Records processed under FOIA Request # 2015-8521; Released by CDRH on 05-10-2016

510(k) SUMMARY

JUN - 5 2006

General Information

Submitted by:	Televere Systems 16275 South Monterey Road, Suite K Morgan Hill, CA 95037 Phone: 408.778.1700 Fax: 408.778.1733
Contact Person:	Mr. Randell Quaal 16275 South Monterey Road, Suite K Morgan Hill, CA 95037 Phone: 408.778.1700 Fax: 408.778.1733 Email: rquaal@tigerview.com
Date Prepared:	April 14, 2006

Device Name

Trade Name:	TigerView Professional
Common Name:	Picture archiving and communications system
Classification Name:	System, Image Processing, Radiological, 21 CFR 892.2050

Predicate Device

Manufacturer	Product Name	510(k) No.
EagleSoft, A Patterson Co.	EagleSoft ChairSide Software Application	K982422
Tau Corp.	TigerScan/TigerView	K955237

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

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Device Description

TigerView Professional is an image management system that allows the physician to acquire, display, edit (e.g., resize, adjust contrast, crop, etc.), review, store, print, and distribute medical images within a Picture Archiving and Communication System (PACS) environment. TigerView Professional runs on standard PC-compatible computers and is compatible with capture devices which attach to the computer using a Network Adaptor, USB port, PCI slot, parallel port, memory card, S-video port on a video capture card, or SCSI card.

Intended Use

TigerView Professional is a clinical software application that receives images and data from various imaging sources (e.g., radiographic devices, digital video capture devices, and generic image devices such as scanners). In addition, TigerView Professional enables the storage of clinical notes, audio recordings, and clinical exam data.

It is intended to acquire, display, edit (e.g., resize, adjust contrast, crop, annotate, etc.), review, store, print, and distribute images using standard PC hardware.

Technological Comparison

TigerView Professional, TigerScan/TigerView, and EagleSoft ChairSide are each software applications that have similar indications for use and overall function and perform in a similar manner with respect to image processing systems (i.e. PACS).

Testing

TigerView Professional has been demonstrated to perform as intended.

Conclusions

TigerView Professional is substantially equivalent to legally marketed Image Processing Systems (i.e. PACS).

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

Records processed under FOIA Request # 2015-8521; Released by CDRH on 05-10-2016

DEPARTMENT OF HEALTH & HUMAN SERVICES

JUN - 5 2006

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

Televere Systems
% Ms. Melissa Mahall
Director, Regulatory Affairs
Bio-Reg Associates, Inc.
6304 Belmont Circle, Bldg 2
MOUNT AIRY MD 21771

Re: K061035
Trade/Device Name: TigerView Professional
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: April 14, 2006
Received: April 14, 2006

Dear Ms. Mahall:

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.

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

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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.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 (301) 443-6597 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

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INDICATIONS FOR USE

510(k) Number (if known): K061035

Device Name: TigerView Professional

Sponsor Name: Televere Systems

Indications for Use:

TigerView Professional is a clinical software application that receives images and data from various imaging sources (e.g., radiographic devices, digital video capture devices, and generic image devices such as scanners). In addition, TigerView Professional enables the storage of clinical notes, audio recordings, and clinical exam data.

It is intended to acquire, display, edit (e.g., resize, adjust contrast, crop, annotate, etc.), review, store, print, and distribute images using standard PC hardware.

Prescription Use ☒ (21 CFR 801 Subpart D) ~~And~~/Or Over-The-Counter Use ☐ (21 CFR 807 Subpart C)

Do Not Write Below This Line – Continue on Another Page if Needed

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Lepore

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K061035

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

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DEPARTMENT OF HEALTH & HUMAN SERVICES

JUN - 5 2006

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

Televere Systems
% Ms. Melissa Mahall
Director, Regulatory Affairs
Bio-Reg Associates, Inc.
6304 Belmont Circle, Bldg 2
MOUNT AIRY MD 21771

Re: K061035
Trade/Device Name: TigerView Professional
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: April 14, 2006
Received: April 14, 2006

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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

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~~And~~/Or

Over-The-Counter Use ☐ (21 CFR 807 Subpart C)

Do Not Write Below This Line – Continue on Another Page if Needed

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Legrow

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K061035

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

Records processed under FOIA Request #2015-8521; Released by CDRH on 05-10-2016

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

April 17, 2006

TELEVERE SYSTEMS
C/O BIO-REG ASSOCIATES, INC.
6304 BELMONT CIRCLE BLDG 2
MOUNT AIRY, MD 21771
ATTN: MELISSA MAHALL

510(k) Number: K061035
Received: 14-APR-2006
Product: TIGERVIEW
PROFESSIONAL

The Food and Drug Administration (FDA), Center for Devices and Radiological Health (CDRH), has received the Premarket Notification you submitted in accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act(Act) for the above referenced product. We have assigned your submission a unique 510(k) number that is cited above. Please refer prominently to this 510(k) number in any future correspondence that relates to this submission. We will notify you when the processing of your premarket notification 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.

On May 21, 2004, FDA issued a 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. Please review this document at http://www.fda.gov/cdrh/mdufma/guidance/1219.html. On August 12, 2005 CDRH issued the Guidance for Industry and FDA Staff: Format for Traditional and Abbreviated 510(k)s. This guidance can be found at http://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).

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 premarket notification submission. Also, please note the new 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.

Records processed under FOIA Request # 2015-8521; Released by CDRH on 05-10-2016

You should be familiar with the regulatory requirements for medical device available at Device Advice http://www.fda.gov/cdrh/devadvice/". If you have other procedural or policy questions, or want information on how to check on the status of your submission, please contact DSMICA at (301) 443-6597 or its toll-free number (800) 638-2041, or at their Internet address http://www.fda.gov/cdrh/dsmamain.html or me 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

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K061035

Televere Systems

Premarket Notification [510k]
TigerView Professional

April 14, 2006

Volume 1 of 2

K44

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

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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: (b)(4) (b)(4)
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)

TELEVERE SYSTEMS LLC
16275 S. Monterey Rd. Ste K
Morgan Hill CA 95037
US

1.1 EMPLOYER IDENTIFICATION NUMBER (EIN)
752692534

2. CONTACT NAME
Jill Davies White
2.1 E-MAIL ADDRESS
jdavieswhite@tigerview.com
2.2 TELEPHONE NUMBER (include Area code)
408-778-1700
2.3 FACSIMILE (FAX) NUMBER (include Area code)
NO DATA

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

7. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION (FOR FISCAL YEAR 2005)
(b)(4) 07-Apr-2006

Form FDA 3601 (08/2003)

Close Window

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

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

CDRH PREMARKET REVIEW SUBMISSION COVER SHEET

Form Approved
OMB No. 9010-0120
Expiration Date: May 31, 2007.
See OMB Statement on page 5.

Date of Submission	User Fee Payment ID Number	FDA Submission Document Number (if known)
April 14, 2006	(b)(4)	

SECTION A TYPE OF SUBMISSION

PMA	PMA & HDE Supplement	PDP	510(k)	Meeting
☐ Original Submission	☐ Regular (180 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	Establishment Registration Number *(if known)*		
Televere Systems	2954358		
Division Name *(if applicable)*	**Phone Number** *(including area code)*		
	(408) 778-1700		
Street Address	**FAX Number** *(including area code)*		
16275 South Monterey Road, Suite K	(408) 778-1733		
City	**State / Province**	**ZIP/Postal Code**	**Country**
Morgan Hill	California	95037	USA
Contact Name			
Mr. Randell Quaal			
Contact Title	**Contact E-mail Address**		
General Manager	rquaal@tigerview.com		

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

Company / Institution Name			
Bio-Reg Associates, Inc.			
Division Name *(if applicable)*	**Phone Number** *(including area code)*		
	(301) 829-2468		
Street Address	**FAX Number** *(including area code)*		
6304 Belmont Circle, Bldg 2	(301) 829-2841		
City	**State / Province**	**ZIP/Postal Code**	**Country**
Mount Airy	MD	21771	USA
Contact Name			
Ms. Melissa Mahall			
Contact Title	**Contact E-mail Address**		
Director, Regulatory Affairs	mmahall@bioreg.com		

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

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Records processed under FOIA Request # 2015-8521; Released by CDRH on 05-10-2016

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
- ☒ Other Reason *(specify)*:

The company which developed the TigerScan/TigerView product (Tau Corporation) was purchased by Televere Systems and the indications for the TigerView product are being expanded.

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

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SECTION E ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS

Product codes of devices to which substantial equivalence is claimed

1	LLZ	2		3		4	
5		6		7		8	

Summary of, or statement concerning, safety and effectiveness information

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

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

	510(k) Number		*Trade or Proprietary or Model Name*		*Manufacturer*
1	K982422	1	EagleSoft ChairSide Software Application	1	EagleSoft, A Patterson Co.
2	K955237	2	TigerScan/TigerView	2	Tau Corp.
3		3		3	
4		4		4	
5		5		5	
6		6		6	

SECTION F PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS

Common or usual name or classification

Image Processing System (PACS)

	Trade or Proprietary or Model Name for This Device		Model Number
1	TigerView Professional	1	
2		2	
3		3	
4		4	
5		5	

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

1 K955237	2	3	4	5	6
7	8	9	10	11	12

Data Included in Submission

☒ Laboratory Testing ☐ Animal Trials ☐ Human Trials

SECTION G PRODUCT CLASSIFICATION - APPLICATION TO ALL APPLICATIONS

Product Code	C.F.R. Section *(if applicable)*	Device Class
LLZ	21 CFR 892.2050	☐ Class I ☒ Class II
Classification Panel Radiology		☐ Class III ☐ Unclassified

Indications *(from labeling)*

TigerView Professional is a clinical software application that receives images and data from various imaging sources (e.g., radiographic devices, digital video capture devices, and generic image devices such as scanners). In addition, TigerView Professional enables the storage of clinical notes, audio cordings, and clinical exam data.

It is intended to acquire, display, edit (e.g., resize, adjust contrast, crop, annotate, etc.), review, store, print, and distribute images using standard PC hardware.

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

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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: 2954358	☒ Manufacturer ☐ Contract Manufacturer ☐ Contract Sterilizer ☐ Repackager / Relabeler	
Company / Institution Name: Televere Systems		Establishment Registration Number: 2954358	
Division Name *(if applicable)*		Phone Number *(including area code)*: (408) 778-1700	
Street Address: 16275 South Monterey Road, Suite K		FAX Number *(including area code)*: (408) 778-1733	
City: Morgan Hill	State / Province: CA	ZIP/Postal Code: 95037	Country: USA
Contact Name: Mr. Randell Quaal	Contact Title: General Manager	Contact E-mail Address: rquaal@tigerview.com	

☐ Original ☐ Add ☐ Delete	FDA Establishment Registration Number	☐ Manufacturer ☐ Contract Manufacturer ☐ Contract Sterilizer ☐ 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/Postal Code	Country
Contact Name	Contact Title	Contact E-mail Address	

☐ Original ☐ Add ☐ Delete	FDA Establishment Registration Number	☐ Manufacturer ☐ Contract Manufacturer ☐ Contract Sterilizer ☐ 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/Postal 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

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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	NEMA PS 3.1 – 3.18	National Electrical Manufacturers Association (NEMA)	Digital Imaging and Communications in Medicine (DICOM)		2000
	Standards No.	Standards Organization	Standards Title	Version	Date
2					
	Standards No.	Standards Organization	Standards Title	Version	Date
3					
	Standards No.	Standards Organization	Standards Title	Version	Date
4					
	Standards No.	Standards Organization	Standards Title	Version	Date
5					
	Standards No.	Standards Organization	Standards Title	Version	Date
6					
	Standards No.	Standards Organization	Standards Title	Version	Date
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

An 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

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Televere Systems, LLC
16275 South Monterey Road, Suite K
Morgan Hill, CA 95037
☎: 800.385.9593 Fax: 408.778.1733

April 14, 2006

Document Mail Center (HFZ-401)
Center for Devices and Radiological Health
U.S. Food and Drug Administration
9200 Corporate Blvd.
Rockville, MD 20850

RE: 510(k) Notification for TigerView Professional

Dear Document Control Clerk:

In accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act and in conformance with 21 CFR 807, two copies of this 510(k) Notification are being submitted at least 90 days prior to the date when Televere Systems proposes to introduce this product into interstate commerce for commercial distribution. The proposed product is a modification (an expansion of the indications for use) of the TigerScan/TigerView product which was developed by Tau Corporation, a company purchased by Televere Systems.

The following information is being submitted in conformance with 21 CFR 807.87:

1. Classification Name: System, Image Processing, Radiological

   Common/Usual Name: Picture Archiving and Communications System

   Trade/Proprietary Name: TigerView Professional

2. The registration number for Televere Systems is 2954358.

3. Picture archiving and communications systems have been classified as Class II (special controls) devices under 21 CFR 892.2050. Panel designation for similar devices is under Radiology, with Product Classification Code: LLZ.

4. No mandatory performance standards under Section 514 have been developed by FDA for picture archiving and communications systems.

5. Proposed labeling for TigerView Professional is described in Section 13.

6. The TigerView Professional is substantially equivalent to other marketed devices previously cleared under Section 510(k). These include:

Manufacturer	**Product Name**	**510(k) No.**
EagleSoft	EagleSoft ChairSide Software Application	K982422
Tau Corp.	TigerScan/TigerView	K955237

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

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The enclosed sections contain the following information for your review:

Section 1.0	Medical Device User Fee Cover Sheet (Form FDA 3601)
Section 2.0	CDRH Premarket Review Submission Cover Sheet
Section 3.0	510(k) Cover Letter
Section 4.0	Indications for Use Statement
Section 5.0	510(k) Summary
Section 6.0	Truthful and Accuracy Statement
Section 7.0	Class III Summary and Certification
Section 8.0	Financial Certification or Disclosure Statement
Section 9.0	Declarations of Conformity and Summary Reports
Section 10.0	Executive Summary
Section 11.0	Device Description
Section 12.0	Substantial Equivalence Discussion
Section 13.0	Proposed Labeling
Section 14.0	Sterilization and Shelf Life
Section 15.0	Biocompatibility
Section 16.0	Software
Section 17.0	Electromagnetic Compatibility and Electrical Safety
Section 18.0	Performance Testing—Bench
Section 19.0	Performance Testing—Animal
Section 20.0	Performance Testing—Clinical

Should you have any questions or require further information, please feel free to contact our authorized regulatory consultant, Bio-Reg Associates, Inc. at 6304 Belmont Circle, Bldg 2, Mount Airy, MD 21771. The telephone number is (301) 829-2468. Please ask for Ms. Melissa Mahall. In addition, please provide a copy of any official correspondence to Bio-Reg Associates.

Sincerely,

Randell Quaal
General Manager

Enclosures

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

Records processed under FOIA Request # 2015-8521; Released by CDRH on 05-10-2016

INDICATIONS FOR USE

510(k) Number (if known): _____

Device Name: TigerView Professional

Sponsor Name: Televere Systems

Indications for Use:

TigerView Professional is a clinical software application that receives images and data from various imaging sources (e.g., radiographic devices, digital video capture devices, and generic image devices such as scanners). In addition, TigerView Professional enables the storage of clinical notes, audio recordings, and clinical exam data.

It is intended to acquire, display, edit (e.g., resize, adjust contrast, crop, annotate, etc.), review, store, print, and distribute images using standard PC hardware.

