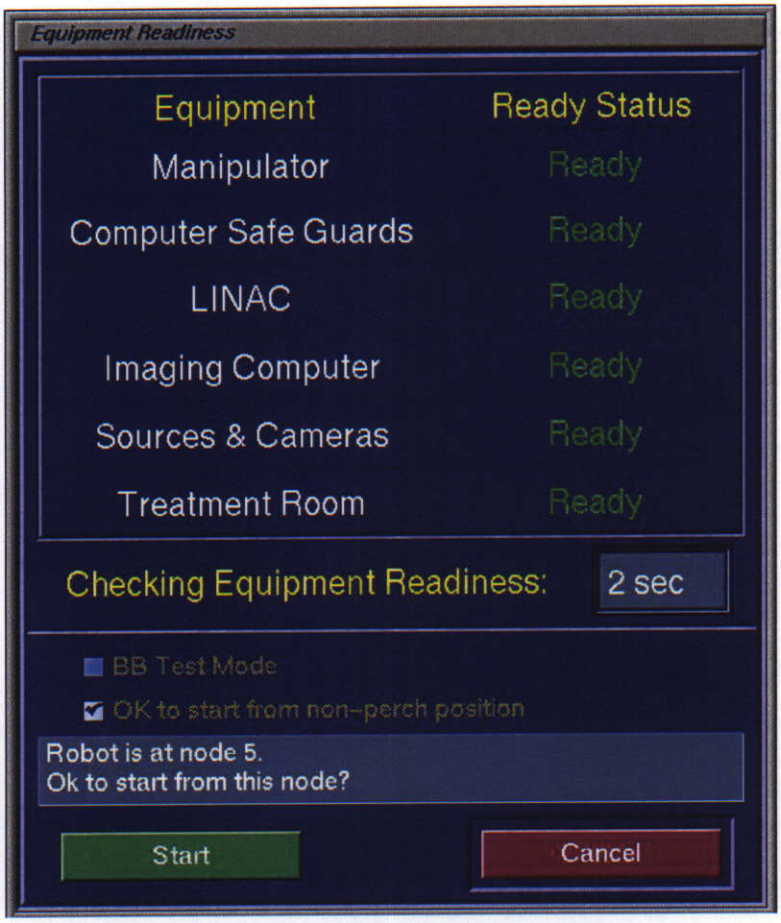



**Figure 50 Equipment Readiness Window**



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

1121

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



## Abort

When the **ABORT** button is activated, the message, "Updating database." is displayed in the Treatment Status Message. While the database is being updated, a makeup fraction is being created. When the makeup fraction is created, the message "A makeup plan has been created. Please wait for abort sequence to complete." is displayed. When the abort sequence is completed, the treatment status message appears.
(*Figure 51 Successful Abort Message, page 57*)

**Figure 51 Successful Abort Message**

### Unrecoverable Error

When the abort sequence is completed, the **OK** button in the Treatment Status Message window becomes active. Clicking the **OK** button displays the Treatment Error Summary window (*Figure 48 Sample Treatment Error Message, page 54*). The Treatment Status Message window disappears. The Treatment Error Summary window displays a summary of the errors that result from aborting the treatment. To print the error summary, click **PRINT**.

To remove the Treatment Error Summary window, click **CONTINUE**. The Parameter Display window appears with the **EXIT** button active. All other buttons are inactive. Click **EXIT** and the power to the CyberKnife System automatically turns off if the abort was a result of an unrecoverable condition.

### Recoverable Error

Following a recoverable error when the abort sequence is completed, the **OK** button in the Treatment Status Message window becomes active. Click the **OK** button and the Treatment Status Message window will disappear.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



# ERRORS

**NOTE:** If you have purchased the Xsight Spine Tracking System option, refer to section, Error Handling in the Xsight Spine Tracking System module, located in tab "16" in this manual.

If an error occurs when you are in the treatment process, the system will pause (*see section, Pausing Treatment, page 54*). The Treatment Error Message appears with the errors leading to the system pause. If the errors are recoverable, the system allows you to resume after the errors are corrected (*See module, Errors*). If the errors are unrecoverable, the system only allows you to abort the treatment process. The abort and resume functions are activated from the Manipulator Pause window (*Figure 49 Manipulator Pause Options, page 55*).

## Contact Detection Sensor

The Contact Detection Sensor is a secondary safety feature. It is installed on the secondary collimator housing of the Linac assembly that is carried by the robotic manipulator.

**CAUTION:** Always pay close attention to the location of the robot in relationship to obstacles in the treatment room, even when the Contact Detection Sensor is on.

### Error 221

An E-Stop (error 221) is initiated when the sensor comes in contact with an obstacle. Robot movement is stopped upon contact. To correct the error, perform the following procedure:

**Step 1.** Using the teach pendant, secure patient away from the contact area.

**Step 2.** Move the robot to safety by:

1. Moving the robot away from the obstacle,
2. and then moving the robot to the perch position.

**Step 3.** Reposition the patient or remove the obstacle that the robot came in contact with.

**Step 4.** Resume treatment following the standard E-Stop recovery procedure.

**NOTE:** If the adjusted patient position is beyond the limits for imaging correction, the treatment will become unrecoverable.

**Report any malfunctions of the contact sensor to Accuray customer support.**



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



# PATIENT RE-ALIGNMENT

If an error occurs, or you click **PAUSE** during the treatment process, alignment of the patient must be confirmed before treatment can continue. This confirmation occurs through the Re-Alignment window. This window is identical to the Alignment window, with slight exceptions noted below (*Figure 52 Re-Alignment, page 59*).

The Re-Alignment window is very similar to the Alignment window with a key difference: The **CLOSE** button is insensitive during alignment, but in re-alignment it allows you to see the Treatment Graph and Beam Data windows for reference.

Use the **PATIENT ALIGNMENT** button to return to the full Re-Alignment display.

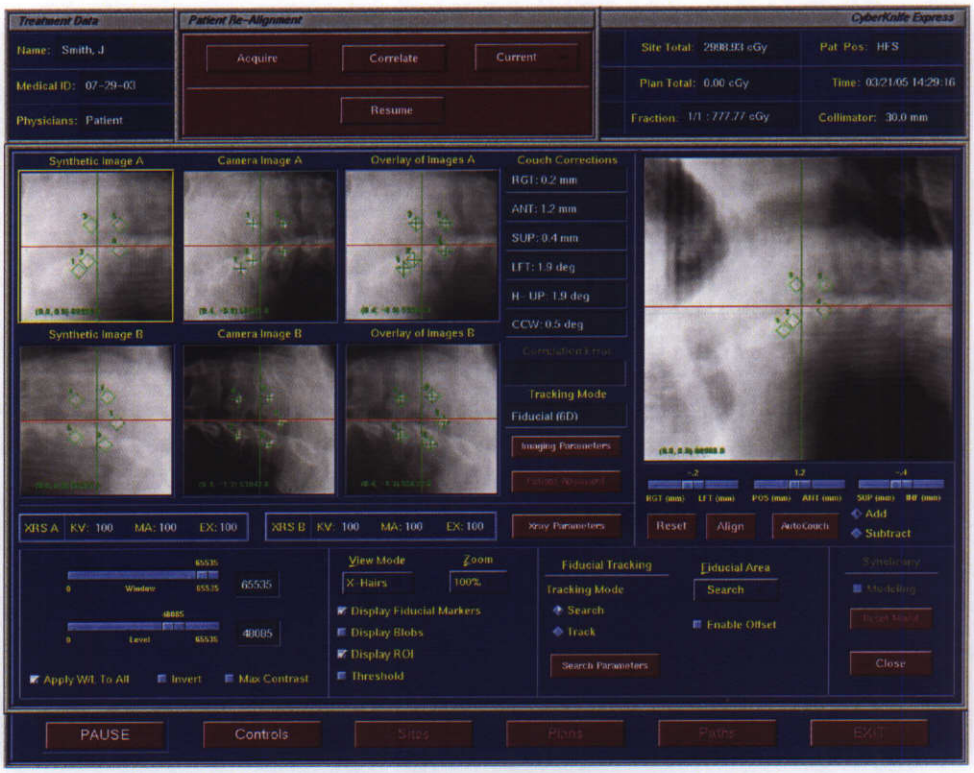



**Figure 52 Re-Alignment**

The **PREVIOUS** button in the Controls window causes the patient position corrections used for the last treatment node to be used again. Extreme caution must be taken when using the **PREVIOUS** button and should only be used when normal imaging is not possible (i.e., when the manipulator blocks the images).



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



**WARNING: Selecting the PREVIOUS option and then clicking TREAT causes a radiation dose to be delivered based on the patient's position at the last dose delivery. Using the PREVIOUS option should only be used when the manipulator or some other obstruction prevents successful acquisition of new radiographic images. Misuse of the PREVIOUS option can lead to incorrect radiation dose delivery.**

Before treatment delivery can resume, either new radiographic images must be taken to confirm the patient's position or this operation must be overridden using the **PREVIOUS** option to allow the system to deliver radiation based on the patient's position at the last treatment node.

# MAKEUP FRACTIONS

A makeup fraction is created when a fraction of a plan is terminated before the total dose was delivered. Makeup fractions (*Figure 53 Makeup Plan Created Message, page 60*) are created when the **ABORT** button is activated from the Manipulator Pause window and when activating **CANCEL** from the Treatment Paths window after returning to this window by activating the **PATHS** button in the Parameter Display window (*Figure 37 Treatment Delivery, page 43*).

The makeup fraction consists of all paths of the terminated fraction that were not executed and, if needed, a makeup path similar to the path in which the termination occurred. The makeup path contains the same set of nodes as the terminated path, except that nodes that were delivered have a zero dose and the node where the termination occurred contains only the dose remaining. The makeup fraction is shown in the Plan Fractions window.

When a makeup fraction is created, the total number of fractions of a plan reduces by one and the number of makeup fractions increases by one. The name of the makeup fraction has the following format: "plan-name_fraction-number_mkupZZZ_plan", where "*plan-name*" is the name of the plan for which a makeup plan was created, "*fraction-number*" is the fraction of the plan being executed when a makeup fraction was created, "ZZZ" is the number of times a makeup fraction was created for that plan and fraction.

For example, "ellipse_shape_f2_mkup3_plan" means the third makeup plan for the second fraction of the plan "ellipse_shape".

**Figure 53 Makeup Plan Created Message**



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

1125

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



# Synchrony Respiratory Tracking System
## Table of Contents


**Patient Setup and Immobilization** ..... 1
- **Application of the Synchrony Tracking Vest** ..... 2
  - Using the Synchrony Vest ..... 2
    - Patient Setup and Immobilization ..... 2
- **Patient Immobilization** ..... 3
  - Evaluation of LED Tracking Markers ..... 3

**CT/MRI/PET Acquisition** ..... 4
- **Treatment Planning** ..... 5

**Equipment Power** ..... 6
- **Powering Up the CyberKnife System** ..... 6

**Treatment** ..... 9
- **Initiating Treatment** ..... 9
  - Plan Verification ..... 9
- **Path Downloading** ..... 11
- **Patient Setup** ..... 11
  - Patient Preparation and Application of Synchrony Tracking Vest ..... 11
  - Patient Setup and Immobilization ..... 11
  - Application and Connection of Tracking Markers ..... 11
- **Patient Alignment** ..... 13
  - Patient Alignment: General Operation ..... 13
    - Patient Alignment Window ..... 14
    - Patient Alignment Controls Window ..... 15
    - Initial Condition of the Patient Alignment Window ..... 15
    - Acquiring Live Images ..... 16
- **Building a Correlation Model** ..... 16
  - Acquiring Images for the Correlation Model ..... 17
- **Optimizing Fiducial Tracking and Alignment** ..... 21
  - Correlation of Live Images ..... 21
  - Aligning the Patient in Fiducial Tracking Mode with Synchrony Tracking ..... 21
  - Ensuring Proper Fiducial Identification ..... 22
  - Adjusting Patient Position ..... 23
  - Algorithm Parameters Area ..... 24
- **Start Treatment** ..... 25
- **Treatment Delivery** ..... 25




Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

1126

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



**Pausing Treatment** ..... **25**
**Errors** ..... **25**
**Patient Re-Alignment** ..... **26**
**Makeup Fractions** ..... **26**
**Synchrony Respiratory Tracking System User Interface** ..... **26**
Tracking Markers ..... 27
Correlation Graphs ..... 27
Correlation Error ..... 28
Summary Info ..... 28
Marker Status ..... 29
Graph Controls ..... 30
Connection Status ..... 30
Menu ..... 31
Display Control ..... 31
Error Control ..... 32
Dynamic Correction ..... 33
Prediction Deviation ..... 34



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

1127

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



# SYNCHRONY™ RESPIRATORY TRACKING SYSTEM

## PATIENT SETUP AND IMMOBILIZATION

The CyberKnife® System with the Synchrony Respiratory Tracking System identifies a target's position throughout the treatment and synchronizes treatment delivery to the motion of the target throughout the respiratory cycle. The Synchrony System simultaneously tracks both movement of the target and breathing patterns of the patient. The robotic arm adjusts and compensates for these movements ensuring more accurate treatment and eliminating breath-holding or gating requirements.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

1128

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



# Application of the Synchrony Tracking Vest

Use the sizing guidelines as provided in the Patient Kit Instructions for Use (IFU) as shown below.

## Using the Synchrony Vest

### Patient Setup and Immobilization

**Step 1.** Select the appropriate Synchrony Tracking Vest size for the patient.

**Table 1: General Guidelines**

| | |
|---|---|
| **Small Vest** | Height < 5'5" (1.68 m) |
| | Weight < 130 lbs (59 Kg) |
| **Medium Vest** | Height 5'5" – 6'0" (1.68 – 1.83 m) |
| | Weight 130 – 180 lbs (59 – 81.6 Kg) |
| **Large Vest** | Height > 6'0" (1.83 m) |
| | Weight > 180 lbs (81.6 Kg) |

**NOTE:** These are general guidelines and they may not work for all patients. A patient's body shape may also affect vest selection. In such cases changing to one size larger or one size smaller may be necessary.

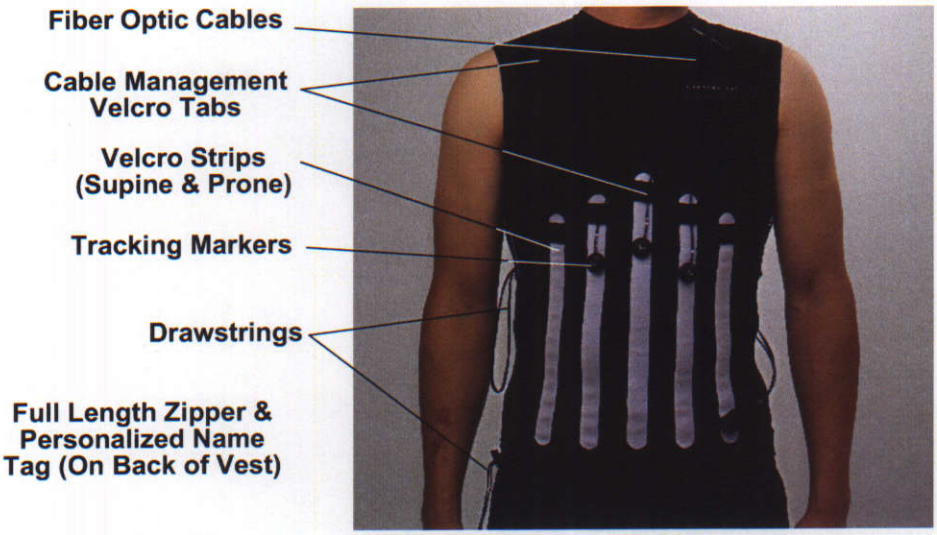



**Figure 1 Synchrony Tracking Vest**

**Step 2.** Take the Vest out of the pouch and write the patient's name on the name tag, located on the back of the vest.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

1129

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



**Step 3.** Instruct the patient to put on the Synchrony Vest or, if unable, assist the patient to put on the Vest:

1. Unzip the back of the Vest and detach the Velcro tab at the bottom, back of the Vest.
2. Ensure the three drawstrings are in the loosest position.
3. Remove all clothes from upper body. (Jog bra with no metal inserts or fasteners is permissible if necessary for large breasted patients.)
4. Slip Vest over head of patient.
5. Slip arms into arm holes of the Vest.
6. Fasten Velcro tab at the bottom, back of the Vest.
7. Pull the string attached to the zipper or the zipper itself down to the bottom of the Vest.
8. Detach the Velcro tab at the bottom of the Vest to ensure the zipper has been pulled all the way to the bottom and re-fasten the Velcro tab.
9. Pull the whole Vest down as far as possible and cinch the bottom drawstring for a snug fit – this will aid in preventing the Synchrony Vest from riding up.
10. When removing the Synchrony Vest, only unzip the back of the vest and slip it over the patient's head. DO NOT readjust the draw strings.

# Patient Immobilization

Use of the indexing table will facilitate patient setup. An immobilization device is created for the patient using either a vacuum bag or alpha cradle. Following standard directions, instruct the patient to relax and breathe normally. With the patient lying down on the table (supine or prone), cinch the mid-thoracic abdominal draw strings for a snug fit – this will prevent "tenting" of the Synchrony Tracking Vest ensuring it follows the contour of the patient's body. It is important to evaluate the patient immobilization for comfort and reproducibility.

## Evaluation of LED Tracking Markers

Proper placement of the Tracking Markers can be assessed using several tools. These tools are covered in more detail in the *section, Synchrony Respiratory Tracking System User Interface, page 26.* View the Tracking Marker graph on the Synchrony computer and evaluate the breathing waveforms displayed for the three LED Tracking Markers for several breathing cycles. The Synchrony computer requires the use of only one Tracking Marker in order to create the model. It is possible to turn off 1 or 2 Tracking Markers and still be able to create a usable model. It may be necessary to adjust the placement of the Tracking Markers and/or the Camera Array in order to obtain an acceptable breathing waveform. Once the correlation model is created, check the correlation error value. This value is located on the treatment delivery screen below the Couch Correction values (*Figure 9 Patient Alignment, page 14*). The text box below the Couch Corrections shows the correlation error between the target offsets as defined by the correlation model and the target offsets as found with the fiducial algorithm. It is ideal to have the correlation error value close to 0 mm. If the correlation value exceeds 5 mm, an E-Stop will be triggered. The model will need to be rebuilt. Re-evaluate the correlation error to ensure it is less than 5 mm and as close to 0 mm as possible.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



# CT/MRI/PET ACQUISITION

Follow standard protocol guidelines for appropriate scan for extra cranial applications. The patient must wear the Synchrony Vest during all pre-treatment scanning.

**Step 1.** Instruct the patient to breathe normally until acquiring the scan, at which time the patient must hold their breath at end of normal expiration.

**Step 2.** If the patient cannot hold their breath for the entire scan, pause the CT scan allowing the patient to breathe normally and then ask the patient to hold their breath again at the end of normal expiration.

**NOTE:** It is recommended to practice the appropriate breath hold with the patient prior to scanning. If you know the patient may not be able to hold their breath for the entire scan, it would be helpful to check the position of the fiducials on the scout/scanograms so you know a good place to pause the scan if necessary.

**Step 3.** Continue acquiring the images until the CT scan is completed.

**NOTE:** It is important that the CT scan is not paused during imaging of the target tumor and surrounding fiducials. If necessary, the pauses should occur above or below the target.



1131 Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



# Treatment Planning

Path selection choice varies from site to site depending on the geometry of the treatment room.

**Step 1.** Select standard body treatment paths then select either single or 3 path.

**Step 2.** It is also necessary to select the Synchrony Tracking option (*Figure 2 Treatment Planning Screen, page 5*).

**Step 3.** Locate fiducials and create treatment plan using standard practice for body treatments with fiducials.

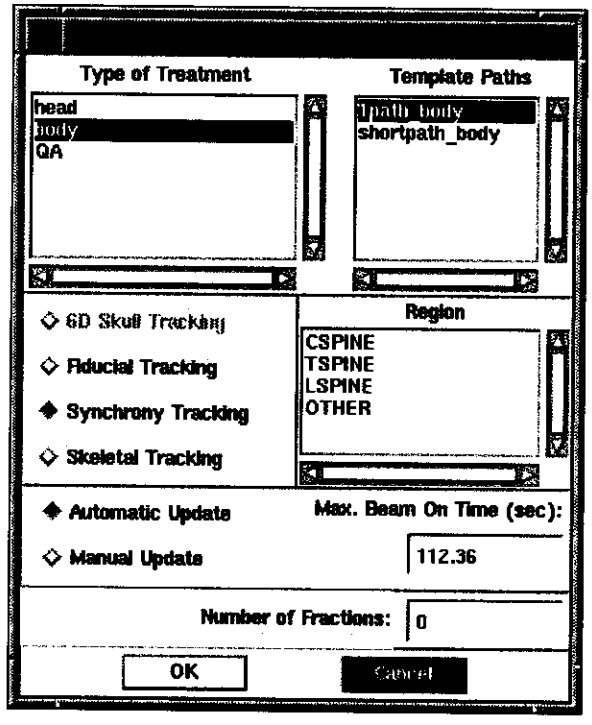



**Figure 2 Treatment Planning Screen**

**NOTE:** To create a treatment plan with the Synchrony System, follow the instructions for using MultiPlan Treatment Planning system.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



# EQUIPMENT POWER

## Powering Up the CyberKnife System

The equipment power screen shows equipment status for the Synchrony System. If the Synchrony System feature is enabled, the Synchrony power indicator displayed on the screen will be green and the text "ON" will be displayed (*Figure 3 Equipment Power Status – Synchrony Enabled, page 6*).

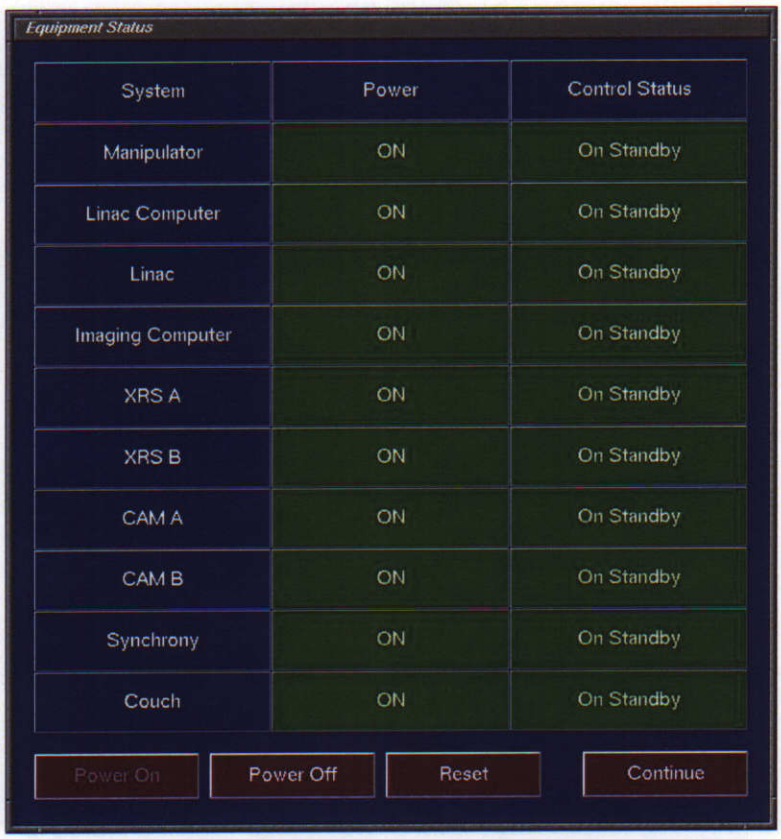



**Figure 3 Equipment Power Status – Synchrony Enabled**



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

1133

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015

**Figure 4 Equipment Power Status – Synchrony Not Available**



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



If the Synchrony System feature is enabled but for some reason cannot be powered on correctly, the Synchrony power indicator displayed on the screen will be grey and the text "Disabled" will be displayed (*Figure 5 Equipment Power Status – Synchrony System Disabled, page 8*). In this mode, all non-Synchrony System treatments can be delivered normally, but Synchrony System treatments cannot be delivered.

**Figure 5 Equipment Power Status – Synchrony System Disabled**



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

1135

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



# TREATMENT

This section provides instructions for starting the CyberKnife System to deliver radiosurgery treatment to a patient using the Synchrony System.

## Initiating Treatment

For more information regarding initiating treatment, refer to *module, Treatment, sections, Select Treatment Feature and Path Selection*.

### Plan Verification

After a path has been selected from the Treatment Paths window, the Patient and Treatment Verification window (*Figure 6 Patient and Treatment Verification, page 10*) appears. The window contains a patient information verification section and a treatment information verification section.

The patient information section contains the name of the patient, the medical ID and the name of the physician. The treatment information section shows:

- Type name of the plan
- Name of site to be treated
- Control mode of the plan
- Tracking mode of the plan
- Synchrony status of the plan
- Dose per fraction
- Current fraction of the plan being executed
- Name of the path
- Path dose
- Patient treatment position
- Type of anatomy being treated
- Camera layout geometry
- Collimator size

**WARNING: It is important that you verify that this patient is in fact the one to be treated and the plan is the correct one to use.**



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118 1136

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



The only buttons active when the Patient and Treatment Verification window appears are the patient information **DATA OK** button and **CANCEL**.

**To indicate that the patient and treatment information are correct:**

**Step 1.** If the patient data is correct, click the **DATA OK** checkbox in the **patient** information section. The treatment information **DATA OK** check box becomes active and highlighted. If the information is not correct, click **CANCEL**.

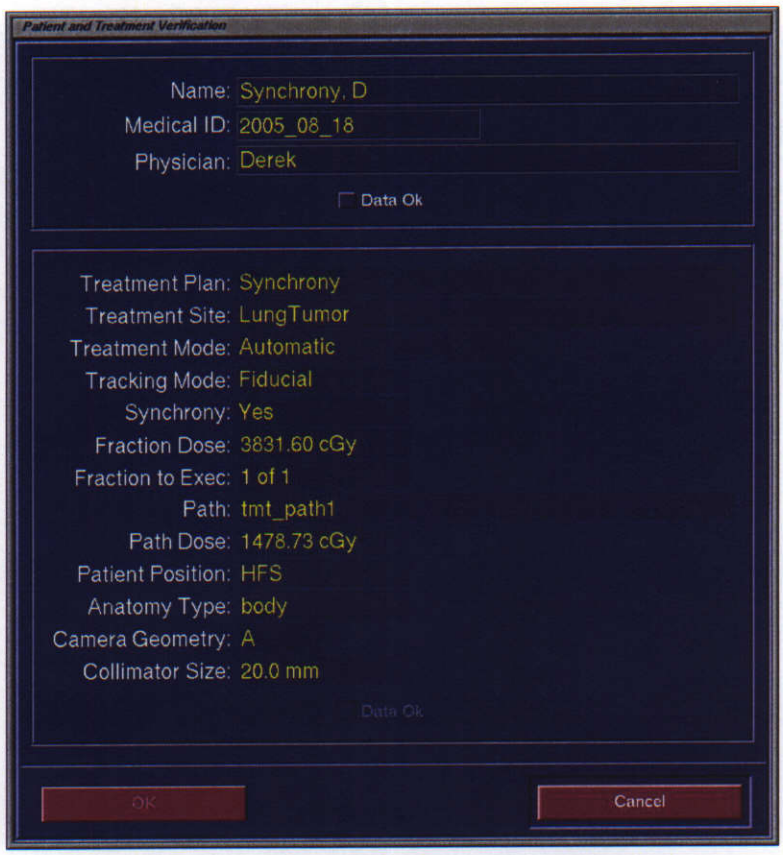



**Figure 6 Patient and Treatment Verification**

**Step 2.** If the treatment data is correct, click the **DATA OK** checkbox in the **treatment** information section. The **OK** button becomes active (turns green). If the information is not correct, click **CANCEL**.

**Step 3.** Click **OK**. The Loading Treatment Files window appears.

The Treatment Paths window appears when **CANCEL** is clicked.

**NOTE:** The Treatment Data window is displayed again when the Loading Treatment Files window appears. All text areas in the Treatment Data window contain information on the patient and treatment plan.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

1137

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



# Path Downloading

Refer to *module, Treatment, section, Path Downloading.*

# Patient Setup

## Patient Preparation and Application of Synchrony Tracking Vest

Instruct the patient to put on the Synchrony Tracking Vest or if necessary, assist the patient with putting on the Vest as outlined in *section, Application of the Synchrony Tracking Vest, page 2.* All undergarments should be removed from the waist up. A jog bra with no metal inserts or fasteners is permissible for large breasted patients. Ensure that the zipper has been pulled all the way down to the bottom and the Velcro tab fastened. Pull the entire Vest down as far as possible – this will aid in preventing the Vest from riding up.

**NOTE:** DO NOT readjust the draw strings.

## Patient Setup and Immobilization

Position patient on the immobilization device created. Instruct the patient to relax and breathe normally.

## Application and Connection of Tracking Markers

Evaluate patient's breathing to identify location of maximum respiratory motion during respiration – most typically the diaphragm area, but possibly the lower thoracic or upper abdominal area. Apply the 3 Tracking Markers onto the white Velcro strips on the patient's Synchrony Vest at the location of maximum body motion due to respiration. In the supine position, this is usually along the diaphragm on the front of the patient. In the prone position, this is usually in the thoracic area on the back of the patient.

**NOTE:** Do not place Tracking Markers over the tumor location unless this is the location of maximum body motion during breathing.

Position the patient in the approximate treatment position. Connect the Tracking Marker Harness connector to Fiber Optic Interface Box. Secure the Tracking Marker Harness cables using the Cable Management Velcro tabs on the Vest. Lower the Camera Array so that it is directly in-line with the patient (not angled from the side of the patient), not closer to the patient than just above the patient's feet (but preferably farther away) and is approximately 5-7 feet (2 meters) from the floor. Continue to adjust the position of the Tracking Markers and Camera Array until the Tracking Markers are visible by the Camera Array as confirmed by very fast blinking action from each of the Markers. This can best be viewed by standing directly under the Camera Array looking at the Markers. (A good test is to place your hand in front of one of the three cameras in the Camera Array and compare the beams emanating from the Markers. When not seen by the Camera Array, the beams appear as solid lights.) This can also be confirmed by reviewing the breathing waveforms displayed on the Synchrony computer. Final evaluation of the placement of the Tracking Markers should take place after patient alignment and identification of the fiducials has been completed.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118 

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



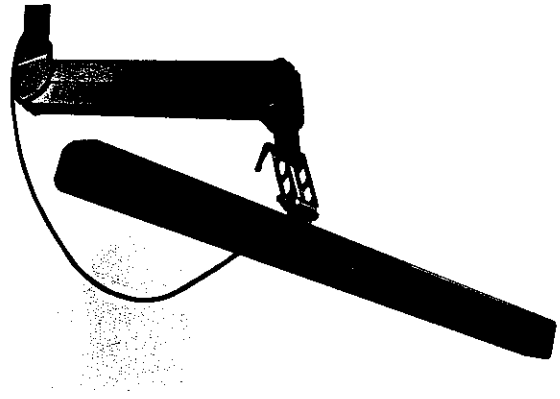


**Figure 7 Synchrony Camera Array**

**NOTE:** Keeping the Camera Array low will reduce incidence of the manipulator or linac obscuring the Tracking Markers from the Camera Array. Moving the Camera Array forward can increase risk of potential collisions of the manipulator or linac with the Camera Array.



1139

1149

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



# Patient Alignment

## Patient Alignment: General Operation

After the Treatment Files have been downloaded to the treatment delivery computer and the imaging computer, the Patient Alignment window (*Figure 8 Patient Alignment Window, page 13*) automatically appears. The Patient Alignment window has a number of different interface areas. The Synchrony System includes its own user interface (*Figure 15 Main Synchrony Controls, page 26*).