Prescription Use ☒ (21 CFR 801 Subpart D) And/Or Over-The-Counter Use ☐ (21 CFR 807 Subpart C)

Do Not Write Below This Line – Continue on Another Page if Needed

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

Records processed under FOIA Request # 2015-8521; Released by CDRH on 05-10-2016

510(k) SUMMARY

General Information

Submitted by: Televere Systems
16275 South Monterey Road, Suite K
Morgan Hill, CA 95037

Phone: 408.778.1700
Fax: 408.778.1733

Contact Person: Mr. Randell Quaal
16275 South Monterey Road, Suite K
Morgan Hill, CA 95037

Phone: 408.778.1700
Fax: 408.778.1733
Email: rquaal@tigerview.com

Date Prepared: April 14, 2006

Device Name

Trade Name: TigerView Professional
Common Name: Picture archiving and communications system
Classification Name: System, Image Processing, Radiological, 21 CFR 892.2050

Predicate Device

Manufacturer	Product Name	510(k) No.
EagleSoft, A Patterson Co.	EagleSoft ChairSide Software Application	K982422
Tau Corp.	TigerScan/TigerView	K955237

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

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Device Description

TigerView Professional is an image management system that allows the physician to acquire, display, edit (e.g., resize, adjust contrast, crop, etc.), review, store, print, and distribute medical images within a Picture Archiving and Communication System (PACS) environment. TigerView Professional runs on standard PC-compatible computers and is compatible with capture devices which attach to the computer using a Network Adaptor, USB port, PCI slot, parallel port, memory card, S-video port on a video capture card, or SCSI card.

Intended Use

TigerView Professional is a clinical software application that receives images and data from various imaging sources (e.g., radiographic devices, digital video capture devices, and generic image devices such as scanners). In addition, TigerView Professional enables the storage of clinical notes, audio recordings, and clinical exam data.

It is intended to acquire, display, edit (e.g., resize, adjust contrast, crop, annotate, etc.), review, store, print, and distribute images using standard PC hardware.

Technological Comparison

TigerView Professional, TigerScan/TigerView, and EagleSoft ChairSide are each software applications that have similar indications for use and overall function and perform in a similar manner with respect to image processing systems (i.e. PACS).

Testing

TigerView Professional has been demonstrated to perform as intended.

Conclusions

TigerView Professional is substantially equivalent to legally marketed Image Processing Systems (i.e. PACS).

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

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Televere Systems, LLC
16275 South Monterey Road, Suite K
Morgan Hill, CA 95037
☎: 800.385.9593 Fax: 408.778.1733

PREMARKET NOTIFICATION

TRUTHFUL AND ACCURATE STATEMENT

[As Required by 21 CFR 807.87(k)]

I certify that as a responsible representative of Televere Systems, I believe, to the best of my knowledge and understanding, that all data and information submitted in this premarket notification are truthful and accurate and that no material fact has been omitted.

Randell Quaal
General Manager

Televere Systems

April 14, 2006

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

Records processed under FOIA Request # 2015-8521; Released by CDRH on 05-10-2016

PREMARKET NOTIFICATION

CLASS III SUMMARY AND CERTIFICATION

This section does not apply as the proposed device is classified as Class II (special controls) under 21 CFR 892.2050.

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

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PREMARKET NOTIFICATION

FINANCIAL CERTIFICATION OR DISCLOSURE STATEMENT

This section does not apply as no clinical studies were necessary to support this 510(k) submission.

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

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PREMARKET NOTIFICATION

DECLARATIONS OF CONFORMITY AND SUMMARY REPORTS

This section does not apply since declaration of conformances to recognized standards are not being provided.

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

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EXECUTIVE SUMMARY

1.1 Device Description

TigerView Professional is an image management system that allows the physician to acquire, display, edit (e.g., resize, adjust contrast, crop, etc.), review, store, print, and distribute medical images within a Picture Archiving and Communication System (PACS) environment. TigerView Professional utilizes the same programming routines to capture the images as the original version of TigerView (K955237). The minimum computer requirements for the TigerView Professional software application are as follows:

Computer Platform	Hardware Specifications/Requirements
Computer Workstation	Operating System: Windows 2000 SP 4 or later, Windows XP Professional SP 1A or later CPU: 2 GHz Pentium class or higher RAM: 256MB or higher CD-ROM Drive: 4x speed or higher, 1 writer per network recommended but not required Hard Drive: 100MB or more of free space for the program Monitor: 1024x786 setting minimum Floppy Drive: 1 per network Motherboards should avoid SIS USB ports
Computer Printer	720dpi or higher inkjet or photo printer, laserjets can be used but are not recommended
Computer Network	Not required. If there is one it should be a Client/Server topology. Microsoft or Novell. Network, speed: 100mbps or faster.
Computer Network Server	Hard Drive: 80GB or more free space for the image database

TigerView Professional is compatible with capture devices which attach to the computer using a Network Adaptor, USB port, PCI slot, parallel port, memory card, S-video port on a video capture card, or SCSI card. Examples of capture devices which are compatible are the Strato from Owandy, EVA Sensor from Dent-X, EHD Sensor from Gendex, Orthoralix DDE from Gendex, ScanX from Air Techniques, and Pan/Ceph ProMax and ProLine models from Planmeca.

TigerView Professional is comprised of four (4) main tabs: Patients and Images, Acquire, Mount, and Print and Send. Additionally, there is an Image Viewer Window and an Export Image function.

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

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TigerView Professional includes functionality to compress images called Adaptive Image Processing (AIP), as well as software logic called Dynamic Exposure Monitoring System (DEMS) to aid in the acquisition of high quality images.

Further description of the windows and additional software functionality is as follows:

Patients and Images

Patients and Images is comprised of two sub windows: the Patients tab window and the Images tab window.

- Patients Tab
  The Patients tab window is divided into two sections: the Patients area, where patient data is added, selected, deleted, and/or edited, and a Search Criteria area, which is used to locate specific images or groups of images for the patient.

- Image Tab
  To display an image for a patient, the user must click on the Images tab. Images in the Image tab are displayed based on their age, i.e., the newest image will be displayed first. Images can be deleted, exported, or opened in the Image Viewer for viewing and manipulation, taken to the Mount window for viewing and mounting, or taken to Print and Send to be placed in a report and printed or emailed.

Acquire

Images are entered into TigerView through the Acquire Window. The input methods consist of X-rays, Video, (digital) Photos, Documents or images acquired by flatbed scanner, and digital images acquired through Import.

- X-ray
  Various X-ray devices (e.g., ScanX Scanner, flatbed scanner, EVA Sensor, Gendex Scanner, Sensor or Pan Devices, Optime Scanner, Owandy Strato Pan Device, Veraviewepocs Pan Device, and Planmeca Pan, Ceph and Sensor Devices) are compatible with the TigerView Software. Associated with X-Ray acquisition are a number of functions, some specific to the attached hardware device.

  The optional scan settings for the attached hardware device are displayed in windows. The following is an overall list of options available to the user to fine-tune the images, not every option is available for each hardware device.

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- Adaptive Image Processing (AIP)
- Advanced Settings
- Allow Scan Edit
- Auto Flip
- Auto-Optimize
- Auto-Segment
- Brightness
- Contrast
- DEMS
- Extra-oral Settings
- Film Mask
- Film Types
- Gamma
- Invert
- Median Filter
- Plate Types
- Prompt for Date
- Reset
- Resolution
- Retrieve Last Image
- Scan Settings
- Sensor Image Orientation
- Show Image Preview/Dental Chart
- Show Preview
- Timeout Value

- Video

  Video clips and still pictures from video camera devices are acquired in the Video tab window. Video options include the specific video camera device from which to capture images, input types, size options, a still picture versus movie clip setting, and the option to change device-specific video camera settings.

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- Photos
  Photographs acquired through the use of TWAIN compatible devices - typically flatbed scanners or certain digital cameras - are acquired in the Photos tab window. Photo options include selecting the appropriate TWAIN device matching the connected hardware, the image color settings, the image size, and the image resolution. Scanned photographs have the option of being stored with a date specified by the user. The acquired images may also be auto-mounted in available mounting styles.

- Documents
  Documents, forms, and letters acquired through the use of TWAIN compatible devices - typically flatbed scanners - are acquired in the Documents tab window. Document options include selecting the appropriate TWAIN device matching the connected hardware, the color settings for the scan, the page size, and image resolution. Scanned documents have the option of being stored with a date specified by the user.

- Import
  Digital images, documents and videos may be acquired through the import of various file types in the Import tab window. The user specifies the location of the image, document, or video file to import, and then the selected files are imported. The imported image, document and video files may be saved, single or multiple imported image, document and video files may be deleted, an image or document file may be opened using the Image Viewer or Viewer windows, a video file may be played, the image file may be mounted, and the image or document file may be included in a report or email.

Mount

The Mount function allows multiple images to be grouped together in a user specified arrangement similar to placing pictures on a cardboard mat that has multiple openings. Mounted images are viewed, emailed, exported, or otherwise manipulated together as one image. The user may create new mounts or edit existing mounts, including mounts used for auto-mounting, a function which automatically places newly acquired images into an existing mount.

Print & Send

Customizable or predefined reporting of images, graphics, text, and other data is performed in the Print & Send window. Completed reports may be printed or emailed. A number of functions are available to support these reporting activities:

- Change the size of the report on-screen between normal and print-preview size

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- Bring images to the Print & Send window by clicking on the images then clicking on the Print & Send tab
- Place images on the report
- Place free form comments on a report at run time
- Print the report
- Send a report via email
- Choose from existing reports to print or email
- Create a new report
- Edit an existing report
- Delete an existing report

Image Viewer

The Image Viewer may be used to examine, manipulate, and perform measurements on an image. Various tools are available to the user in the Image Viewer:

- Pan Box
- Zoom
- Annotation Mode
- Measurement
- Line Profile
- Magnifying Glass
- Rotation
- Flip
- Restore Orientation
- Colorize
- Emboss
- Black to White
- Print Image
- Brightness and Contrast
- Color Slide
- Hue Slide
- Gamma Slide Bar
- Sharpness Slide Bar
- Reset

Viewer

The Viewer may be used to examine, manipulate, and perform measurements on an image. The Viewer provides advanced image manipulation tools and has the capability of manipulating multiple images at once. Various tools are available to the user in the Viewer:

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- Zoom
- Full Screen
- Reset Zoom
- Rotation
- Flip
- Reset Orientation
- Automatically Arrange Panes
- Manually Arrange Panes
- Measure
- Annotate
- Magnifying Glass
- Crop
- Density Profile
- Stitch Images Together
- Print Image
- Negate
- Colorize Image
- Pseudo 3D
- Sharpen Image Edges
- Reset Original Image
- Sharpness Slide Bar
- Remove From Viewer
- Brightness and Contrast
- Window Leveling

Adaptive Image Processing

Adaptive Image Processing (AIP) is used to compress acquired images to a smaller file size for faster display and reduced space requirements. For x-ray images, this algorithm also takes into account the medical use of the image and removes unnecessary information to further reduce the size of the image. For example, TigerView removes image information relating to the cheek in front of the teeth being x-rayed, when AIP is turned on.

Dynamic Exposure Monitoring System (DEMS)

Dynamic Exposure Monitoring System is an aid to the user in quickly identifying images that are of potentially lower quality than what the particular hardware is capable of acquiring. DEMS provides a green, yellow, or red light to indicate the amount of data available in the image to render the object being imaged. The amount of data (measured in terms of bits acquired from the hardware device)

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required to meet the criteria for determining these status colors is specific to each hardware device supported by TigerView based on input from the hardware device manufacturer and testing. Should the image data obtained from a device contain fewer bits of information than desired for a quality image, the software prompts the user to retry image acquisition. Each hardware device has threshold bit levels set by default on installation. In any case, the user decides to either accept the image or change the imaging hardware settings and reacquire.

1.2 Indications for Use

TigerView Professional is a clinical software application that receives images and data from various imaging sources (e.g., radiographic devices, digital video capture devices, and generic image devices such as scanners). In addition, TigerView Professional enables the storage of clinical notes, audio recordings, and clinical exam data.

It is intended to acquire, display, edit (e.g., resize, adjust contrast, crop, annotate, etc.), review, store, print, and distribute images using standard PC hardware.

1.3 Technological Comparison

TigerView Professional is substantially equivalent to the EagleSoft ChairSide Software Application (K982422) and TigerScan/TigerView (K955237). TigerView Professional, TigerScan/TigerView, and EagleSoft ChairSide are each software applications that have similar indications for use and overall function and perform in a similar manner with respect to image processing systems (i.e. PACS). TigerView Professional is compatible with similar types of hardware devices (e.g. scanners, digital sensors, digital cameras, digital video camera, etc.) and has similar options for displaying, editing, and printing/sending images as the predicate devices.

A comparison of the features and performance of these devices is provided in the following table.

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

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Parameters	TigerView Professional Televere Systems (modified device)	TigerScan/TigerView Tau Corp. K955237	EagleSoft ChairSide Software Application EagleSoft, A Patterson Co. K982422
Patient/Image Management	Yes	Yes	Yes
Acquire Images			
X-Ray	Yes	Yes	Yes
Video	Yes	No	Yes
Photos	Yes	No	Yes
Documents	Yes	No	Yes
Import	Yes	Yes	Yes
Display Images	Yes	Yes	Yes
Save/Store Images	Yes	Yes	Yes
Print/Send/Export Images	Yes	Yes	Yes
Enhance Images	Yes	Yes	Yes

1.4 Performance Testing

(b)(4)

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

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INDICATIONS FOR USE AND DEVICE DESCRIPTION

11.1 Indications for Use

TigerView Professional is a clinical software application that receives images and data from various imaging sources (e.g., radiographic devices, digital video capture devices, and generic image devices such as scanners). In addition, TigerView Professional enables the storage of clinical notes, audio recordings, and clinical exam data.

It is intended to acquire, display, edit (e.g., resize, adjust contrast, crop, annotate, etc.), review, store, print, and distribute images using standard PC hardware.

11.2 Device Description

TigerView Professional is an image management system that allows the physician to acquire, display, edit (e.g., resize, adjust contrast, crop, etc.), review, store, print, and distribute medical images within a Picture Archiving and Communication System (PACS) environment. TigerView Professional utilizes the same programming routines to capture the images as the original version of TigerView (K955237). The minimum computer requirements for the TigerView Professional software application are as follows:

Computer Platform	Hardware Specifications/Requirements
Computer Workstation	Operating System: Windows 2000 SP 4 or later, Windows XP Professional SP 1A or later CPU: 2 GHz Pentium class or higher RAM: 256MB or higher CD-ROM Drive: 4x speed or higher, 1 writer per network recommended but not required Hard Drive: 100MB or more of free space for the program Monitor: 1024x786 setting minimum Floppy Drive: 1 per network Motherboards should avoid SIS USB ports
Computer Printer	720dpi or higher inkjet or photo printer, laserjets can be used but are not recommended
Computer Network	Not required. If there is one it should be a Client/Server topology. Microsoft or Novell. Network, speed: 100mbps or faster.
Computer Network Server	Hard Drive: 80GB or more free space for the image database

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

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TigerView Professional is compatible with capture devices which attach to the computer using a Network Adaptor, USB port, PCI slot, parallel port, memory card, S-video port on a video capture card, or SCSI card. Examples of capture devices which are compatible are provided in the table below.