**Figure 8 Patient Alignment Window**



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

1140

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



## Patient Alignment Window

The Patient Alignment window (*Figure 9 Patient Alignment, page 14*) has a number of different user interface areas. The following describes what has been modified for the Synchrony System. For a description of the other features, *see module, Treatment, section, Alignment Window.*

**NOTE:** It is important to completely align the patient prior to building a model for a Synchrony treatment. For details on patient alignment, *see module, Treatment, section, Patient Alignment* and in this module, *section, Initial Condition of the Patient Alignment Window, page 15.*

**Figure 9 Patient Alignment**

## Synchrony Control Area

This area, in the bottom right corner of the Patient Alignment window, provides controls for the Synchrony System. It is only enabled when the Synchrony System is enabled as noted in the Equipment Status Startup window. The Synchrony computer must also be powered on for the Synchrony System to be functional for treatment delivery.

When the **MODELING** checkbox is checked, the Synchrony System processes all **ACQUIRE** and **CORRELATE** commands for use in modeling. When this checkbox is not checked, **ACQUIRE** and **CORRELATE** commands have no effect on the Synchrony System. The **MODELING** checkbox must be checked for the fiducial tracking algorithm to use the correlation model as an aid in Region of Interest (ROI) placement.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

1141

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



When using the Synchrony System for a patient treatment, at least 3 images (and at times 4 or more images) must be acquired and successfully correlated with the Synchrony System enabled (by checking the **MODELING** checkbox) before a model between the fiducials and Tracking Markers can be established and verified. Treatment cannot begin until this has occurred.

Clicking the **RESET MODEL** button will pop up a dialog box requesting confirmation that the model should be reset. Confirming this will purge all data points from the current model.

**NOTE:** Clicking the **RESET MODEL** button will invalidate the current model. At least 3 images will need to be acquired before the model is valid again and treatment can continue. Take care not to reset the model when the manipulator or linac is at a position that blocks the path of the diagnostic X-ray sources, because it will not be possible to re-establish a model if this is the case. Should you find yourself unable to re-establish a model, it is necessary to pause and abort the treatment, move the manipulator or linac back to the perch position and continue treatment with a make-up plan.

## Patient Alignment Controls Window

The Patient Alignment Controls window (*Figure 10 Patient Alignment Controls Window, page 15*) has four buttons used to control image acquisition, correlate these images with the reference of CT images, and start treatment delivery.

- **ACQUIRE** button, when clicked, causes the system to acquire new live radiographic images used to determine the tumor target location.
- **START** button removes the Patient Alignment window and brings up the Equipment Readiness window. The **START** button is not active until after the patient has been aligned within acceptable bounds. For a Synchrony treatment, this means at least 3 valid images have been acquired and a model has been established. *See module, Treatment, section Controls Window* for more details on these features.

**Figure 10 Patient Alignment Controls Window**

## Initial Condition of the Patient Alignment Window

When the Patient Alignment window appears after the Loading Treatment Files window, the **START** button is inactive. The Synthetic Image display windows show Digitally Reconstructed Radiograph (DRR) images of the optimal patient position. The Live Image display windows are blank.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



### Acquiring Live Images

It is necessary to change the exposure time for the acquisition of images when using the Synchrony system. Begin with decreasing the exposure time to 75 EX. It may be necessary to decrease it further depending on the patient's breathing pattern. Modification of the KV and mA X-ray settings may be required to enable adequate visualization, identification and tracking of fiducials.

Click the **ACQUIRE** button to capture live images. Within a few seconds, the system responds either with new images and suggested couch corrections or an E-Stop, signifying the patient is out of bounds.

Make sure no person other than the patient is in the treatment room when live images are generated.

## Building a Correlation Model

Ensure that the Modeling function has been selected. It requires the acquisition of at least 3 images to build the model. The first two images are used to build a model and the third image is used to confirm the model. A maximum of 15 model points are used.

**Step 1.** To build a robust model it is recommended that 6 - 8 images be acquired, if target movement is >20 mm. Ideally these images are distributed evenly and cover the whole range of respiration.

Based on the model points, Synchrony chooses an optimal model type to minimize the overall correlation error. The available model types are:

- **Linear**: Only two model points are needed to establish an origin and principal axis. Most target motions display linear motion and use this model type.
- **Curvilinear**: Used when the target moves back and forth along an arc, or in a curved motion. A minimum of four model points are required to establish this type of model.
- **Dual-Curvilinear**: Used when the target moves along an arc and uses different paths during inspiration and expiration. Organ path is split into two curvilinear paths to distinguish the data points during inspiration and expiration cycles. A minimum of seven model points are required to establish this model.

These models can accommodate target motion that differs between inspiration and expiration phases of respiration. The chosen Model Type is shown by the icon indicator and listed in the message window pane (bottom right box on the main Synchrony Controls window).

**Step 2.** Acquire the confirmatory image. This is always necessary.

Once the model is created and confirmed with a subsequent image, the **START** button becomes active.

**NOTE:** The **START** button is activated when at least three model points (images) are available and the model points cover a minimum of 40% of the respiration range.



1143 Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



**Step 3.** After the model is confirmed, 3 - 5 additional images can be taken at different phases of the breathing cycle to add to the model reference database. A total of 15 images are stored in the model reference database at any one time employing a first-in, first-out (FIFO) approach.

**NOTE:** Even distribution of model points is critical to building an accurate and robust model. Try to spread the model points over the entire respiration range.

## Acquiring Images for the Correlation Model

To acquire images for the correlation model, follow these steps:

**Step 1.** Check the Modeling box.

**Step 2.** Acquire an image.

**Step 3.** Locate fiducials using offsets.

**Step 4.** Do not resize or redraw ROI boxes. Use the default ROI size as much as possible.

**Step 5.** Acquire second image.

**Step 6.** Locate fiducials using offsets.

**Step 7.** Acquire third image.

Location of fiducial ROIs is updated automatically based on model.

**Step 8.** Continue acquiring images to refine the Correlation Model.

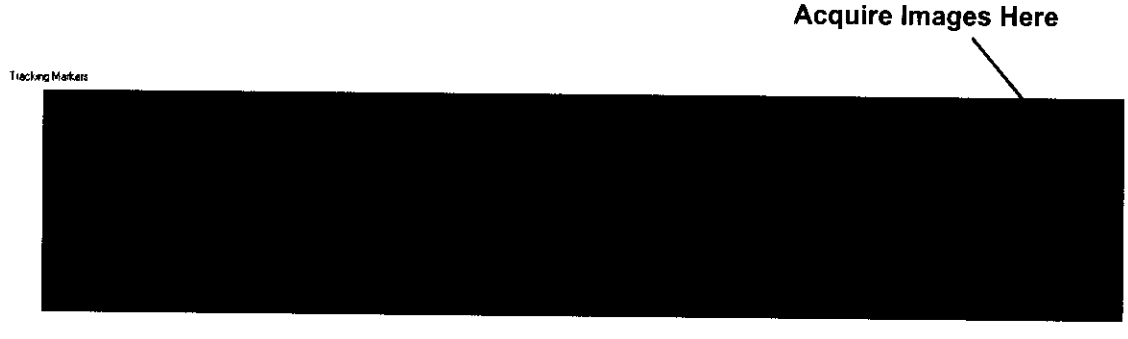



**Figure 11 Typical Breathing Pattern**

**NOTE:** The following information is important.

A minimum of 3 images is required to build a model:

- 2 images to build a model.
- 1 image to confirm the model.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



- Up to 15 images can be used if required.

Acquisition of 6 - 8 images is recommended if target movement is > 20 mm or suspected to be complex in nature or out of phase with breathing motion.

Technique for building a good Correlation Model:

- Note if organ takes different paths during inspiration and expiration.
- Acquire 2 - 4 images spaced out evenly through the inspiration.
- Acquire 2 - 4 images spaced out evenly through the expiration.

You can delete the most recently acquired model point. Deleting the most recent model point removes it from the data set used to build the Correlation Model. Follow these steps:

**Step 1.** Right-click on the Correlation Error graph. The graph is located on the Model Graph tab in the main Synchrony Controls window.

**Step 2.** Select **Remove Model Point** from the context menu.

**Step 3.** In the Remove Model Point dialog, click the **OK** button to remove the most recent model point, or click **Cancel** to close the dialog without deleting the model point.



1145 Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



A methodology for acquiring images is illustrated below (*Figure 12 Image Acquisition Technique, page 19*) that may help to build a reliable model.

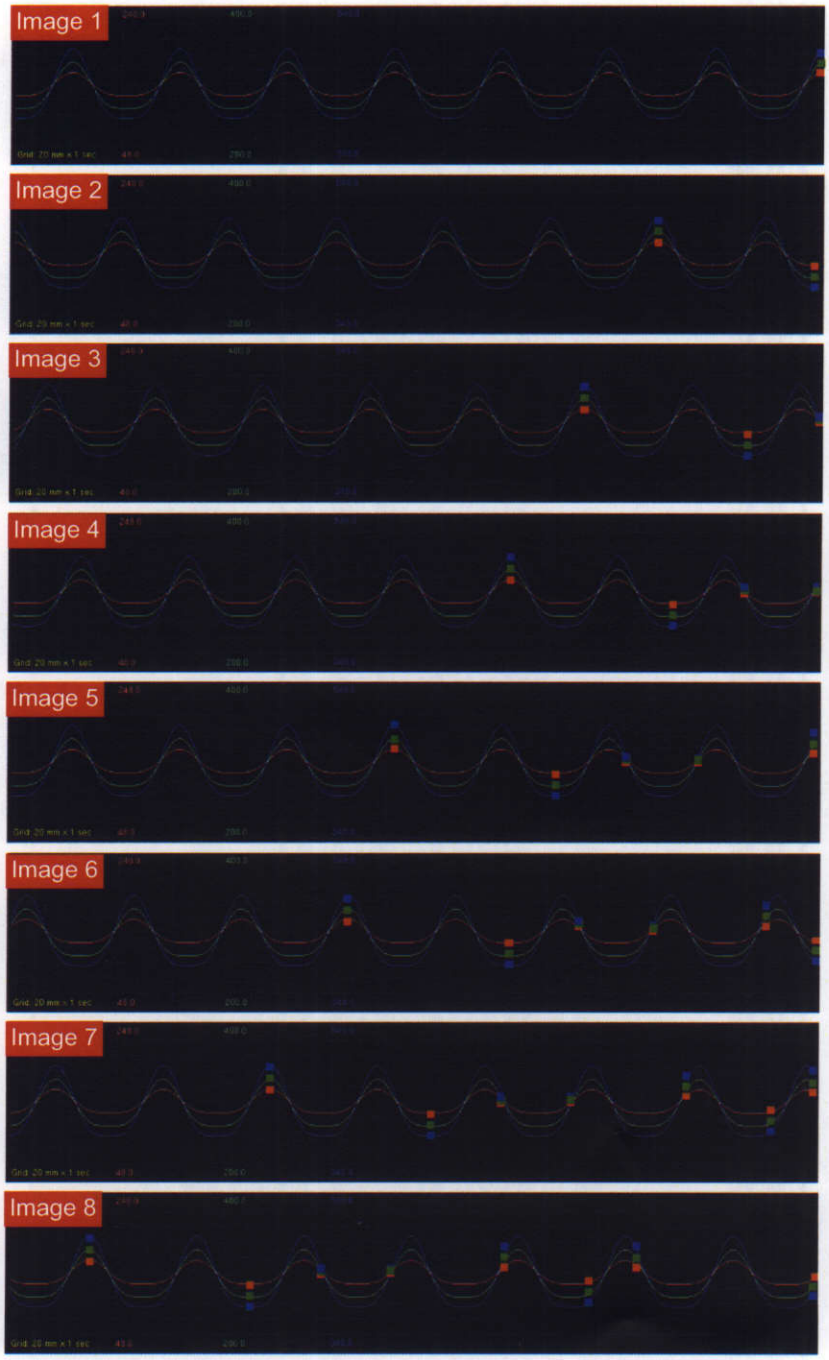



**Figure 12 Image Acquisition Technique**



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



Images 1 - 2 show model points representing the first two images, acquired at full inspiration and expiration. Images 3 - 4 show model points representing the next two images, acquired at the midpoint of inspiration and expiration. Images 5 - 8 represent four more images, acquired between these points in the respiratory cycle.

**NOTE:** When the images are being acquired, it is important to validate that the fiducials are being identified and tracked accurately. If not, inaccurate information will be added to the model reference database.

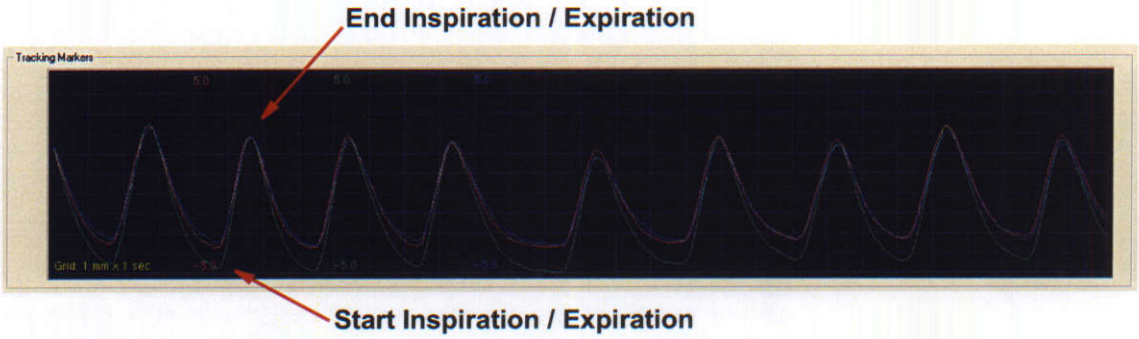



**Figure 13 Breathing Model Waveforms Display**

**NOTE:** Peaks and valleys in the waveforms indicate the two ends of the respiratory cycle (Start Inspiration/Expiration and End Inspiration/Expiration). Depending on the movement of each Tracking Marker, peaks may correspond to full inspiration in one waveform and full expiration in another waveform.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

1147

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



# Optimizing Fiducial Tracking and Alignment

## Correlation of Live Images

Depending on whether the **MODELING CHECKBOX** is checked, the Synchrony System will be used to assist in correlation of the Live Images. If a correlation model between the fiducial positions and Tracking Marker positions has been established, that model will be used to predict the fiducial positions and adjust the fiducial ROIs accordingly.

If a model has not yet been established, or the model is not valid for any reason, it is likely that the fiducial tracking system will fail to find the fiducials correctly. In this case, it is necessary for you to assist the algorithm by shifting the fiducial ROIs manually. This can be done using the Offset view mode to move all ROIs simultaneously. You should line up the green dots displayed in the Offset view mode with the fiducials as seen in the live images. Moving the offsets automatically enables the **ENABLE OFFSET** checkbox.

Once the offsets have been adjusted to match the current fiducial position, you should click **CORRELATE**. When **CORRELATE** is clicked while the **OFFSET CHECKBOX** is enabled, the user-defined offsets are downloaded to the fiducial tracking system and used as adjustments to the fiducial ROIs.

**CAUTION:** It is possible that the fiducial tracking algorithm will incorrectly find the fiducials without returning an error. In this case, couch corrections and a correlation error will be displayed, but the green plus sign (+) markers on the image will not be positioned over the actual fiducials. It is important that you adjust fiducial offsets using the OFFSET view mode and then CORRELATE before continuing. Failure to use CORRELATE before ACQUIRE in this case can corrupt the model, possibly leading to excessive correlation errors or inaccurate radiation delivery.

Located in the Couch Corrections area of the Patient Alignment window are six text boxes displaying the difference in current patient positioning from the patient's position when the CT was acquired. The translational values will be compensated dynamically by the CyberKnife® System robot up to +/- 25 mm based on the correlation model created between the Tracking Markers and the fiducials identified and being used for tracking. Therefore, it is not necessary that the patient be aligned exactly to zero in X, Y, and Z directions. Rotational movements will be corrected by the CyberKnife System robot based on the last static image acquired, compensating for roll and pitch up to 1 degree and up to 3 degrees for yaw.

The text box below the Couch Corrections area shows the Correlation Error between the target offsets as defined by the Synchrony model and the target offsets found with the fiducial algorithm and the live radiographic images.

## Aligning the Patient in Fiducial Tracking Mode with Synchrony Tracking

After acquiring live images, the Synthetic Image windows show the reference DRR images, the Live Image Display windows show the live images and the Overlay of Images windows show the live images overlaid on the DRR images. If the fiducial location was successful, the Couch Corrections box will show suggested couch movements to place the patient in correct alignment. Aligning the patient in Fiducial Tracking mode consists of two steps:

**Step 1.** Ensure that the fiducial algorithm has found the fiducials properly.

**Step 2.** Adjust the patient position until proper alignment is reached.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

1148

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



## Ensuring Proper Fiducial Identification

Once images have been acquired, the Fiducial Location Algorithm attempts to locate the fiducials in the images. Once located, fiducials are marked in the live image with a plus sign (+). If the fiducials have been found correctly, the plus signs (+) and the diamond shapes should overlap in the overlay images, indicating that the correct fiducial configuration was found. If this is the case, verify that the plus signs (+) in the live image are actually marking fiducials by deselecting the **Display Fiducial Markers** checkbox and visually noting the fiducials under each marker. You may need to modify the window and level settings for the live images to see the fiducials. Once you verify that each fiducial has been located with a plus sign (+) and that the fiducials are in the correct configuration, proceed to adjust the patient position.

If the fiducials are not properly located, there will either be an E-Stop and error generated or the fiducial plus signs (+) in the live image will not mark the fiducials. To correctly locate the fiducials, you can attempt one or more of the following:

1. Modify the ROI offsets to move the Track or Search ROIs so that the live fiducials are contained within them. Do this by selecting **OFFSET** from the view mode window and dragging the dots so that they overlay the fiducials.
2. Modify the X-ray parameters to improve the quality of the image. If there is too little detail in the images, try increasing the MA and EX to increase the exposure. If the image is too dark, try decreasing the MA and EX to decrease the exposure. If the fiducials appear blurred, try decreasing the EX and increasing the MA to compensate. For Fiducial Location it is best to maximize the contrast between the fiducials and the surrounding tissue. Once the X-ray parameters are modified, reacquire the images to reattempt Fiducial Location.
3. Modify the Thresholding Range through the Search Parameters or Tracking Parameters windows.

   Another method for finding the threshold range is to use the crosshairs to determine the gray level of the fiducials and adjacent tissue. Set the minimum above the value of the adjacent tissue and ensure the maximum value is set high enough to include the fiducials.
4. Set an appropriate ROI for the current Tracking mode. If the Fiducial Location Algorithm is failing to find the fiducials, but the fiducials are visible in the live image display, set a region of interest around the area where the fiducials are found, to reduce the scope of the fiducial search. Do this by selecting ROI from the View Mode window and drawing a box around the area of the fiducials.

   If in Search mode, draw the box around the entire fiducial area. If in Track mode, draw the box around only the location of the currently selected fiducial. After the boxes are drawn in both image A and image B, enter the Search Parameters or Track Parameters window, depending on current Tracking mode, and click the **USE ROI** button for both window A and window B. Then click **OK**.



11 49 Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



After attempting one or more of the above, you must attempt to find the fiducials again. If the X-ray parameters have been changed, you must acquire new images by clicking the **ACQUIRE** button on the Patient Alignment Controls window to get new images with the new X-ray parameters. If only the thresholding range and/or ROI areas have been changed, you can attempt to correlate in the current image by clicking the **CORRELATE** button on the Patient Alignment Controls window. New images will not be acquired, but the Fiducial Location Algorithm will attempt to find fiducials using the new settings in the most recently acquired image.

**WARNING: If the Synchrony System is in use and fiducials were found incorrectly (that is values were returned for couch corrections but the fiducials are mis-marked) it is necessary to adjust the fiducial parameters to correlate before re-acquiring images to maintain the validity of the model.**

Once the new acquisition or correlation is complete, you should once again attempt to ensure that the fiducials have been correctly located. If they have not, repeat the above steps and try again.

## Adjusting Patient Position

Once the fiducials have all been correctly located, the patient must be moved into alignment.

1. Move the couch by the numbers suggested in the top three Couch Corrections boxes. This should bring the patient very close to translational alignment. Once this is done, acquire new images by clicking the **ACQUIRE** button on the Patient Alignment Controls window and ensure that the fiducials are properly identified in the live image. If they are not, return to the previous section and modify settings so that the Fiducial Location Algorithm locates them successfully.
2. Move the couch by the numbers suggested in the bottom three Couch Corrections boxes, which display the rotational corrections. Once this is done, acquire new images by clicking the **ACQUIRE** button in the Patient Alignment Controls window and ensure that the fiducials are properly identified in the live image. If they are not, return to the previous section and modify settings so that the Fiducial Location Algorithm locates them successfully. Minimizing rotations enhances accuracy.
3. When using Synchrony Tracking mode with modeling enabled (that is, with the **MODELING CHECKBOX** checked) it is necessary to reset the model after each adjustment of the couch position. After adjusting the couch, click the **RESET MODEL** button and confirm yes in the confirmation dialog to reset the model, then re-establish the model in the new patient position.
4. If the patient is within translational and rotational bounds, proceed with the treatment by clicking the **START** button on the Patient Alignment Controls window. If not, repeat the previous two steps until the patient is within translational and rotational bounds.

**NOTE:** When the patient is aligned after the fiducials have been found by setting specific ROIs, the patient will often be positioned so that the fiducial is no longer imaged within the area of the ROIs. New ROIs will often need to be set after such alignment.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



**WARNING:** ***Visually verify*** **that the fiducials have been correctly located throughout treatment.**

**WARNING: When treating with Synchrony Tracking mode enabled, it is necessary to RESET and re-establish the correlation model after each adjustment of the patient position or the couch position. Failure to reset and re-establish the correlation model may result in inaccurate radiation delivery.**

**WARNING: Change the Tracking mode from Search to Track prior to beginning treatment delivery.**

## Algorithm Parameters Area

The Patient Alignment window has a button that allows you to adjust imaging and algorithm parameters for skull and fiducial tracking. Clicking the **IMAGING PARAMETERS** button pops up the Imaging Parameters window (*Figure 14 Imaging Parameters Window, page 24*).

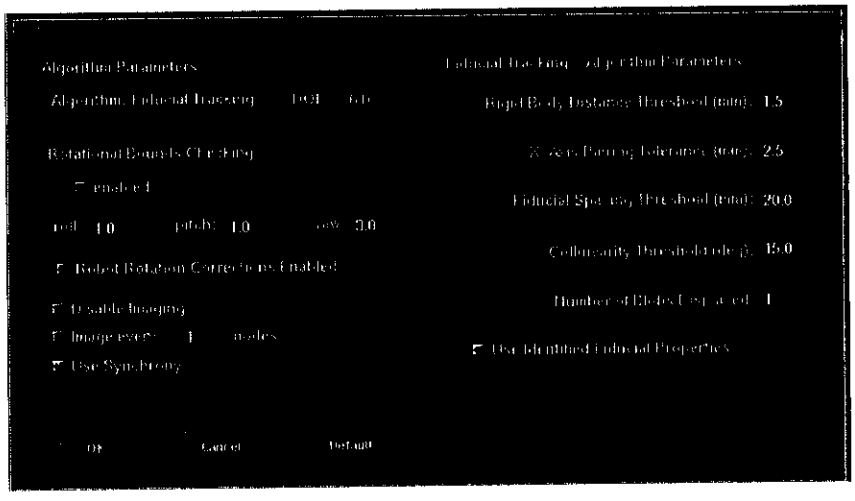


**Figure 14 Imaging Parameters Window**

Unchecking the **USE SYNCHRONY** checkbox will switch from Synchrony Tracking mode to standard Non-Respiratory Tracking treatment delivery.

**NOTE:** The **USE SYNCHRONY** checkbox is only available if Synchrony Tracking mode was enabled for this plan at planning time.



1151 Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



## Start Treatment

If the **START** button of the Equipment Readiness window is active, the CyberKnife System is ready to start treatment. *See module Treatment, section, Start Treatment* for details.

**WARNING: While the treatment is in progress, at least one user should watch robot motion using the video monitors.**

**WARNING: When the START button is selected, the robot starts to move. The robot may move toward its perch position. If the robot was not in a safe location, it should fail the perch check. Use the teach pendant to move the robot near the perch position.**

## Treatment Delivery

Information regarding treatment delivery can be found in *module, Treatment, section, Treatment Delivery.*

## Pausing Treatment

**WARNING: Avoid pausing the system for extended periods of time when the robot blocks the X-ray or LED imaging systems. In these cases, verifying the correlation model is not possible prior to delivering radiation for the node. Treatment must be aborted and robot returned to the perch position if Verification is required due to passage of time. A makeup plan can then be run.**

**WARNING: Avoid adjusting couch or patient positions when the robot blocks the X-ray system. When the couch or patient position is adjusted, the model must be reset and re-established, which is not possible if the imaging systems are blocked. Should this occur, a makeup plan must be created and the robot must be returned to perch prior to re-establishing the model.**

Information regarding pausing treatment can be found in *module, Treatment.*

## Errors

If an error occurs when you are in the treatment process, the system will pause. *See module, Treatment, section, Errors* for more information.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118 1152

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



## Patient Re-Alignment

If an error occurs, or you press **PAUSE** during the treatment process, alignment of the patient must be confirmed before treatment can continue. This confirmation occurs through patient re-alignment. *See module, Treatment, section, Patient Re-Alignment and in this module, Patient Alignment, page 13*, for details.

## Makeup Fractions

A makeup fraction is created when a fraction of a plan is terminated before the total dose was delivered. *See module, Treatment, section, Makeup fractions* for details.

## Synchrony Respiratory Tracking System User Interface

The Synchrony System user interface allows direct control and manipulation of the Synchrony Respiratory Tracking System. This user interface is displayed on the Synchrony computer monitor. It consists of a main Synchrony Controls window (*Figure 15 Main Synchrony Controls, page 26*) with two tabs, the Model Graphs tab and the Real-Time Graphs tab. The Tracking Marker display is shown above the tabs. Near the bottom of the main Synchrony Controls window are four groups of controls.

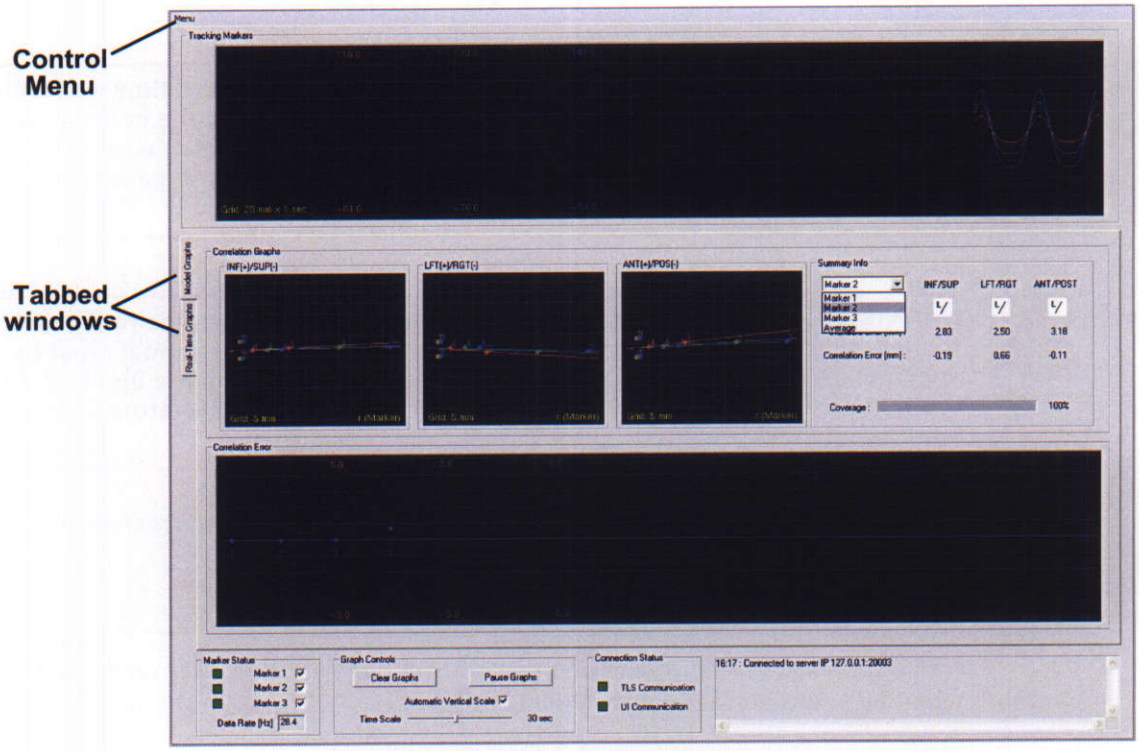



**Figure 15 Main Synchrony Controls**



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

1153

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



## Tracking Markers

The Tracking Markers display (*Figure 16 Tracking Markers Display, page 27*) is always located at the top of the main Synchrony Controls window. The graph shows waveforms representing breathing patterns for up to 3 positional Tracking Markers.

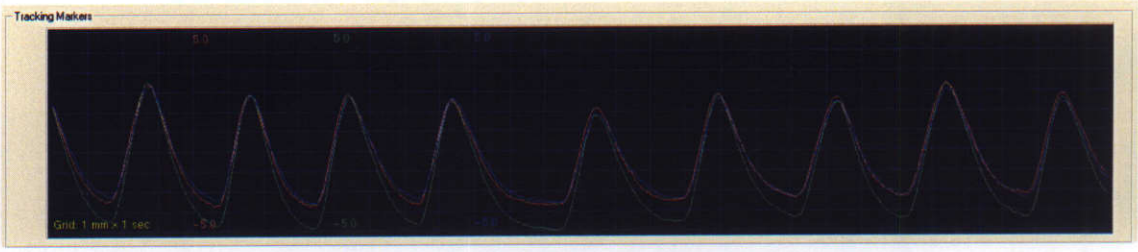



**Figure 16 Tracking Markers Display**

## Correlation Graphs

The Correlation Graphs display (*Figure 17 Correlation Graphs, page 27*) is located on the Model Graphs tab in the main Synchrony Controls window. This display provides a graphical representation of the current model. One Correlation Graph is displayed for each of the three principal axes of the patient coordinate system.

On each graph, a point is drawn for each correlation image acquired. This point represents Tracking Marker position vs. fiducial position measured along the X, Y, Z, or radial (R) axis. By default, positional measurements along the R axis are shown. A best-fit straight line or curvilinear line is drawn through these points. A good visual indication of a high-quality model is a graph with all of its points lying on this line.

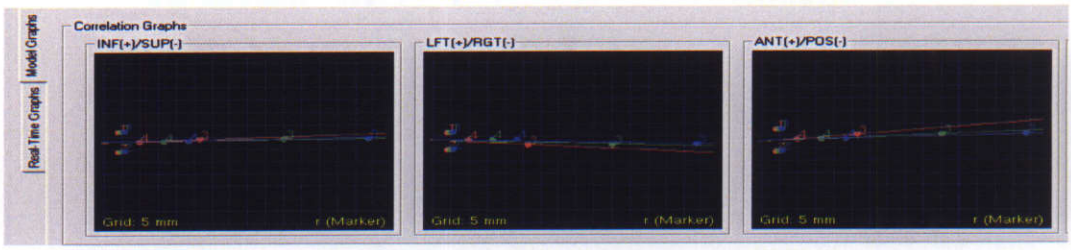



**Figure 17 Correlation Graphs**



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



## Correlation Error

The Correlation Error display (*Figure 18 Correlation Error Display, page 28*) is located on the Model Graphs tab in the main Synchrony Controls window. This display shows the error for each point in the current model, calculated as the difference between the actual position of the target, as determined by the X-ray images, and the predicted position of the target, as computed using the model. The graph is updated after each image is acquired and the target location data has been received from the Target Locating System (TLS).

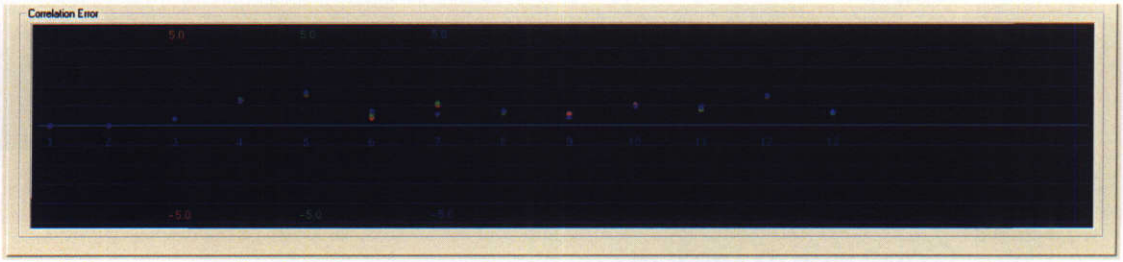



**Figure 18 Correlation Error Display**

## Summary Info

The Summary Info display (*Figure 19 Summary Info, page 28*) is located on the Model Graphs tab in the main Synchrony Controls window.

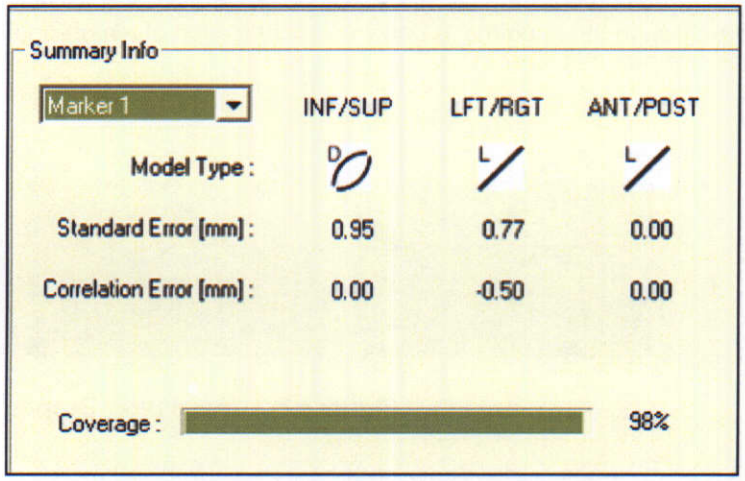



**Figure 19 Summary Info**

This display lists the model type selected and the model errors in each principal direction expressed in the patient coordinate system. Since each Tracking Marker has its own model, the user can use the drop down list to select either individual markers or the aggregate (average) errors for the whole set.



1155

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



The values displayed are as follows:

**Standard Error:** This is the standard error of the model and is a good indicator of the overall difference between the Synchrony model and the model points. It is defined as follows:

eStd = sqrt( sum(e_i^2) / n )

where:

e_i is the difference between the model curve and the model point, and n is the number of model points.

**Correlation Error:** This is the difference between the Synchrony model and the most recent model point added to the data set. It is a good indicator of how well the most recent model point agrees with the Synchrony model.

Using the above notation for the standard error, eStd, the Correlation Error, e_n, is defined as the difference between the model curve and the most recent model point, where n is the number of model points.

**Coverage:** This is an indicator of how much of the respiration range is covered by the current set of model points. It does not take into account the distribution of model points. If two model points have been taken at the two extremes of respiration, the coverage value would be 100%.

## Marker Status

The Marker Status group (*Figure 20 Marker Status, page 29*) contains buttons which allow you to select the Tracking Markers used for tracking patient respiration. For each Tracking Marker there is an indicator, which displays the following colors:

- **Yellow:** Tracking Marker is not present.
- **Red:** Tracking Marker is present but not currently visible.
- **Green:** Tracking Marker is both present and visible.

For each Tracking Marker there is a checkbox that allows you to specify whether this Tracking Marker is to be used for tracking. When this checkbox is enabled, the corresponding Tracking Marker will be used for tracking if it is visible. When the checkbox is disabled (unchecked), the corresponding Tracking Marker will not be used for tracking. The Data Rate is a computed value based on the positional update rate at which the Tracking Markers are seen by the Synchrony Camera Array.

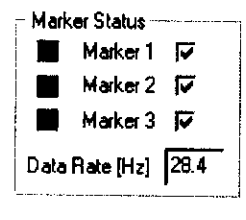



**Figure 20 Marker Status**



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118 1156

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



## Graph Controls

The Graph Controls group (*Figure 21 Graph Controls, page 30*) contains controls which allow you to control real-time graphs including the Tracking Markers, Dynamic Correction, and Prediction Deviation graphs.

- **CLEAR GRAPHS** button will reset the contents for real-time graphs.
- **PAUSE GRAPHS** button will pause the graphs when clicked.
- **Automatic Vertical Scale** checkbox when enabled will continually adjust the vertical scale and center line of the graph to optimize the display.
- **Time Scale** slider adjusts the time range for the output of real-time graphs.

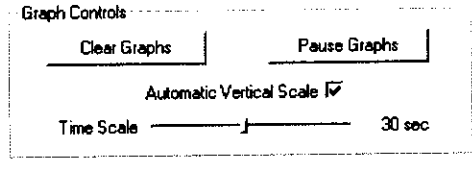



**Figure 21 Graph Controls**

## Connection Status

The Connection Status group has two communication indicators:

- **TLS Communication** indicates green when the Target Locating System (TLS) computer is connected to the Synchrony computer and generating valid communication messages.
- **UI Communication** indicates green when the Synchrony user interface is connected to the Synchrony computer and indicates red when the Synchrony user interface is not connected.

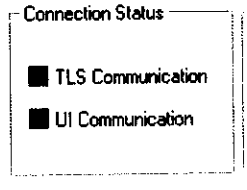



**Figure 22 Connection Status**

## Message Window

The Message Window displays text information that may be useful for advanced users or for troubleshooting.



1157 Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



# Menu

Clicking **Menu** at the top left corner of the main Synchrony Controls window opens a menu with options to change the display of the Correlation Graphs and the Correlation Error displays.

## Display Control

Selecting the **Display Control** menu item opens the Marker Graph Display Control window. This window displays three tabs.

### Marker Graph Tab

The Marker Graph tab (*Figure 23 Marker Graph Display Control, page 31*) allows you to select which positional data measurements are shown in the Correlation Graphs display. Each row of buttons on this tab corresponds to positional measurements along the X, Y, Z and radial (R) axes for a single Tracking Marker. When a button is clicked, the correlation model for that Tracking Marker along that axis is displayed in the Correlation Graphs.

Only one axis can be selected at a time for each Tracking Marker (that is, only one button can be clicked at a time in each row). The data range along the selected axis is displayed on the Correlation Graphs using the same color as the selected button. By default, the radial axis (R) is selected for each Tracking Marker.

**NOTE:** The radial axis (R) should be selected for each Tracking Marker during patient treatment.

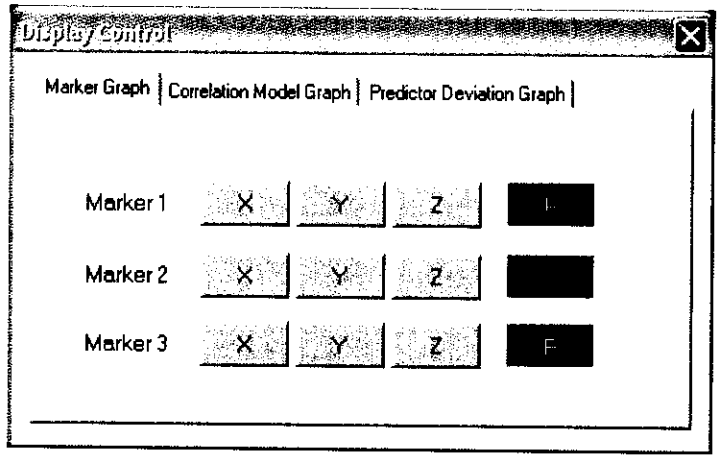



**Figure 23 Marker Graph Display Control**



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



## Correlation Model Graph Tab

The Correlation Model Graph tab (*Figure 24 Correlation Model Graph Display Control, page 32*) allows you to select which positional data measurements are displayed. Correlation error can be shown corresponding to the X, Y, Z or radial (R) positional measurements. Average Error can also be displayed by enabling the **DISPLAY AVERAGE ERROR** checkbox.

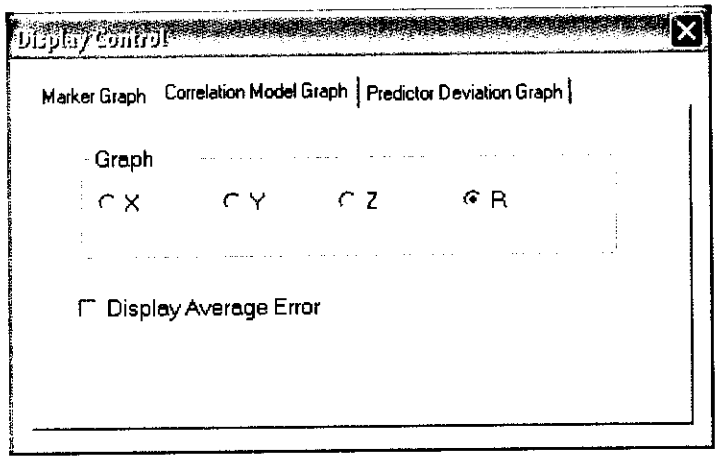



**Figure 24 Correlation Model Graph Display Control**

## Error Control

Selecting the **Display Control** menu item opens the Error Control dialog (*Figure 25 Error Control, page 33*). This dialog allows you to set the following error control options:

- **Marker Excursion Checking** checkbox allows you to enable maximum motion limits for the Tracking Markers before an error condition is signaled. The margin parameter specifies the maximum range the Tracking Markers are allowed to deviate from their expected motion based on their most recent history of motion (as specified by the Lookback parameter). The default value for the margin parameter is 10 millimeters. The Lookback parameter specifies the historical time interval used as the baseline Tracking Marker motion against which the current Tracking Marker motion is checked. The default time value for this parameter is 30 seconds.
- **Model Expires In** textbox sets how long a model remains valid before it must be verified by another X-ray image acquisition. If more than this amount of time passes without an image acquisition and the system tries to use the model for target tracking, an E-Stop will be generated. To recover from this E-Stop you must acquire and successfully correlate an image. This verifies the validity of the model. The default time value for this control is 10 minutes.



1159 Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



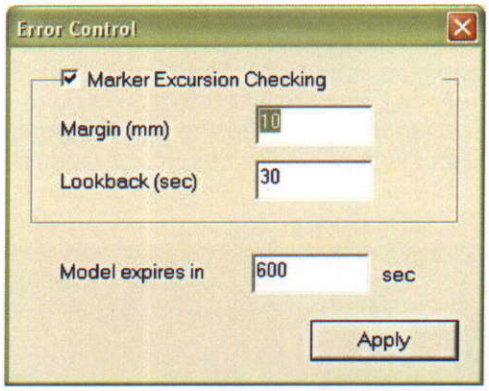



**Figure 25 Error Control**

## Dynamic Correction

The Dynamic Correction display (*Figure 26 Dynamic Correction Display, page 33*) is located on the Real-Time Graphs tab in the main Synchrony Controls window. This display shows the displacement values in millimeters being sent to the robotic manipulator from the Synchrony computer. This graph will only be scrolling when correction factors are being sent to the robotic manipulator. The graph shows three lines, one for each axis of robotic manipulator motion in the global frame:

- **Red line:** indicates motion away from the face of the robotic manipulator base (typically a combination of LEFT and INF patient axes).
- **Green line:** indicates motion to the right of the face of the robotic manipulator base (typically a combination of RIGHT and INF patient axes).
- **Blue line:** indicates upward motions (ANT patient axis).

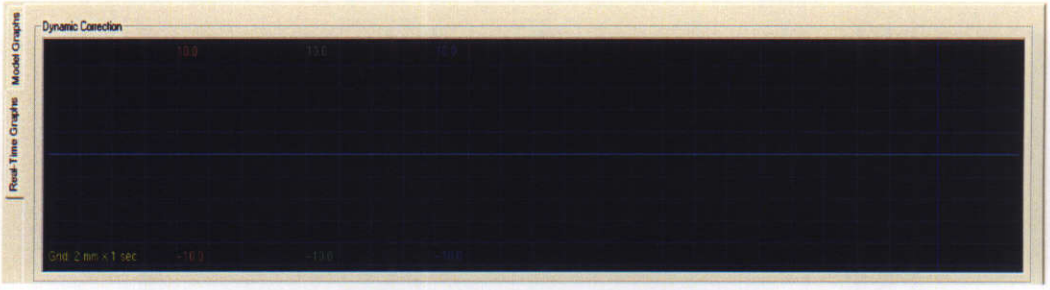



**Figure 26 Dynamic Correction Display**



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

1160

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



## Prediction Deviation

The Prediction Deviation display (*Figure 27 Prediction Deviation Display, page 34*) is located on the Real-Time Graphs tab in the main Synchrony Controls window. The Prediction Deviation graph shows the difference between the correction used to drive the robotic manipulator and the coordinates received from the Tracking Marker system. The graph indicates how effectively the robotic manipulator is tracking the patient, disregarding any possible error in the model.

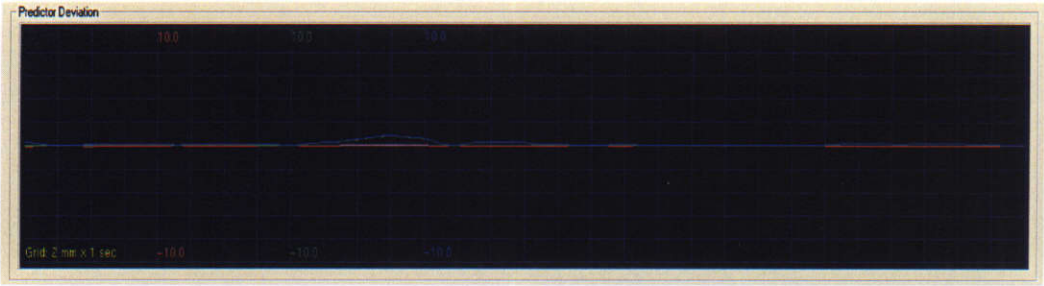



**Figure 27 Prediction Deviation Display**



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

1161

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



# Error Messages
## Table of Contents

**What To Do About Errors** ..... 1
Error List and Action ..... 2



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118 1162

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015





1163

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



# ERROR MESSAGES

## WHAT TO DO ABOUT ERRORS

**WARNING: Any hardware or software related problems should be recorded in the appropriate log and reported to Accuray as soon as possible. Failure to do so may result in injury or death of users and patients.**

The CyberKnife® System displays two types of errors, recoverable and unrecoverable, which are shown in the error message windows (*Figure 1 Example Treatment Error Message, page 1*). The example window shows that E-Stops are active and lists the errors and actions you may take. Generally, the first item in a list of errors is the main cause of the problem. However, it is important to review the entire list as another item may have triggered the error. You can correct recoverable errors, but an Accuray service technician must correct unrecoverable errors.

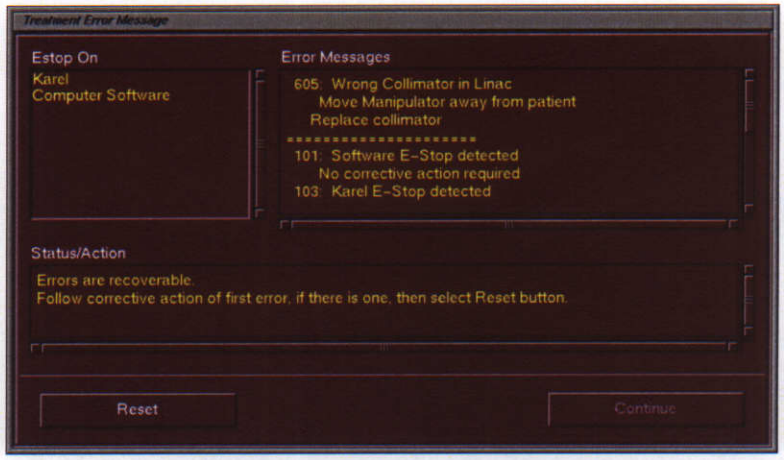



**Figure 1 Example Treatment Error Message**



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

1164

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



Errors can be caused by hardware or software. All software-related errors and hardware errors can be either recoverable or unrecoverable.

Errors generate an E-Stop which causes termination of the beam delivery and manipulator motion. If a recoverable error occurs and is corrected (*Table 1: List of all presently known errors of the CyberKnife System, page 2*), you must reset the CyberKnife System to continue operation. Resetting invoked by the selection of the **RESET** button involves clearing all E-Stops and error detection systems. After the CyberKnife System has been successfully reset, the Manipulator Pause window will appear allowing you to either abort or resume treatment.

**Figure 2 Manipulator Paused Screen**

## Error List and Action

The following is a list of all presently known errors of the CyberKnife System. Follow the suggested action for correcting the problem. Errors numbered greater than 1000 are unrecoverable; those numbered less than 1000 are recoverable.

**Table 1: List of all presently known errors of the CyberKnife System**

| NO. | TYPE | ERROR | DESCRIPTION | RESOLUTION |
|---|---|---|---|---|
| **100** | E-Stop | Linac E-Stop detected | MODULATOR E-Stop: The Manipulator Controller E-Stop out signal, the E-Stop button on the MCC maintenance panel, or the LCF Mod E-Stop, causes the modulator to emergency stop (kills the high voltage power supply and Beam on conditions). The reverse is NOT true. A modulator E-Stop does NOT cause the manipulator controller to enter the E-Stop state. | No corrective action required. |
| **101** | E-Stop | Software E-Stop detected | SOFTWARE E-Stop (SW 0 - 26): The SGI SOFTWARE controls the OPENING and CLOSING of an RS-232 serial port (data terminal ready signal) that is monitored in the ESCC. When the SGI serial port is OPEN, the E-Stop safety loop is closed, which allows the manipulator and modulator to operate. When the SGI serial port is closed, the loop is opened and manipulator operations stop, as well as shutting off the beam and high voltage. | No corrective action required. |



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

1165

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



**Table 1: List of all presently known errors of the CyberKnife System**

| NO. | TYPE | ERROR | DESCRIPTION | RESOLUTION |
|---|---|---|---|---|
| **102** | E-Stop | Mechanical button E-Stop detected | MANUAL PUSH BUTTON E-Stop (SW 0 - 27): all the wall mounted E-Stop switches. If ANY switch is pressed (open), the manipulator stops, as well as shutting off the beam and high voltage. | To disengage E-Stop depressed button must be twisted or pulled out. If this does not clear E-Stop call Service. |
| **103** | E-Stop | Karel E-Stop detected | MAC E-Stop OUT (SW 0 - 28): Internal to the manipulator controller there is an E-Stop relay that is held closed by a no emergency stop condition. Any internal or external emergency stop condition will OPEN the current loop, allowing the relay to de-energize, indicating an E-Stop condition. If this fault is not accompanied by another E-Stop, it indicates that the MAC controller has detected a fault condition internal to the manipulator or controller. This will cause CONDITION -B-. | No corrective action required. |
| **104** | E-Stop | Door E-Stop detected | TREATMENT ROOM DOOR CIRCUIT E-Stop (SW 0 - 29): The door circuit consists of a door closed switch and a bypass key switch. When the door is opened, the circuit is interrupted and the manipulator stops, as well as shutting off the beam and high voltage. The bypass key switch uses the same key as the operator panel enable X-ray key switch. When turned on, the key switch bypasses the door switch so that the door can be opened without an E-Stop. | Make sure that all doors to the treatment room are closed and reset error. If this fails check the connection from the ESCC to the building. If the error persists, call Service. |
| **105** | E-Stop | Cable stretch E-Stop detected | MANIPULATOR CABLE STRETCH E-Stop (SW 0 - 30): Included in the cable bundle that goes from the arm module to the X-ray head, there is a segmented cable connected together with RCA jacks. If the cable bundle gets pulled tight, one of the RCA jacks will come unplugged and cause this E-Stop. This will also shut off the beam and high voltage. | If there is no damage to the cables, look for break in string of RCA connectors and re-connect. If damage to cables or if error persists, call Service. |
| **106** | E-Stop | Operator panel E-Stop detected | OPERATOR PANEL MANUAL BUTTON E-Stop (SW 0 - 31): On the desk next to the SGI monitor / keyboard is the operator control panel. Located there is a large red mushroom E-Stop button. When pressed, it will cause an E-Stop, this status bit and will also shut off the beam and high voltage | To disengage E-Stop depressed button must be twisted or pulled out. If this does not clear the E-Stop, call Service. |
| **107** | E-Stop | LCF E-Stop detected | LCF MODULATOR E-Stop COMMAND (SW 2 - 13): A latch on the STIF board in the VME system can be set and reset by the LCF. When this latch is set, it opens the modulator E-Stop circuit. | No corrective action required. |



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



**Table 1: List of all presently known errors of the CyberKnife System**

| NO. | TYPE | ERROR | DESCRIPTION | RESOLUTION |
|---|---|---|---|---|
| **108** | E-Stop | Teach Pendant Manual E-Stop detected | MAC TEACH PENDANT MANUAL E-Stop (SW 2 - 26): There is a red E-Stop button on the teach pendant; this indicates that it has been pressed. This will also shut off the beam and high voltage. | To disengage E-Stop, depressed button must be twisted or pulled out. If this does not clear the E-Stop, call Service. |
| **109** | E-Stop | ESCC modulator E-Stop detected | E-Stop CONTROL CHASSIS MODULATOR E-Stop (SW 2 - 28): This is a status indicator from the E-Stop control chassis that the modulator E-Stop circuit is open, indicating an internal E-Stop. | To disengage E-Stop depressed button must be twisted or pulled out. If this does not clear the E-Stop, call Service. |
| **151** | LCF | Linac SF6 gas is low | SF6 GAS PRESSURE FAULT (SW 0 - 01): The pressure detector, located in the J-box behind the manipulator, has detected low pressure in the Sulfur Hexafluoride (SF6) Dielectric Gas in the X BAND RF waveguide from the magnetron to the linear accelerator. | Recharge the system with SF6 Gas; consult Service Manual for procedure. If error persists, call Service. |
| **153** | LCF | Linac water flow error | WATER FLOW FAULT (SW 0 - 00): The flow detector, located in the J-box behind the manipulator, has detected a low water flow condition to the magnetron and linear accelerator. | Check filter in water chiller, remove deposits if necessary. If the problem persists, call Service. |
| **154** | LCF | Linac Vacuum Fault | VACUUM FAULT (SW 0 - 02): the magnetron and the linear accelerator are vacuum tubes and contain a device that removes material from their interiors to maintain the vacuum. Circuits have detected an over current condition in this vac-ion pump power supply, indicating foreign material is present. This fault will happen occasionally and will trigger a fault, but a restart is recommended | Select the Reset button to reset the linac. |
| **157** | LCF | Collimator fault | COLLIMATOR MISSING FAULT (SW 0 - 11): The size of the secondary collimator is indicated by a voltage derived from a pair of slide potentiometers that are depressed by a step on the collimator. The total range is one inch and the difference between collimator steps is 1/16 inch; such as a 60 mm is 1/16 inch longer than a 50 mm. If the IFCC circuit for the coll-a analog voltage indicate that there is NO collimator present, the fault is set. This can be disabled using the ESCC maintenance panel. | If collimator is missing or incorrect collimator is installed, install the correct collimator. If the error persists, call Service. |
| **220** | LCF | No Software E-Stop detected during power up sequence | LCF sees no E-Stops at power up on warm-up complete. | Check that the software E-Stop bypass switch is not on. |



1167

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



**Table 1: List of all presently known errors of the CyberKnife System**

| NO. | TYPE | ERROR | DESCRIPTION | RESOLUTION |
|---|---|---|---|---|
| **221** | MAN | Recoverable | Linac controller has detected a robot error. | Use the teach pendant to move the robot to the perch position. Call service. |
| **225** | LCF | High voltage went off unexpectedly | High voltage off during linac calibration; no other errors. | Call service. |
| **570** | TLS | XRS A Recoverable Fault | X-ray source A has a recoverable fault. | Check Door Interlock. If problem persists, call service. |
| **571** | TLS | XRS B Recoverable Fault | X-ray source B has a recoverable fault. | Check Door Interlock. If problem persists, call service. |
| **582** | TLS | TLS not responding to X-ray Parameter message | TLS is not responding to X-ray parameter message. | Send parameters again. If timeout again, Call Service. |
| **584** | TLS | TLSC X-ray exposure error | Recoverable TLSC X-ray exposure error. | Reset can be attempted. |
| **605** | MAN | Wrong Collimator in Linac | COLLIMATOR - A SIZE A-TO-D (SW 1 - 08/15): The removable secondary collimator size is monitored by two pots located in the X-ray head. This A-to-D monitors the voltage from one of these pots. COLLIMATOR - B SIZE A-TO-D (SW 1 - 00/07): The removable secondary collimator size is monitored by two pots located in the X-ray head. This A-to-D monitors the voltage from the other pot. | Move Manipulator away from patient and replace collimator. |
| **631** | TLS | Fiducial Tracking Optimizer Error | Fiducial tracking algorithm fails to find a suitable match for reference fiducial configuration.. | Retry Correlation. Check X-ray parameters and verify visibility of fiducials. If this fails again, call service. |
| **632** | TLS | Fiducial Location Constraint Error | One or more live fiducials has deviated significantly from the reference fiducial configuration. Likely excessive fiducial migration. | Retry acquisition and/or attempt re-alignment. Consider disregarding the errant fiducial. |



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118 1168

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



**Table 1: List of all presently known errors of the CyberKnife System**

| NO. | TYPE | ERROR | DESCRIPTION | RESOLUTION |
|---|---|---|---|---|
| **633** | TLS | Fiducial Extraction Error | Fiducials could not be found in live image. | Check X-ray parameters and extraction thresholds. Then retry acquisition and/or attempt realignment. |
| **634** | TLS | Fiducial Pairing Error | Failure to pair fiducials found in image A to fiducials found in image B. | Check X-ray parameters and extraction thresholds. Then retry acquisition and/or attempt realignment. |
| **635** | TLS | Fiducial Identification Error | Failure to match fiducials found in live images to reference fiducials. | Check X-ray parameters and extraction thresholds. Then retry acquisition and/or attempt realignment. |
| **653** | IPS | IP image out of bounds | Patient position out of bounds. | Realign patient. If this fails again, call Service. |
| **654** | IPS | IP image brightness error | Live image brightness ERROR. | Adjust camera gains and acquire another image. If the error persists, call Service. |
| **655** | IPS | IP Uframe deltas error | Uframe delta out of bounds. | Retake image. If that fails, call Service. |
| **656** | IPS | IP Reference Image Download Error | Reference DRRs not downloaded successfully. | Retry downloading DRRs. If that fails, call Service. |
| **660** | IPS | IP Computation Error | Error in computation of Patient Offset. | Reset TLS power. If problem persists, call Service. |
| **661** | IPS | Error detected during IP rotational calculations | ERROR detected during IP rotational calculations (seco #0032). | Call Service. |



1169

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



**Table 1: List of all presently known errors of the CyberKnife System**

| NO. | TYPE | ERROR | DESCRIPTION | RESOLUTION |
|---|---|---|---|---|
| **663** | IPS | Camera gains can not be adjusted automatically | Camera gains cannot be adjusted automatically. | Adjust camera gains and acquire another image. If the error persists, call Service. |
| **664** | IPS | Patient Out of Alignment | Patient out of alignment. | Reposition patient and acquire a new image. |
| **665** | IPS | IP image brightness error | Brightness error during patient alignment. | Adjust camera gains and acquire another image. If error persists, call Service. |
| **669** | IPS | Acquiring image time-out. | Cameras timed out during image acquisition. | Retry image acquisition. If problem persists call Service. |
| **673** | IPS | Reference DRR file load failed. | System failed to load Reference DRR for image comparison. | Retry DRR file load. If error reoccurs, call Service. |
| **678** | IPS | TLSC File transfer error | TLSC File transfer protocol error. | Reset can be attempted. If reset fails, call service. |
| **679** | IPS | TLSC Illegal Camera ID error | TLSC Illegal camera ID specified. | Reset can be attempted. If reset fails, call service. |
| **680** | IPS | TLSC DRR reference error | TLSC illegal DRR reference error. | Reset can be attempted. If reset fails, call service. |
| **681** | IPS | TLSC Patient Tag Error | TLSC illegal patient tag error. | Reset can be attempted. If reset fails, call service. |
| **682** | IPS | TLSC tracking algorithm failure. | Imaging system could not calculate patient location. | Reacquire image. If problem persists, call Service. |
| **683** | IPS | TLSC raw image to live image transformation error. | Could not transform raw image to system live image. | Reacquire image. If problem persists, call Service. |



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



**Table 1: List of all presently known errors of the CyberKnife System**

| NO. | TYPE | ERROR | DESCRIPTION | RESOLUTION |
|---|---|---|---|---|
| **684** | IPS | TLSC no target reference error. | DRRs improperly downloaded. | Attempt to download DRRs again. If error reoccurs, call Service. |
| **685** | IPS | TLSC image acquisition error. | Imaging system failed to properly acquire image. | Attempt to reacquire image. If error persists, call Service |
| **686** | IPS | TLSC Communications error | TLSC general communication error. | Reset can be attempted. If error persists, restart TLS computer. |
| **687** | IPS | TLSC Illegal command error | TLSC Illegal command error. | Reset can be attempted. If error persists, call service. |
| **688** | IPS | TLSC Emergency Abort | TLSC emergency abort error. | Reset can be attempted. If error persists, call service. |
| **689** | IPS | TLSC Power Down Abort | TLSC power down abort error. | Reset can be attempted. If error persists, call service. |
| **690** | IPS | Unspecified TLSC error. | Unspecified recoverable TLSC error. | Reset can be attempted. If error persists, call service. |
| **691** | IPS | TLSC Camera A has a recoverable fault. | Fault occurred during acquisition of image in Camera A. | Recycle TLS power. If problem persists, call Service. |
| **692** | IPS | TLSC Camera B has a recoverable fault. | Fault occurred during acquisition of image in Camera B. | Recycle TLS power. If problem persists, call Service. |
| **693** | IPS | TLCS system has a recoverable fault. | Fault occurred in TLCS system. | Recycle TLS power. If problem persists, call Service. |
| **694** | IPS | IPS timed out waiting for a reply message from the TLSC. | TLSC did not send a reply before the IPS timed out. | Recycle TLS power. If problem persists, call Service. |





Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



**Table 1: List of all presently known errors of the CyberKnife System**

| NO. | TYPE | ERROR | DESCRIPTION | RESOLUTION |
|---|---|---|---|---|
| **998** | WDG | Master Process Not Responding | Master Process is not responding. | Call Service. |
| **999** | | Pause button pressed by user | Pause button pressed on screen. | Press reset button on the screen to continue. |
| **1001** | GEN | Communications Error | Defines the ID of an error coming from the COM process. | Call Service. |
| **1002** | GEN | Communications Error | Receive message error. | Call Service. |
| **1003** | GEN | Transmit message error | Message failed to be transmitted. | Call Service. |
| **1004** | GEN | IP system initialization failure | The receive process for the IP system failed during initialization. | Call Service. |
| **1005** | GEN | Invalid process ID | The process ID was invalid. | Call Service. |
| **1006** | GEN | Unknown error | Unrecognizable ERROR. | Call Service. |
| **1007** | GEN | Unexpected process termination error | Used in notifying that a child process died. | Call Service. |
| **1008** | GEN | Sproc failed | Spawn process failed to create a process. | Call Service. |
| **1009** | GEN | Msgsnd failed to send | Msgsnd failed to send a MSG. | Call Service. |
| **1010** | GEN | Port attribute error | This means that a failure occurred while trying to modify an attribute on a socket. | Call Service. |
| **1011** | GEN | Comm Port Lock Failed | Communications Port Lock Failed. | Call Service. |
| **1012** | GEN | Shared memory error | Attempt to allocate shared memory segment. | Call Service. |
| **1013** | GEN | Semaphore error | | Call Service. |
| **1014** | GEN | Couldn't initialization queues | This message is generated when the queues failed to initialize. | Call Service. |