Devices that attach to the computer in the following manner:	**Device Examples**
Network Adaptor	Strato from Owandy
USB Port	MPSe Sensor from Progeny
	EVA Sensor from Dent-X
	EHD Sensor from Gendex GX Sensor from Gendex DenOptix from Gendex DenOptix QST from Gendex
	Dixi 3 Sensor from Planmeca Pan/Ceph ProMax and ProLine models from Planmeca
	Strato from Owandy
	ScanX from Air Techniques Acclaim Intra-oral camera from Air Techniques
	Einstein Intra-oral camera from RF System Lab
	M305 digital camera from HP
PCI Slot	Orthoralix DDE from Gendex Orthoralix DPI from Gendex
	Dixi 3 Sensor from Planmeca Pan/Ceph ProMax and ProLine models from Planmeca
Parallel Port	ScanX from Air Techniques
Memory Card	Strato from Owandy
S-video port on a video capture card	Pan/Ceph ProMax and ProLine models from Planmeca
	Acclaim Intra-oral camera from Air Techniques
	Various digital microscopes

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

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Devices that attach to the computer in the following manner:	Device Examples
SCSI Card	Perfection 4870 Photo Scanner from Epson Expression 1680 Pro Scanner from Epson ScanMaker 9800XL Scanner from Microtek

TigerView Professional is comprised of four (4) main tabs: Patients and Images, Acquire, Mount, and Print and Send. Additionally, there is an Image Viewer Window and an Export Image function.

TigerView Professional includes functionality to compress images called Adaptive Image Processing (AIP), as well as software logic called Dynamic Exposure Monitoring System (DEMS) to aid in the acquisition of high quality images.

Further description of the windows and additional software functionality is as follows:

11.2.1 Patients and Images

Patients and Images is comprised of two sub windows: the Patients tab window and the Images tab window.

Patients Tab
The Patients tab window is divided into two sections: the Patients area, where patient data is added, selected, deleted, and/or edited, and a Search Criteria area, which is used to locate specific images or groups of images for the patient.

Image Tab
To display an image for a patient, the user must click on the Images tab. Images in the Image tab are displayed based on their age, i.e., the newest image will be displayed first. Images can be deleted, exported, or opened in the Image Viewer for viewing and manipulation, dragged to the Mount window for viewing and mounting, or taken to Print and Send to be placed in a report, printed, or emailed.

Additionally, by right clicking on a specific image, the user will be able to play a video, view an image, copy an image, archive images, email images, export images, print a report, attach a patient's photo, view a diagram of the anatomical region, add/delete annotations, add/delete audio

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notes, add/delete keywords, add/delete procedures, flip the image, rotate the image, and/or add/delete special effects to the image. Some of these features will only work if the user's computer is equipped with the hardware to accommodate the feature. For example, the user would be unable to utilize the audio notes feature if his/her computer did not have a microphone installed.

To export an image file, the user will select either DICOM or Standard (jpeg, bitmap and Tiff image files formats plus the AVI (Audit Video Interleave) video format). The DICOM image files may be saved to a Hard Drive, Memory Stick, CD or DVD, or a DICOM server. The Standard image files may be saved to a Hard Disk, Memory Stick, CD or DVD. The user also has the option to include a copy of the TigerQuickView program, which provides a way to view the image files using only the Zoom In/Out capability.

11.2.2 Acquire

Images are entered into TigerView through the Acquire Window. The input methods consist of X-rays, Video, (digital) Photos, Documents or images acquired by flatbed scanner, and digital images acquired through Import. These methods are displayed on tabs in the Acquire Window.

11.2.2.1 X-Ray

Various X-ray devices (e.g., ScanX Scanner, flatbed scanner, EVA Sensor, Gendex Scanner, Sensor or Pan Devices, Optime Scanner, Owandy Strato Pan Device, Veraviewepocs Pan Device, and Planmeca Pan, Ceph and Sensor Devices) are compatible with the TigerView Software. Associated with X-Ray acquisition are a number of functions, some specific to the attached hardware device.

Settings
The optional scan settings for the attached hardware device are displayed in windows. The following is an overall list of options available to the user to fine-tune the images, not every option is available for each hardware device.

- Adaptive Image Processing (AIP)
  When enabled, AIP is used to compress acquired images to a smaller file size for faster display and reduced space requirements. See section 11.2.7 for more detail.

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- Advanced Settings
  Displays advanced settings for Gendex devices only.

- Allow Scan Edit
  When enabled, this option permits the user to draw boxes around images, or edit the boxes TigerView draws automatically if Auto-Segment is enabled. This option is only available for flatbed scanners.

- Auto-Flip
  When an image is Auto Flipped the view is as though sitting on the other side of the item being x-rayed looking at the x-ray head.

- Auto-Optimize
  See Adaptive Image Processing (AIP). This option is only available for flatbed scanners.

- Auto-Segment
  When enabled, TigerView attempts to recognize separate items on a flatbed scanner as separate images. When scanning standard size negatives, for example, a green box is placed around each negative indicating that the area within the box is recognized as a separate image. A blue box is placed around an image that is not recognized as a standard size negative but is recognized as a separate image to scan.

- Brightness
  Raises or lowers the lightness for every pixel in the image.

- Contrast
  Makes white areas whiter and the black areas blacker, with the effect of making details more noticeable in the image.

- DEMS
  Allows specification of threshold values for the Dynamic Exposure Monitoring System. See section 11.2.8 for more detail.

- Extra-oral Settings
  Extra-oral settings include Film Mask, Noise Reduction, Auto-Flip, Invert, AIP, Brightness, Contrast, and Gamma settings, similar to Intra-oral settings.

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- Film Mask
  A Film Mask is a black border around the image similar to a mat around a photograph. The border can make the edges of the image appear sharper.

- Film Types
  This option lists each size of intra-oral film and the option to scan it vertically or horizontally. Image orientation may be changed later by the user.

- Gamma
  Raises or lowers the lightness of the mid-range grayscale values without changing the whitest or blackest values.

- Invert
  Inverting an image causes the white areas to become black and the black areas to become white.

- Median Filter
  When disabled, the image will have a more "salt and pepper" look, but the edges of the image will appear more defined.

  When enabled, the "salt and pepper" look will not be as apparent, but the edges of the images will appear not as defined.

- Plate Types
  This option lists each size of intra-oral plate and the option to scan it vertically or horizontally. Image orientation may be changed later by the user.

- Prompt for Date
  If enabled, the user is prompted to identify a date to be associated with the image. If disabled, TigerView uses the date of image acquisition.

- Reset
  Restores the default settings that came with TigerView.

- Resolution
  Allows selection of High or Super High resolution, for Optime scanners only.

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- Retrieve Last Image
  A temporary toggle switch to have an Optime scanner display the last image it scanned.

- Scan Settings – ScanX Scanner
  The scan settings allow for standard, high, or very high resolutions. Selecting a high or very high resolution with more line pair per millimeter will result in a greater amount of detail in the resulting image. It will also save a larger digital image requiring more hard drive space. For most x-rays, a standard resolution scan setting is appropriate.

- Sensor Image Orientation
  Allows the selection of vertical or horizontal sensor position for standard or large Gendex sensors only.

- Show Image Preview/Dental Chart
  If enabled, a preview of the image with a dental chart is displayed.

- Show Preview
  Provides a preview of the image acquisition during the scanning process.

- Timeout Value
  Specifies how much time TigerView should wait before the EVA sensor finishes initializing and is ready to receive commands.

Software enabled setting options for the different types of hardware devices vary and examples are provided in the following table:

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Device-Specific Settings	EVA Sensor	Gendex: DenOptix Flatbed Scanner	Gendex: GX Phosphor Plate	Orthoralix DDE/DPI Sensor	Optime Scanner	Owandy Strato Pan	Planmeca: Intra-Oral Sensor	Planmeca: Panoramic/Ceph	ScanX
Adaptive Image Processing (AIP)									✔
Advanced Settings			✔	✔	✔				
Allow Scan Edit		✔							
Auto Flip			✔	✔	✔		✔	✔	✔ ✔
Auto-Optimize		✔							
Auto-Segment		✔							
Brightness	✔	✔	✔	✔	✔		✔	✔	✔ ✔
Contrast	✔	✔	✔	✔	✔		✔	✔	✔ ✔
DEMS	✔	✔	✔	✔	✔		✔	✔	✔ ✔
Extra-oral Settings									✔
Film Mask	✔	✔	✔	✔	✔		✔	✔	✔ ✔
Film Types		✔							
Gamma	✔	✔	✔	✔	✔		✔	✔	✔ ✔
Invert			✔	✔	✔		✔	✔	✔ ✔
Median Filter			✔	✔	✔	✔	✔	✔	✔ ✔
Plate Types			✔						✔
Prompt for Date		✔							
Reset		✔							✔
Resolution						✔			
Retrieve Last Image						✔			
Scan Settings									✔
Sensor Image Orientation	✔			✔				✔	
Show Image Preview/Dental Chart						✔			
Show Preview								✔	✔
Timeout Value	✔								

Auto-Mount

When enabled, the auto-mount function places acquired images into a previously created mount in the order which they are acquired. Alternatively, images may be manually placed in mounts through dragging and dropping the desired images into image placeholders.

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Image Buttons
After images have been acquired, single or multiple images may be selected and then deleted or saved as desired.

Open an Image with the Image Viewer or Viewer
Double-clicking an image displays the image in the Image Viewer or Viewer window. See section 11.2.5 for using the Image Viewer, or section 11.2.6 for using the Viewer.

Mount an Image or Include an Image in a Report
Clicking an image allows the image to be mounted as described in section 11.2.3, or to be printed or sent in email as described in section 11.2.4.

Right-Click Image Menu
Basic image manipulation functionality is available via the right-click image menu, including image flip, rotation, annotation, viewing of properties, addition of keywords and procedures and audio notes, special image effects, copying, archiving, emailing, exporting, and printing.

11.2.2.2 Video

Video clips and still pictures from video camera devices are acquired in the Video tab window. Video options include the specific video camera device from which to capture images, input types, size options, a still picture versus movie clip setting, and the option to change device-specific video camera settings.

Video image acquisition is performed using the Freeze/Record function, which takes into account the acquisition mode of still image or movie clip recording. Video images may be saved, single or multiple images or videos may be deleted, an image may be opened using the Image Viewer or Viewer windows, a video may be played, and an image may be mounted or included in a report or email.

Additionally, basic image manipulation functionality is available via the right-click image menu, including video play back, image flip, rotation, annotation, viewing of properties, addition of keywords, procedures and audio notes, special image effects, copying, archiving, emailing, exporting, and printing.

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11.2.2.3 Photos

Photographs acquired through the use of TWAIN compatible devices - typically flatbed scanners or certain digital cameras - are acquired in the Photos tab window. Photo options include selecting the appropriate TWAIN device matching the connected hardware, the image color settings, the image size, and the image resolution. Scanned photographs have the option of being stored with a date specified by the user. The acquired images may also be auto-mounted in available mounting styles.

Photo image acquisition is performed using the Start function. Recorded images may be saved, single or multiple images may be deleted, an image may be opened using the Image Viewer or Viewer windows, and the image may be mounted or included in a report.

Additionally, basic image manipulation functionality is available via the right-click image menu, including image flip, rotation, annotation, viewing of properties, addition of keywords, procedures and audio notes, special image effects, copying, archiving, emailing, exporting, and printing.

11.2.2.4 Documents

Documents, forms, and letters acquired through the use of TWAIN compatible devices - typically flatbed scanners - are acquired in the Documents tab window. Document options include selecting the appropriate TWAIN device matching the connected hardware, the color settings for the scan, the page size, and image resolution. Scanned documents have the option of being stored with a date specified by the user.

Document acquisition is performed using the Start function. Recorded documents may be saved, single or multiple documents may be deleted, a document may be opened using the Image Viewer or Viewer windows, and the document may be mounted or included in a report.

Additionally, basic image manipulation functionality is available via the right-click image menu, including image flip, rotation, annotation, viewing of properties, addition of keywords, procedures and audio notes, special image effects, copying, archiving, emailing, exporting, and printing.

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11.2.2.5 Import

Digital images, documents and videos may be acquired through the import of various file types in the Import tab window. The user specifies the location of the image, document, or video file to import, and then the selected files are imported. The imported image, document and video files may be saved, single or multiple imported image, document and video files may be deleted, an image or document file may be opened using the Image Viewer or Viewer windows, a video file may be played, the image file may be mounted, and the image or document file may be included in a report or email.

Additionally, basic image manipulation functionality is available via the right-click image menu, including video play back, image flip, rotation, annotation, viewing of properties, addition of keywords, procedures and audio notes, special image effects, copying, archiving, emailing, exporting, and printing.

11.2.3 Mount

The Mount function allows multiple images to be grouped together in a user specified arrangement similar to placing pictures on a cardboard mat that has multiple openings. Mounted images are viewed, emailed, exported, or otherwise manipulated together as one image. The user may create new mounts or edit existing mounts, including mounts used for auto-mounting, a function which automatically places newly acquired images into an existing mount.

Using the right-click menu on an image holder in the mount, the user is able to perform the following functions:

- Automatic assignment of a specific anatomical region to the image that is moved to that mount location
- Automatic assignment of specific keywords to the image that is moved to that mount location
- Image rotation by 90°
- Automatic flip of any image placed in that particular image holder
- Remove the image from the image holder

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Using the right-click menu on an image in an image holder, the user is able to perform the following functions:

- View the image using the Image Viewer
- Extract an image from the mount to the area below the Mount box
- Copy an image to the clipboard
- Annotate the image
- Remove an image from the Mount box

Additionally, basic image manipulation functionality is available via the right-click image menu, including rotation, annotation, viewing of properties, addition of keywords, procedures and audio notes, special image effects, copying, archiving, emailing, exporting, and printing.

11.2.4 Print & Send

Customizable or predefined reporting of images, graphics, text, and other data is performed in the Print & Send window. Completed reports may be printed or emailed. A number of functions are available to support these reporting activities:

- Change the size of the report on-screen between normal and print-preview size
- Bring images to the Print & Send window by clicking on the images then clicking on the Print & Send tab
- Place images on the report
- Place free form comments on a report at run time
- Print the report
- Send a report via email
- Choose from existing reports to print or email
- Create a new report
- Edit an existing report
- Delete an existing report

Creating or editing an existing report requires the following:

- Provide a description of the report
- Specify page orientation: landscape or portrait mode
- Place a text box, containing predefined text fields or user-defined text, on the report
- Place an image box on the report
- Place a graphic box on the report
- Change text fonts
- Save the report

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Sample reports immediately follow this section.

11.2.5 Image Viewer

The Image Viewer may be used to examine, manipulate, and perform measurements on an image. Various tools are available to the user in the Image Viewer:

- Pan Box
  Narrows the view to a particular portion of a zoomed in image.

- Zoom
  Narrows the view to a particular portion of an image that has been enlarged. Zooming in (enlarging) may focus on a specific point or on an area. Zooming out (reducing the image size) may be to a specific point or to the original image size.

- Annotation Mode
  Provides tools with which to add, edit or delete annotations of the image, including text, shapes, lines, arrows, and options to customize each of these including size, font, and color. Annotations may remain on the image and be displayed, be hidden from sight, or be deleted.

- Measurement
  Allows measurement of the distance between points or the angle between lines. Calibration is required before measurements are made. Measurement lines may remain on the image and be displayed, be hidden from sight, or be deleted.

- Line Profile
  Surface deviations shown in an image are observed using the Line Profile tool which displays a histogram of the shades of gray in an image for a specified line.

- Magnifying Glass
  Permits closer visual inspection of a particular region of an image using multiple-sized areas of magnification, different magnification amounts, and the application of effects such as high contrast, inversion, or colorization.

- Rotation
  Allows rotation of the image by 90° left or right, or by 180°.

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- Flip
  Allows flipping of the image, either left-to-right or top-to-bottom.