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



**Table 1: List of all presently known errors of the CyberKnife System**

| NO. | TYPE | ERROR | DESCRIPTION | RESOLUTION |
|---|---|---|---|---|
| **1150** | LCF | Linac power supply error | DOSE POWER SUPPLY FAULT (SW 0 - 08): The dosimetry system has duplicate electronics, one for dose-A and another set for dose-B. The separate power supplies are cross-checked 7 different ways. PS-1 voltage < 224 VDC. PS-2 voltage <224 VDC. dose cell voltage <224 VDC. PS-3 +15 VDC and -15 VDC. PS-4 +15 VDC and -15 VDC. All combined into one fault signal. | Call Service. |
| **1152** | LCF | Linac high voltage error | HIGH VOLTAGE OVER CURRENT FAULT (SW 0 - 03): In the modulator the first step in generating the power required to generate the X rays is the 230 V AC input power supply that generates 8000 VDC output to the PFN (pulse forming network). If an over current condition of this 8000 VDC supply is detected, this fault is generated. | Call Service. |
| **1155** | LCF | Linac inverse current error | INVERSE CURRENT FAULT (SW 0 - 04): The modulator delivers a 4 microsecond wide pulse at 8000V dc at 360 amps to the pulse transformer in the X-ray head via the high voltage pulse cable. If there is a short in the cable or transformer, the reflected (inverse) current pulse is detected and this fault is generated. | Call Service. |
| **1156** | LCF | Linac computer error | INTERFACE CONTROL CHASSIS COMPUTER FAULT (SW 2 - 14): This fault is a summary of various faults detected in the IFCC and sent to the fault logic in the MCC, where it will generate a fault summary. | Call Service. |
| **1158** | LCF | Magnetron filament UC fault | MAGNETRON FILAMENT UNDER CURRENT FAULT (SW 0 - 05): The high voltage pulse of 8000 Volts and 360 Amps is stepped up in the pulse transformer to 36,000 Volts and 80 Amps. This is the input to the magnetron, which generates 9.3 Gigahertz RF power. If the cathode filament heater is allowed to get cold when the high voltage pulse occurs, arcing inside the magnetron will do severe damage to the magnetron, so this circuit monitors the mag heater current and generates this fault if the current goes to zero. | Call Service. |
| **1159** | LCF | DOSE/STIF board time-out fault | DOSE/STIF board time-out fault. | Call Service. |
| **1160** | LCF | GRID power supply fault | GRID POWER SUPPLY FAULT (SW 0 - 09): The grid power supply provides isolated +150 VDC and -150 VDC and +15 VDC and -15 VDC, with its ground reference at 15 to 20 thousand volts, to the gun cathode power supply. | Call Service. |



1173

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



**Table 1: List of all presently known errors of the CyberKnife System**

| NO. | TYPE | ERROR | DESCRIPTION | RESOLUTION |
|---|---|---|---|---|
| **1161** | LCF | LCF warm-up not completed in time | If modulator and other hardware devices have not begun their power-up cycle within 20 seconds from initiation, this error will be triggered. | Call Service. |
| **1162** | LCF | MCC power supply fault | MODULATOR CONTROL CHASSIS POWER SUPPLY FAULT (SW 2 - 20) (NYI): Using the power supplied by the IFCC VME system, the modulator control chassis power supplies are checked for an over voltage or under voltage condition. The function of these circuits is to detect a slow (2 week) power supply voltage drift condition, which could cause undetectable digital errors. | Call Service. |
| **1163** | LCF | VME power supply fault | INTERFACE CONTROL CHASSIS VME POWER SUPPLY FAULT (SW 2 - 21) (NYI): Using the power supplied by the modulator control chassis, the IFCC power supplies are checked for an over voltage or under voltage condition. The function of these circuits is to detect a slow (2 week) power supply voltage drift condition, which could cause undetectable digital errors. | Call Service. |
| **1164** | LCF | LCF wrote to registers while beam was on | BEAM WRITE FAULT (SW 2 - 22): While the beam ON status is active the dose and STIF boards are in a read only state. Any write instruction from the VME microprocessor system will cause a fault. | Call Service. |
| **1165** | LCF | Write to dose counters outside diagnostic mode | Write to dose counters outside diagnostic mode. | Call Service. |
| **1166** | LCF | Communication error from ESCC/ MCC | DOSE COMPARITOR -B- FAULT (SW 2 - 16): The circuits that compare the 32 bit dose count to the 32 bit stop register are duplicates and if they don't agree, then it is assumed that there is a problem with the circuits and causes a computer fault in the modulator. | Check cable connection between ESCC/ MCC}. |
| **1167** | LCF | Communication error to ESCC/ MCC | DOSE BOARD TIME-OUT FAULT (SW 2 - 19): On the dose counter board there is a one second timer that must be reset by reading the status. If the timer is not reset in time, the hardware assumes that the computer has died and causes a computer fault in the modulator. | Check cable connection between ESCC/ MCC}. |



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



**Table 1: List of all presently known errors of the CyberKnife System**

| NO. | TYPE | ERROR | DESCRIPTION | RESOLUTION |
|---|---|---|---|---|
| **1168** | LCF | ESCC command fault | DOSE OVERFLOW -A2- FAULT (SW 2 - 24): There are two 32 bit dose counters that accumulate the dose pulses from the dosimetry system. Since the 32 bits allow for almost 43 million MUs, any overflow out of the high order bits is obviously an error and causes a computer fault in the modulator. The exact bits (16 - 23) that are used to trigger this fault are switch set-able on the dose board. | Check cable connection between ESCC/ MCC}. |
| **1169** | LCF | ESCC bus time-out | DOSE OVERFLOW -B2- FAULT (SW 2 - 25): There are two 32 bit dose counters that accumulate the dose pulses from the dosimetry system. Since the 32 bits allow for almost 43 million MUs, any overflow out of the high order bits is obviously an error and causes a computer fault in the modulator. The exact bits (16 - 23) that are used to trigger this fault are switch set-able on the dose board. | Call Service. |
| **1170** | LCF | MCC command fault | MCC command fault. | Check cable connection between ESCC/ MCC}. |
| **1171** | LCF | MCC bus time-out | MCC bus time-out. | Call Service. |
| **1172** | LCF | Could not turn off the beam | The linac process running on the IFCC could not turn of the linac beam. | Call Service. |
| **1173** | LCF | Linac reset failed | Attempt to reset the linac failed. | Call Service. |
| **1174** | LCF | Overdose for node | Overdose for node. | Call Service. |
| **1175** | LCF | Overdose for path | Overdose for path. | Call Service. |
| **1176** | LCF | Under dose for node detected by LCF | Underdose for node from LCF. | Call Service. |
| **1177** | LCF | Attempt to set stop register A failed | Attempt to set stop register A failed. | Call Service. |
| **1178** | LCF | Attempt to set stop register B failed | Attempt to set stop register B failed. | Call Service. |
| **1179** | LCF | Reset kill beam failed; beam on denied | Attempt to reset the kill beam latch failed; beam enable will not be allowed. | Call Service. |



1175

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



**Table 1: List of all presently known errors of the CyberKnife System**

| NO. | TYPE | ERROR | DESCRIPTION | RESOLUTION |
|---|---|---|---|---|
| **1180** | LCF | Manipulator moving while beam is on | BEAM MOTION FAULT: If the treatment beam on status (SW 0 - 15) from the MCC is on at the same time as the manipulator motion status (SW 2 - 23) from the MAC, a hazardous condition exists and the LCF will cause a modulator E-Stop. | Call Service. |
| **1181** | LCF | Set LCF E-Stop failed | Set LCF E-Stop failed. | Call Service. |
| **1182** | LCF | Reset LCF E-Stop failed | Reset LCF E-Stop failed. | Call Service. |
| **1183** | LCF | LCF power-up diagnostics failed | LCF power-up diagnostics failed. | Call Service. |
| **1184** | LCF | LCF could not spawn a task | LCF could not spawn a task. | Call Service. |
| **1185** | LCF | LCF watchdog timer fault | LCF watchdog timer fault. | Call Service. |
| **1186** | LCF | Attempt to reset dose while beam is on | Attempt to reset dose while beam is on. | Call Service. |
| **1187** | LCF | Attempt to resume LCF while E-Stop is on | Attempt to resume LCF while E-Stop is on. | Call Service. |
| **1188** | LCF | MUs from counter A and MUs from counter B are too far apart | Dose counter values don't agree after mu conversion. | Call Service. |
| **1189** | LCF | Dose rate A higher than limit | Dose rate A greater than limit. | Use scope to check PRF. If greater than 166 Hz, reduce to 166 Hz. If the error persists, call Service. |
| **1190** | LCF | Dose rate B higher than limit | Dose rate B greater than limit. | Use scope to check PRF. If greater than 166 Hz, reduce to 166 Hz. If the error persists, call Service. |
| **1191** | LCF | Beam on too long | Beam on too long. | Call Service |



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



**Table 1: List of all presently known errors of the CyberKnife System**

| NO. | TYPE | ERROR | DESCRIPTION | RESOLUTION |
|---|---|---|---|---|
| **1192** | LCF | Leakage from counter A greater than limit | Leakage from counter A > limit. | Call Service. |
| **1193** | LCF | Leakage from counter B Greater than limit | Leakage from counter B > limit. | Call Service. |
| **1194** | LCF | Attempt to turn beam on in wrong state | Software denied attempt to turn beam on in wrong state. | Call Service. |
| **1195** | LCF | New stop register setting less than old | New stop register setting < old. | Call Service. |
| **1196** | LCF | Attempt to set registers while beam on | Attempt to set stop registers while beam on. | Call Service. |
| **1197** | LCF | Attempt to set registers in wrong mode | Attempt to set stop registers in wrong mode. | Call Service. |
| **1198** | LCF | Attempt to reset counter A failed | Reset counter A failed. | Call Service. |
| **1199** | LCF | Attempt to reset counter B failed | Reset counter B failed. | Call Service. |
| **1200** | LCF | Dose A Greater than stop A and beam is on | Dose A >= stop A and beam is on. | Call Service. |
| **1201** | LCF | Dose B Greater than stop B and beam is on | Dose B >= stop B and beam is on. | Call Service. |
| **1202** | LCF | Attempt to set diagnostic mode failed | Attempt to set diagnostic mode failed. | Call Service. |
| **1203** | LCF | Attempt to set CPU mode failed | Attempt to set CPU mode failed. | Call Service. |
| **1204** | LCF | Fault in overflow comparator A1 | DOSE OVERFLOW -A1- FAULT (SW 2 - 17): There are two 32 bit dose counters that accumulate the dose pulses from the dosimetry system. Since the 32 bits allow for almost 43 million MUs, any overflow out of the high order bits is obviously an error and causes a computer fault in the modulator. The exact bits (24 - 31) that are used to trigger this fault are switch set-able on the dose board. | Call Service. |



1177

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



**Table 1: List of all presently known errors of the CyberKnife System**

| NO. | TYPE | ERROR | DESCRIPTION | RESOLUTION |
|---|---|---|---|---|
| **1205** | | | DOSE OVERFLOW -B1- FAULT (SW 2 - 18): There are two 32 bit dose counters that accumulate the dose pulses from the dosimetry system. Since the 32 bits allow for almost 43 million MUs, any overflow out of the high order bits is obviously an error and causes a computer fault in the modulator. The exact bits (24 - 31) that are used to trigger this fault are switch set-able on the dose board. | Call Service. |
| **1206** | LCF | LCF Start Denied. | Attempt to start LCF in wrong state. | Call Service. |
| **1207** | LCF | Karel Command Error | Linac controller has detected system command inconsistent with system status. | Call Service. |
| **1208** | LCF | A/D dose rate too high | A/D dose rate too high. | Call Service. |
| **1209** | LCF | A/D dose rate too low | A/D dose rate too low. | Call Service. |
| **1210** | LCF | Cumulative under dose detected by LCF | Cumulative underdose from LCF. | Call Service. |
| **1211** | LCF | AFC positive current too high | AFC positive current too high. | Call Service. |
| **1212** | LCF | AFC positive current too low | AFC positive current too low. | Call Service. |
| **1213** | LCF | AFC negative current too high | AFC negative current too high. | Call Service. |



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015





Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



# System Shutdown
## Table of Contents

Powering Down Equipment .....1
Logging Out .....3
System Shutdown Check List .....4



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118 1180

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015





1181 Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



# SYSTEM SHUTDOWN

## POWERING DOWN EQUIPMENT

**CyberKnife System Menu -> Equipment Status -> Electrical Power Shutdown Warning**

**To power down the CyberKnife System:**

**Step 1.** Click the **EQUIP POWER** button on the CyberKnife® System menu. The CyberKnife System menu disappears and the Equipment Status window (*Figure 1 Equipment Power Status On, page 1*) appears.

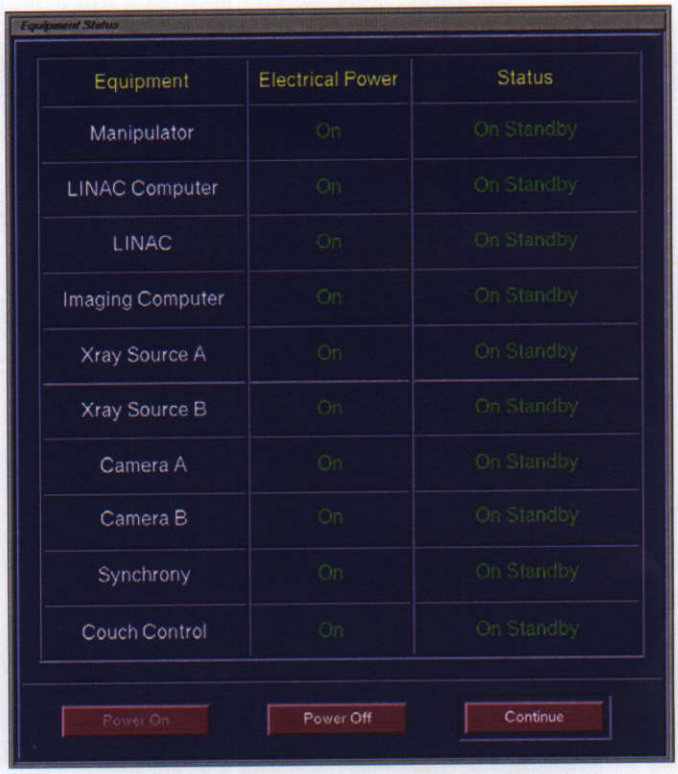



**Figure 1 Equipment Power Status On**



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



**Step 2.** Click the **POWER OFF** button. The Electrical Power Shutdown Warning window (*Figure 2 Power Shutdown Warning, page 2*) appears with a message that requests you to confirm the intent to shut off electrical power to the manipulator, Linac and its subsystems and the diagnostic X-ray power supplies.

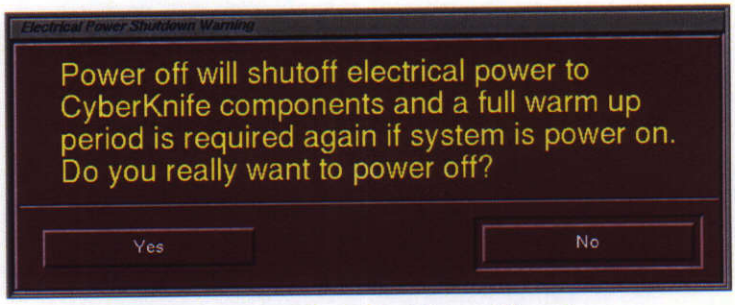



**Figure 2 Power Shutdown Warning**

**Step 3.** Click **YES** to turn off electrical power. The warning disappears and the **POWER OFF** button on the Equipment Status window becomes inactive. It takes a few seconds for the status to change to the power off state. Once the power is off, the **POWER ON** button becomes active.

For the systems with the KUKA robot, wait an additional 60 seconds prior to powering up the system.

**Step 4.** Clicking **NO** returns to the Equipment Status window with the **POWER OFF** button active.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

1183

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



# LOGGING OUT

### CyberKnife System Menu -> CyberKnife Log-in -> Shutdown Warning

**To log off the CyberKnife System:**

**Step 1.** Click the **EXIT** button on the CyberKnife Log-in window. The CyberKnife Log-in window disappears and the Shutdown Warning window (*Figure 3 Logoff Power Shutdown Warning, page 3*) appears. This window asks you to confirm the shutdown.

**Figure 3 Logoff Power Shutdown Warning**

**Step 2.** If yes, click **YES**. All computer processes cease and all electrical power to the system turns off. The computer log-in window appears.

**Step 3.** If not, click the **NO** button and the CyberKnife Log-in window appears.

**Step 4.** If the CyberKnife System menu displays, click the **EXIT** button and the CyberKnife Log-in window appears. Proceed with Steps 1 through 3 above.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

1184

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



# SYSTEM SHUTDOWN CHECK LIST

1. DO NOT turn off power to the user control console workstation.
2. Check that the MCC, cooler and manipulator controller power are off.
3. Turn off the treatment room monitoring cameras and controllers.
4. Turn off the lights to the room.
5. Leave the door open to the treatment room.
6. Turn off the console monitor.
7. Secure the safety interlock key.

**NOTE:** Chiller and Cooling Fan on the X-ray head will keep running approximately 60 minutes after electrical power is off.

Gun Filament Voltage (stand-by) and High Voltage of Vacuum Pump for ACC guide and Magnetron are always on.

TLS PC, MTS PC, UPS, Primary Workstation, Couch, PDU air fan on the electrical rack, Switching Hub, Serial Server, Firewall, IFCC and ESCC are always on.



1185 Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



# System Administration
## Table of Contents

Add New User ..... 1
Delete User ..... 6
Change User Status ..... 7
User Preference, Changing Password ..... 8
Database Backup ..... 10
Restore Database ..... 13
Print Screen ..... 17
Remote Diagnostics ..... 18
Computer Shutdown ..... 19



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118 1186

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015





1187 Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



# SYSTEM ADMINISTRATION

This module gives information for performing CyberKnife® System computer administration tasks, such as adding or deleting a user, changing user status, database backup, restoring the database, print screen and computer shutdown. In addition, this section describes how users can change their passwords.

## ADD NEW USER

The designated CyberKnife computer administrator enters the names and access permissions for users of the CyberKnife System and assigns and changes the access level of the user. The access level limits the access to various console computer functions of the system. The levels of access are as follows:

**Level 1**
Limited to activating the **PATIENTS**, **CTS**, **EQUIP POWER**, **PRESCRIPTION** and **TREATMENT** buttons of the CyberKnife System menu.

**Level 2**
Access to all buttons except **DRRS**, **PHYSICS and** the Administration menu Computer Submenu User buttons on the CyberKnife System menu.

**Level 3**
Full access to all functions of the CyberKnife System menu.

### CyberKnife System Menu -> CyberKnife Users -> New User -> Password and Access Level Verification -> Status Messages

**Step 1.** Click the **ADMINISTRATION** item in the menu bar on the CyberKnife System menu. (*Figure 1 CyberKnife System Menu with Computer Submenu Visible, page 2*) A submenu appears.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118 

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015

**Figure 1 CyberKnife System Menu with Computer Submenu Visible**

**Step 2.** Click the **COMPUTER** item. Another submenu appears.

**Step 3.** Click the **USERS** item. The CyberKnife System menu disappears and the CyberKnife Users window (*Figure 2 CyberKnife User's Menu, page 2*) appears. A list of users is displayed in this window.

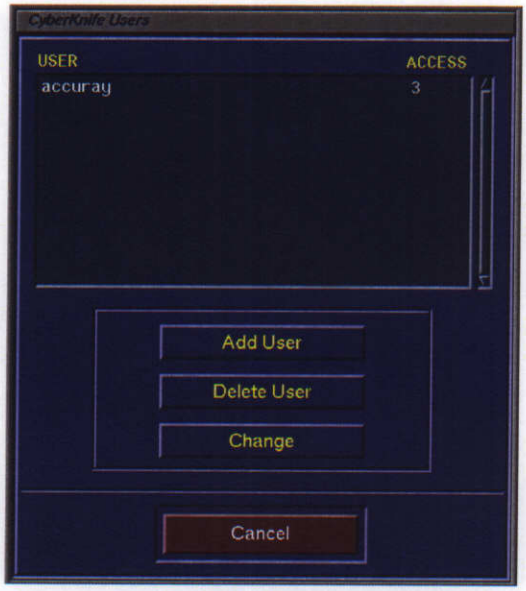



**Figure 2 CyberKnife User's Menu**

**Step 4.** Click the **ADD USER** button and the New User window (*Figure 3 New User Screen, page 3*) appears. Clicking **CANCEL** on the Add User window returns you to the CyberKnife System menu. Click in the New User text area to activate the text area. The 'I' shaped text pointer appears in the text area.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



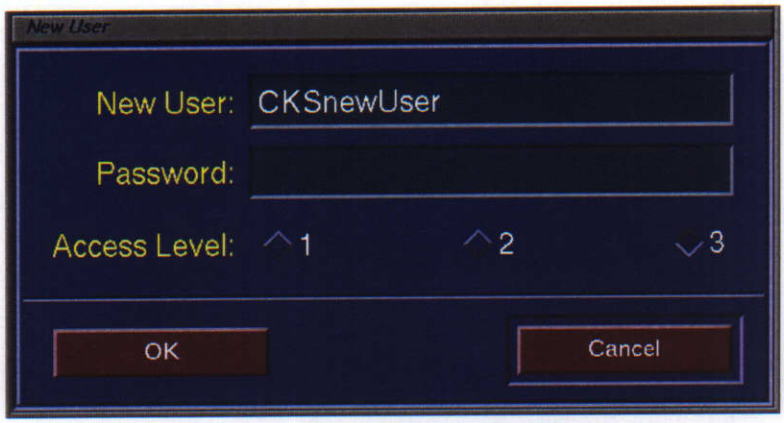



**Figure 3 New User Screen**

**Step 5.** Type in the name of the user. Do not use blanks or start a name with a numeric character. Press <Enter>.

**Step 6.** Type in the password. The cursor moves when a character is typed, but no character is displayed in the Password box. This is a form of password protection. When done, press <Enter>. The pointer moves to the **ACCESS LEVEL** buttons. Select the desired access level.

The access levels are categorized in the following way:

**Access Level 1: Operator**

- Treatment
- Add patient
- Load CT/ MIRIT
- Prescription
- Preferences->Password

**Access Level 2: Administrator**

- Treatment
- Add patient
- Patient archive
- Patient restore
- Database backup
- Database restore
- Administration -> computer -> shutdown
- Preferences->Password



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



**Access Level 3: Super User**

- Treatment
- Simulation
- Linac calibration
- Treatment planning
- Add patient
- Load CT/MIRIT
- DRR generation
- Prescription
- Physics
- Patient archive
- Patient restore
- Administration ->computer -> users
- Database backup
- Database restore
- Administration ->computer -> shutdown
- Preferences -> passwd

**Step 7.** Click **OK**. The Password and Access Level Verification window (*Figure 4 Password and Access Verification Screen, page 4*) appears. Clicking **CANCEL** on the New User window redisplays the CyberKnife System menu.

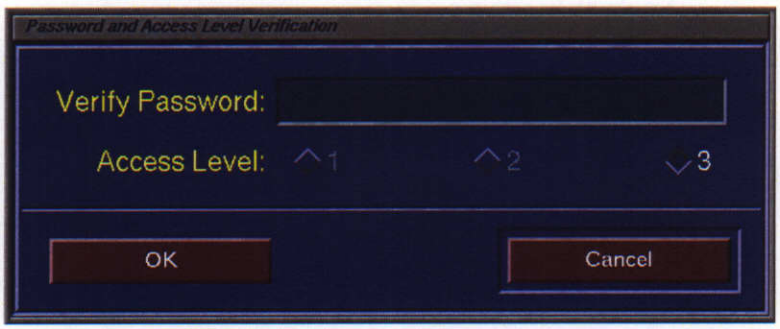



**Figure 4 Password and Access Verification Screen**

**Step 8.** Move the pointer into Verify Password text area. Type in the password. Visually check the access level. If the information is not accurate, click **CANCEL** to return to the New User window.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

1191

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



**Step 9.** Click **OK**. The Status Message (*Figure 5 New User Status Message, page 5*) informs you that the new user data is being entered into the CyberKnife System database. Clicking **OK** on the Status Message redisplays the CyberKnife Users window. The new user name and access level are displayed in the User list area.

**Figure 5 New User Status Message**

### Errors

Any errors appear in the Error Message. Follow the instructions and click **CONTINUE** to return to the appropriate window for corrections.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



# DELETE USER

Data for users who can no longer have access to the CyberKnife System should be deleted from the CyberKnife database. Only a user with Level 3 access can delete a user from the system.

**CyberKnife System Menu -> CyberKnife Users -> Verify Selection -> Access Level -> Status Messages**

**Step 1.** From the CyberKnife Users window, select the name of the user to delete.

**Step 2.** Click the **DELETE USER** button and the Confirmation Message (*Figure 6 Delete User Confirmation Message, page 6*) appears. The system prompts you to verify that the correct item will be deleted.

**Step 3.** Click **YES** to delete the selected user and the Status Message appears with a message confirming the deletion of the user. Click **OK** to return to the CyberKnife Users window. If you click **NO** in the Verify Selection window, no action is taken and the CyberKnife Users window reappears.

**Figure 6 Delete User Confirmation Message**

### Errors

If any errors are displayed in the Error Message. Follow the instructions and click **CONTINUE** to return to the appropriate window for corrections.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

1193

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



# CHANGE USER STATUS

A user's password and access level can be changed as needed. Any user with Level 3 access can perform this activity.

**CyberKnife System Menu -> CyberKnife Users -> Change User's Password and Access Level -> Password and Access Level Verification -> Status Messages**

**Step 1.** From the CyberKnife Users window, click the name of the user. This selects the item for changes to password or access level.

**Step 2.** Click the **CHANGE** button. The CyberKnife Users window disappears and the Change User's Password and Access LeveL window (*Figure 7 Change User's Password and Access Level, page 7*) appears. This window displays the user's name and access level.

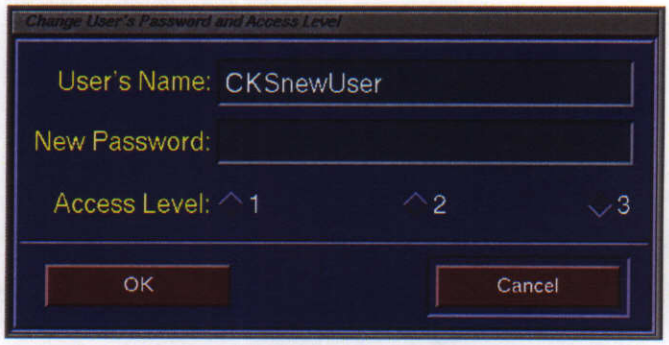



**Figure 7 Change User's Password and Access Level**

**Step 3.** Move the cursor into the New Password text area and type in the password. Click the desired access level button. This selects the new access level.

**Step 4.** Click **OK** and the Password and Access Level Verification window (*Figure 4 Password and Access Verification Screen, page 4*) appears. Type the new password in the Verify Password text area. Visually verify the access level. If the information is not correct, click **CANCEL** to return to the Change User's Password and Access Level window.

**Step 5.** If the data is correct, click OK and the STATUS MESSAGE appears. This window informs you that the changes have been incorporated into the CyberKnife database. Clicking **OK** on the Status Message redisplays the CyberKnife System Menu.

### Errors

Any errors are displayed in the Error Message. Follow the instructions and click **CONTINUE** to return to the appropriate window for corrections.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



# User Preference, Changing Password

This subsection allows any user to change their password.

**CyberKnife System Menu -> Password -> Status Message**

**Step 1.** Click the **PREFERENCE** button in the menu bar on the CyberKnife System menu. The **PASSWORD** button appears.

**Step 2.** Click the **PASSWORD** button and the Password window (*Figure 8 Change Password Window, page 8*) appears.

**Figure 8 Change Password Window**

**Step 3.** Type in the old password in the Old Password text area. Notice that no characters appear on the screen when the password is entered, but that the cursor moves. The characters are present but hidden for security. Use the <Delete> and <Backspace> keys to make corrections in the text. When the password is entered, press <Enter>. The 'I' shaped text pointer moves to the New Password text area. To return to the CyberKnife System menu at any time from the Password window, click **CANCEL**. No changes will be made to the CyberKnife System database.

**Step 4.** Type in the new password. When finished, press <Enter>. The text pointer moves to the Verify Password text area.

**Step 5.** Type in the new password. When finished, click **OK**. The Password window disappears and the Status Message (*Figure 9 Password Changed Status Message, page 9*) appears with a message that the new password is accepted.

**Step 6.** Click **OK** on the Status Message to redisplay the CyberKnife System menu.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

1195

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



### Errors

Any errors are displayed in the Error Message. Follow the instructions and click **CONTINUE** to return to the appropriate window for corrections.

**Figure 9 Password Changed Status Message**



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

1196

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



# DATABASE BACKUP

This procedure allows you to backup the CyberKnife System database and all configuration data files to 12 GByte DAT tapes.

**NOTE:** You should make a periodic backup to protect your data in case of disk corruption.

**Step 1.** Click the Administration menu in the menu bar of the CyberKnife System menu. The Administration submenu appears.

**Step 2.** Click the Computer menu to bring up the submenu.

**Step 3.** Click **BACKUP DB**. The CyberKnife System Database Backup window (*Figure 10 CyberKnife System Database Backup Screen, page 12*) appears.

**Step 4.** Follow the instructions displayed in the CyberKnife System Database Backup window. The following message is shown:

Backup CyberKnife System database
==========

Calculating size of your database...

You have xxx Megabytes of data. It will take about xx minutes and need x tapes (12 Gigabyte).

Insert new tape into tape drive and Press <Enter> key to continue or type in 'q' to abort this backup.

where **xxx** = the number of megabytes of data

**xx** = the approximate number of minutes to backup the database

**x** = the number of tapes needed to backup the database



1197

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



**Step 5.** If a new tape is placed into the tape drive, the system begins to backup the database to tape.

**Step 6.** If a used tape is placed into the tape drive, one of the following messages may be displayed:

a. Tape is write-protected. Set it to unsafe mode and insert the tape back into the drive.

b. Tape drive has Patient Archive data tape. Do you want to overwrite this tape? [y=yes, n=no, q=quit]

c. Tape drive has Unknown data tape. Do you want to overwrite this tape? [y=yes, n=no, q =quit]

d. Tape drive has Database backup tape. Do you want to overwrite this tape? [y=yes, n=no, q=quit]

When you see message 6a, remove the tape from the drive and set the write-protect tab to unlocked position.

When you see messages 6b, 6c, or 6d, make sure the data is not needed before you overwrite the tape. For the questions with the options of yes (y), no (n), or quit (q):

- If you specify **Y**, the backup software overwrites the tape and continues to backup.
- If you specify **N**, the backup process asks you to insert new tape into the tape drive and press <Enter>.
- If you specify **Q**, the system returns to the main menu on the CyberKnife System Database Backup window.

**Step 7.** When the backup is completed successfully, follow the instructions in the window. The following is the message displayed:

Backup completed successfully.
Remove the tape from the drive and make sure to put a label on the tape.
Press <Enter> key to return to CyberKnife System menu.

The CyberKnife System menu appears and the database backup disappears.