- Restore Orientation
  Returns the image to the original orientation.

- Colorize
  Substitutes colors for grayscale values in an image. Colors used may be changed to increase contrast.

- Emboss
  Applies a 3-D effect to the image plus the addition of a light source to the image. Customizable options include the location of the light source along with a depth value indicating the difference in grayscale values used for the 3-D effect.

- Black to White
  Converts areas on an image that are black to white, and areas that are white to black.

- Print Image
  Opens the Microsoft Print window in order to print the image in a pre-setup report that includes some patient and office information.

- Brightness and Contrast
  Changes the brightness and contrast levels of the image.

- Color Slide
  Allows conversion of a color image to varying levels of grayscale.

- Hue Slide
  Moves all colors in an image through the color scale.

- Gamma Slide Bar
  Raises or lowers the lightness of the mid-range grayscale values without changing the whitest or blackest values, which are generally edges.

- Sharpness Slide Bar
  Increases contrast on edges in the image, causing the image to appear sharper.

- Reset
  Resets the image to its original state when the Image Viewer was opened.

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11.2.6 Viewer

The Viewer may be used to examine, manipulate, and perform measurements on an image. The Viewer provides advanced image manipulation tools and has the capability of manipulating multiple images at once. Various tools are available to the user in the Viewer:

- Zoom
  Narrows the view to a particular portion of an image that has been enlarged. Zooming in (enlarging) may focus on a specific point or on an area. Zooming out (reducing the image size) may be to a specific point or to the original image size.

- Full Screen
  Fills the Viewer Window with the selected image.

- Reset Zoom
  Resets the image to its original size.

- Rotation
  Allows rotation of the image by 90° left or right, or by 180°.

- Flip
  Allows flipping of the image, either left-to-right or top-to-bottom.

- Reset Orientation
  Returns the image to the original orientation.

- Automatically Arrange Panes
  Places images in the Viewer in the position they occupied originally upon opening the Viewer.

- Manually Arrange Panes
  Allows images to be placed to any position in the Viewer.

- Measure
  Allows measurement of the distance between points or the angle between lines. Calibration is required before measurements are made. Measurement lines may remain on the image and be displayed, be hidden from sight, or be deleted.

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- Annotate
  Provides tools with which to add, edit or delete annotations of the image, including text, shapes, lines, arrows, and options to customize each of these including size, font, and color. Annotations may remain on the image and be displayed, be hidden from sight, or be deleted.

- Magnifying Glass
  Permits closer visual inspection of a particular region of an image using multiple-sized areas and shapes of magnification, different magnification amounts, and the application of effects such as high contrast, inversion, or colorization.

- Crop
  Allows the user to create a new image by copying a portion of an existing image and saving it with the patient data.

- Density Profile
  Surface deviations shown in an image are observed using the Density Profile tool that displays a histogram of the shades of gray in an image for a specified line.

- Stitch Images Together
  Merges two separate images creating a third image with a specified amount of image blending.

- Print Image
  Opens the Microsoft Print window in order to print the image in a pre-setup report that includes some patient and office information.

- Negate
  Converts image areas that are black to white, and areas that are white to black.

- Colorize Image
  Substitutes colors for grayscale values in an image. Colors that are substituted may be changed to increase contrast.

- Pseudo 3D
  Applies a 3-D effect to the image plus the addition of a light source to the image. Customizable options include the location of the light source along with a depth value indicating the difference in grayscale values used for the effect.

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- Sharpen Image Edges
  Increases contrast on edges in the image, causing the image to appear sharper.

- Reset Original Image
  Resets the image to its original state when the Viewer Window was opened.

- Sharpness Slide Bar
  Increases contrast on edges in the image, causing the image to appear sharper.

- Remove From Viewer
  Removes the image from the Viewer but does not delete the image.

- Brightness and Contrast
  Changes the brightness and contrast levels of the image.

- Window Leveling
  Changes the focus of the image to either bone or flesh.

11.2.7 Adaptive Image Processing (AIP)

Adaptive Image Processing (AIP) is used to compress acquired images to a smaller file size for faster display and reduced space requirements. For x-ray images, this algorithm also takes into account the medical use of the image and removes unnecessary information to further reduce the size of the image. For example, TigerView removes image information relating to the cheek in front of the teeth being x-rayed, when AIP is turned on.

On installation, TigerView AIP is turned off, and image data is stored in its entirety without compression in the standard TIFF format. The user has the option to choose a standard compression format, known as lossy JPEG compression, or an alternative format without compression, known as lossless JPEG.

AIP is also available to be used when scanning x-rays with a flatbed scanner. Scanners cannot properly interpret what should be pure white or pure black, since the film being scanned is not completely transparent or opaque in these areas. Auto-Optimize, the flatbed version of AIP, takes the lightest white and makes it pure white, and the darkest black and makes it pure black. It then adjusts the grayscale values of the image to fall between those values, increasing the sharpness of the image and using a full 8-bit grayscale that would otherwise be lost by the scanner.

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11.2.8 Dynamic Exposure Monitoring System (DEMS)

Dynamic Exposure Monitoring System is an aid to the user in quickly identifying images that are of potentially lower quality than what the particular hardware is capable of acquiring. DEMS provides a green, yellow, or red light to indicate the amount of data available in the image to render the object being imaged. The amount of data (measured in terms of bits acquired from the hardware device) required to meet the criteria for determining these status colors is specific to each hardware device supported by TigerView based on input from the hardware device manufacturer and testing. Should the image data obtained from a device contain fewer bits of information than desired for a quality image, the software prompts the user to retry image acquisition. Each hardware device has threshold bit levels set by default on installation, and users are advised not to change these values consulting a TigerView representative.

The DEMS system of indicator lights is not intended to serve as a diagnostic tool, but rather provide a quick visual to the user that an image may need to be retaken. Threshold values affect how many warnings a user may receive upon acquiring an image; higher thresholds will require higher quality images which may prompt the user more often to reacquire. Lower thresholds may not cause the software to prompt the user to acquire a better quality image.

In any case, the user decides to either accept the image or change the imaging hardware settings and reacquire.

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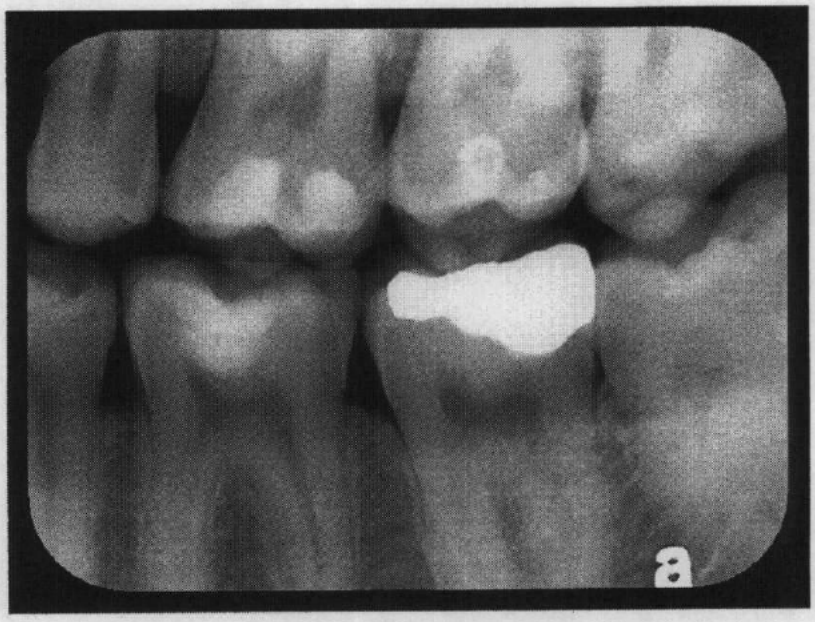
Single Image Letter

(b)(4), (b)(6)



TigerView

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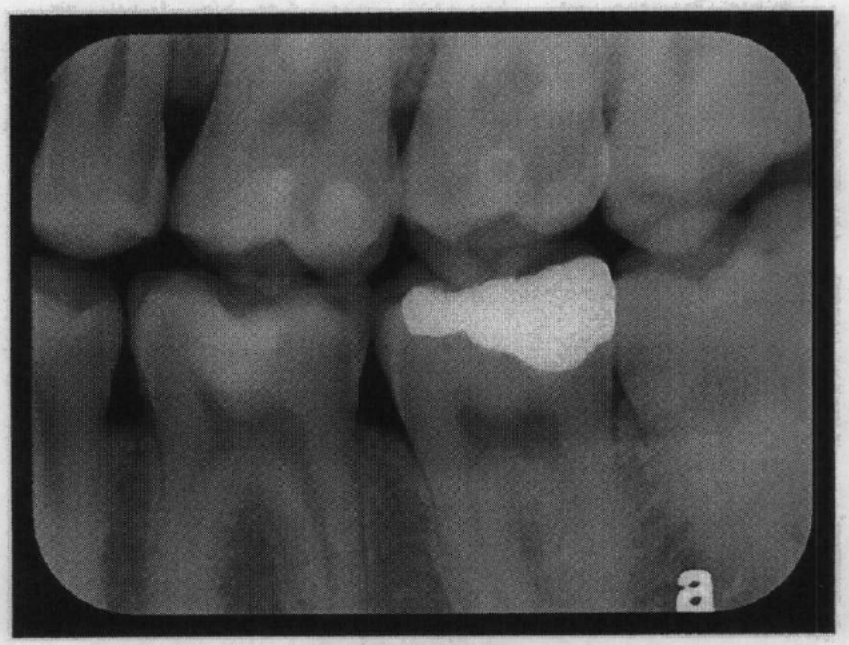
TigerView Professional
Sample Reports

Single Image Report

(b)(4), (b)(6)



TigerView

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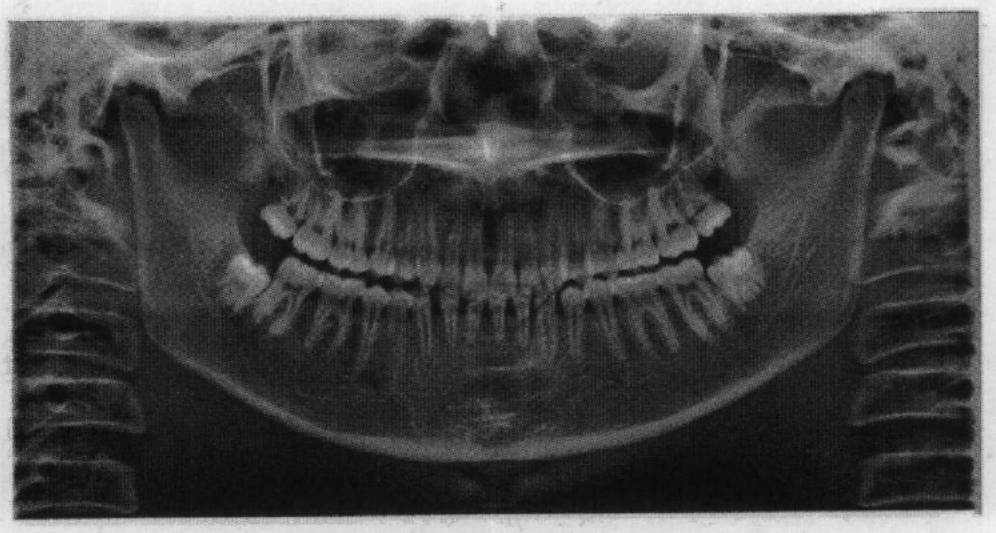
FMX/Pan Report

(b)(4), (b)(6)



TigerView

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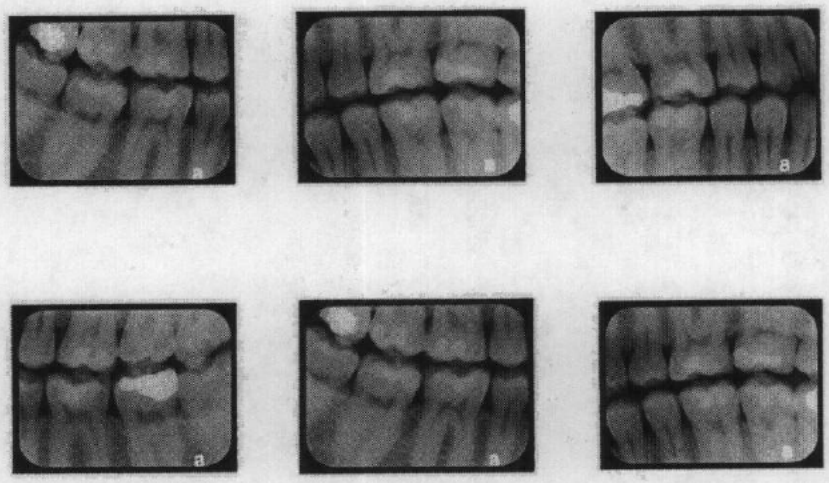
Up to 6 X-ray or Video Images Report

(b)(4), (b)(6)

DOB:
SSN:

Sep 13, 2004



Message from (b)(6)

TigerView

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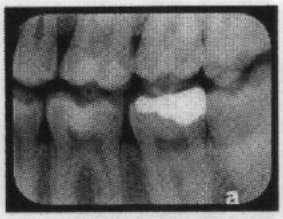
Pre-Op/Post-Op Report

(b)(4), (b)(6)

Patient:
ID #:
DOB:
SSN:

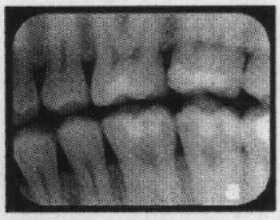
Sep 14, 2004

Pre-Op:



Message:

Post - Op:



Message:

TigerView

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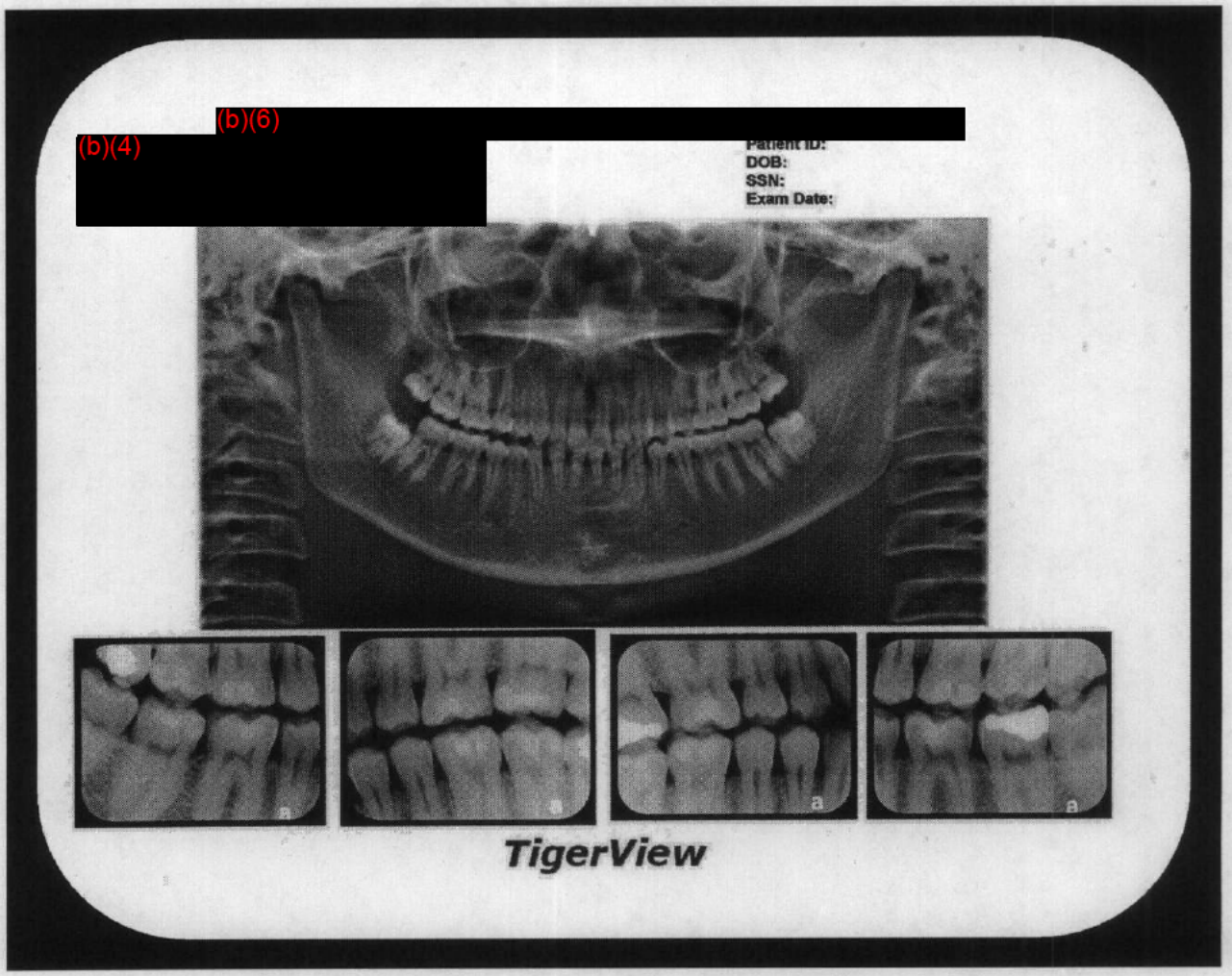
Pan/4 BWX Report



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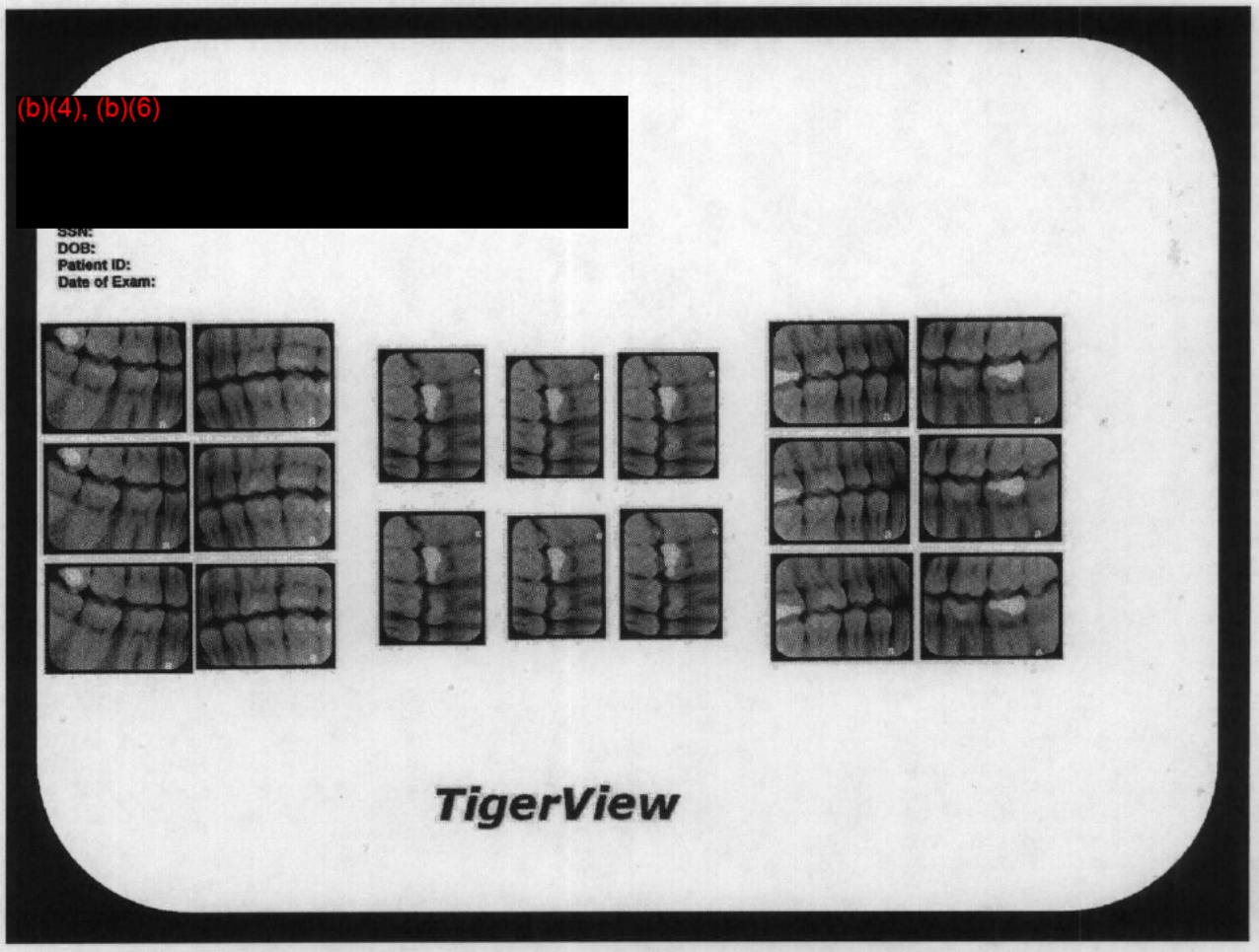
TigerView Professional
Sample Reports

FMX Series



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Preset Report

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SUBSTANTIAL EQUIVALENCE AND PREDICATE COMPARISON

TigerView Professional is substantially equivalent to the following predicate devices:

Manufacturer	Product Name	510(k) No.
EagleSoft, A Patterson Co.	EagleSoft ChairSide Software Application	K982422
Tau Corp.	TigerScan/TigerView	K955237

This conclusion is based on the following aspects:

Indications for Use:

TigerView Professional is a clinical software application that receives images and data from various imaging sources (e.g., radiographic devices, digital video capture devices, and generic image devices such as scanners). In addition, TigerView Professional enables the storage of clinical notes, audio recordings, and clinical exam data.

It is intended to acquire, display, edit (e.g., resize, adjust contrast, crop, annotate, etc.), review, store, print, and distribute images using standard PC hardware.

Technological Comparison:

TigerView Professional, TigerScan/TigerView, and EagleSoft ChairSide are each software applications that have similar indications for use and overall function and perform in a similar manner with respect to image processing systems (i.e. PACS). TigerView Professional is compatible with similar types of hardware devices (e.g. scanners, digital sensors, digital cameras, digital video camera, etc.) and has similar options for displaying, editing, and printing/sending images as the predicate devices.

A more detailed comparison of the features and performance of these devices is provided in the following table.

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Parameters	TigerView Professional Televere Systems (modified device)	TigerScan/TigerView Tau Corp. K955237	EagleSoft ChairSide Software Application EagleSoft, A Patterson Co. K982422
Indications for Use	TigerView Professional is a clinical software application that receives images and data from various imaging sources (e.g., radiographic devices, digital video capture devices, and generic image devices such as scanners). In addition, TigerView Professional enables the storage of clinical notes, audio recordings, and clinical exam data. It is intended to acquire, display, edit (e.g., resize, adjust contrast, crop, annotate, etc.), review, store, print, and distribute images using standard PC hardware.	Uses of TigerScan and TigerView in the dental industry include the following: - Scanning of film and archival storage for on-line access by patient - Electronic transmission of digital radiographs with insurance claims. - Radiograph viewing and manipulation for diagnostic purposes, patient education and consultation, and insurance claims adjudication. - Electronic transmission of radiographs to specialists for consultation.	EagleSoft's ChairSide is a clinical software program that enables dental offices to keep records of hard and soft tissue charts, treatment plans, clinical notes, audio recordings, and clinical exam data. In addition, it also offers an imaging module for image acquisition, editing, and storage of digital images. It is designed to be a single-source solution for a dentist's software needs for clinical and diagnostic use when serving the general public. Images can be acquired from standard dental imaging devices including Digital Radiographic Devices, Digital Video Capture Devices, and Generic Image Devices such as scanners. Non-diagnostic images can then be edited (i.e. resized, contrast, cropped, etc.). Images can also be easily imported and exported.

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Parameters	TigerView Professional Televere Systems (modified device)	TigerScan/TigerView Tau Corp. K955237	EagleSoft ChairSide Software Application EagleSoft, A Patterson Co. K982422
Patient/Image Management	Yes	Yes	Yes
Acquire Images			
X-ray (i.e., Phosphor Storage, Digital Sensor, Digital Panoramic)	Yes	Yes	Yes
Video	Yes	No	Yes
Photos	Yes	No	Yes
Documents	Yes	No	Yes
Import	Yes	Yes	Yes
Display Images	Yes	Yes	Yes
Save/Store Images	Yes	Yes	Yes
Produce Reports	Yes	Yes	Yes
Print/Send/Export Images	Yes	Yes	Yes

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Parameters	TigerView Professional Televere Systems (modified device)	TigerScan/TigerView Tau Corp. K955237	EagleSoft ChairSide Software Application EagleSoft, A Patterson Co. K982422
Enhance Images			
Brightness	Yes	Yes	Yes
Contrast	Yes	Yes	Yes
Colorize	Yes	Yes	Yes
Crop	Yes	Yes	Yes
Rotate	Yes	Yes	Yes
Zoom In/Out	Yes	Yes	Yes
Invert	Yes	Yes	Yes
Sharpen	Yes	Yes	Yes
Measure	Yes	Yes	Yes
Over/Under Exposure	Yes	Yes	Yes
Annotate	Yes	Yes	Yes
Run on standard PC-compatible computers	Yes	Yes	Yes

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PRODUCT LABELING

The labeling for the proposed device, TigerView Professional, follows this page.

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Communicating with Images...

TigerView Professional Manual Dentistry

Medical Imaging Software

Televere Systems – 16275 Monterey Road, Suite K – Morgan Hill, CA 95037
(800) 385-9593

SOLD EXCLUSIVELY THROUGH QUALIFIED DEALERS

TigerView Pro 7.0.3

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Indications for Use

TigerView Professional is a clinical software application that receives images and data from various imaging sources (e.g., radiographic devices, digital video capture devices, and generic image devices such as scanners). In addition, TigerView Professional enables the storage of clinical notes, audio recordings, and clinical exam data.

It is intended to acquire, display, edit (e.g., resize, adjust contrast, crop, annotate, etc.), review, store, print, and distribute images using standard PC hardware.

Caution: Federal law restricts this device to sale by or on the order of a dentist or any other practitioner licensed by the law of the State in which he/she practices to use or order the use of the device.

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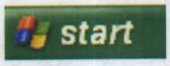
To Open TigerView Pro

On your desktop, double click on the TigerView icon.

Or

On your desktop, click on the Start button 

Go to All Programs

Select TigerView

Then select TigerView again.

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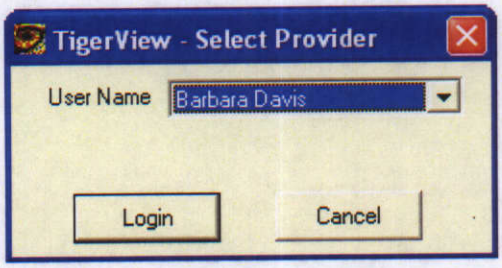
Select a Provider

The first TigerView window that opens is the Select Provider Window.



A provider is a doctor. If the name that displays is the correct provider click on the Login button. Otherwise, click on the User Name down arrow to display a drop down box of other providers that may be selected from. If the necessary provider does not appear in the drop down box, click on the cancel button to exit TigerView then open TigerView Administration and enter a new provider. For instructions on how to use TigerView Administration, please refer to the TigerView Administration manual.

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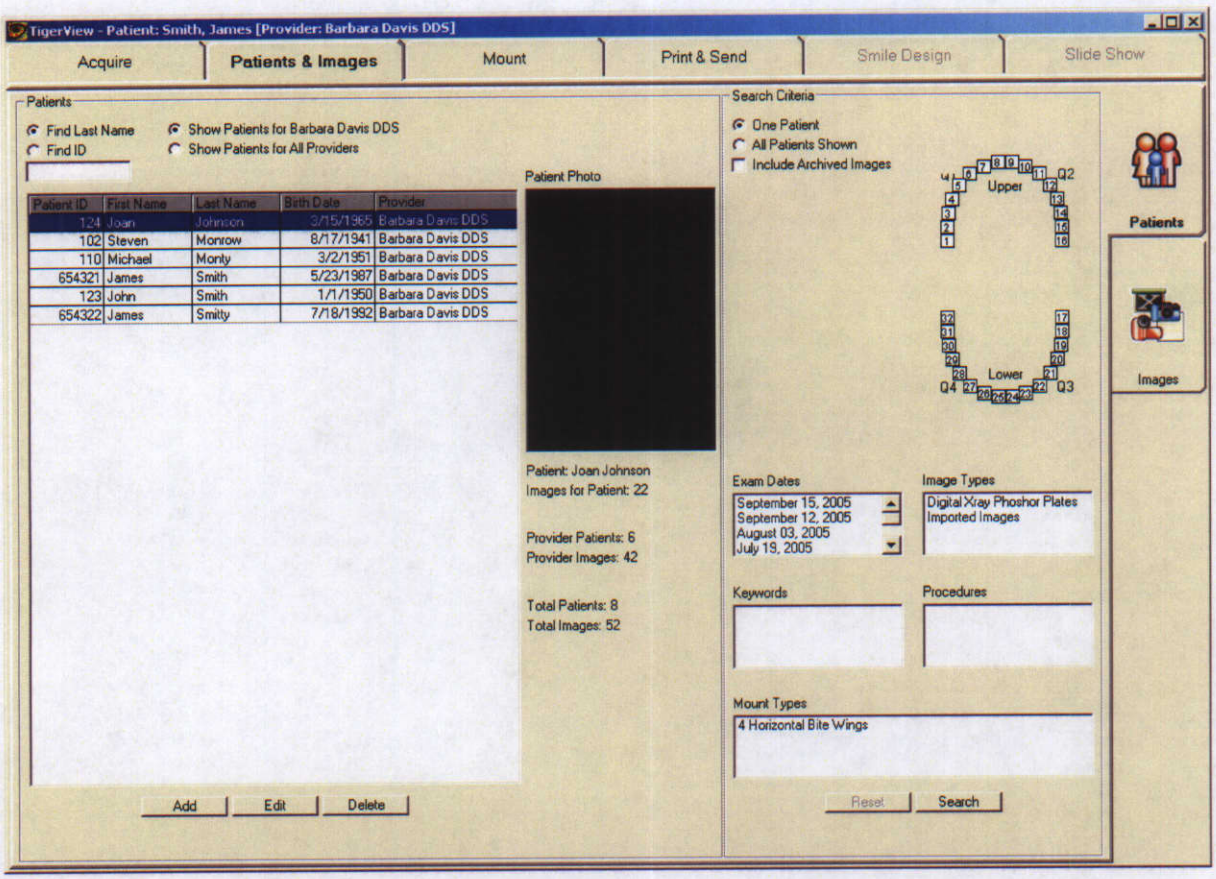
Patients & Images Window



The Patient window is broken up into two sections: a Patient area where a patient is selected, added, deleted, or has his information edited, and a Search Criteria area which is used to locate specific images. On the right side of the Patient window are two tabs: a Patients tab which identifies the window that is currently in view, and an Images tab which identifies the window on which small views (called thumbnails) of the selected patient's images are displayed

Patients Tab - Patients Area

The Patient window initially opens without a patient selected. Notice on the top bar of the window where the provider, TigerView icon, and TigerView name display, the message "No Current Patient" also displays.

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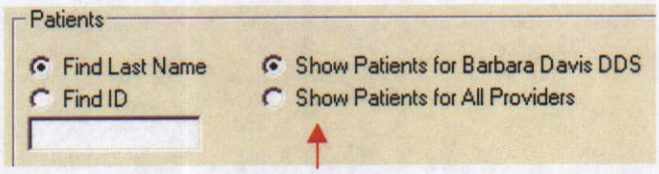
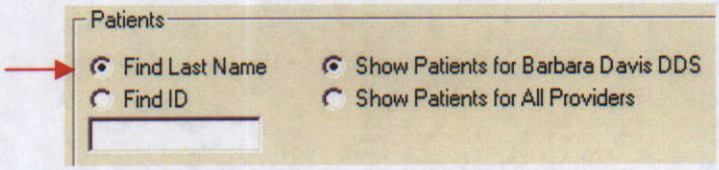
After a patient is selected the patient's name will display here. Always check this area of the screen to make sure that the correct patient is selected before starting an activity in TigerView.

Display Existing Patients

At the top of the Patient area in the Patient window are several selections that will affect how patients will be located in TigerView.



- All of the patients that belong to the currently selected provider can be displayed (note the top bar of this window where the name of the currently selected provider is displayed), or
- All of the patients in TigerView can be displayed.



- Patients can be located by entering their last name into the Find Patient box, or
- Patients can be located by entering their patient ID into the Find Patient box.

Directly beneath the patient selection criteria the patients are listed in alphabetical order by last name.

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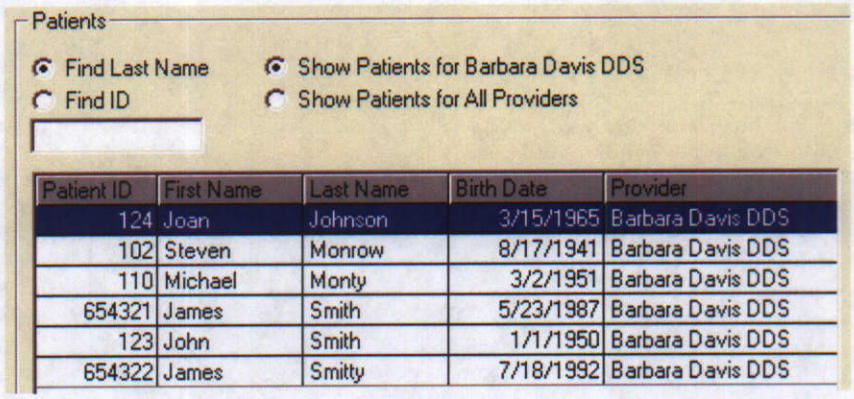
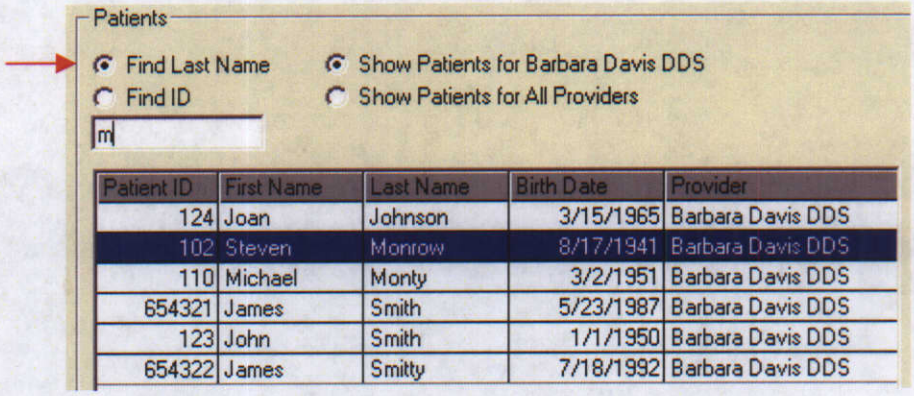


Patient ID	First Name	Last Name	Birth Date	Provider
124	Joan	Johnson	3/15/1965	Barbara Davis DDS
102	Steven	Monrow	8/17/1941	Barbara Davis DDS
110	Michael	Monty	3/2/1951	Barbara Davis DDS
654321	James	Smith	5/23/1987	Barbara Davis DDS
123	John	Smith	1/1/1950	Barbara Davis DDS
654322	James	Smitty	7/18/1992	Barbara Davis DDS

Find a Patient

To the left of the patient selection criteria is the Find Patient box. As the last name of the patient is entered into the box, TigerView will advance through the list of patients, moving to the first patient whose last name displays all of the letters in the Find Patient box.



Patient ID	First Name	Last Name	Birth Date	Provider
124	Joan	Johnson	3/15/1965	Barbara Davis DDS
102	Steven	Monrow	8/17/1941	Barbara Davis DDS
110	Michael	Monty	3/2/1951	Barbara Davis DDS
654321	James	Smith	5/23/1987	Barbara Davis DDS
123	John	Smith	1/1/1950	Barbara Davis DDS
654322	James	Smitty	7/18/1992	Barbara Davis DDS

In the example above, the letter “m” was entered into the Find Patient box and TigerView moved to the first patient whose last name begins with an “m”.

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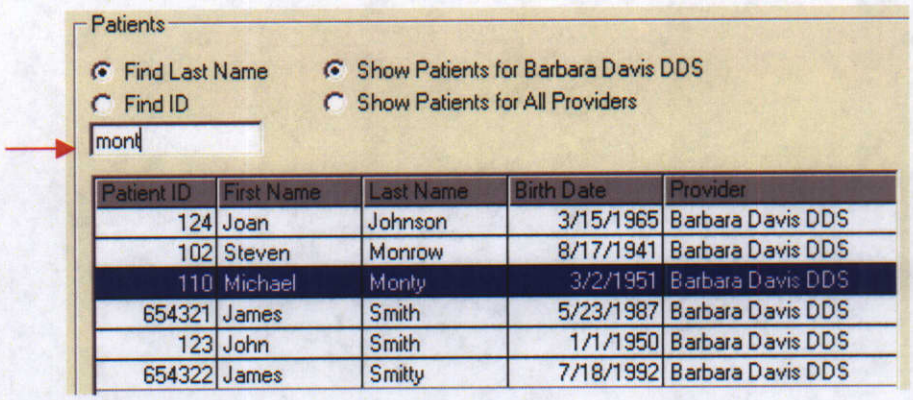
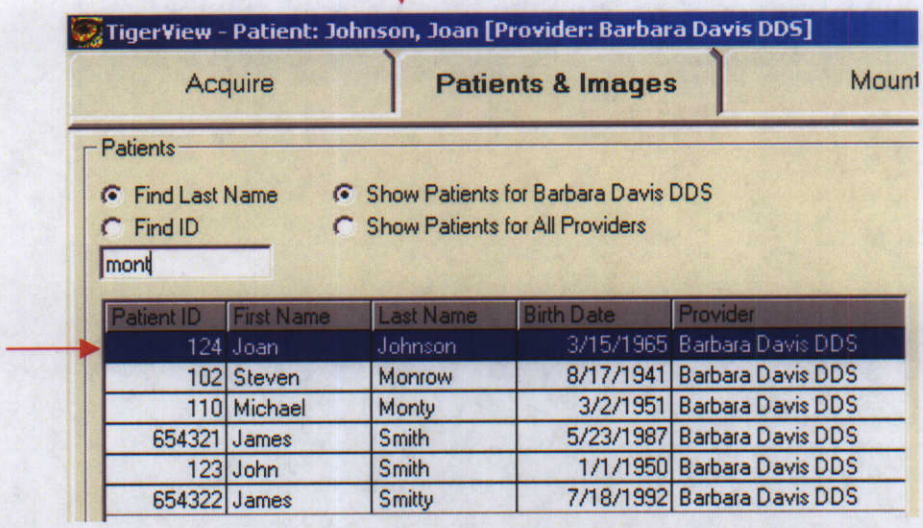


In this second example, the letters "mont" were entered into the Find Patient box. TigerView moved past "Monroe" whose fourth letter is an "r" to "Monty" whose fourth letter is a "t" which matches the Find Patient criteria.

Select a Patient

To select a patient, double click anywhere on the patient's information in the patient list (Patient ID, First Name, Last Name, Date of Birth or Provider). The patient's name will display in the top bar of this window letting you know that the patient has been selected.



Once the patient has been selected, TigerView will move to either the Images tab where this patient's images can be viewed and manipulated, or to a message indicating that this patient's images are not available. If the message is

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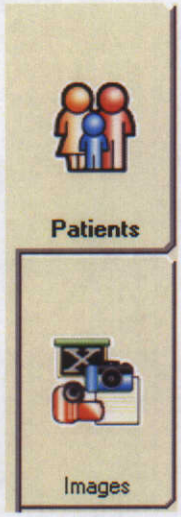
displayed, click on the OK button to close the message window.

If the patient has images in TigerView, the Images window will display instead of the message box above when a patient is selected. To move between the patient's information and the patient's images click on the Patients or Images tabs on the far right side of the TigerView window.



Patient Photo

A picture of the patient can appear in the Patient Photo box on the Patients window. To appear, the picture must be entered into TigerView and designated as the Patient Photo. For instructions on how to designate an image as the Patient Photo see the Images Window, Right Click on an Image, Set Patient Photo section of this manual.

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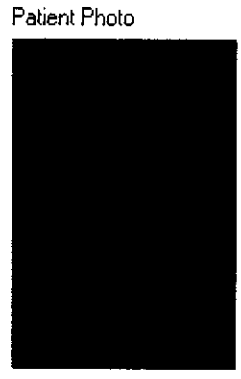


TigerView Totals

Displayed beneath the Patient Photo box are some TigerView totals. The totals include:

- The total number of images the current patient has in TigerView.
- The total number of patients the current provider has in TigerView.
- The total number of images for all of the current provider's patients in TigerView.
- The total number of patients TigerView holds for all providers.
- The total number of images TigerView holds for all providers.

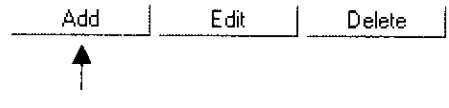
Patient: Joan Johnson
Images for Patient: 4

Provider Patients: 4
Provider Images: 8

Total Patients: 5
Total Images: 9

Add a Patient

To add a new patient, click on the Add button at the bottom of the Patients section of the Patients window.



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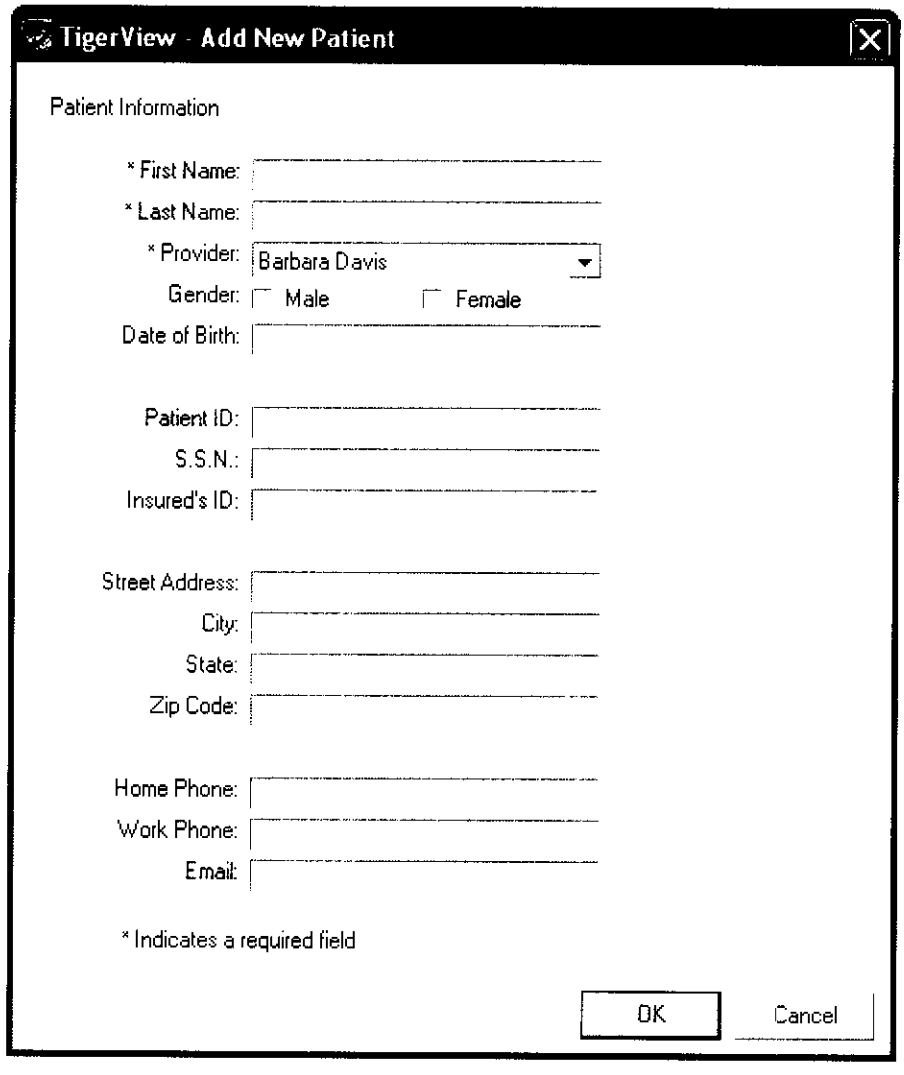
The Add New Patient window will display.



First Name

Enter the first name of the patient. This is required to save the record.

Last Name

Enter the last name of the patient. This is required to save the record.

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Provider

Select the correct provider from the drop down box. This is required to save the record.

Gender

If the patient is male, click on the radio button labeled "male". If the patient is female, click on the radio button labeled "female".

Date of Birth

Enter the date the patient was born. The date must be entered with slashes and a four-digit year (MM/DD/YYYY).

Patient ID

Enter the ID this patient will use in TigerView.

S.S.N.

Enter the patient's social security number. If you would like the social security number to display with dashes, enter the dashes.

Insured's ID

Enter the ID of the patient who has the insurance policy that covers this patient.

Street Address

Enter the street address of the patient's home.

City

Enter the city the patient lives in.

State

Enter the state the patient lives in.

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Zip Code

Enter the zip code the patient lives in.

Home Phone

Enter the patient's home phone number. If you would like the phone number to display with a separator for ease of viewing, such as dashes, enter one.

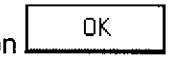
Work Phone

Enter the patient's phone number where he works. If you would like the phone number to display with a separator for ease of viewing, such as dashes, enter one.

Email

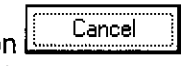
Enter the e-mail address the patient uses.

OK

Click on the OK button 

at the bottom of the Add New Patient window to save the patient record. The patient record can be saved at any point after the patient's first name, last name and provider have been entered. Once saved, the patient record will appear in its alphabetical position by last name in either the list of patients that belong to his provider, or in the list of all of the patients in TigerView.