**NOTE:** f problems occur while transferring data to tape, clean the tape drive head with a standard cleaning tape. To avoid problems due to dirty tape drive heads, clean the tape drive once a month.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118 1198

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



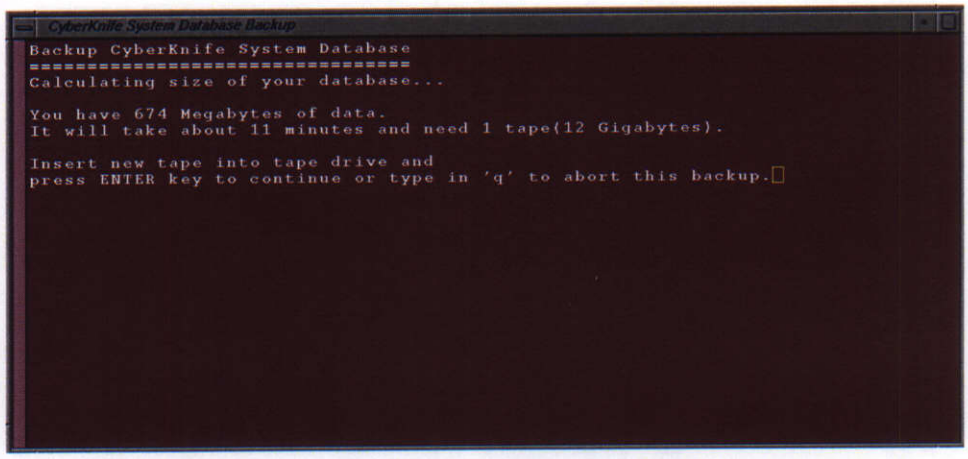



**Figure 10 CyberKnife System Database Backup Screen**



1199

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



# RESTORE DATABASE

This procedure allows you to restore the CyberKnife System database and the configuration data files from the backup tape. This procedure replaces your database and configuration data files with the backup you made previously.

**CAUTION:** When you start this process, make sure you really want to do this. Once it starts, it removes the current database and configuration data files and replaces them with your backup. It is impossible to recover the removed database! Consult your System Administrator/Database Administrator before doing this.

**Step 1.** Click the **ADMINISTRATION** selection in the menu bar on the CyberKnife System menu to activate the submenu.

**Step 2.** Click **COMPUTER** and another submenu appears.

**Step 3.** Click **RESTORE DB**. The CyberKnife System Database Restore window (*Figure 11 CyberKnife Restore System Database Screen, page 13*) appears.

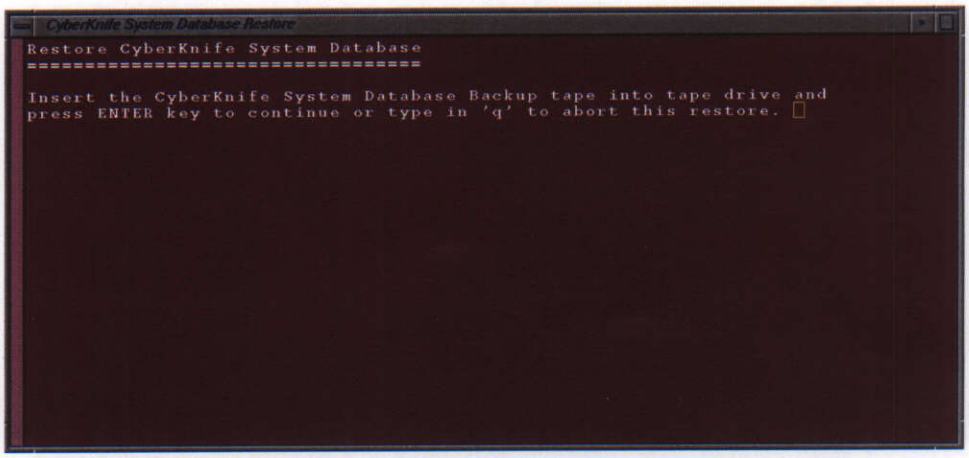



**Figure 11 CyberKnife Restore System Database Screen**

**Step 4.** Follow the instructions shown in the CyberKnife System Database Restore window. The following message appears:

Restore CyberKnife System database

==========

Insert the CyberKnife System Database Backup tape into tape drive and press the <Enter> key to continue or type in 'q' to abort this restore.

**NOTE:** To abort the restore process, type 'q' and press <Enter> to return to the CyberKnife System menu.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

1200

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



**Step 5.** The restore process verifies the data on the tape. It displays the result of verification and one of the following messages are shown:

a. This tape contains no data.

b. Tape not found in the tape drive.

c. Tape drive has Patient Archive data.

d. Tape drive has Unknown data tape. Insert the CyberKnife System Database Backup tape into tape drive and press the <Enter> key to continue or type in 'q' to abort this restore.

e. Tape drive has Database backup tape. Do you want to restore this tape? [y=yes, n=no, q=quit]





Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



When the restore process checks the database backup tape, message 6e appears.

- Type in 'y' and press <Enter> to continue restoring the database.
- If you specify 'n' and press <Enter>, put in another tape.
- If you specify 'q' and press <Enter>, follow the instructions on the screen. The following messages appear.

Restore aborted.
Press <Enter> key to return to CyberKnife System Menu.

If any other messages are displayed, correct the problem and insert the database backup tape into the tape drive and follow the instructions on the screen. Before restoring information from the tape, the following warning messages are displayed on the screen.

***WARNING: You can not stop Restoring process from this point.
***WARNING: This process will erase all CyberKnife System Database

and

***WARNING: restore it from this tape.
***WARNING: Once this process starts, you can not stop this process.
***WARNING: After restoring is completed, CyberKnife System will be shutdown automatically.
Are you sure to continue? [y=yes, n=no]
Type in 'y' to continue with the tape in the drive, or 'n' to abort this process.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118 

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



Once the restoring process has begun, the following messages are displayed:

Note:==========

When your CyberKnife System Database can not be contained on one tape, you will see the following messages on this screen when the first tape is fully read:

Reached end of medium on input.

If you want to go on, type device/file name when ready:

When you see this message, insert the next tape into the tape drive, type in "/dev/tape" and press <Enter> key at the prompt.

==========

Restoring CyberKnife System Database...

When you are instructed to put in the next tape, remove the tape from the tape drive and put the next tape into the drive. Using the keyboard, type in /dev/tape and press <Enter>.

The following message appears at the end of a successful restoration:

Restore completed successfully.

Press <Enter> key to return to CyberKnife System Menu.

When you press <Enter>, the CyberKnife System deactivates all buttons from the CyberKnife System menu except **EXIT**. The system needs to be restarted. Click **EXIT** and continue to log off the CyberKnife software.

Log in again to view the restored database.



1203

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



# PRINT SCREEN

**CAUTION:** Do not press the **PRINT SCREEN** key while treating a patient. The screen capture process needs extensive computer resources; the normal treatment process may be interrupted.

There are two ways to print displays from screens. The easiest way is by clicking the **PRINT SCREEN** key, which prints the full screen and sends it to your default printer as a postscript file. The other way is to take a snapshot of a selected area of your screen and send it to your default printer. Consult your System Administrator to setup your default printer.

**Step 1.** Right-click over the background screen to reveal a hidden menu. Select the **SAVE IMAGE** button (*Figure 12 CyberKnife Hidden Buttons, page 17*). The **SNAPSHOT** button appears at the bottom left of the screen (*Figure 13 Snapshot Button, page 17*).

**Figure 12 CyberKnife Hidden Buttons**

**Step 2.** Position the pointer over the **SNAPSHOT** button and press the <Shift> key or middle mouse button. A special pointer appears in the shape of a camera.

**Figure 13 Snapshot Button**

**Step 3.** While still holding the **SHIFT** key or middle mouse button, move the camera pointer over to the starting point of the area to be captured, generally a corner. Click and hold the left mouse button. The pointer changes to a corner shape. Once the left mouse button is held, the <Shift> key or middle mouse button can be released.

**Step 4.** Left click, hold and drag a box around the area to be captured. When you've outlined the area, release the mouse.

**Step 5.** Click **PRINT IMAGE** to print the snapshot of the selected area.

**Step 6.** Click **EXIT** to exit the Snapshot.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

1204

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



# Remote Diagnostics

**CAUTION:** Do not select any of the transfer options while treating a patient. The data collection process may interrupt the normal treatment process.

Accuray provides four options to transfer system information using the Transfer Options menu. The purpose of collecting and transferring system information, is to help an Accuray Service Engineer better understand a particular problem.

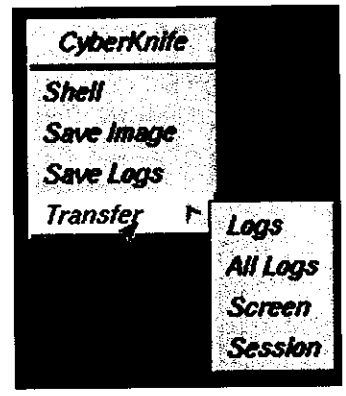



**Figure 14 CyberKnife System Transfer Options**

**Logs** used to transfer a subset of the CyberKnife System logs. The subset includes the log files that are most likely to reveal the system problem.

**All Logs** used to transfer all CyberKnife System logs.

**Screen** used to transfer the active visible interface. This gives an Accuray Service Engineer a view into a particular local problem.

**Session** used to transfer all information needed for an Accuray Service Engineer to reproduce the current imaging environment. Files that are transferred include the patient DRR's and the last pair of live images captured.



1205

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



# COMPUTER SHUTDOWN

Use these steps to shut down the user console computer for computer maintenance. You must use an account with Access Level 2 or 3 to shut down the console computer.

**Step 1.** Click the **ADMINISTRATION** selection menu bar on the CyberKnife System menu. The Administration submenu appears.

**Step 2.** Click the **COMPUTER** selection. Another submenu appears.

**Step 3.** Click the **SHUTDOWN** selection. The Confirmation Message (*Figure 15 Computer Shutdown Warning Message, page 19*) appears. Follow the instructions shown in this window. The window presents the following messages.

> You are about to shut down the computer.
> It will be safe to turn off the Computer after:
> All CyberKnife screens disappear and
> The Computer System Maintenance Menu appears.
> CyberKnife System power will automatically be turned off.
> Do you really want to shut down the user console computer?"

**Step 4.** To shut down the computer, click **YES**.

**Step 5.** Wait until the Computer System Maintenance Menu appears.

**Step 6.** When you see the Computer System Maintenance Menu, it is safe to turn the power off.

**Figure 15 Computer Shutdown Warning Message**



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

1206

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015





Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

1207

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



# Patient Archive and Restore System
## Table of Contents


**Introduction** ..... 1
- User Login ..... 1
- Main Patient Archive and Restore System Screen ..... 2

**General Use of the Patient Archive and Restore System** ..... 3
- Disk Space View ..... 3
- Title Bar ..... 4
- Status Bar ..... 4
- Folder List ..... 5
- Patient List View ..... 6
- Action Bar ..... 6
- Action Tabs ..... 7
  - View ..... 7
  - Archive ..... 9
    - Archive to Online Storage ..... 10
    - Copy To DVD ..... 11
  - Restore ..... 13
    - Restore From Online Storage ..... 13
    - Restore From DVD ..... 15
  - Maintenance ..... 17
    - Online Patient Record Deletion ..... 17
    - Patient Record Identification ..... 18




Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118 1208

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015





1209 Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



# PATIENT ARCHIVE AND RESTORE SYSTEM

## INTRODUCTION

This module explains the operational procedures for the CyberKnife® Patient Archive and Restore System. The Patient Archive and Restore System consists of a PC with a DVD burn device located on the CyberKnife LAN, that allows users to perform patient record archive and restore operations.

The Patient Archive and Restore System supports archiving to the PC hard drive and to DVD. Both DVD+R and DVD+R Dual Layer disks are supported.

To start using the Patient Archive and Restore System, double-click the CyberKnife program icon to launch the application. When the application is launched the Login screen is displayed.

### User Login

The user login interface provides two fields to capture a user's id and password.

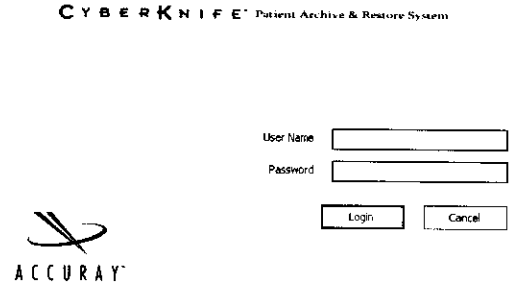



**Figure 1 Login screen**

**Step 1.** Type in your User Name.

**Step 2.** Type in your Password, click the **LOGIN** button.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118 1210

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



# Main Patient Archive and Restore System Screen

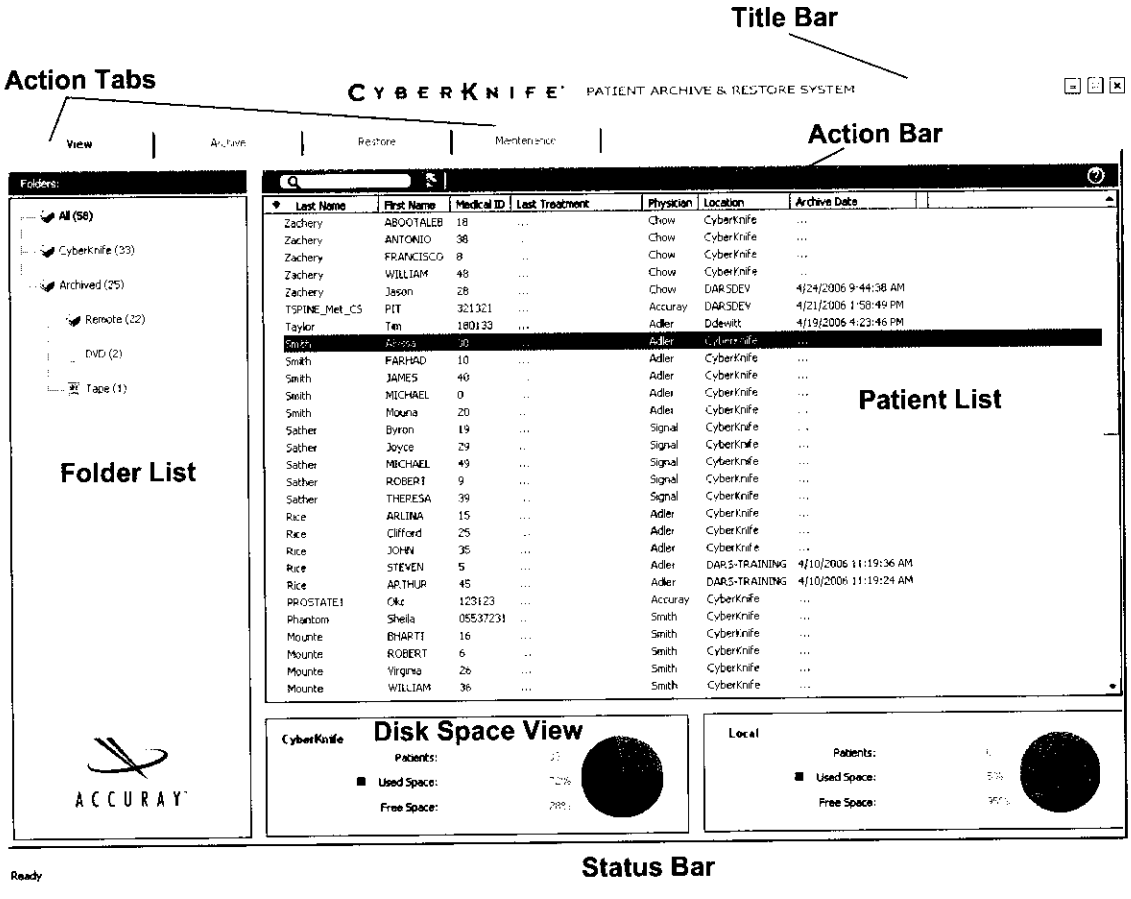



**Figure 2 Main Patient Archive and Restore System screen**

After logging in, the Main Interface is displayed. It consists of the following:

- Title Bar
- Action Tabs
  - View
  - Archive
  - Restore
  - Maintenance
- Action Bar
- Folder List
- Patient List
- Disk Space View
- Status Bar



1211

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



# General Use of the Patient Archive and Restore System

Once the user logs in the All folder is selected, and the system displays a list of all patients and the current location of their patient record. The list includes the following data:

- Last Name
- First Name
- Medical ID
- Last Treatment
- Physician
- Location of the patient record
- Archive Date

Several options are available on the system:

1. Sort the patient list by selecting the header of any of the displayed data.
2. Find a patient using the search tool on the action bar.
3. Filter the patient list by selecting a folder.
4. Archive, restore or perform maintenance on patient records.

## Disk Space View

The system provides a visual indication of the amount of space being utilized on the main CyberKnife database and on the local hard drive.

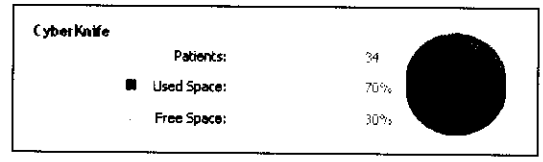



**Figure 3 Disk Space View**

**NOTE:** If the CyberKnife or the local disk space used exceeds 90%, a warning appears.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118 1212

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



## Title Bar

The title bar displays the product name, and provides **MINIMIZE**, **MAXIMIZE**, and **EXIT** buttons. The **MINIMIZE** button hides the main page from the user, the **MAXIMIZE** button expands the application until the desktop is filled. The **EXIT** button initiates application exit.

**Figure 4 Title Bar**

**NOTE:** If the **EXIT** button is selected during an active archive or restore session, the system displays a warning message that exiting the application will cancel the active session. Users must either confirm or cancel the exit request. If the exit request is confirmed, the system cancels the active session and closes the application. If the exit request is cancelled, the system returns to complete the active session.

## Status Bar

Provides a section to display text feedback, a scrolling progression bar used to indicate activity, and a screen drag button.

**Figure 5 Status Bar**



1213 Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



# Folder List

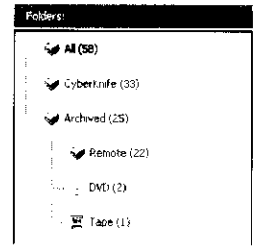



**Figure 6 Folder List**

Provides selectable folders that represent locations of CyberKnife patient records. The number in ( ) next to the folder name indicates the total number of patient records stored in that folder. There are seven selectable folders:

- **All**

  Combination of patient records included in both the Archived and the CyberKnife folders.
- **CyberKnife**

  Patient records stored on the CyberKnife database.
- **Archived**

  Combination of patient records archived to Local, Remote, DVD, and Tape.
  - **Local**

    Archived patient records stored on local hard drive.
  - **Remote**

    Archived patient records stored on other Patient Archive and Restore System hard drives.
  - **DVD**

    Archived patient records stored on DVD's.
  - **Tape**

    Archived patient records stored on Tape.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118 1214

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



# Patient List View

Displays the patient records associated with a selected folder. For each patient the system displays: last name, first name, medical id, physician, last treatment date, record location, and the archive date. You can sort the patient list by clicking on the column header of the field to be sorted by.

| Last Name | First Name | Medical ID | Last Treatment | Physician | Location | Archive Date |
|---|---|---|---|---|---|---|
| Carry | Mary | 27 | .. | Volica | Tape | .. |
| Zachery | ABOOTALEB | 18 | .. | Chow | CyberKnife | . |
| Jones | ALFREDO | 11 | .. | Smith | CyberKnife | .. |
| **Smith** | **Alyssa** | **30** | **...** | **Adler** | **CyberKnife** | **...** |
| Zachery | ANTONIO | 38 | . | Chow | CyberKnife | . |
| Rice | ARLINA | 15 | ... | Adler | CyberKnife | ... |
| Jones | Badi | 21 | .. | Smith | CyberKnife | .. |
| Mounte | BHARTI | 16 | . | Smith | CyberKnife | .. |

**Figure 7 Patient List View**

# Action Bar

Provides capabilities that can be used for patients displayed in the patient list. The following actions are available on all views:

### Search Text Field

Allows a user to reduce the patient list to entries that contain text entered. For example if a user enters "X", the patient list is reduced to those entries starting with "X" in any of the fields.

### Help Menu

The Help menu contains an About menu item that displays information about the application.

**NOTE:** Actions specific to individual functions will be described in each function section of this manual.

**Figure 8 Action Bar**



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

1215

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



# Action Tabs

## View

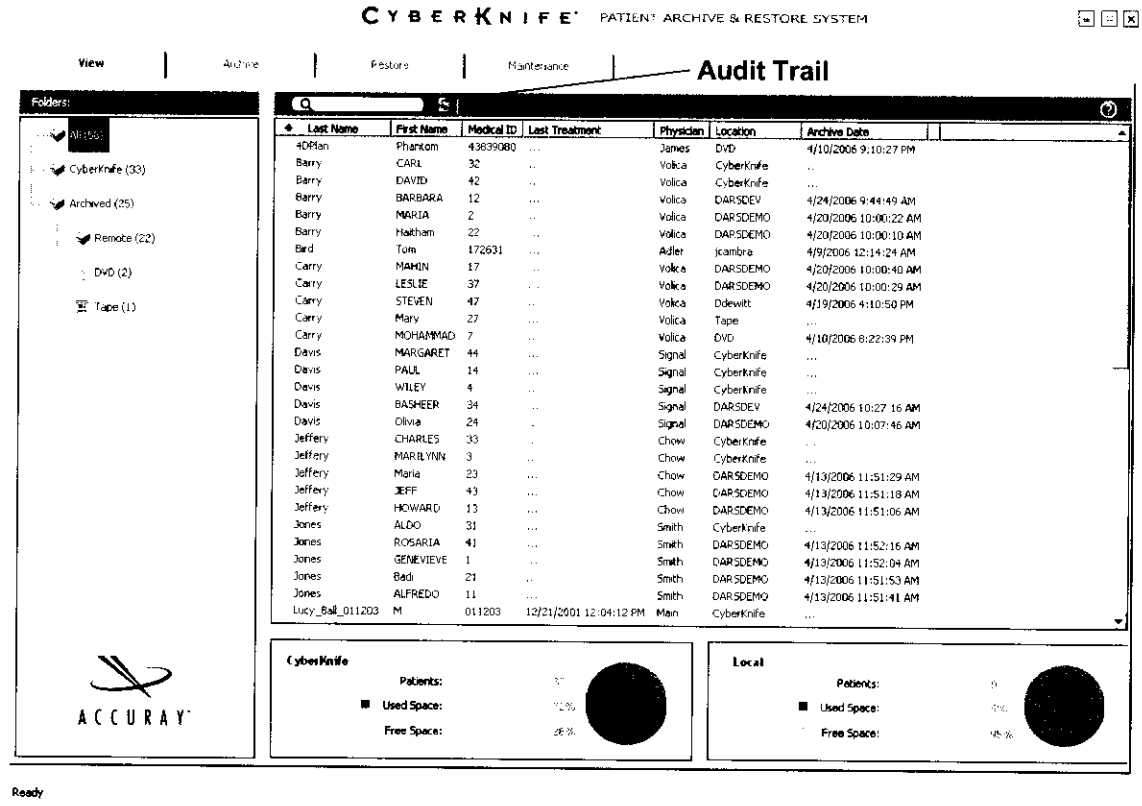



**Figure 9 View Screen**

When the View tab is selected, in addition to viewing the complete list of patients and the current location of their patient records, the user can view an audit trail of all Archive and Restore actions performed on a patient record. To view an audit trail select the **VIEW AUDIT TRAIL** icon on the Action bar. The Audit Trail view replaces the disk space (*Figure 10 Audit Trail View, page 8*), and the **VIEW AUDIT TRAIL** icon changes to the **HIDE AUDIT TRAIL** icon. Once the Audit Trail view appears, select a patient from the patient list. All Archive and Restore actions performed on the selected patient's record are displayed in the Audit Trail view.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

1216

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



| | | | | | | |
|---|---|---|---|---|---|---|
| Jones | ALDO | 31 | ... | Smith | jcambra | 4/12/2006 11:13:57 AM |
| Lucy_Ball_011203 | M | 011203 | 12/21/2001 12:04:12 PM | Main | jcambra | 4/9/2006 2:41:21 AM |
| LUNG_left_NSC_CS | Phx | 112233 | ... | Accuray | CyberKnife | ... |

| | Medical ID | Date | Action | User | Machine |
|---|---|---|---|---|---|
| 1 | 42 | 4/10/2006 7:24:41 PM | Archived to Local Drive | a | 10.20.22.84 |
| 2 | 42 | 4/10/2006 7:24:41 PM | Archived to Local Drive | a | 10.20.22.84 |
| 3 | 42 | 4/10/2006 7:24:41 PM | Archived to Local Drive | a | 10.20.22.84 |
| 4 | 42 | 4/10/2006 7:24:41 PM | Archived to Local Drive | a | 10.20.22.84 |
| 5 | 42 | 4/10/2006 7:24:41 PM | Archived to Local Drive | a | 10.20.22.84 |
| 6 | 42 | 4/10/2006 7:24:41 PM | Archived to Local Drive | a | 10.20.22.84 |

**Figure 10 Audit Trail View**

For each action listed the following information is provided:

- Medical ID
- Date & Timestamp of action
- Action performed
- User who performed action
- IP address of the machine where the action was performed.

When another patient is selected, the audit trail list clears, and the selected patient's audit entries appear. Hide the audit trail by selecting the **HIDE AUDIT TRAIL** icon. The disk space view becomes visible.



1217 Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



# Archive

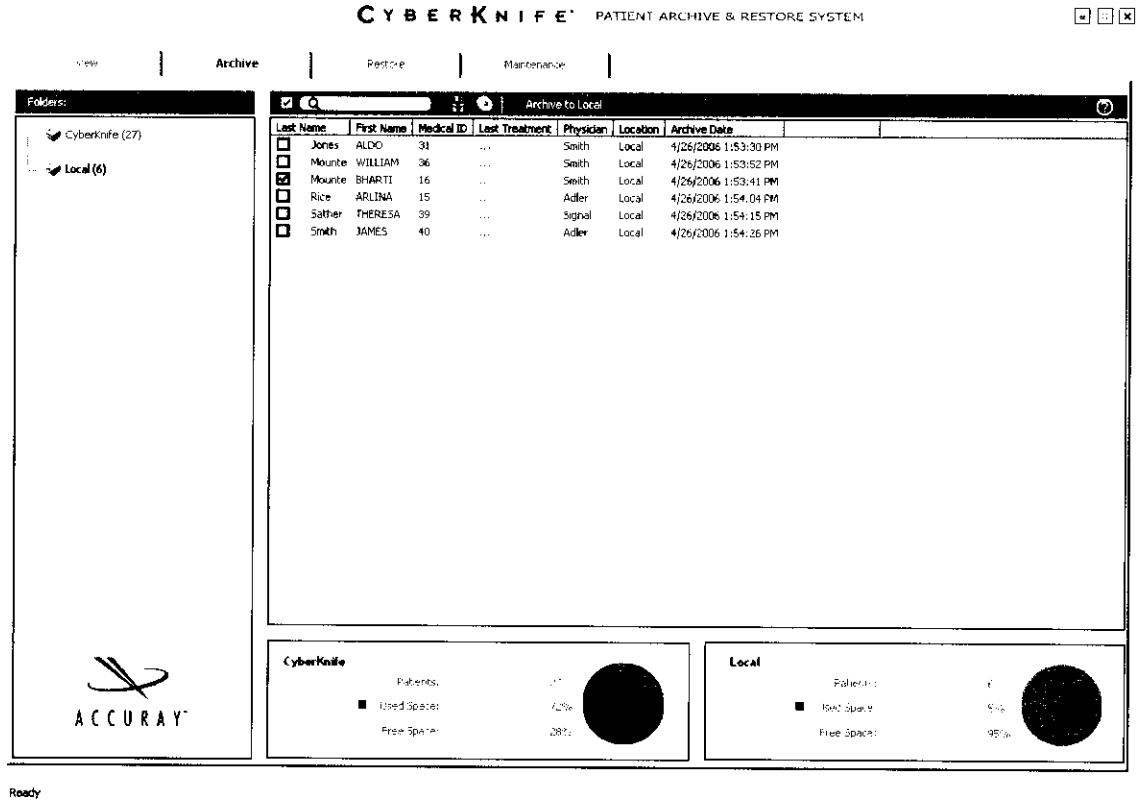



**Figure 11 Archive Screen**

The Archive tab provides a way to archive a patient record from the CyberKnife onto online storage, and a way to copy an archived patient record from online storage to DVD.

When the Archive tab is selected two icons are displayed in the Action bar which are Active or Inactive depending on which folder is selected. For instance, when the CyberKnife folder is selected, the **ARCHIVE TO LOCAL DRIVE** icon is active. When the Local folder is selected, the **COPY TO DVD** icon is active. In addition a **SELECT ALL** icon appears to the left of the search text field.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118 1218

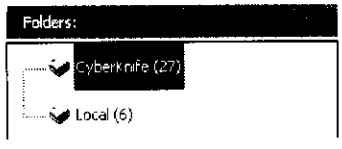
Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



## Archive to Online Storage

To archive a patient from the CyberKnife onto online storage:

**Step 1.** Select the CyberKnife folder.

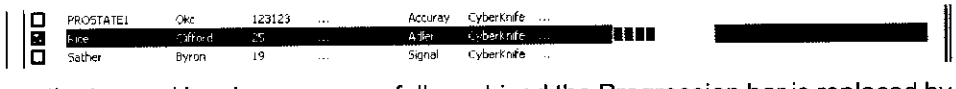



The Patient List view is updated to show patients whose records are located in the CyberKnife database.

**Step 2.** Select one or more patients and then select the **ARCHIVE TO LOCAL** icon located on the Action bar.

A patient can be selected by either double clicking the patient record, selecting the patient checkbox or selecting the **SELECT ALL** icon located on the Action bar. Deselect a patient by double clicking the selected patient, selecting a checked patient check box, or deselecting the **SELECT ALL** icon.

During the archive a Progression bar appears in the patient list view next to the patient whose record is being archived, and is updated as the patient files are copied from the CyberKnife to the local disk. The state of the operation is displayed in the Status bar.




Once the patient record has been successfully archived the Progression bar is replaced by a check mark. If more than one patient was selected for online archive, the system advances to archive the next patient record, displaying the Progression bar next to that patient's name. This continues until all selected patient records are archived. An archive can be canceled by selecting the **STOP** icon located on the Action bar. If the system fails to archive a patient record, the patient entry in the patient list view is highlighted red, and the Progression bar is replaced with an "X" mark. Following the online patient archive session a Report Summary dialog appears.

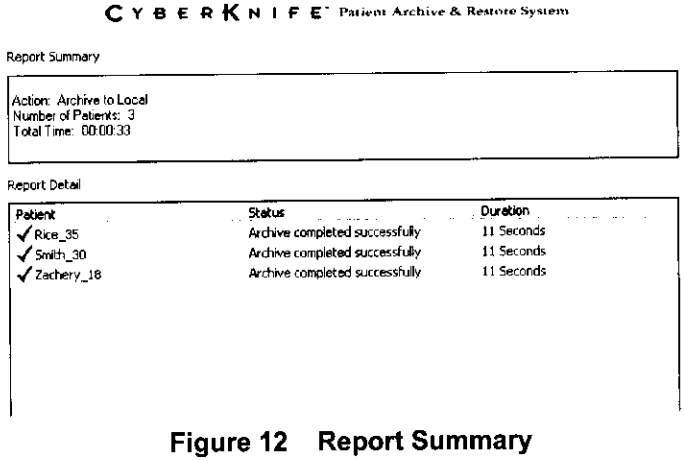



**Figure 12 Report Summary**

**Notification:** It is recommended that each archived patient record be copied onto DVD.



1219 Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

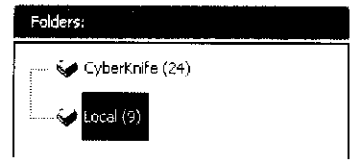
Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



## Copy To DVD

To copy an archived patient record to DVD from online storage:

**Step 1.** Select the Local folder.



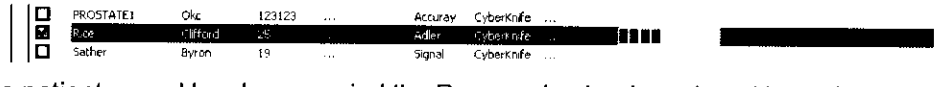

The Patient List view is updated to show patients whose records are located on the hard drive.

**Step 2.** Load a DVD into the DVD writer on the computer.

**NOTE:** Only one patient can be archived to a single DVD.

**Step 3.** Select one or more patients and then select the **COPY TO DVD** icon located on the Action bar.

During the copy a Progression bar appears in the patient list view, and is updated as the patient files are copied from local disk to the DVD. The state of the operation is displayed in the Status bar, and the Activity Progression bar is activated.




Once the patient record has been copied the Progression bar is replaced by a check mark. If more than one patient is selected to be copied to DVD, when the first patient record is completed the system will prompt the user to remove the DVD and insert another DVD. The system then advances to copy the next patient record to the DVD. This continues until all selected patient records are copied. Copy can be canceled by selecting the **STOP** icon located on the Action bar.

If the system fails to copy a patient record to DVD, the patient entry in the patient list view is highlighted red, and the Progression bar is replaced with an "X" mark. Following the offline patient archive session a Report Summary dialog appears.

It is recommended that the DVD be labeled with information to identify the patient who's record is copied there. If the user is unsure of the information stored on a DVD, use the Identify DVD feature described in *Maintenance, page 17*.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



CYBERKNIFE® Patient Archive & Restore System

Report Summary

Action: Archive to Local
Number of Patients: 3
Total Time: 00:00:33

Report Detail

| Patient | Status | Duration |
|---|---|---|
| ✓ Rice_35 | Archive completed successfully | 11 Seconds |
| ✓ Smith_30 | Archive completed successfully | 11 Seconds |
| ✓ Zachery_18 | Archive completed successfully | 11 Seconds |

Close

**Figure 13 Report Summary**

**NOTE:** Once an archived record has been copied to DVD, that record is now available on both the local hard drive and the DVD. A patient record can be copied to multiple DVD's. To remove the patient record from the local hard drive, refer to *Maintenance, page 17.*

**WARNING: Improper handling of DVD can cause data lost and/or corruption. Here are some general handling guidelines:**

**1. Hold the DVD on the outer edge or through the center hole to avoid fingerprints on the bottom of the DVD.**
**2. Avoid flexing the DVD when removing them from a player, recorder or a storage case.**
**3. Do not put excessive pressure on the center hub when inserting the DVD in its case.**
**4. Pick the DVD straight up from a flat surface; do not slide the DVD.**

**WARNING: Improper storage of DVD can result in data lost and/or corruption. Here are some general storage guidelines:**

**1. Optical discs should be kept in storage cases for protection against contaminants, light, or accidental scratches.**
**2. Storage cases should stand on their edges so that the disc hangs from its center hub.**
**3. The ideal storage environment should be cool, dry, and dark. 4° C (39° F) < Ideal storage range < 20° C (68° F).**



1221 Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



# Restore

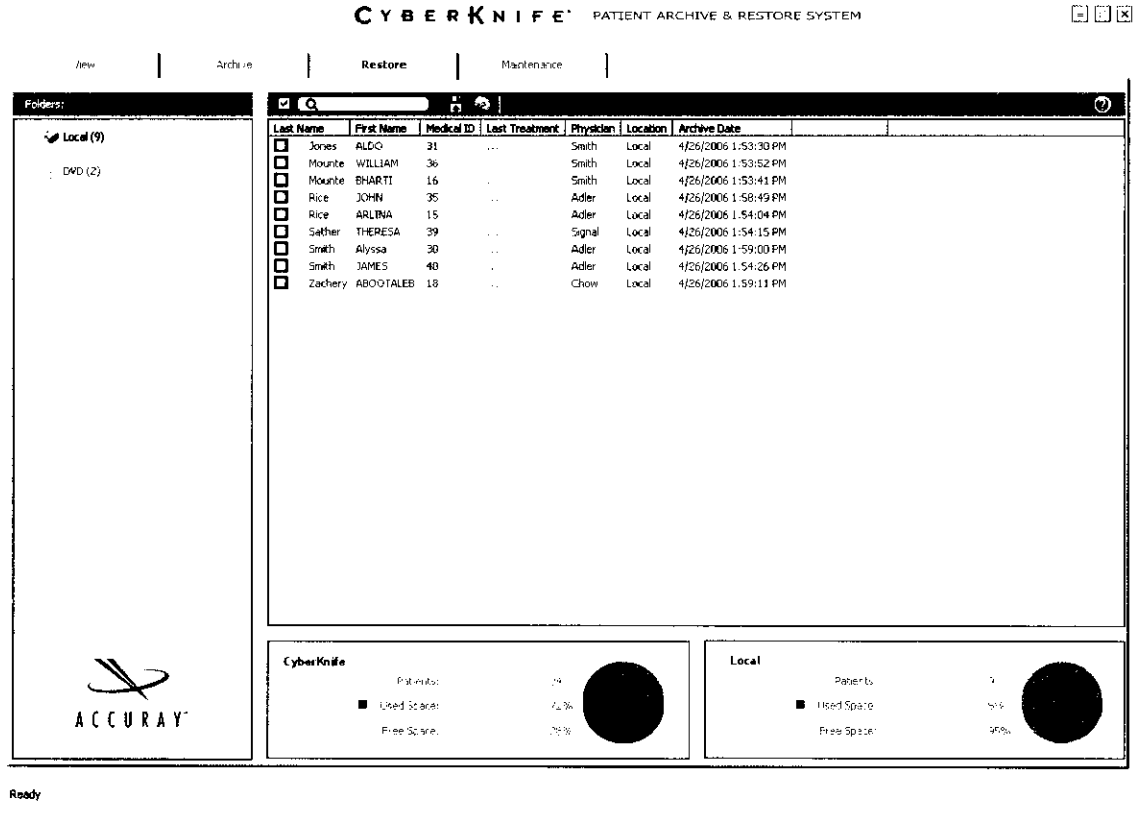



**Figure 14 Restore Screen**

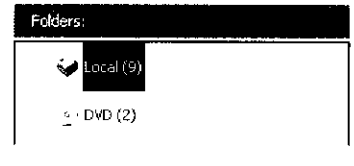
The restore tab provides a way to restore a patient record from either online storage or from DVD to the CyberKnife.

When the Restore tab is selected, two icons are displayed in the Action bar which are Active or Inactive depending on which folder is selected. For example, when the Local folder is selected, the **RESTORE FROM LOCAL** icon is active. When the DVD folder is selected, the **RESTORE FROM DVD** icon is active. In addition, a **SELECT ALL** icon appears to the left of the Search text field.

## Restore From Online Storage

To restore a patient to the CyberKnife from online storage:

**Step 1.** Select the Local folder.






Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118 1222

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015

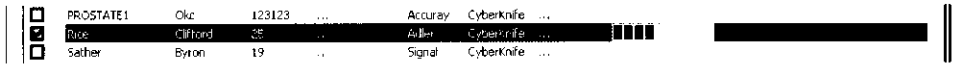


The Patient List view is updated to show patients located on the local hard drive.

**Step 2.** Select one or more patients and then select the **RESTORE FROM LOCAL** icon located on the Action bar.

A patient can be selected by either double-clicking the patient record, selecting the patient checkbox or selecting the **SELECT ALL** icon located on the Action bar. Deselect a patient by double clicking the selected patient, selecting a checked patient check box, or deselecting the **SELECT ALL** icon.

During restore a Progression bar appears in the patient list view, and is updated as the patient files are restored to the CyberKnife. The state of the operation is displayed in the Status bar.




Once the patient record has been restored the Progression bar is replaced by a check mark. If more than one patient was selected to restore, the system advances to restore the next patient record, displaying the Progression bar next to that patient's name. This continues until all selected patient records are restored. Cancel a restore by selecting the **STOP** icon located on the Action bar. If the system fails to restore a patient record, the patient entry in the patient list view is highlighted red, and the Progression bar is replaced with an X mark. Following the online patient record restore session a Report Summary dialog appears.

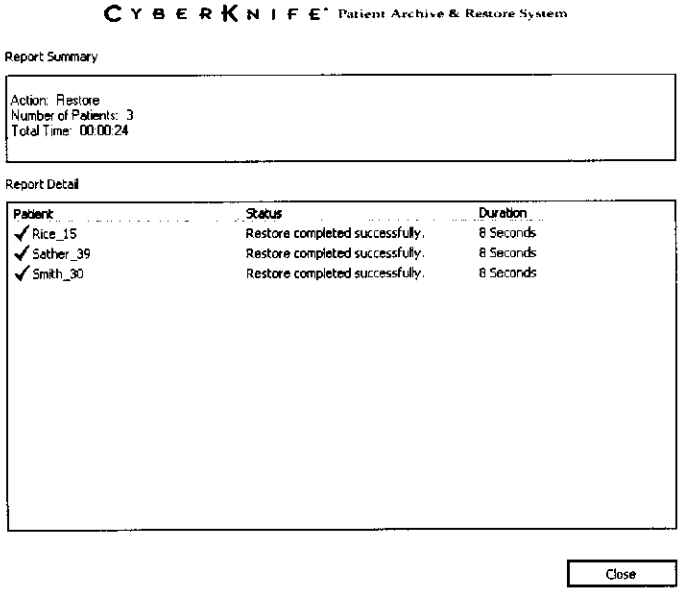



**Figure 15 Report Summary**



1223 Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



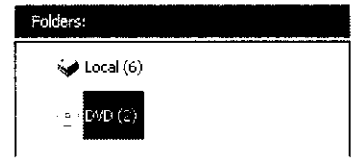
## Restore From DVD

To restore a patient record to the CyberKnife from DVD:

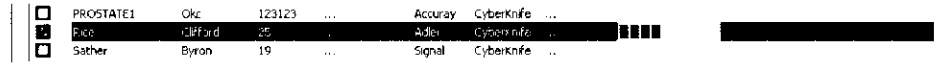
**Step 1.** Load a DVD into the DVD writer located on the computer.

**Step 2.** Select the DVD folder. The Patient List view is updated to show patients located on DVD.

**Step 3.** Select one or more patients and then select the **RESTORE FROM DVD** icon located on the Action bar.




During the restore a Progression bar appears in the patient list view, and is updated as the patient files are restored to the CyberKnife from DVD. The state of the operation is displayed in the Status bar.




Once the patient record has been restored the Progression bar is replaced by a check mark. If more than one patient is selected to be restored from DVD, when the first patient record is completed the system will prompt the user to remove the DVD and insert the next DVD to be restored. The system then advances to restore the next patient record from the inserted DVD. This continues until all selected patient records are restored. Cancel a restore by selecting the **STOP** icon located on the Action bar. If the system fails to restore a patient record, the patient entry in the patient list view is highlighted red, and the Progression bar is replaced with an "X" mark. Following the restore session a summary dialog appears.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118 1224

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



CYBERKNIFE Patient Archive & Restore System

Report Summary

Action: Restore
Number of Patients: 3
Total Time: 00:00:24

Report Detail

| Patient | Status | Duration |
|---|---|---|
| ✓ Rice_15 | Restore completed successfully. | 8 Seconds |
| ✓ Sather_39 | Restore completed successfully. | 8 Seconds |
| ✓ Smith_30 | Restore completed successfully. | 8 Seconds |

Close

**Figure 16 Report Summary "Restore from DVD"**

If the user is unsure of the information stored on a DVD, use the Identify DVD feature described in *Maintenance, page 17.*



1225 Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



# Maintenance

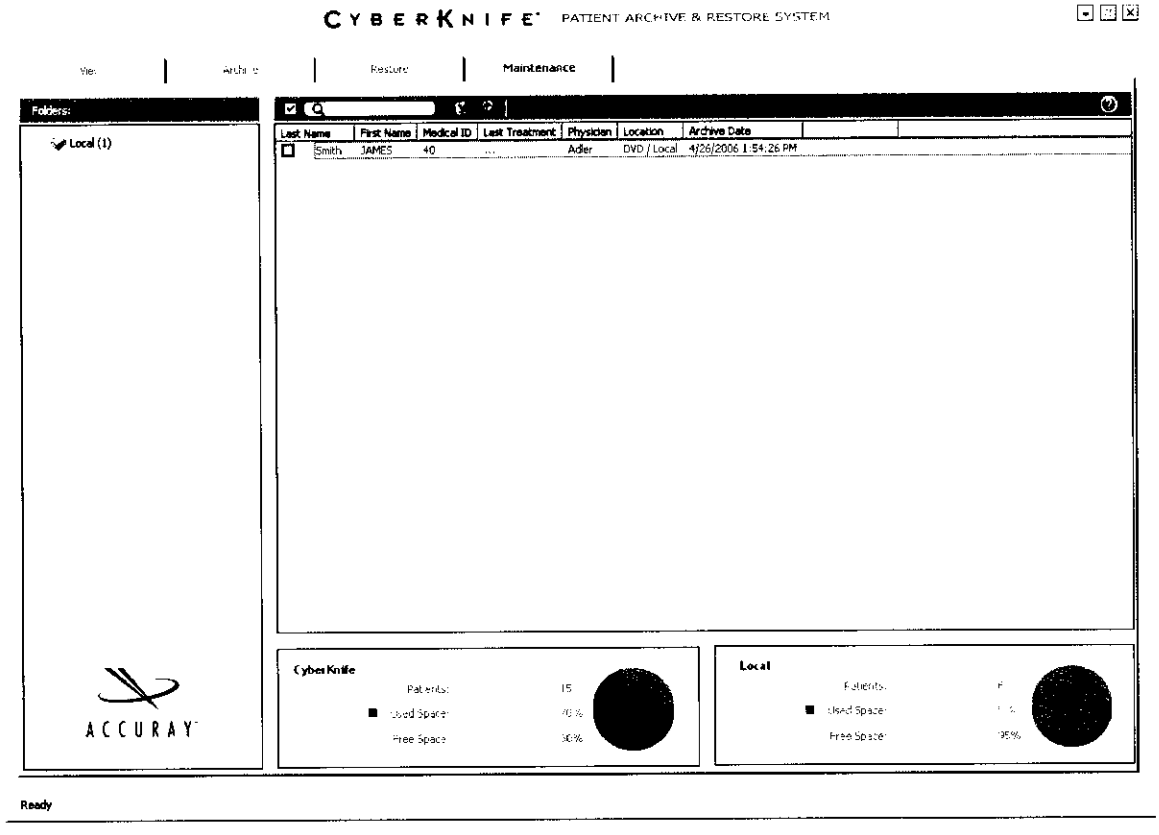



**Figure 17 Maintenance Screen**

The maintenance tab provides a way to remove local archived patient records that have been copied to DVD, and a way to identify an archived patient record located on DVD.

When the Maintenance tab is selected three icons are displayed in the Action bar; including a **SELECT ALL** icon, a **DELETE PATIENT RECORD** icon and an **IDENTIFY DVD** icon.

## Online Patient Record Deletion

To delete archived patient records from local hard drive:

**Step 1.** Select the Local folder. Archived patients located on the local hard drive that have been copied to DVD are listed.

**Step 2.** Select one or more patients and then select the **DELETE** icon located on the Action bar.

A patient can be selected by either double clicking the patient record, selecting the checkbox or selecting the **SELECT ALL** icon located on the Action bar. Deselect a patient by double clicking a selected patient, selecting a checked patient check box, or deselecting the **SELECT ALL** icon.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

1226

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



During the deletion a prompt appears requesting confirmation of the deletion. Either terminate the deletion session, skip to the next selected patient, or continue with the patient deletion. Following the deletion session a summary dialog appears.

## Patient Record Identification

To identify an archived patient record located on DVD:

**Step 1.** Select the **IDENTIFY DVD** icon located on the Action bar. If a DVD is not present, a prompt for a DVD appears.

**Step 2.** Insert a DVD, or cancel the identification request.

If a patient record is located, a dialog appears with the record information. Fields displayed in the dialog include:

- Last Name
- First Name
- Medical ID
- Physician
- Last Treatment Date
- Record Location
- Archive Date
- Record Size in Bytes
- Archive Record ID
- Offline Patient Archive Date
- Disk Number.

In addition there is a text section that informs the user if the patient record on the DVD can be restored to the CyberKnife.



1227 Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



# Xsight™ Spine Tracking System (OPTION)
## Table of Contents

**Xsight System Spine Tracking System** ..... 1
- Xsight System Overview ..... 1
- Visual Evaluation ..... 2
- CT Protocol ..... 2
- CT Acquisition ..... 3

**Treatment Planning** ..... 4
- Tracking Mode Selection ..... 4
- CT Center Selection ..... 5
  - CT Center Placement Guidelines ..... 5
- Sample DRR Generation ..... 7

**Treatment** ..... 8
- Patient Alignment ..... 8
  - X-ray Parameters ..... 9
  - Imaging Parameters ..... 9
  - Tracking Skeletal Structures ..... 11
  - Error Handling ..... 14
  - Fluctuations in R/L Roll ..... 15



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

1228

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015





1229

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



# XSIGHT™ SPINE TRACKING SYSTEM (OPTION)

## XSIGHT SYSTEM SPINE TRACKING SYSTEM

The Xsight Spine Tracking System enables tracking of skeletal structures in the spine region for accurate patient positioning and radiation beam delivery using the CyberKnife® System. The Xsight System provides the capability to deliver radiation treatments without the need for implanting fiducials. The Xsight System is capable of accurately and automatically tracking a wide range of skeletal structures, including all cervical, most thoracic, and lumbar and sacral areas. The Xsight System is capable of tracking non-rigid deformations typically observed in multiple vertebral structures.

### Xsight System Overview

The Xsight System works by computing the displacement of the skeletal structures within the patient body. The skeletal structure(s) to be tracked is pre-determined during treatment planning as a reference point (or CT center) in the patient CT study. The CT center should be chosen so that the center is close to the target and is in a region with sufficient skeletal features.

The Xsight System computes patient displacement in all six degrees of freedom: three translations of the reference point (CT center) using a form-free non-rigid model and three global rotations using a rigid-body approximation for the skeletal structures being tracked.

During patient alignment, the displacements computed by the Xsight System can be used for adjusting the patient position. During treatment delivery, the robot manipulator adjusts the position of the treatment radiation generator (Linac), to correct for the residual rotations and translations.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



## Visual Evaluation

Visual QA ensures that the skeletal structure is tracked correctly by the algorithm, this is essential for safe treatment delivery using Xsight System. During treatment planning, sample DRR's should be generated and inspected for suitability to track using Xsight System.

*See section, Sample DRR Generation, page 7* for details of generating sample DRR's. DRR images that clearly show skeletal structures (or other radio opaque structures) against the background indicate that the patient can be tracked using Xsight System during treatment delivery.

During treatment delivery, the user interface provides several useful tools for verifying that Xsight System is able to register the skeletal structures in the live images with the corresponding features in the DRR's. *Section, Patient Alignment, page 8* provides details of this interface.

**WARNING: Visual evaluation assures that the tracking algorithm is working correctly at a coarse level, but is not adequate for verifying sub-mm accuracy.**

## CT Protocol

A reproducible patient position on the CT couch will minimize the patient setup time during treatment.

The patient CT scan must be performed in the following way:

- Patient rotation should be minimized.
- Targets (lesions) should be in the central region of the CT volume.

Use the end of expiration breath-hold technique to reduce respiratory motion, which causes streaks on DRR's.

Follow the Accuray protocol for acquiring CT images:

1. Bring immobilization devices to the CT couch to replicate setup for the treatment
2. Basic CT Parameters:
   A. Gantry Angle = 0
   B. Maximum 300 slices
   C. kVp = 120, mAs = scanner maximum (minimum 400)
   D. Contiguous 1.0 - 1.5 mm slice thickness
3. CT Rules for Xsight tracking:

   Set Field of View (FOV)

- Patient must be centered in the L/R and ANT/POS in the FOV.
- Target should be centered in te INF/SUP direction with a minimum 10 - 15 cm scanned in either direction.
- FOV should include the entire patient circumfrence (use the largest field of view possible) - anatonomy left out of scan will cause beams to be excluded by treatment planning system.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



## CT Acquisition

The CyberKnife system utilizes the CT image to plan and deliver the treatment. The quality of the CT scan will determine the accuracy of dilineation and treatment delivery. It is critical that the CT images are acquired following the Accuray protocol.

**NOTE:** Ensure that there is no patient movement during the CT acquisition. Utilize breath-holding at the end of the expiration to minimize motion during respitation

Follow standard protocol guidelines for appropriate scan of extra cranial applications.

1. Instruct the patient to breathe normally until acquiring the scan, at which time the patient must hold their breath at end of normal expiration.
2. If the patient cannot hold their breath for the entire scan, instruct the patient on breathing technique:
   a. Breath in.
   b. Expire and hold breath out as much as possible.
   c. Breathe shallow if unable to hold further.

   **NOTE:** It is recommended to practice the appropriate breath hold with the patient prior to scanning.

3. Continue acquiring the images until the CT scan is completed.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118 1232

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



# TREATMENT PLANNING

This section presents special features for the Xsight Tracking mode in Treatment Planning

## Tracking Mode Selection

When making a new plan, select Skeletal Tracking and Region (*Figure 1 Tracking Mode Selection in Planning when Using the Xsight System, page 4*).

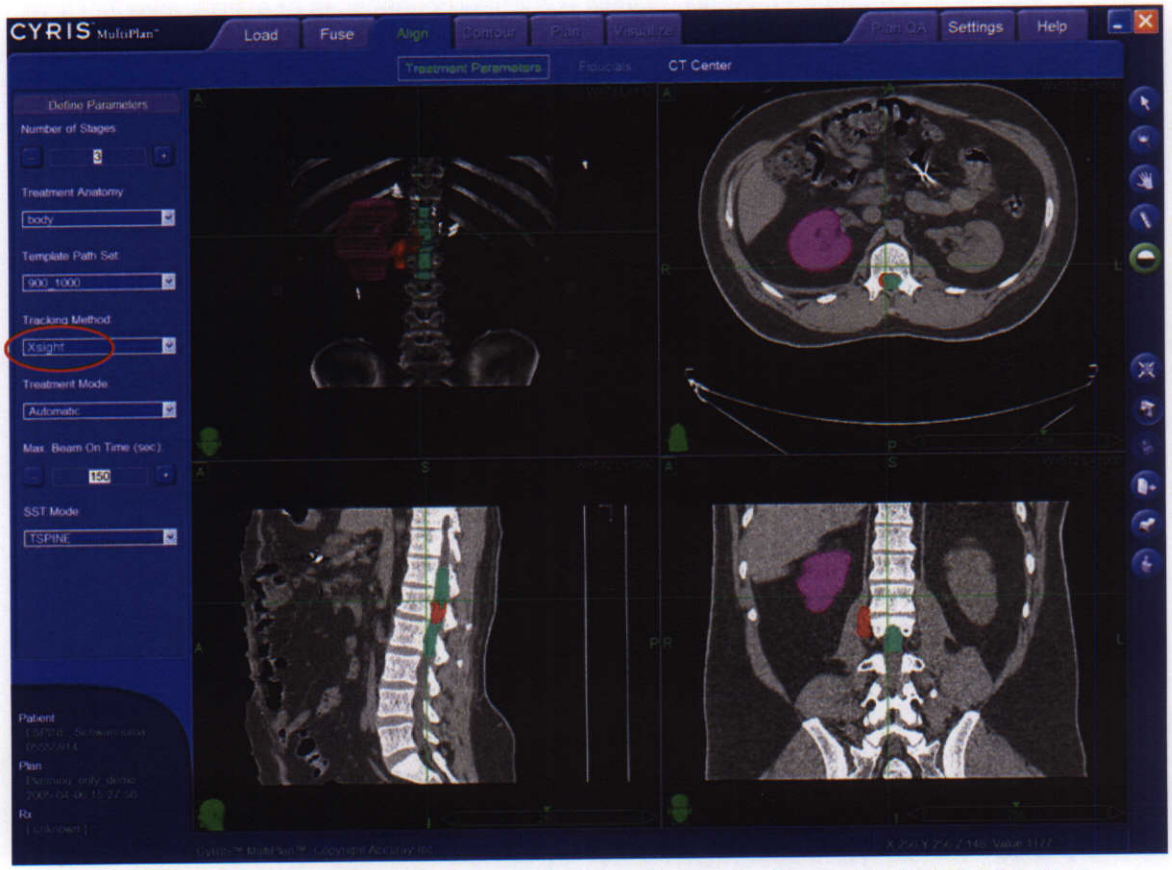



**Figure 1 Tracking Mode Selection in Planning when Using the Xsight System**



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



# CT Center Selection

During treatment it is important that the machine center is set with respect to the CT study in such a way that the imaging system can function correctly.

The Display View includes 5 windows. The top two are digital reconstructed radiographs (DRR) of the patient, given the current machine center. The algorithm used to generate these DRR's differs from the algorithm used by the delivery system.

The algorithm used to generate these DRR's differs fom the algorithm used by the delivery system, and the image results will vary from those seen during treatment delivery.

## CT Center Placement Guidelines

The CT center should be properly selected to make sure that:

1. the CT center is within 5 cm of the parget
2. the CT center is in an area that has rich skeletal structures for image registration



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118 

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



Example of an incorrect selection is shown in *Figure 2 Detailed view of Correct and Incorrect Selection of the CT Center, page 6.*

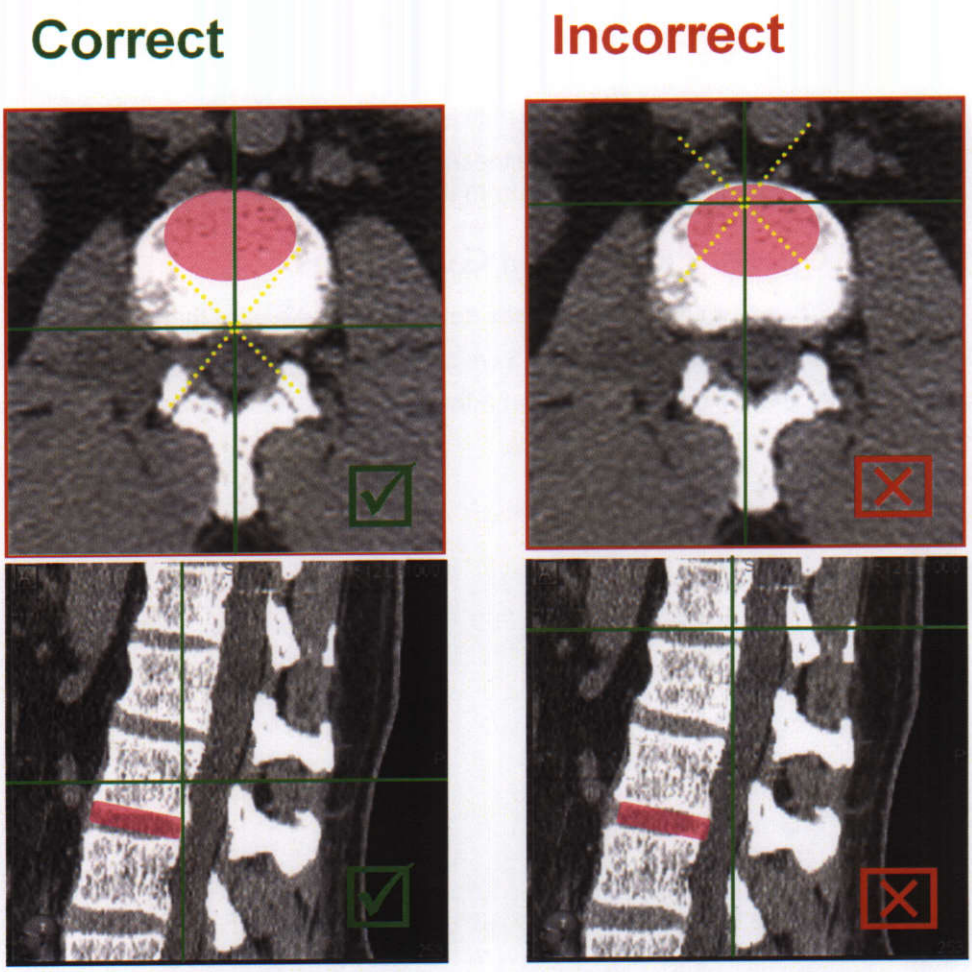



**Figure 2 Detailed view of Correct and Incorrect Selection of the CT Center**

**WARNING: Place the CT Center using the following guidelines to maximize accuracy.**

**NOTE:** Non-rigid motion of the tumor with respect to the CT Center is not taken into account by the tracking algorithm.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

1235

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



# Sample DRR Generation

After the CT center is selected, make sample DRR images. From the DRR images (*Figure 3 Visualization of Skeletal Structures in Sample DRR Images, page 7*), the skeletal features can be visualized. If the skeletal structures are not sufficient, the Xsight System cannot be used for treatment and it is recommended that fiducial tracking be used.

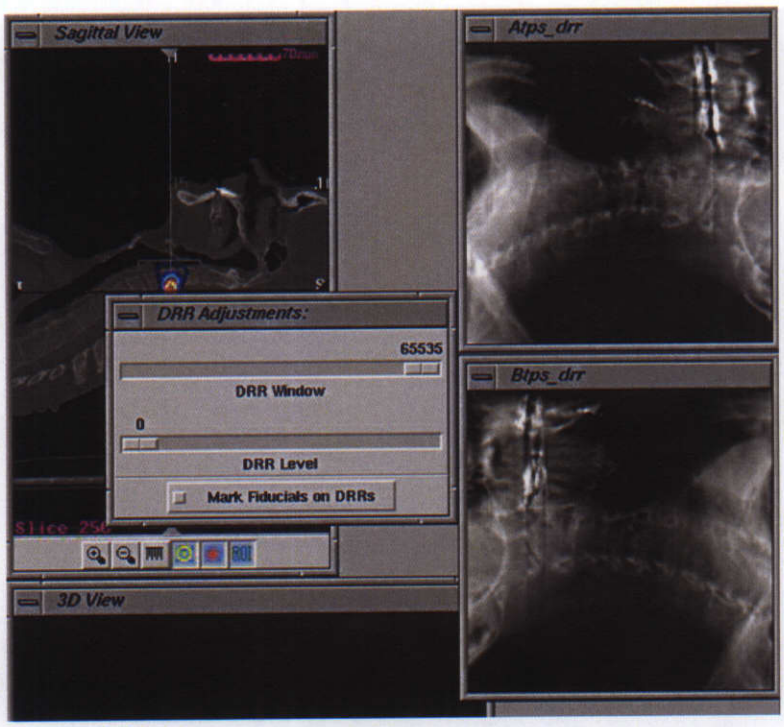



**Figure 3 Visualization of Skeletal Structures in Sample DRR Images**



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

1236

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



# TREATMENT

This section presents how to use the Xsight System for Treatment Delivery.

## Patient Alignment

Patient alignment begins with path downloading. During the path download, a pair of DRR images is loaded and the Xsight System is initialized. For more detail regarding Path Downloading, *see section, Path Downloading in module, Treatment*.

On completion of the Path Download, the Align Patient window (*Figure 4 Initial Patient Alignment, page 8*) automatically appears.

**Figure 4 Initial Patient Alignment**



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

1237

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



## X-ray Parameters

The general recommendations for setting the X-ray parameters is lower X-ray energy for C-spine and the upper part of T-spine and higher X-ray energy for the lower part of T-spine and L-spine.

Based on phantom tests, (105~125KV, 100MA, 100EX) is good for C-spine. For the normal cases of T-spine and L-spine, (125KV, 100MA, 100EX) is recommended. For some difficult cases, for example, patient with a large body, larger values of MA and EX may be needed for more X-ray penetration of soft tissues.

## Imaging Parameters

Click the **IMAGING PARAMETERS** button in the Align Patient Window to display the Imaging Parameters Window (*Figure 5 Imaging Parameters Window for Xsight System, page 9*). In the right part of the window Skeletal Tracking – Algorithm Parameters, all the parameters are configurable within the specified range. The default setting is adequate for most cases and is recommended for use. When the tracking algorithm fails, tuning some of these parameters may be necessary to make tracking successful. These parameters and the guidelines for tuning them are explained below.