Cancel

Click on the Cancel button 

at the bottom of the Add New Patient window to close the window without any further saving.

Edit a Patient

To change information in a patient record, select the patient by double clicking on his line in the Patient List, then click on the Edit button at the bottom of the Patients section of the Patients window.

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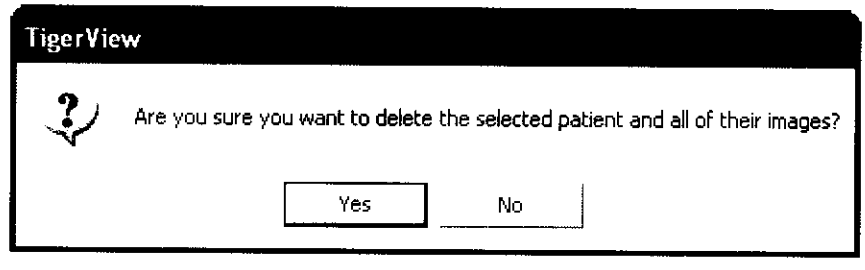
The Edit Patient Info window will display. The Edit Patient Info window contains the same information fields as the Add New Patient window. For an explanation of each entry please refer to the Add A Patient section of this manual.

Delete A Patient

To delete a patient, select the patient by double clicking on his line in the Patient List, then click on the Delete button at the bottom of the Patients section of the Patients window.

A window that asks if you are sure that you want to delete the patient and all of the patient's images will appear. Check the patient name at the top of the TigerView window to make sure this is the correct patient before proceeding.



Click on yes if you are sure that you want to delete the currently selected patient with all of his or her images. Click on No if you are not sure.

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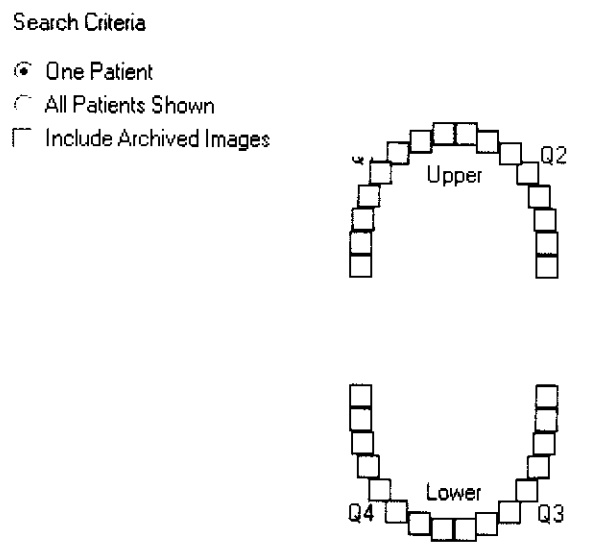
Patients & Images Window



Patients Tab - Search Criteria Area

The Search Criteria section of the Patient window is used to find a specific image, or group of images, from among a possibly large number of images. At the top of the section is the first set of decisions that needs

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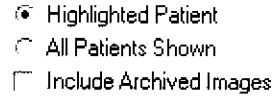
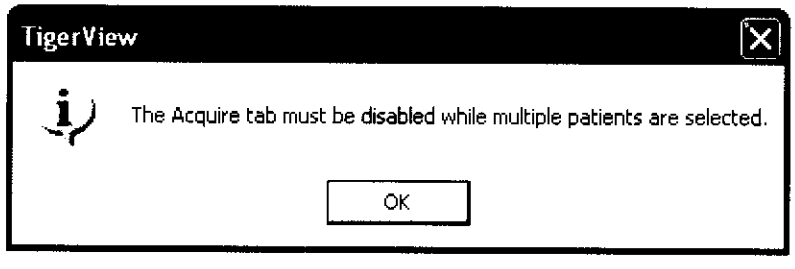
to be made in order to narrow down the number of possible image matches.



Click on Highlighted Patient to search through only those images that belong to the currently selected patient, or, click on All Patients Shown to search through all of the images that belong to all of the patients shown in the Patient List box.

If All Patients Shown is selected, a window will display that says the Acquire tab, at the top of the TigerView window, is going to be disabled. During the selection process, images will not be retrievable from the computer that is being used to find the image. Images are retrievable from other computers that have TigerView running on them as long as the other computer is connected to an image source.



To return the Acquire tab to use, either finish the search by clicking on the Search or Reset button at the bottom of the Search Criteria section, or click on any selectable option elsewhere in TigerView.

Click on the Include Archived Images check box if there are any archived images that should also be searched. Be sure to put the archive disk in the disk drive before beginning the search.

If any images have anatomical information specified, the Anatomical Region diagram will display green on the corresponding teeth. To search for images of a specific tooth or set of teeth, click on the green teeth to turn them blue. To search for images involving teeth in an entire jaw, click on either the word "Upper" or the word "Lower" on the diagram.

The final search decision involves the information that is displayed in the Exam Dates, Image Types, Keywords, Procedures, and Mount Types list boxes in the Search Criteria section of the Patients window. Click on any

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information in each list box that can be used to further narrow the image search.

For example, referring to the Search Criteria window section pictured above this paragraph, the search could be narrowed to only those images that were taken of a carie on 2/9/2005 using a Digital X-ray Phosphor image. To do this, the carie entry in the Keywords list box would be clicked on, the Digital X-ray Phosphor image entry in the Image Types list box would be clicked on, and the 2/9/2005 date in the Exam Dates list box would be clicked on. When the Search button is then clicked, only those images that were of a carie on 2/9/2005 using a Digital X-ray Phosphor image would display. By right clicking on each image, the annotations and the general information listed in the properties for each image could be checked and the selection of the exact image required made.

The information in all of the list boxes in the Search Criteria area, other than the Exam Dates and Image Types, is entered by right clicking on the image and using the Right Click Menu that appears. For instructions on how to use the Right Click Image Menu, see Right Click On An Image in the Patients & Images - Images Tab section of this manual.

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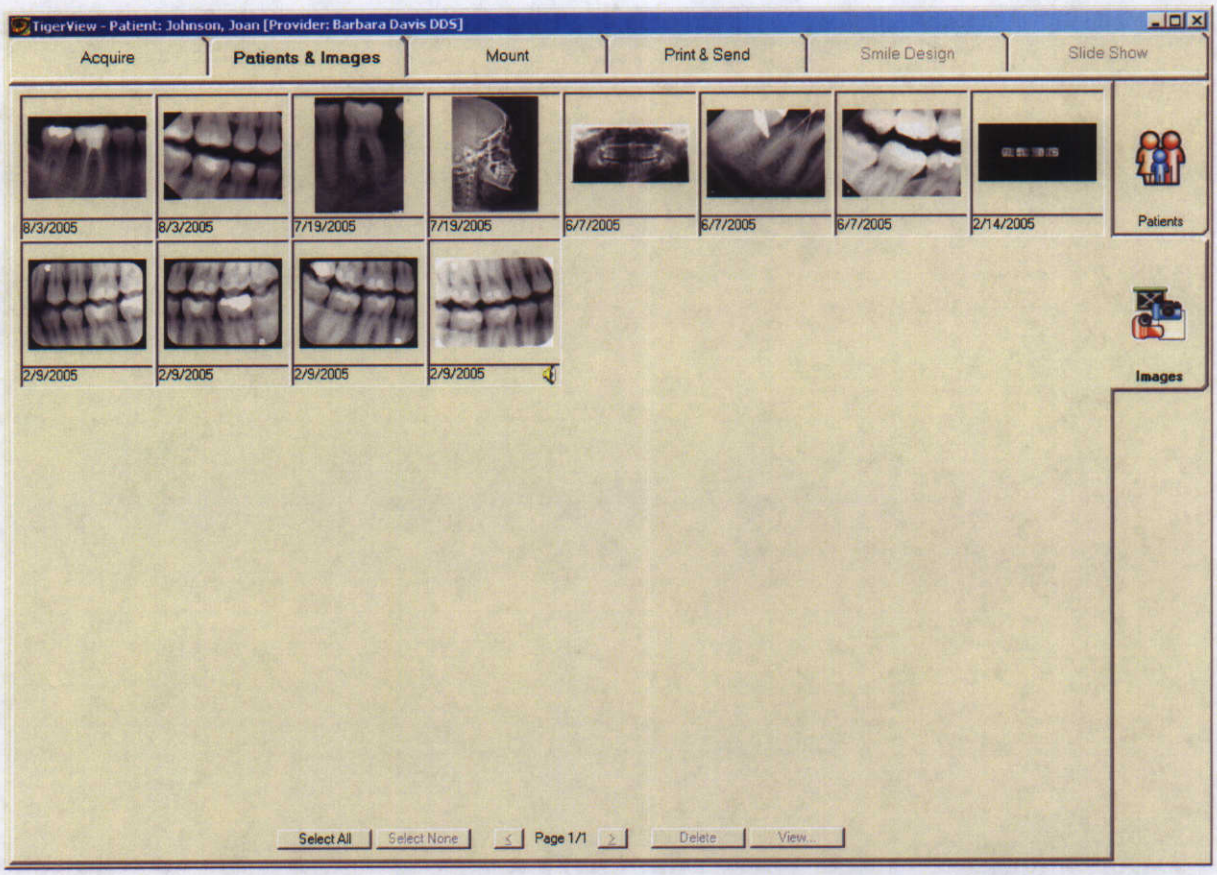
Patients & Images Window



Images Tab

To display the Images window, click on the Patients & Images tab at the top of the TigerView window then click on the Images tab on the right side of the window.

The images in the Image window will display based on their age. The newest images display first. Images can be deleted, exported, opened into the Image Viewer or Viewer window for viewing and manipulation, dragged to the Mount window for viewing and mounting, or dragged to the Print and Send window to be placed into a report and printed or e-mailed.

Select an Image

To manipulate an image in any fashion the image must be selected first.

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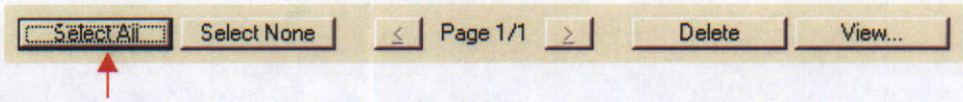
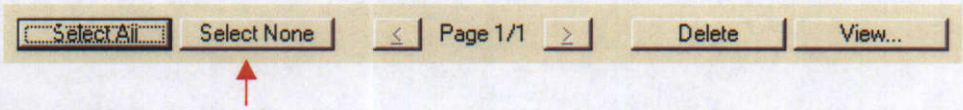
To select an image, left click on it. To select multiple images, left click once on each image. To select all of the images click on the Select All button at the bottom of the Images window.



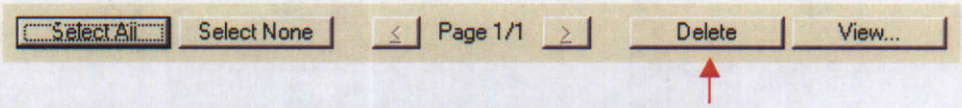
Deselect an Image

To deselect an image, left click on it once more. To deselect all of the images click on the Select None button at the bottom of the Images window.



Delete an Image

To delete an image, first select the image or images to be deleted, and then click on the Delete button at the bottom of the Images window. Once deleted, an image is not restorable.



Open an Image into the Image Viewer or Viewer Window

To open an image in the Image Viewer or Viewer window, first select the image or images to be viewed, and then click on the View button at the bottom of the Images window. Another way of opening images in the Image Viewer or Viewer window is to first select the image or images to be viewed, then right click on one of the images and select View from the right click menu.

For instructions on how to use the Image Viewer window, please refer to the Image Viewer Window section of this manual. For instructions on how to use the Viewer window, please refer to the Viewer Window section of this manual.

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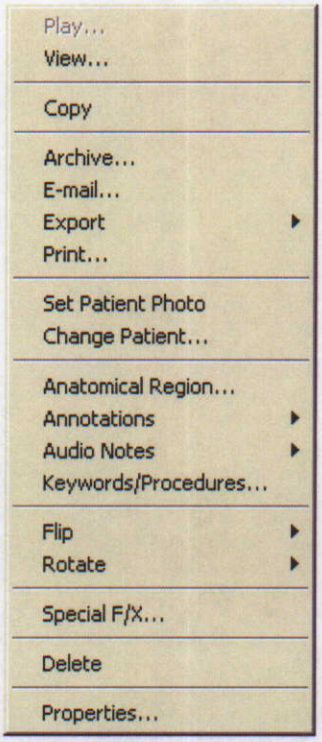
Mount an Image, Include an Image in a Report or Email

To mount an image or to include an image in a report or email, click on the image then click on either the Mount tab or the Print & Send tab. Both tabs are located at the top of the TigerView window.

Right Click on an Image

When you right click on an image the following menu will appear:



Three of the Right Click Menu selections are only available when the image is located on the Patients & Images window, Images tab. These three selections are Archive, Set Patient Photo, and Change Patient.

Play

Play is available for use only when the Right Click Menu is invoked for a movie. Selecting Play will open the Video Playback window that has controls similar to a VCR for playing movies.

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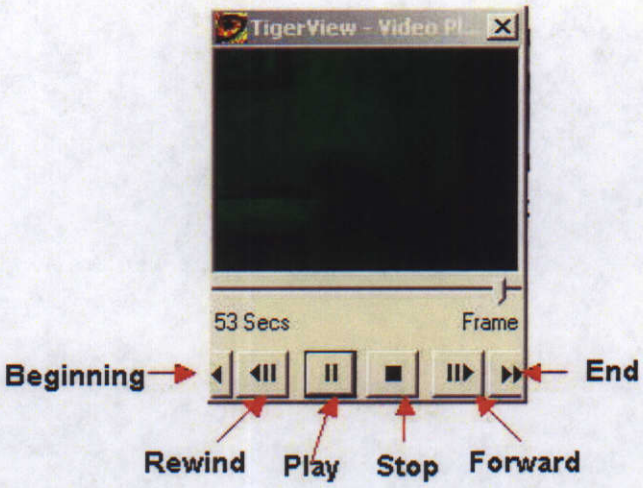

If the movie is located on the Acquire window (the movie has not been saved into TigerView yet), Play will allow individual frames from the movie to be extracted and saved as images. Once the movie has been saved and is no longer on the Acquire window individual frames can no longer be extracted

View

The selected image will display in the TigerView Image Viewer or Viewer window. For instructions on how to use the Image Viewer, please refer to the Image Viewer Window section of this manual. For instructions on how to use the Viewer, please refer to the Viewer Window section of this manual.

Copy

The selected image will be copied to the clipboard. The image can then be pasted into another program that uses the clipboard such as Microsoft Word.

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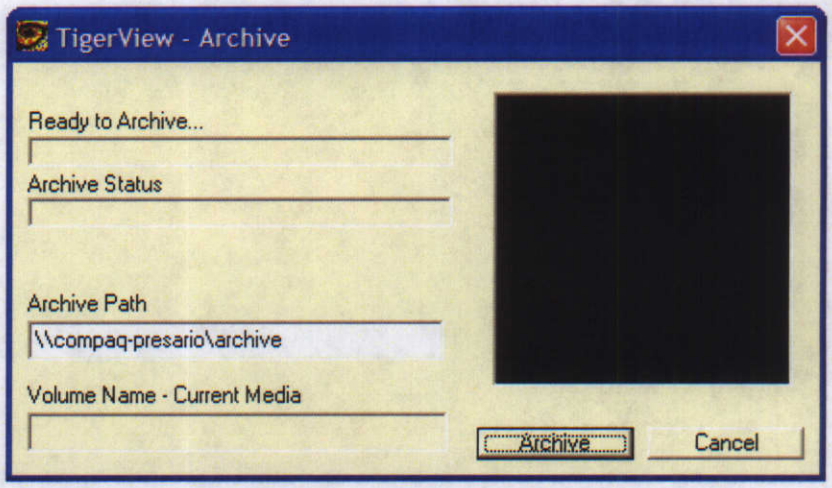
Archive



The ability to archive is available only when the image the Right Click Menu was invoked for is located on the Patients & Images window, Images tab.