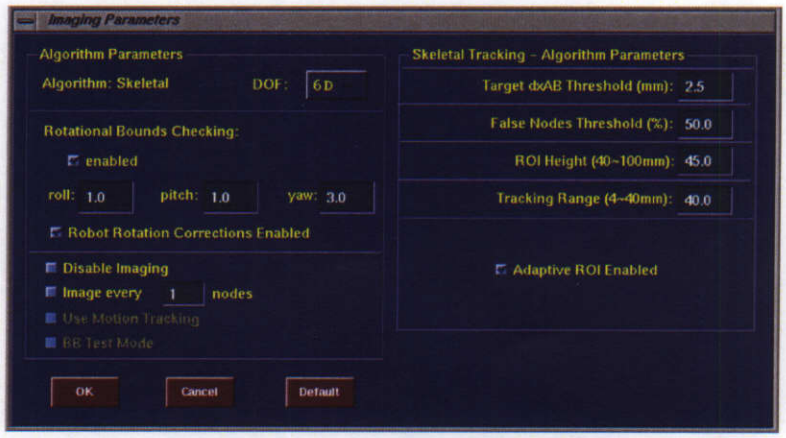



**Figure 5 Imaging Parameters Window for Xsight System**

**Target dxAB Threshold** and **False Nodes Threshold** are used to prevent the tracking algorithm from giving the wrong output. When the number of mesh nodes with false estimation exceeds the preconfigured threshold, mismatching between DRR and X-ray images usually occurs. At this time, there is no output of tracking algorithm and only an error message with some corrective actions pops up. The target dxAB is the absolute difference between the sup/inf translations for camera A and camera B. When the algorithm works correctly, this value should be small. Although, in the presence of large rotations, the dxAB could be little larger, for instance, more than 2 mm.

The default value of false nodes threshold is 50%. For most cases, the actual false nodes are much less than this default. Although, in some lumbar and lower thoracic spine cases, the threshold may need to be increased. It is the user's option of the amount of increase. In case of using larger false nodes threshold, it is very important to do visual inspection after the tracking results are displayed. When this threshold is changed and the OK button is clicked in the Imaging Parameters Window (*Figure 5 Imaging Parameters Window for Xsight System, page 9*), a dialog box (*Figure 6 Confirmation of the Change in False Nodes Threshold, page 10*) will displayed for confirmation of this change.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



**ROI Height** defines the height of ROI for image registration. The ROI width is proportional to the ROI height by the ratio 2:3. The default ROI size is good for all C-spine and the upper part of T-spine. The ROI size could increase to contain more skeletal structures for lower part of T-spine and L-spine.

**Tracking Range** specifies the largest displacements of patients that the tracking algorithm is able to track. The range could be set to a large value during the patient initial alignment and it could be set to a smaller value when the patient is well aligned and the patient is under treatment delivery. From the tracking algorithm perspective, the larger the search range, the more possibly the mismatching occurs. When the tracking algorithm fails, decreasing the tracking range may be attempted.

**ADAPTIVE ROI ENABLED** optimizes the location of the ROI so that the ROI contains most of skeletal structures for best registration. By default, this button is enabled and it works well for most of cases. In C1~C3 regions, if it is found that the ROI contains a part of jaws, the button should be disabled.

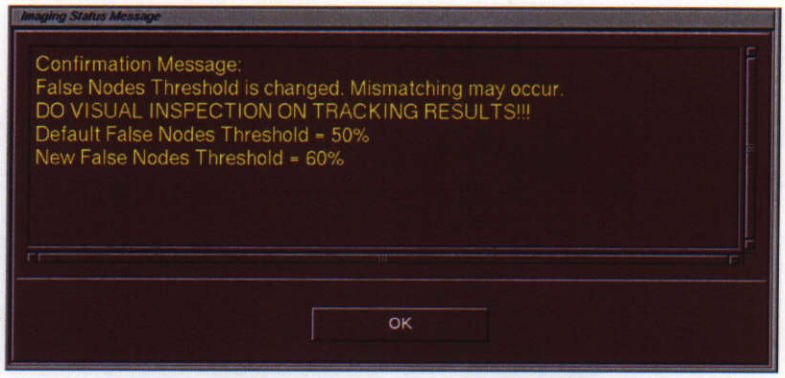



**Figure 6 Confirmation of the Change in False Nodes Threshold**



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

1239

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



## Tracking Skeletal Structures

Using the default setting in the Imaging Parameters window, click the **ACQUIRE** button in the Patient Alignment window (Figure 7 Patient Alignment, page 11). X-ray images are acquired and image registration is processed.

The tracking results are displayed (*Figure 8 Using Skeletal Mesh to Display Tracking Results, page 12*). There are two ways for displaying the results:

**Skeletal Mesh** and **CT-Center**. In the lower middle part of *Figure 8 Using Skeletal Mesh to Display Tracking Results, page 12*, there are two buttons for the result displaying options.

1. Display Skeletal Mesh is the default option. The meshes in DRR and Live images appear immediately after image correction is done. When the **ALIGN** button is clicked, the meshes in DRR and Live images in both projections A and B are aligned, as shown in *Figure 9 Using Skeletal Mesh to Display Aligned Tracking Results, page 12*.
2. Clicking the **DISPLAY SKELETAL MARKERS** button results in the visualization of the tracking results using markers as indicated in *Figure 10 Using Skeletal Markers to Display Aligned Tracking Results, page 13*. Similar to the fiducial tracking, the tracking results can be visually inspected from the alignment of the markers in DRR and Live images.

**NOTE:** The **ALIGN** button only uses the translations to perform alignment. When large rotations exist, the rotations of mesh in the Live images can clearly be seen. In the Overlay images, the correctness of tracking can be visually inspected from the alignment of mesh nodes in the area close to the image center.

**Figure 7 Patient Alignment**

The meshes in the DRR's and Live images are displayed in different colors. Also, in Live images, the false nodes (nodes for which the estimated translation in 2-D did not agree with the surrounding nodes), is displayed in a different color from the rest of the mesh. The smaller the number of false nodes, the more reliable the estimates are from the tracking algorithm.

Xsight System relies on skeletal structures in the ROI for accurate tracking. You should inspect the ROI's for both live X-ray images to verify that the ROI includes sufficient skeletal structures.

**WARNING: Inspect the ROI's for both camera images to verify that the ROI includes sufficient skeletal structures.**



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



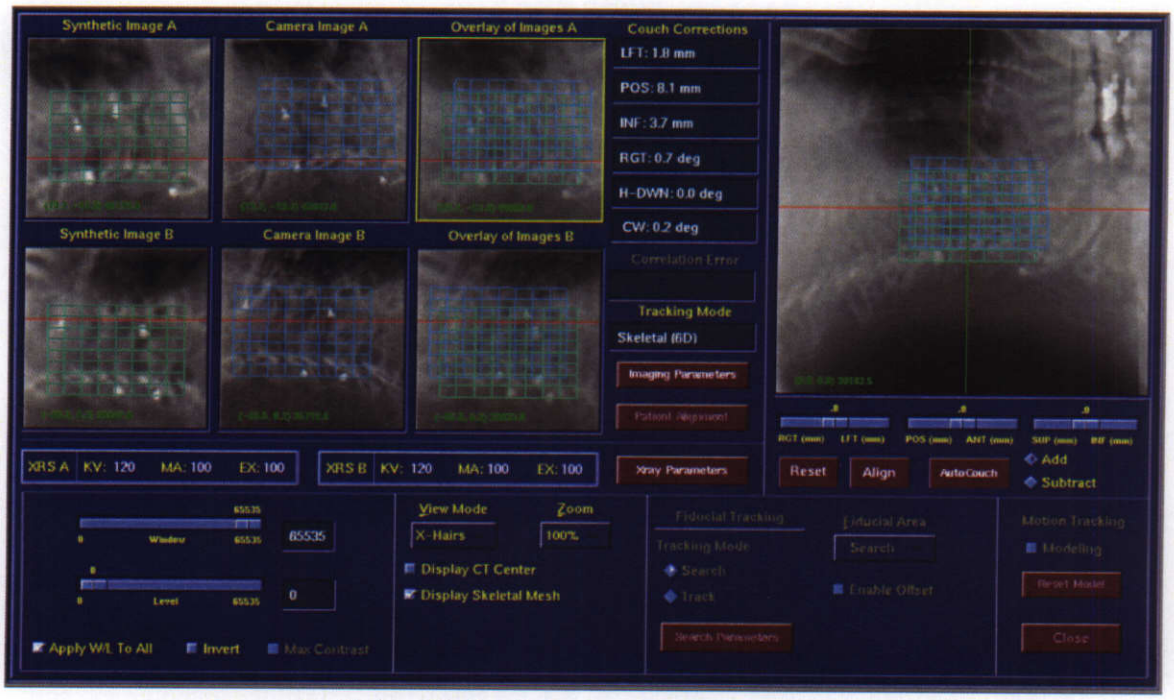



**Figure 8 Using Skeletal Mesh to Display Tracking Results**

**Figure 9 Using Skeletal Mesh to Display Aligned Tracking Results**



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

1241

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015

**Figure 10 Using Skeletal Markers to Display Aligned Tracking Results**

The Xsight System relies on the regions in the center columns of the ROI for estimating patient roll rotations (rotation about the inferior-superior axis). You should inspect the ROI's in both live X-ray images to ensure that the nodes in the center columns of the ROI include skeletal structures in them.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



## Error Handling

When the tracking algorithm fails, there are two possible cases:

1. false nodes error,
2. target dxAB error.

The algorithm parameters in the Imaging Parameters window (*Figure 5 Imaging Parameters Window for Xsight System, page 9*) should be adjusted to make the algorithm work.

1. The X-ray images usually mismatch with DRR images. Several solutions are suggested in *Figure 11 Imaging Status Dialog for False Nodes Error, page 14* to make the algorithm find the right corrections.
2. Evaluate patient setup to remove any misalignment of the patient position.

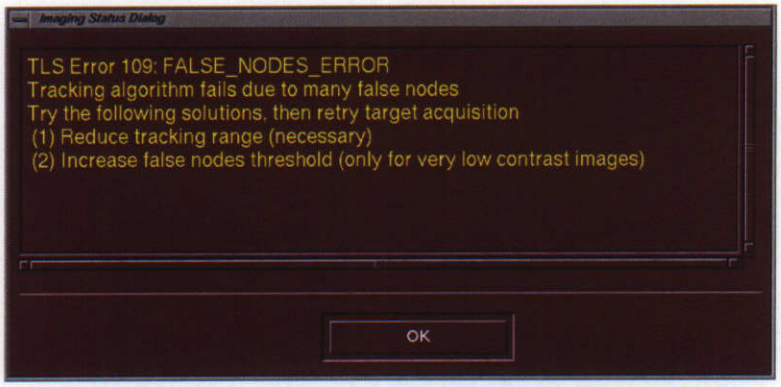



**Figure 11 Imaging Status Dialog for False Nodes Error**

**Figure 12 Imaging Status Dialog for Target DxAB Error**



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

1243

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



## Fluctuations in R/L Roll

During the patient alignment, the left/right roll rotation estimate is less accurate and may fluctuate in subsequent image acquisitions. Potential causes include the following:

- Noisy images
- Lack of features in the center columns of the ROI
- Hardware implants
- Incorrect CT center placement
- In most cases, left/right rotations vary within a range of (-1° +1°). In worst case scenario, this innacuracy may be as high as 2°.

Ways to resolve:

- Decrease exposure time in X-ray parameters to minimize motion artifacts.
- Increase grid size.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015





1245 Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



# GLOSSARY

## Definitions and Acronyms

### 6 degrees of freedom

A Cartesian coordinate system with 6 parameters: x, y, z, w (yaw), p (pitch), and r (roll). X, y, and z represent the three Cartesian axes, while w is the rotation about the z-axis, p is the rotation about the y-axis, and r is the rotation about the x-axis. This coordinate system is used by the robotic system and when aligning the patient on the treatment couch.

### CK-6™

The powerful tracking algorithm that identifies and corrects the patient position throughout the entire treatment enabling the CyberKnife® System to achieve total clinical sub-mm accuracy. This algorithm is able to perform this correction in all translations and rotations in real-time.

## A

### Accelerator

The portion of the Linac which accelerates electrons from a gun into a high-energy electron beam. See Linac and waveguide.

### Axial

An **axial plane** divides the body into upper and lower segments. Similar to "slicing" the body like a loaf of bread starting at the top of the head and working down.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118 1246

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



# B

## Ball cube

The ball cube is a QA tool designed by Accuray for measuring stereotactic targeting accuracy. Physically it is an ABS plastic film cassette used for holding two pieces of radiochromic film. The notched films are placed orthogonally in the ball cube. The ball cube is 2.5" on each side and contains a 1.25 inch acrylic ball, which is visible in CT and used as a treatment target.

## Beam

The CyberKnife® System utilizes three X-ray beams, the high therapeutic energy (6MV) radiosurgical beam emanating from the Linac and two low diagnostic energy beams used for image generation. See Linac, XRS, and collimator.

## Beam selection

One of the primary algorithms of the Treatment Planning System (TPS). Beams are selected according to the given lesion size and shape. The selection uses a reachability model of the manipulator workspace. Multiple beam directions with a high degree of collimation are used to accurately target the lesion while sparing normal tissue.

# C

## Centigray (cGy)

A unit of radiation dose equal to the rad, 1/100 of a Gray. Radiation dose is a measure of radiation energy deposited per unit mass.

## CKS

CyberKnife System.

## Cold spot

A region being irradiated which receives an under-dose of radiation. See also under-dose.

## Collimator

X-rays radiate in all directions when an electron beam strikes the target. Since X-rays cannot be focused, heavy metal collimators are used to block the unwanted portion of the radiation to create a narrow beam.

The Linac has two collimators, a fixed primary collimator and a changeable secondary collimator. The primary collimator surrounds the X-ray target and limits the X-ray beam to a narrow cone in the forward direction. Secondary collimators of different sizes may be fitted to produce different beam sizes. The secondary collimator produces a beam with a circular cross section and a diameter ranging from 5 to 60 mm in 12 sizes (Defines at a distance from the source of 80 cm). Each secondary collimator has a different length in 1/16" steps based on its beam diameter. The Linac contains dual independent linear potentiometers to detect the length of the currently installed secondary collimator. Treatment cannot proceed with the wrong collimator installed.

A collimator is also used on each of the imaging X-ray sources to minimize patient exposure.



1247 Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



## Conformal

The extent to which the radiosurgical treatment dose is restricted to the target volume, sparing surrounding healthy tissue, which may be critical and/or sensitive to radiation.

See also Dose.

## Coronal

A frontal image of the body. A **coronal plane** divides the body into front and back segments.

## Couch

See patient treatment table.

## Critical region

An important anatomical structure that is especially sensitive to radiation such as the eyes, optic nerve, or brain stem.

## CT

Computed Tomography is an imaging procedure in which many X-rays images are taken from different angles of a part of the body. These images are combined by a computer to produce cross-sectional pictures of internal organs. Except for the injection of a dye (needed in some but not all cases), this is a painless procedure that can be done in an outpatient clinic. CT images are used by the CyberKnife System for treatment planning and to produce the reference images (DRRs) for treatment simulation and delivery. CT images used in the CyberKnife System may be either of the patient or of a phantom. The images are generally created at a different site from treatment planning and delivery. They may be loaded to the CyberKnife System either from tape or Ethernet (TCP/IP).

## CyberKnife®

The CyberKnife System is a radiosurgery device used to treat cancer throughout the body by focusing many high energy beams precisely to the tumor delivering a very conformal dose. The CyberKnife System consists of three key components: 1) an advanced, lightweight linear accelerator (LINAC) (this device is used to produce a high energy (6MV) of radiation), 2) a robot, also called the manipulator, which can point the linear accelerator from a wide variety of angles, and 3) X-ray cameras (imaging devices) that are combined with powerful software to track patient position. The cameras obtain frequent pictures of the patient during treatment, and use this information to target the radiation beam emitted by the linear accelerator.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118 1248

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



# D

## DICOM

A data standard used to transfer medical image and radiation therapy planning studies from the medical image scanner or contouring workstation to the CyberKnife System site via a network prior to treatment planning.

## Dmax

The depth at which the radiation dose reaches a maximum in water or water-equivalent material, such as soft tissue.

## DOF

Degrees of Freedom. The CyberKnife System manipulator has 6 degrees of freedom, three of translation (x, y, z) and three of rotation (yaw, pitch, and roll).

## Dose

A measure of accumulated radiation exposure. The region receiving the high radiation dose should match the target region. To protect healthy tissue, sharp dose drop-off should be achieved in the healthy tissue surrounding the tumor. Dose homogeneity for certain lesions is essential to prevent complications. The dose in the surrounding tissue should also be uniform. Certain structures (e.g. the optic nerves, arteries, and brain stem) are very critical and/or radiation sensitive. The dose in such critical regions should be very small. See also Hot spots, Cold spots, Conformal, Under-dose, and cGy.

## Dose Calculation

One of the primary algorithms of the Treatment Planning System (TPS).

The dose calculation algorithm, in the TPS, has two main purposes. The first is the calculation of Monitor Units (MUs) to be delivered by the Linac for each beam to irradiate the tumor with the prescribed isocentric dose (ID). The second is the calculation of dose distribution inside the head and body (including tumor, critical regions, and normal tissue) given the monitor units being delivered by the Linac.

## Dosimetry system

Dosimeters measure the energy carried by a beam over time. The dosimetry system in the Linac uses dual independent dosimeters (named A and B or primary and secondary) at the X-ray source to measure its output. They are configured in a redundant dose monitoring combination to safeguard against incorrect dose delivery. Irradiation at a node is terminated by the dosimeter hardware when the delivered dose at the node is equal to the planned dose. The first dosimeter to reach the desired dose causes the Linac to shut off. The software uses the dose from the primary dosimeter (dosimeter A) as the measure of delivered dose. The dosimetry software verifies that the two dosimeters differ by no more than +or- 5% at any node. If elapsed irradiation time at a node exceeds the planned time by more than 50%, a timer in the RCS terminates irradiation. If a dosimetry error occurs, this is considered an unrecoverable error and patient treatment is aborted.



1249 Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



### DRR

Digitally Reconstructed Radiographs created from the patient's CT data. The DRRs are used as reference images by the Image Processing System for patient alignment during treatment or simulation. During simulation, the phantom does not move, but the initial position must be known.

### DVH

Dose Volume Histogram, a graph plotting structure tissue volume (in $mm^3$) receiving at least the dose plotted on the x-axis (i.e. a cumulative DVH).

## E

### E-Stop

Emergency Stop. E-Stop buttons (also referred to as pause buttons) are located on each piece of equipment, the treatment and control rooms. An emergency stop pauses the system. If a recoverable error has occurred, the system can be restarted from an E-Stop.

### Emergency Stop Control Chassis (ESCC)

The central unit responsible for handling emergency stops. See E-Stop.

### Error recoverable

An error condition that causes an E-Stop. Treatment can resume once the error condition is cleared.

### Error unrecoverable

An error condition that causes an E-Stop. Equipment power must be cycled to reset the E-Stop after the error condition has cleared.

## F

### Feet First Supine (FFS)

A patient orientation available for lower spine and abdomen area treatments.

### Fiducial markers

Artificial references (such as gold seeds or stainless steel screws) which are implanted in or near tissues undergoing radiosurgery or radiotherapy treatment. Where bone and other natural structures are not in the proximity of the tumor site, these markers are used as artificial landmarks by the imaging system. Usually three or more markers are used.

### Film Cube

The film cube is a QA tool designed by Accuray for measuring stereotactic targeting accuracy. Physically it is an HIPS plastic film cassette used for holding up to 14 pieces of radiochromatic film. The films are stacked parallel in the film cube separated by identical spacer plates. The film cube is 2.5" on each side.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118 1250

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



### Forward planning

Treatment planning given beam selection and dosage. The computer finds the dose distribution. See also TPS.

### Fractionated Radiosurgery

Treatment that has been partitioned into several doses repeated over time (e.g. several days). Traditional treatments can be fractionated into a series of 2-30 doses. This may be necessary for large targets where a single treatment would deliver too much radiation to the healthy tissues at one time. In the past, fractionated treatment has been difficult due to the necessity of using a rigidly fixed frame attached to the skull to locate the tissue in space. Fractionated radiosurgery is only possible with the CyberKnife System and is done in 2-5 fractions. See staged.

### Frame

Frame is used in two different contexts in the CyberKnife System:

1. In one context frame refers to the various coordinate systems used to locate the robot, Linac, and patient. Coordinate frames used with the CyberKnife System are in general Cartesian 3D 6 degrees of freedom: 3 of translation (x, y, z) and 3 of rotation (yaw, pitch, roll or w, p, r). See Image frame, Tool frame, Uframe, and World frame.
2. In a different context, radiosurgery systems that do not use a target image location system must use a frame rigidly attached to the skull of the patient to immobilize the head during treatment delivery.

### Frameless

Radiosurgery systems such as the Gamma Knife use a frame rigidly attached to the skull to insure accurate radiation targeting and delivery. The CyberKnife System is considered frameless since only a non-intrusive restraint is used. The CyberKnife System targets off of bony landmarks and fudicials. The imaging system on the CyberKnife System allows the robot to correct for small movements of the patient or target during treatment delivery.

## G

### Gafchromic film

Self developing radiochromic film used to verify system targeting. Gafchromic film is manufactured by ISP. MD55 comes in 5" square sheets and MD22 is custom cut to fit in the film cube and ball cube. A pre-notched version of MD22 is available from Accuray for use in the ball cube. See also film cube and ball cube.

### Gamma rays

Photons in the energy band above ultraviolet light that have been produced by radioactive decay. Similar to X-rays except the source is different. The CyberKnife System uses an X-ray system rather than gamma rays. See also X-rays.

### Gray

A unit of radiation dose equal to 100 rad. Radiation dose is a measure of radiation energy deposited per unit mass (1 Gray = 1 Joule/Kg). See also Centigray.



1251 Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



### Gun (Electron gun)

The unit in the Linac, which injects a low energy electron beam into the accelerator. The Gun is a vacuum tube that consists of the following:

- cathode with a filament heater to produce the electrons
- control grid to turn the electron beam on and off
- anode to provide initial acceleration for the beam.

The high voltage power supply provides a negative voltage to the cathode.

## H

### Headframe

A frame that rigidly immobilizes the patient's head during imaging and radiation treatment.

### HFS

Head First Supine. This is the normal patient orientation for CT scans.

### Hot spot

A region being irradiated which receives an abnormally high dose of radiation. Hot spots, even inside tumors, can cause complications.

## I

### IFCC (Interface Control Chassis)

The Interface Control Chassis is a subsystem that performs two functions: (1) Performs Linac On/off control, and monitors Linac status (2) Serves as a central hardware registry for all ESTOP's. The Linac on/off control is performed under commands from the host computer, and the status of the Linac and ESTOP's are reported back to the host computer.

### Image frame

One of the coordinate systems used by the CyberKnife.System. The Image Frame is a 3D Cartesian coordinate system with rotation (x, y, z, w, p, r) whose origin is at the center of the TLS image location system. Its position is fixed and is established during system installation. See also Tool Frame, Uframe, and World Frame.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



## Imaging system

The imaging system locates the treatment center by comparing real-time radiographs of the patient with radiographs synthesized from CT data. Thus, patient positioning does not require mechanical fixation and lengthy alignment procedures.

The imaging system contains two nearly identical X-ray imaging units. Each unit has the following components:

- standard medical radiographic X-ray tube
- high voltage generator
- tungsten copper X-ray collimator
- X-ray detector

A patient needs to be aligned with respect to the Image Frame before treatment delivery may proceed. The best way to understand this process is to visualize the CT coordinate frame as being "attached" to the patient's head at the time the scan is made. In the CT data file, a precise connection exists between the patient's anatomical data and the CT coordinate frame.

Before alignment, digitally reconstructed radiographs (DRRs) are generated from the CT. The DRRs are generated using a technique that numerically simulates how an image would be taken by the orthogonal cameras. The origin of the CT becomes the origin of the DRRs.

During alignment, the patient's position is first set using a pair of images taken by the orthogonal X-ray detectors. These images are numerically overlaid with the appropriate DRRs. The treatment software calculates required adjustment to the patient's position. The operator performs the adjustment on the treatment table. This process aligns the origin of the CT coordinate frame, which in practice is the center of the patient's head, to the origin of the Image Frame, which is the imaging center.

After alignment, radiation treatment begins. Tracking adjustments are made by instructing the manipulator to modify its pointing angle at each node to compensate for any mismatch between the CT coordinate frame and the TLS image frame caused by misalignment or by patient motion.



1253 Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



## Interlocks

The Linac displays the following safety interlocks and status information on the MCC. They are cleared (not illuminated) when the description shown is not satisfied.

| Interlock Name | Description |
|---|---|
| Door Interlock (Intlk) | All treatment room doors are closed |
| Water Flow Interlock | Cooling water or air flow is adequate |
| Magnetron Filament (Mag Fil) | Magnetron filament voltage is acceptable |
| Heater (Htr) Delay | CyberKnife System has completed an approximately 10 minute warm-up |
| Sulfur Hexafluoride (SF6) Gas | SF6 tank pressure is acceptable |
| Vacuum | No vacuum faults in accelerator waveguide or magnetron |
| Dose Power Supply (P.S.) | Dosimetry high voltage power supplies operating properly |
| Computer | Linac is in computer control mode |
| High Voltage Over-current (HVOC) | Excessive current is not being drawn from the high voltage power supply (to magnetron) |
| Inverse Current (I) | No excessive reverse current returning from X-ray head |
| Manual Override | When the CyberKnife System operates under computer control this light is illuminated |
| Grid Power Supply | Accelerator electron gun power supply working properly |
| E-Stop | E-Stop switch on the MCC is not pressed |
| Beam On | X-ray beam is on |
| Automatic Frequency Control (AFC)/Manual | Magnetron AFC is in automatic |
| Collimator Interlock | Both collimator sense potentiometers are reading the same value |
| Pulse Rate Frequency (PRF) Limit Interlock | No used |
| HV Enable | SGI has enabled high voltage when not in manual mode |
| DC Pwr | Monitors low voltages in the modulator |
| Diagnostic (Diag) Mode | Not used |



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118 1254

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



## Inverse Planning

Treatment planning devised by the software. The user specifies the following constraints:

- minimum lesion dose (in cGy)
- maximum lesion dose (in cGy)
- dose maximum of up to 10 critical regions (in cGy)
- maximum dose of soft tissue boundary that surrounds the lesion (in cGy)
- maximum beam weight (in MU)

The computer uses a linear programming algorithm to find a dose for each beam to satisfy the constraints, a feasible but not necessarily optimal solution. See also Treatment Planning (TPS).

## Ionizing radiation

A radiation beam that, when passing into a biological absorbing medium such as body tissue, transfers some of the energy carried in the beam to the medium sufficiently to ionize the tissue at the molecular level and therefore to disrupt cellular reproduction processes. The energy transferred may produce a biological effect in the medium. Use of the word "radiation" in this document will mean ionizing radiation.

## Isocenter

The point in space where the central axes of treatment beams intersect with the gantry axis or the machine center.

## Isocentric Planning

A model of treatment planning where the lesion is placed at isocenter and can be irradiated from different angles. In radiosurgery, this method typically results in a spherical dose distribution. For symmetrical, roughly spherical lesions, a single isocenter can be used. For asymmetrical lesions, multiple isocentric doses of varying sizes can be used to create a homogeneous dose distribution within the lesion.

## Isocrystal

Target located at the tip of the iso-post that is used with the laser in the linac to perform robot pointing calibration. Indicates the precise position of the system iso-center.

## Isopost

Calibration tool used to establish the machine center. See Isocrystal.



1255 Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



# K

## Key switch

The radiation enable switch in the user control panel. When turned ON, it provides the "high voltage enable" to the Linac for treatment delivery, simulation, or calibration.

# L

## Linac

Acronym for linear accelerator. A linear accelerator is a device that uses high frequency electromagnetic waves to accelerate charged particles such as electrons to high energies through a linear tube. In the CyberKnife System, the Linac uses a Magnetron to produce X-band microwaves to accelerate an electron beam to a nominal energy of 6 MeV. The beam strikes tungsten target where X-rays are produced. Here the X-ray beam energy is measured by two dosimeters. The X-rays are reduced to a narrow beam by a fixed primary collimator and then by a secondary changeable collimator. The entire apparatus is mounted on the end of the robot arm that aims the X-ray beam at the treatment site in the patient. Radiation is only fired from the Linac when the manipulator is stopped and located at a node.

# M

## Magnetron

A magnetron is a vacuum tube device that produces microwaves. It functions as a high-power oscillator, generating microwave pulses of several microseconds duration and with a repetition rate of less than 200 pulses per second. The Linac uses a mechanically tunable magnetron to provide the energy necessary to accelerate the electron beam. See Linac and AFC.

## Makeup plan

A new treatment plan created when an executing plan is aborted during treatment delivery. The makeup plan contains the remaining dose to be delivered to the patient. If a treatment fraction has been terminated due to error or user request, a makeup fraction is created. It consists of all paths of the terminated fraction that was not executed. It contains the same set of nodes as the treatment plan except that the nodes already delivered are set to zero dose and the node where the termination occurred will contain only the amount of dose remaining.

## Menus

The SGI software displays a high level menu so that the users can select the function they wish to perform. The first nine options appear as buttons on the screen and the remaining six options appear as pull down menus under "ADMIN":

## MeV

One million electron volts, a unit of energy used to specify the energy of particles such as the electron beam in the Linac. One electron volt is the energy equivalent of an electron being accelerated in free space through a field of one volt. The Linac produces a nominal 6 MeV electron beam.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118 1256

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



## Modulator

Contains the pulse power modulator generator for the magnetron and the high voltage supply for the Linac gun.

Modulator Control Chassis (MCC)

A unitsubsystem of the Linac. It contains the control logic, fault logic and manual controls for the modulator.

## Monitor Unit

The Monitor Unit, commonly referred to as MU, is the measure of charge integrated by two independent dosimeters. The calibration of MU as a function of dose controls the dose delivery of the CyberKnife System.

Due to variations in linac calibration the MU is calibrated to be within about 5% of the true value. The precise dose calibration is achieved by an additional "calibration factor" measured each day and entered into CyberKnife System by the physicist. The calibration factor (in units of MU/cGy) sets the precise calibration of CyberKnife System.

## MRI

Magnetic Resonance Imaging, an alternate form of imaging not directly used with the CyberKnife System. MR uses magnetic energy and radio waves to create 2D or 3D images of the human body. This type of imaging is particularly useful for discriminating regions within soft tissue. The main component of most MR systems is a large tube shaped or cylindrical magnet. Also now available are MR systems with a C-shaped magnet or other type of open design. The strength of the MR systems magnetic field is measured in metric units called "Tesla". Most of the cylindrical magnets have a strength between 0.5 and 1.5 Tesla and most of the Open or C-shaped magnets have a magnetic strength between 0.01 and 0.35 Tesla. A 1.5 Tesla MR system has a magnetic field 30,000 times stronger than the pull of gravity on the earth's surface.

## MU

See Monitor Unit.

## MV

A medical radiation term that is a measure of the energy of a spectrum of X-ray photons. See MeV.



1257 Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



# N

## Node

One of a set of predefined points at the end of the accelerator, from which radiation is delivered to the tumor target. The location of the set of treatment nodes is fixed at design and is not altered for individual treatment plans, though there will be variations in orientation to point at the current target center or position to compensate for patient motion. A set of nodes is selected at system design which provide useful coverage of the head, avoid physical objects in the treatment room, and avoid blocking the X-ray imaging system.

## Non-isocentric planning

A method of treatment unique to the CyberKnife System, in which the beams are directed to different points around the boundary of within the tumor and inverse planning is used to weight the beams and generate a conformal dose distribution.

# P

## Patient Coordinate Frame

Has its origin at the center of the CT volume with its axes along left-right (x), posterior-anterior (y), and inferior-superior (z) directions. The origin is in the center slice for an odd number of slices or between slices if the number is even. If the patient is supine, the positive x-axis is in the direction of patient right, the positive y-axis is in the anterior direction, and positive z-axis is in the superior direction.

## Patient alignment abbreviation

| | | | |
|---|---|---|---|
| POS – ANT | Posterior / Anterior | ROLL | Left / Right |
| SUP – INF | Superior / Inferior | PITCH | Heads up / Down |
| LFT – RGT | Left / Right | YAW | CW / CCW |

## Patient Treatment Table

The Patient Treatment Table is an X-ray transparent table that supports the patient during treatment. Moves in 5 DOF, x, y, z, roll, pitch.

## PDD

Percent Depth Dose. A measure of the energy, or the ability of a spectrum of radiation to penetrate a material such as water or soft tissue.

## PDP (Proximity Detection Process)

Its software program is used to check how close the robot is approaching stationary objects in the treatment room. It uses treatment room geometry files and real-time data from the robot encoders to detect and signal a proximity error when any part of the robot moves within 5 cm of any stationary object. When a proximity error occurs, robot motion is stopped. The robot is disabled when in manual mode.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118 1258

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



### Penumbra

The edge region surrounding a beam where the energy level drops from 80% to 20% of its maximum.

### Perch position

Rest position of the robot.

### Phantom

A 3D model of the skull or other target bearing portion of the body. A 3D photographic film cube is placed in the phantom in the particular volume. The exposed film shows the dose distribution applied during the simulation run. Upon inspection of the irradiated film, adjustments may be made to the treatment plan prior to its application to the patient.

The phantom with film cube is used to perform an end-to-end and QA test. In this test a CT is generated of a dosimetric phantom and a plan is created to treat a specified location in the film pack. After irradiating the phantom, the film pack is read and a comparison is made of the location of the planned treatment with the center of the delivered dose. In this way the total system accuracy is tested. See also film cube.

### Prescription

Dose to be delivered to the tumor.

## R

### Rad

A unit of radiation dose, replaced by the Centigray (cGy).

### Radiosurgery

The treatment of lesions using stereotactically directed convergent beams of external irradiation, usually in 1-2 fractions. Radiosurgery is usually confined to treating lesions of dimensions less than 3 to 5 cm because of the perceived limitation of normal tissue tolerance. See SRS.

### Robot Coordinate Frame

Same as the Uframe of the robot. The robot coordinate frame's origin is at the same place as the patient frame's origin however the robot coordinate frame is rotated 45 degrees.

### ROI

Region of Interest



1259 Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



# S

## SAD

Source to Axis Distance. The distance from the X-ray source to the tumor target.

## Sagittal

A side image of the body. A **sagittal plane** divides the body into left and right segments.

## Simulation

One of the operational modes of the CyberKnife System, a physical execution of the treatment plan by the system with a dosimetric phantom instead of a patient. A treatment plan may be simulated prior to patient treatment. The primary purpose is to check for the accurate and safe delivery of a patient treatment plan. Simulation requires the use of a dosimetric phantom and a film cube. Treatment simulation is the same as treatment delivery except that the dose actually applied is not recorded in the database. After performing the simulated treatment delivery, the exposed film pack is examined and verified that the center of the dose distribution is at the intended location and that the shape is correct.

## Site

The location of a tumor or other lesion under treatment.

## SRS

Stereotactic Radiosurgery

## Stereotactic

Any device which accurately guides a surgical tool in space. Adjective form of stereotaxis (see).

## Stereotactic Radiotherapy

The treatment of larger lesions using stereotactically directed convergent beams of external irradiation, in several fractions. Radiotherapy is often used in treating lesions of dimensions greater than 5 cm because of the perceived limitation of normal tissue tolerance, whereas radiosurgery is often used for smaller lesions.

## Stereotaxis

Stereotaxis is a branch of neurosurgery that utilizes spatial information provided by neuroradiologic studies to treat certain disorders of the central nervous system with great accuracy.

## Sulfur Hexafluoride (SF 6)

A dielectric gas used to suppress ionization in the Linac waveguide between the magnetron and the accelerator. Also referred to as SF6.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118 1260

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



### Synchrony™

Synchrony is Accuray's system for delivering dynamic radiosurgery to tumors that move with respiration. The Synchrony system precisely tracks tumors in or near the lungs as they move, enabling highly focused beams of radiation to destroy the tumors with minimal damage to adjacent normal tissue. Synchrony records the breathing movements of a patient's chest and combines that information with sequential X-ray pictures of tiny markers inserted inside the tumor to enable precise delivery of radiation during any point in the respiration cycle. CyberKnife System with Synchrony is the only radiosurgery device capable of targeting tumors in this manner.

### System Center

Sometimes referred to as the machine isocenter. The system center is a physical reference point chosen during system installation in the center of the patient treatment area. Under ideal conditions this point would coincide with the center of the image frame and also the Uframe. In reality these are three different reference frames that exist in close proximity and are used to compute the patient's location during treatment.

A second purpose for the system center is to provide a reference point for robot calibration. During system installation and at other times when system calibration is required, the system center is used as the reference to correct the computed node file to provide a precise isocenter, i.e. all beams from the linac are corrected to point at precisely the same point, the system center. The laser alignment unit (LAU) is used to perform this calibration.

## T

### Target

There are two different targets referred to in the CyberKnife System:

1. Inside the Linac, a 6 MeV electron beam is aimed at a tungsten target to generate 6 MV X-rays.
2. The X-ray beam is aimed at a second target, the tumor in the patient.

### Target Locating System (TLS)

The CyberKnife System subsystem that provides the capability to locate the treatment target.

### Teach Pendant

A hand held device used to manually control the manipulator or to program sequences of movements for it. In the CyberKnife System, the operator uses the teach pendant to position the manipulator for calibration or maintenance and to manually power up components such as the alignment lasers or imaging X-ray sources. Maintenance mode can only be accessed with a special key. The CyberKnife System is used for patient treatment only when the robot is under computer control.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



### Tool Frame

One of the coordinate systems used by the CyberKnife System. The Tool Frame is a coordinate system with 6 degrees of freedom (x, y, z, pitch, yaw, and roll). The tool frame location (x, y, and z) is defined relative to the faceplate of the robot with the z-axis perpendicular to it (positive pointing straight out). The tool frame orientation (pitch, yaw, and roll) is the same as the faceplate. The tool frame origin is called the tool center point (TCP). The TCP for the CyberKnife System is at the X-ray source of the Linac. Its position moves with the robot and is continually being recalculated during treatment delivery. See also Frame, Image Frame, Uframe, and World Frame.

### TPS

Treatment Planning System.

The main functionality of TPS is to:

- display the CT data
- delineate the tumor and the critical structures
- generate treatment plans
- evaluate and fine-tune plans.

### Treatment Path

The path which the Linac would follow in moving through a set or a subset of nodes. All defined nodes are visited during radiation treatment or simulation. No nodes are skipped even if radiation is not activated at all nodes. Normally radiation is only activated at a subset of the defined nodes. For the CyberKnife System, there are single or 3 path options available.

## U

### Uframe

One of the coordinate systems used by the CyberKnife System. The Uframe is a coordinate system (x, y, z) whose origin is at the center of the CT images. The location of the Uframe represents distances along the x, y, and z-axes of the world coordinate system; the orientation represents rotations around those axes (w, p, r). See also Frame, Image Frame, Tool Frame, and World Frame.

### UPS

Uninterruptible Power Supply used with the SGI to maintain power during power interruptions.

### User Control Panel

The purpose of the control panel is to allow the user to turn the high voltage on or off to the Linac. Once the high voltage is on, radiation can be generated and delivered.

See also **key switch**.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118 1262

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



# V

## Voxel

A 3-dimensional pixel, an atomic element of a 3D image.

# W

## Water cooling system

The linac uses a water cooling system to remove heat from the X-ray head. The water is cooled by a chiller located in the equipment room.

## Water phantom

A precise radiation measurement device used for characterization and calibration of the Linac beams. Every Linac is different. In the CyberKnife System, the beam from each collimator is characterized using a water phantom and the data collected is stored in a system file. This beam data is used in treatment planning to determine how much dose to deliver.

## Waveguide

The structure in the accelerator that develops the electric fields necessary to accelerate electrons. Utilizes microwaves of the appropriate frequency and power to provide the necessary energy

## Workspace

The workspace is the set of configurations that the robot (or manipulator) can assume without entering a forbidden region. A forbidden region is an obstacle plus any buffer around the obstacle. Defined obstacles in the treatment area include the patient, the couch, the camera stands, the floor, and the ceiling.

## World Frame

One of the coordinate systems used by the CyberKnife System. The World Frame is a Cartesian coordinate system (x, y, z expressed in millimeters) whose origin is predefined by the robot manufacturer for the particular model of robot. For the CyberKnife System, the World Frame origin is located 1 meter (1000 mm.) above the floor. See also Frame, Image Frame, Tool Frame, and Uframe.



1263 Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



# X

## X-band

A frequency spectrum in the microwave band. The Linac magnetron operates in the x-band. X-band microwaves are used in the CyberKnife System Linac because it allows for smaller robot-mounted Linac components than would a lower frequency band. Conventional linac accelerators typically use the lower-frequency S-band.

## X-rays

Photons in the energy band above ultraviolet light that have been produced by high energy particles colliding into a target. See also gamma rays.

## X-ray head

The portion of the linac that is mounted to the end of the robot arm and provides the radio-surgical X-ray beam.

## X-ray detectors

Amorphous silicon flat panel X-ray image detectors used in the TLS to obtain images of the patient for use in patient alignment and motion tracking.

## XRS

X-ray source used in the TLS to illuminate the X-ray detector.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118 1264

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015





1265 Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
Memorandum

From: Reviewer(s) - Name(s) John Chen

Subject: 510(k) Number K 062967

To: The Record - It is my recommendation that the subject 510(k) Notification:

- ☐ Refused to accept.
- ☐ Requires additional information (other than refuse to accept).
- ☒ Is substantially equivalent to marketed devices.
- ☐ NOT substantially equivalent to marketed devices.
- ☐ Other (e.g., exempt by regulation, not a device, duplicate, etc.)

| | | |
|---|---|---|
| Is this device subject to Section 522 Postmarket Surveillance? | ☐ YES | ☒ NO |
| Is this device subject to the Tracking Regulation? | ☐ YES | ☒ NO |
| Was clinical data necessary to support the review of this 510(k)? | ☐ YES | ☒ NO |
| Is this a prescription device? | ☒ YES | ☐ NO |
| Was this 510(k) reviewed by a Third Party? | ☐ YES | ☒ NO |
| Special 510(k)? | ☒ YES | ☐ NO |
| Abbreviated 510(k)? Please fill out form on H Drive 510k/boilers | ☐ YES | ☒ NO |

Truthful and Accurate Statement ☐ Requested ☒ Enclosed

☒ A 510(k) summary OR ☐ A 510(k) statement

☐ The required certification and summary for class III devices

☒ The indication for use form

Combination Product Category (Please see algorithm on H drive 510k/Boilers) N

Animal Tissue Source ☐ YES ☒ NO Material of Biological Origin ☐ YES ☒ NO

The submitter requests under 21 CFR 807.95 (doesn't apply for SEs):

☒ No Confidentiality ☐ Confidentiality for 90 days ☐ Continued Confidentiality exceeding 90 days

Predicate Product Code with class: Class II 892.5050 90-MUJ, 21 CFR

Additional Product Code(s) with panel (optional):

Review: Rota Phillips (Branch Chief) RADB (Branch Code) 10/30/06 (Date)

Final Review: Nancy C. Brogdon (Division Director) 10-30-06 (Date)



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8113

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015

# Screening Checklist
# For all Premarket Notification 510(k) Submissions

| Device Name: CyberKnife Robotic Radiosurgery System | K062967 |
|---|---|
| Submitter (Company): Accuray | |

| Items which should be included *(circle missing & needed information)* | SPECIAL YES | SPECIAL NO | ABBREVIATED YES | ABBREVIATED NO | TRADITIONAL YES | TRADITIONAL NO | ✓ IF ITEM IS NEEDED AND IS MISSING |
|---|---|---|---|---|---|---|---|
| **1. Cover Letter clearly identifies Submission as:** | | | | | | | |
| a) "Special 510(k): Device Modification" | X | | | | | | |
| b) "Abbreviated 510(k)" | GO TO # 2,3 | | GO TO # 2,4,5 | | GO TO #2, 5 | | |
| c) Traditional 510(k) | | | | | | | |

| 2. GENERAL INFORMATION: REQUIRED IN ALL 510(K) SUBMISSIONS | NA | | YES | | NO | | ✓ IF ITEM IS NEEDED AND IS MISSING |
|---|---|---|---|---|---|---|---|
| Financial Certification or Disclosure Statement for 510(k)s with a Clinical Study 807.87(i) | SPECIALS | | ABBREVIATED | | TRADITIONAL | | |
| | YES | NO | YES | NO | YES | NO | |
| a) trade name, classification name, establishment registration number, device class | X | | | | | | |
| b) OR a statement that the device is not yet classified | FDA-may be a classification request; see coordinator | | | | | | |
| c) identification of legally marketed equivalent device | NA | | | | | | |
| d) compliance with Section 514 - performance standards | NA | | | | | | |
| e) address of manufacturer | X | | | | | | |
| f) Truthful and Accurate Statement | X | | | | | | |
| g) Indications for Use enclosure | X | | | | | | |
| h) SMDA Summary or Statement *(FOR ALL DEVICE CLASSES)* | X | | | | | | |
| i) Class III Certification & Summary *(FOR ALL CLASS III DEVICES)* | | | | | | | |
| j) Description of device (or modification) including diagrams, engineering drawings, photographs, service manuals | X | | | | | | |
| k) Proposed Labeling: | X | | | | | | |
| i) package labeling (user info) | X | | | | | | |
| ii) statement of intended use | X | | | | | | |
| iii) advertisements or promotional | X | | | | | | |
| i) MRI compatibility (if claimed) | | | | | | | |
| l) Comparison Information (similarities and differences) to named legally marketed equivalent device (table preferred) should include: | | | | | | | |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| i) Labeling | X | | | | | | |
| ii) intended use | X | | | | | | |
| iii) physical characteristics | X | | | | | | |
| iv) anatomical sites of use | X | | | | | | |
| v) performance (bench, animal, | **NA** | | | | | | |
| vi) safety characteristics | **NA** | | | | | | |
| m) If kit, kit certification | | | | | | | |

| **3. "SPECIALS"** – ONLY FOR MODIFICATIONS TO MANUFACTURER'S OWN CLASS II , III OR RESERVED CLASS I DEVICE | | | | |
|---|---|---|---|---|
| a) Name & 510(k) number of legally marketed (unmodified) predicate device | X | | | |
| b) ***STATEMENT - INTENDED USE AND INDICATIONS FOR USE OF MODIFIED DEVICE AS DESCRIBED IN ITS LABELING HAVE NOT CHANGED**** | X | | * If no - STOP not a special | |
| c) ***STATEMENT - FUNDAMENTAL SCIENTIFIC TECHNOLOGY OF THE MODIFIED DEVICE HAS NOT CHANGED**** | X | | * If no - STOP not a special | |
| d) Design Control Activities Summary | | | | |
| i) Identification of Risk Analysis method(s) used to assess the impact of the modification on the device and its components, and the results of the analysis | X | | | |
| ii) Based on the Risk Analysis, an identification of the verification and/or validation activities required, including methods or tests used and acceptance criteria to be applied | X | | | |
| iii) A declaration of conformity with design controls. The declaration of conformity should include: | X | | | |
| 1) A statement signed by the individual responsible, that, as required by the risk analysis, all verification and validation activities were performed by the designated individual(s) and the results demonstrated that the predetermined acceptance criteria were met | X | | | |
| 2) A statement signed by the individual responsible, that manufacturing facility is in conformance with design control procedure Requirements as specified in 21 CFR 820.30 and the records are available for review. | X | | | |

| | | | | |
|---|---|---|---|---|
| | | | | ✓ IF |

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015

| | SPECIALS | | ABBREVIATED | | TRADITIONAL | | ITEM IS NEEDED AND IS MISSING |
|---|---|---|---|---|---|---|---|
| | YES | NO | YES | NO | YES | NO | |
| 4. **ABBREVIATED 510(K):** SPECIAL CONTROLS/CONFORMANCE TO RECOGNIZED STANDARDS - PLEASE **FILL OUT THE STANDARDS ABBREVIATED FORM ON THE H DRIVE** | | | | | | | |
| a) For a submission, which relies on a guidance document and/or special control(s), a summary report that describes how the guidance and/or special control(s) was used to address the risks associated with the particular device type | | | | | | | |
| b) If a manufacturer elects to use an alternate approach to address a particular risk, sufficient detail should be provided to justify that approach. | | | | | | | |
| c) For a submission, which relies on a recognized standard, a declaration of conformity to the standard. The declaration should include the following: | | | | | | | |
| i) An identification of the applicable recognized consensus standards that were met | | | | | | | |
| ii) A specification, for each consensus standard, that all requirements were met, except for inapplicable requirements or deviations noted below | | | | | | | |
| iii) An identification, for each consensus standard, of any way(s) in which the standard may have been adapted for application to the device under review, e.g., an identification of an alternative series of tests that were performed | | | | | | | |
| iv) An identification, for each consensus standard, of any requirements that were not applicable to the device | | | | | | | |
| v) A specification of any deviations from each applicable standard that were applied | | | | | | | |
| vi) A specification of the differences that may exist, if any, between the tested device and the device to be marketed and a justification of the test results in these areas of difference | | | | | | | |
| vii) Name/address of test laboratory/certification body involved in determining the conformance of the device with applicable consensus standards and a reference to any accreditations for those organizations | | | | | | | |

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015

| | | | | | |
|---|---|---|---|---|---|
| d) Data/information to address issues not covered by guidance documents, special controls, and/or recognized standards | | | | | |

| 5. **Additional Considerations: (may be covered by Design Controls)** | | | | | | | |
|---|---|---|---|---|---|---|---|
| a) Biocompatibility data for all patient-contacting materials, OR certification of identical material/formulation: | | | | | | | |
| i) component & material | | | | | | | |
| ii) identify patient-contacting | | | | | | | |
| iii) biocompatibility of final | | | | | | | |
| b) Sterilization and expiration dating information: | | | | | | | |
| i) sterilization method | | | | | | | |
| ii) SAL | | | | | | | |
| iii) packaging | | | | | | | |
| iv) specify pyrogen free | | | | | | | |
| v) ETO residues | | | | | | | |
| vi) radiation dose | | | | | | | |
| c) Software validation & verification: | | | | | | | |
| i) hazard analysis | | | | | | | |
| ii) level of concern | | | | | | | |
| iii) development documentation | | | | | | | |
| iv) certification | | | | | | | |

***Items shaded under "NO" are necessary for that type of submission. Circled items and items with checks in the "Needed & Missing" column must be submitted before acceptance of the document.***

**Passed Screening _X_ Yes__ _No**

**Reviewer: John Chen, Ph. D.** **Date: 10/24/06**

**Concurrence by Review Branch:** _____



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015

# Special 510(k): Device Modification

## ODE Review Memorandum

**Date:** 10/29/06 **510(k) Number:** K062967

**TRADITIONAL**____ **ABBREVIATED**_____ **SPECIAL** __X___

**CONTACT:** Anne Schlagenhaft **Tel:** 408-716-4628 **Fax:** 408-716-4601

**COMPANY NAME:** Accuray Inc.

**ADDRESS:** 1310 Chesapeake Terrace, Sunnyvale, CA 94089

**TRADENAME:** CyberKnife Robotic Radiosurgery System

**COMMON NAME:** Stereotactic RTP System

**DATED:** 09/28/06 **RECEIVED:** 09/29/06

**PRODUCT CODE:** 90 - MUJ **CLASS:** II **FR CLASSIFICATION NO:** 892.5050

**MANUFACTURING ADDRESS:** 1310 Orleans Drive, Sunnyvale, CA 94089

**INTENDED USE:** The CyberKnife Robotic Radiosurgery System is intended for the treatment planning and image guided stereotactic radiosurgery and precision radiotherapy for lesions and tumors.

**NATURE OF CHANGE:** The change in adding a new tracking algorithm, the Lung Tumor Tracking (LTT) algorithm.

**DEVICE(S) TO WHICH EQUIVALENCE IS CLAIMED AND MANUFATURER:**

**MANUFATURER:** Accuray Inc.

**TRADENAME:** CyberKnife Robotic Radiosurgery System.

**DOCUMENT CONTROL:** K062514

**SUMMARY:**

The CyberKnife Robotic Radiosurgery System is a modification to the previous CyberKnife Robotic Radiosurgery System with adding a new tracking algorithm, the Lung Tumor Tracking (LTT) algorithm. The purpose of tracking is to locate a tumor or lesion for precise radiation targeting during patient alignment and throughout treatment delivery.

The LTT system is accomplished by marching lung tumor in the digitally reconstructed radiographs generated fro pre-treatment images, with real time X-rays of the patient taken during treatment delivery.

Steve Pelham, software specialist, reviewed the software parts, he has no questions.

Accuray has provided evidence that their device is SE to previously marketed device. All issues raised during review of this submission have been addressed.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118 

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015



**ADDITIONAL SUPPORTING INFORMATION:** None.

**RECOMMENDATION:**

**I believe that this device is SE to:** 90-MUJ & IYE
**Classification should be based on:** 892.5050 Radiation Therapy Treatment Planning System
**Class:** II (final)

John J. Chen, Ph. D.

K062967F.REV
10/30/06

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015

# Special 510(k): Device Modification ODE Review Memorandum

To: THE FILE RE: DOCUMENT NUMBER **K062967**

This 510(k) submission contains information/data on modifications made to the SUBMITTER'S own Class II, Class III or Class I devices requiring 510(k). The following items are present and acceptable (delete/add items as necessary):

1. The name and 510(k) number of the SUBMITTER'S previously cleared device. (For a preamendments device, a statement to this effect has been provided.)
2. Submitter's statement that the **INDICATION/INTENDED USE** of the modified device as described in its labeling **HAS NOT CHANGED** along with the proposed labeling which includes instructions for use, package labeling, and, if available, advertisements or promotional materials.
3. A description of the device **MODIFICATION(S)**, including clearly labeled diagrams, engineering drawings, photographs, user's and/or service manuals in sufficient detail to demonstrate that the **FUNDAMENTAL SCIENTIFIC TECHNOLOGY** of the modified device **has not changed.**

**This change was** in adding a new tracking algorithm, the Lung Tumor Tracking (LTT) algorithm.

**Comparison Information** (similarities and differences) to applicant's legally marketed predicate device including, labeling, intended use, physical characteristics, and _____.

4. A **Design Control Activities Summary** which includes:
   a) Identification of Risk Analysis method(s) used to assess the impact of the modification on the device and its components, and the results of the analysis
   b) Based on the Risk Analysis, an identification of the verification and/or validation activities required, including methods or tests used and acceptance criteria to be applied
   c) A declaration of conformity with design controls. The declaration of conformity should include:
      i) A statement signed by the individual responsible, that, as required by the risk analysis, all verification and validation activities were performed by the designated individual(s) and the results demonstrated that the predetermined acceptance criteria were met, and
      ii) A statement signed by the individual responsible, that the manufacturing facility is in conformance with design control procedure requirements as specified in 21 CFR 820.30 and the records are available for review.
5. **A Truthful and Accurate Statement**, a **510(k) Summary or Statement** and the **Indications for Use Enclosure (and Class III Summary for Class III devices).**

The labeling for this modified subject device has been reviewed to verify that the indication/intended use for the device is unaffected by the modification. In addition, the submitter's description of the particular modification(s) and the comparative information between the modified and unmodified devices demonstrate that the fundamental scientific technology has not changed. The submitter has provided the design control information as specified in The New 510(k) Paradigm and on this basis, I recommend the device be determined substantially equivalent to the previously cleared (or their preamendment) device.

_____ 10/30/06
(Reviewer's Signature) (Date)

Comments _____

12

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015

# DRAERD REVIEWER RECORD FOR ORIGINAL 510(K)S, AND PMA AND IDE SUPPLEMENTS

Document No. K062967 Reviewer John Chen Date Assigned _____

*CONSULTING REVIEWS DESIGNATED, AS APPROPRIATE, BY BRANCH CHIEF AND LEAD REVIEWER, AT THE BEGINNING OF THE REVIEW:*

| SPECIALTY | REVIEW NEEDED? YES | NO | REVIEWER | DATES SENT | RETURNED |
|---|---|---|---|---|---|
| CLINICAL | | | | | |
| ENGINEERING/ PHYSICS | | | | | |
| CHEMISTRY/ BIOMATERIALS | | | | | |
| SOFTWARE | ✓ | | Steve Pelham | 10/6 | 10/27/06 |
| BIOLOGICAL/ STERILITY | | | | | |
| TOXICOLOGY/ BIOCOMPATIBILITY | | | | | |
| STATISTICS | | | | | |
| OTHER _____ | | | | | |

**COMMENTS:**

**REVISED** 1/2/96 LMS
**ON LAN AS REVREC.FRM**





Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015

Memorandum of a

# Software Review

## K062967 (SPECIAL)

October 19, 2006

From: Steven Pelham; OSEL-DESE (HFZ-160); (301) 827-5078
To: John Chen, ODE-DRARD (HFZ-470), (301) 594-1212 x122

Subject: Software review CyberKnife Robotic Radiosurgery System by Accuray Inc

---

**Succinct Conclusion: Substantially Equivalent**

The information contained within this submission is sufficient to meet the software concerns as described in the *Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices*, dated May 11, 2005, and it is recommended that, from a software standpoint, this submission be considered **Substantially Equivalent**.

---

## Summary

The CyberKnife Robotic Radiosurgery System is intended to provide planning and image-guided stereotactic radiosurgery and precision radiotherapy for lesions, tumors and conditions anywhere in the body when radiation treatment is indicated. It is a computer controlled medical system for planning and performing minimally invasive stereotactic radiosurgery and precision radiotherapy using a linear accelerator mounted on a manipulator (robot) and a Target Locating Subsystem to accurately deliver high-energy radiation to the treatment target. The CyberKnife System uses skull tracking, Fiducial Tracking (tracking of implanted radiographic markers), Synchrony respiratory tracking and skeletal structure tracking for dynamic positioning and pointing of the linear accelerator.

This submission describes a new tracking algorithm, the Lung Tumor Tracking algorithm (LTT). The purpose of the tracking is to locate a tumor or lesion for precise radiation targeting during patient alignment and throughout treatment delivery. The LTT was devised so that lung tumors can be treated without implanting fiducial markers in the lung. Based on observation and analysis of patient data acquired from previous CyberKnife lung tumor treatments, it was determined that a number of lung tumors are sufficiently visible for delineation and tracking in medical images.

This is a SPECIAL 501(K) submission and therefore only minimal information is required of the manufacturer.

## 1. Software Description

The firm provided an acceptable overview of the device features that are controlled by software, and a description of the intended operational environment.

## 2. Device (including Software) Hazard Analysis

The firm provided an acceptable description of the hazards presented by this device, the causes and severity of the hazards, the method of control of the hazards and the testing done to verify the correct implementation of that method of control, and any residual hazards.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118 4

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015


3. **Software Requirements Specifications (SRS)**
   The firm provided a copy of their software requirements specification document, which clearly documented their functional, performance, interface, design, and development requirements.

4. **Software Design Specification (SDS)**
   The firm provided an acceptable design specification document, which describes what the program does and how it does it.

5. **Verification and Validation (including Testing)**
   The firm provided an acceptable description of their systematic process of life cycle activities, including analysis, evaluation, assurance, and testing of the software, and supporting documentation.

## Recommendation — Substantially Equivalent

The firm has provided acceptable documentation demonstrating that they:
1. have developed the software for this device under an appropriate software development program;
2. have performed a hazard analysis from both the patient's and user's standpoint;
3. addressed those hazards; and
4. carried out an appropriate validation process.

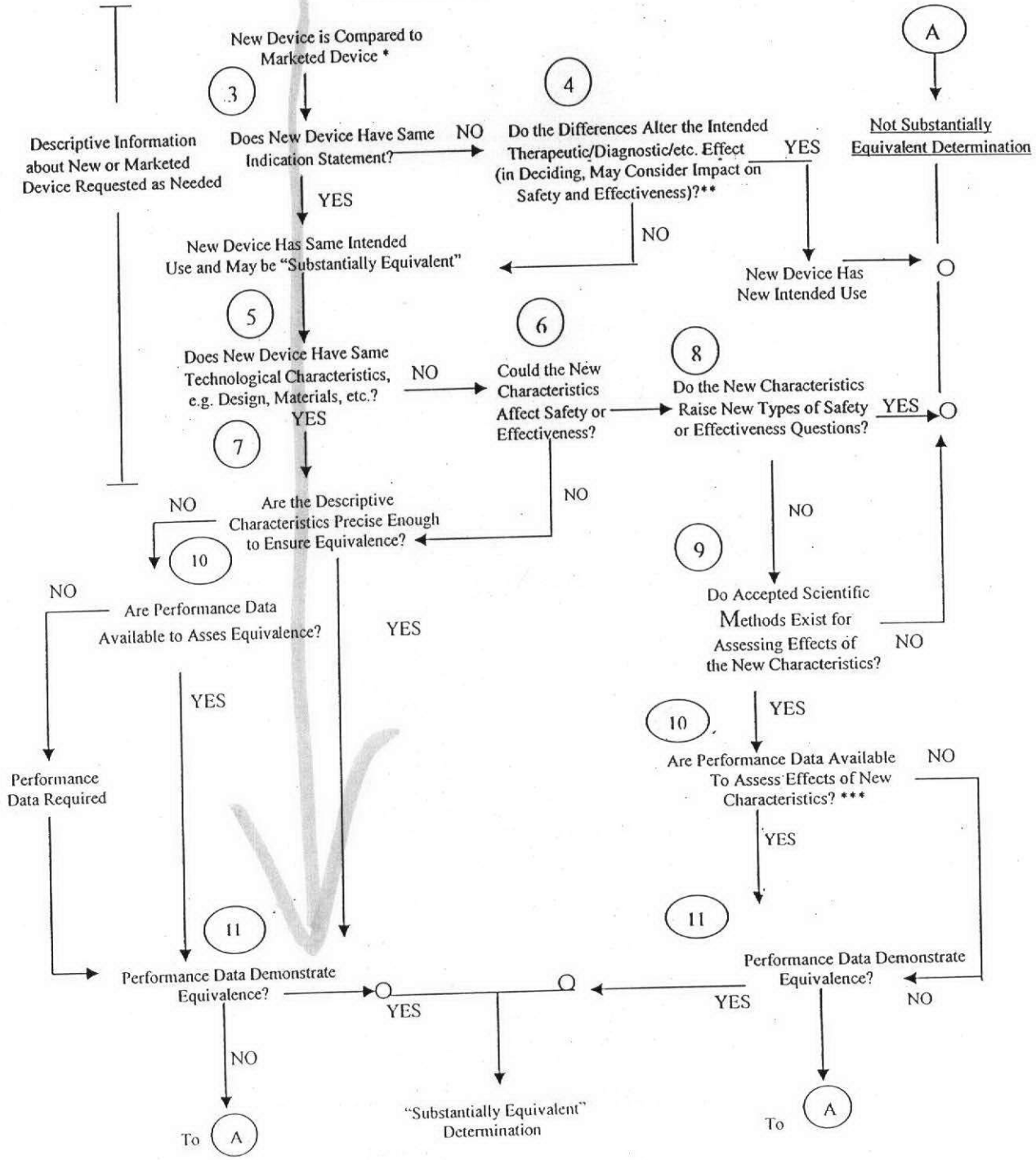
These procedures provide the foundation for assuring, to the extent possible, that the software will operate in a manner described in the specifications, and in no other predictable way. It is recommended that, from a software standpoint, this submission should be considered **Substantially Equivalent**.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-81 15

Records processed under FOIA Request #2014-4820; Released by CDRH on 12-8-2015

# 510(k) "SUBSTANTIAL EQUIVALENCE" DECISION-MAKING PROCESS




* 510(k) Submissions compare new devices to marketed devices. FDA requests additional information if the relationship between marketed and "predicate" (pre-Amendments or reclassified post-Amendments) devices is unclear.

** This decision is normally based on descriptive information alone, but limited testing information is sometimes required.

*** Information may be available in CDRH/OCE/DID, the Center's classification files, or the literature.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118