Click on the Archive button [Archive] to remove the image from TigerView and copy it to the location specified in the Archive Path box. The archive location is specified in the TigerView Administration program. See the TigerView Administration manual for instructions.

E-mail

The selected image will be placed in the e-mail program setup on this computer as its default e-mail program. For instructions on how to use the E-mail feature, please refer to the Print and Send Window, Send the Report section of this manual.

Export

When Export is selected the following window will display:

DICOM is the file format required by most hospitals. Standard includes the Jpeg, Bitmap and Tiff image file formats plus the AVI (Audio Video Interleave) video format.

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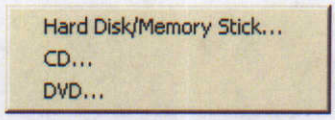
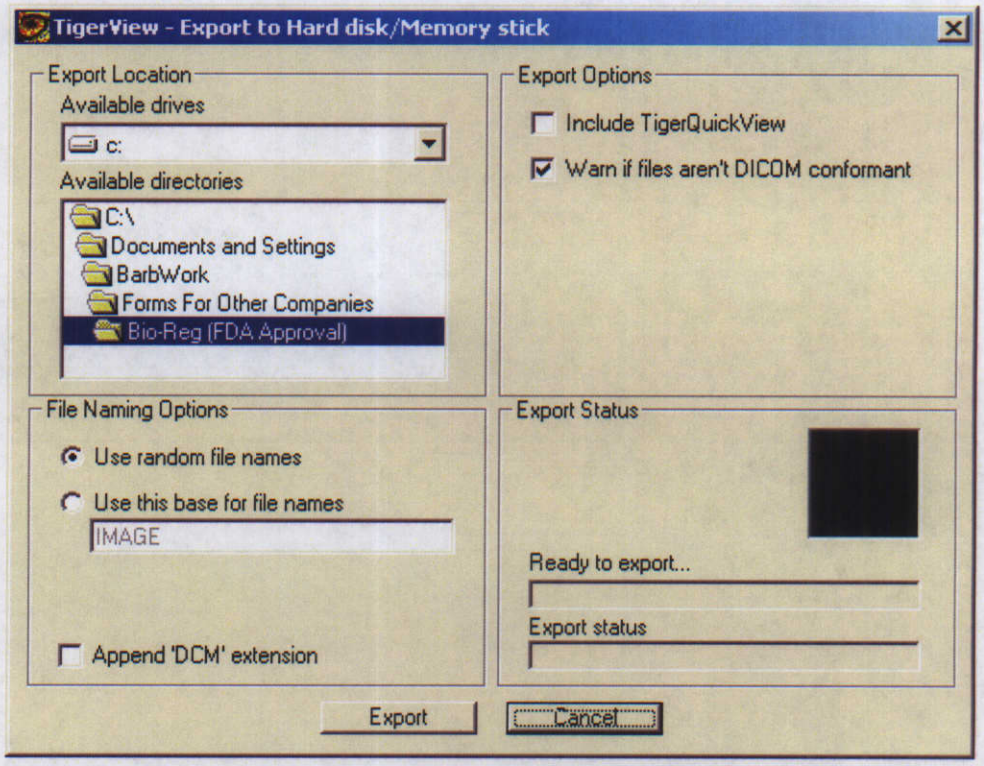
After DICOM is selected, a window will display which asks where the export file should be saved.

After Standard is selected, a slightly different window will display:



DICOM File Saved To A Hard Drive or Memory Stick



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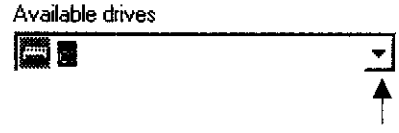
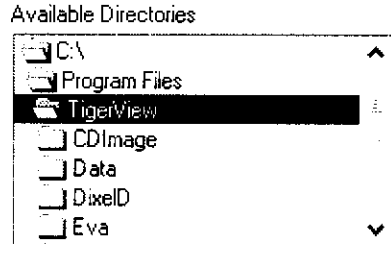
Export Location - Available Drives

To export the image to a hard drive or memory stick that is accessible by this computer, click on the Available Drives down arrow then select the drive from those displayed.



Export Location – Available Directories

The directories (also known as folders) within the selected drive will display. Double click on a folder to display any folders that might be within it.



Select the directory to copy the export file to.

File Naming Options

Click on Use Random File Names to have the computer generate the names of the DICOM files, or click on Use This Base For The File Name to use a user specified name as the start of the file name.

If multiple images are exported at the same time, a number that increases by 1 for each exported image will follow the image name. For example:

ImageName1.jpg
ImageName2.jpg
ImageName3.jpg

When random file names are being used with more than one export file, a different name will be generated for each image.

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File Naming Options – Append 'DCM' Extension

Click on the Append 'DCM' Extension check box to place a check in it if ".dcm" should be added to the end of the file name. The "dcm" identifies this file as a DICOM file.

Export Options

Click on Include TigerQuickView to place a check in the check box if a copy of the TigerQuickView program should be included with the exported images.

Click on Warn If Files Aren't DICOM Conformant to place a check in the check box if the user should be warned about files that TigerView cannot change into DICOM files.

Export

Click on the Export button to export the file.

DICOM File Saved To CD or DVD

Export Options

Exporting a file to a CD or DVD is the same as exporting a file to a hard drive except that it has one additional checkbox in the Export Options area of the Export window: Allow More Files To Be Added Later. Click on Allow More Files To Be Added Later to place a check in the check box if there are more files to be placed on this CD.

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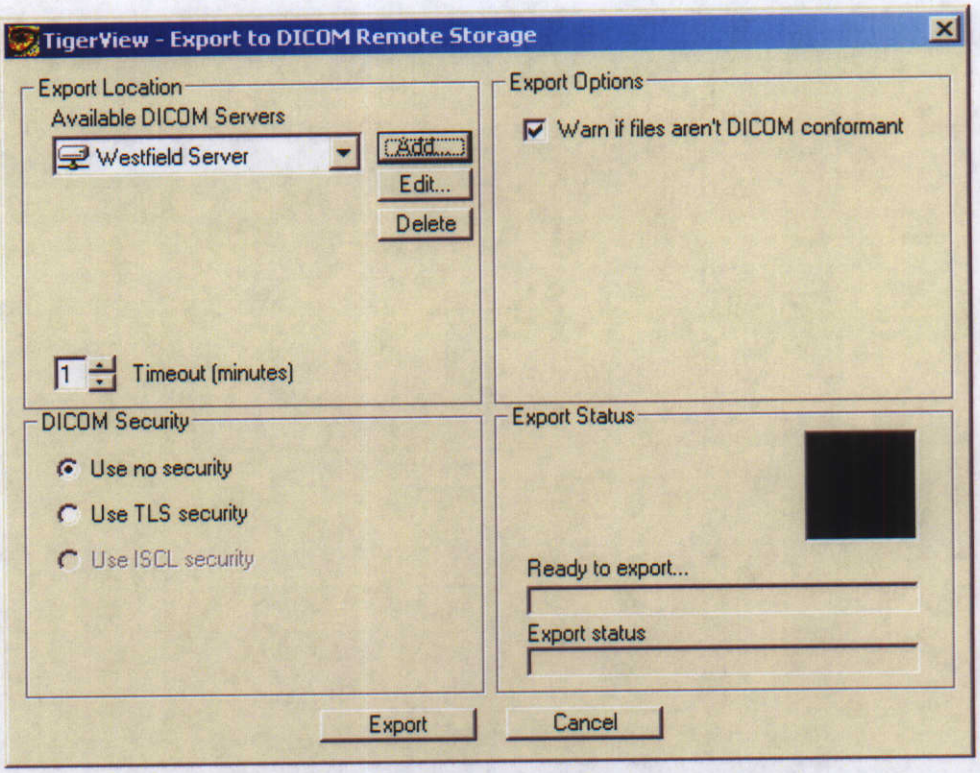
DICOM File Saved To DICOM Server

Export Options



Available DICOM Servers

Click on the drop down arrow to select the DICOM server to send the image to. If a DICOM server does not appear in the drop down list, click on the Add button to add it.

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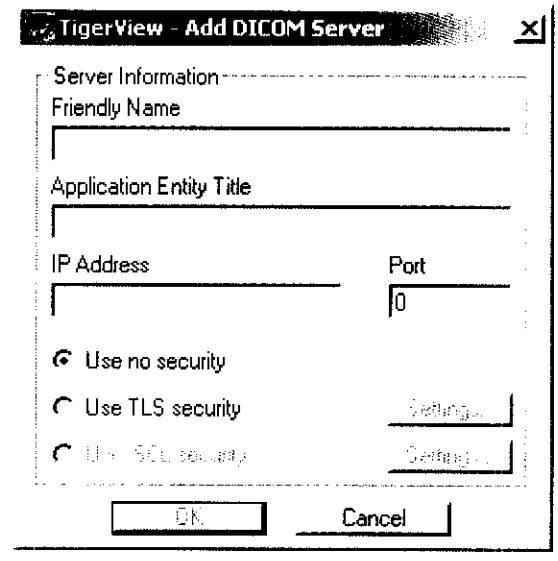
Add a DICOM Server



Friendly Name

Enter a Friendly Name for the DICOM server of up to 16 characters.

Application Entity Title

Enter the Application Title for the DICOM server of up to 16 characters.

IP Address

Enter the IP Address of the DICOM server in the standard IP address format.

Port

Enter the number of the port that is used to access the DICOM server.

Security

Click on the type of security that should be used to transmit the DICOM file.

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Timeout (minutes)

Enter the number of minutes the export can use to connect with the DICOM server and send the files.

DICOM Security

Click on the type of security that should be used to transmit the DICOM file.

Warn if Files aren't DICOM Compliant

Click on Warn if Files Aren't DICOM Compliant to place a check in its checkbox if the user should be notified that the files being sent do not have enough information to be DICOM compliant.

Export

Click on the Export button to export the file.

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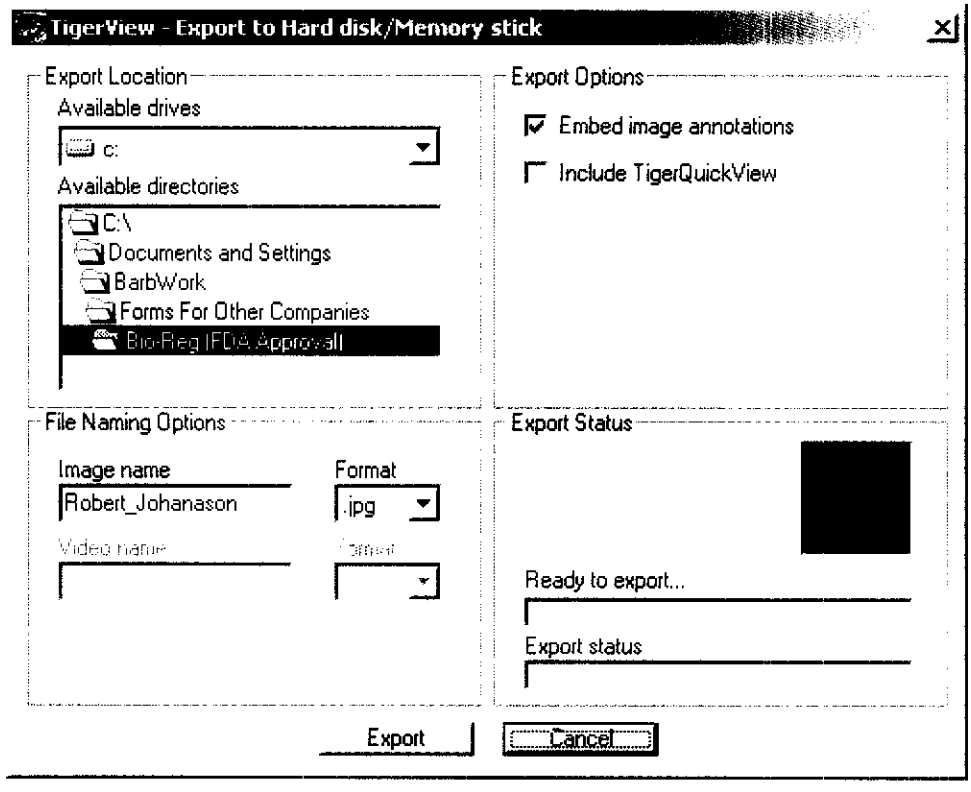
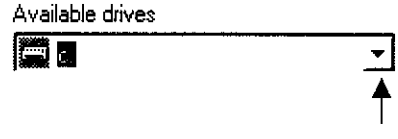
Standard File Saved To A Hard Drive or Memory Stick



Exporting a standard file is similar to exporting a DICOM file.

Export Location - Available Drives

To export the image to a hard drive or memory stick that is accessible by this computer, click on the Available Drives down arrow then select the drive from those displayed.



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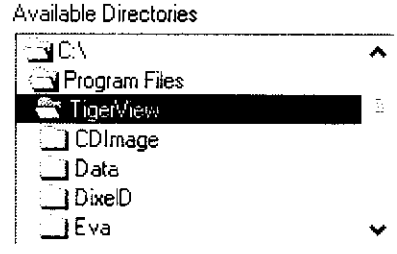
Export Location – Available Directories

The directories (also known as folders) within the selected drive will display. Double click on a folder to display any folders that might be within it.



Select the directory to copy the export file to.

File Naming Options – Image Name

Click on Image Name to enter a user specified name as the start of the file name.

If multiple images are exported at the same time, a number that increases by 1 for each exported image will follow the image name. For example:

ImageName1.jpg
ImageName2.jpg
ImageName3.jpg

File Naming Options – Format

Click on the Format drop down box down arrow to select the file format for the export file. Available formats include bitmap (.bmp), jpeg (.jpg) and tiff (.tif) for single images and AVI (.avi) for videos.

Export Options

Click on Embed Image Annotations to place a check in the check box if the annotations entered should be included with the image.

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Click on Include TigerQuickView to place a check in the check box if the TigerQuickView program should be copied and exported along with the file. If the office the file is being sent to does not have an image-viewing program they can use the TigerQuickView program to view the image.

Export

Click on the Export button to export the file.

Standard File Saved To CD or DVD

Export Options

Exporting a file to a CD is the same as exporting a file to a hard drive except that it has one additional checkbox in the Export Options area of the Export window: Allow More Files To Be Added Later. Click on Allow More Files To Be Added Later to place a check in the check box if there are more files to be placed on this CD.

Print

The selected image will be printed along with the patient's name, ID, gender, date of birth, provider, phone number and the date the image was taken.

Set Patient Photo

The ability to designate an image as the Patient Photo is available only when the image the Right Click Menu was invoked for is located on the Patients & Images window, Images tab.

The selected image will appear on the Patients window in the Patient Photo box. For instructions on how to import a picture of the patient, please refer to the Acquire Window – Import Tab section of this manual.

Change Patient

The ability to move an image to another patient is available only when the image the Right Click Menu was invoked for is located on the Patients & Images window, Images tab.

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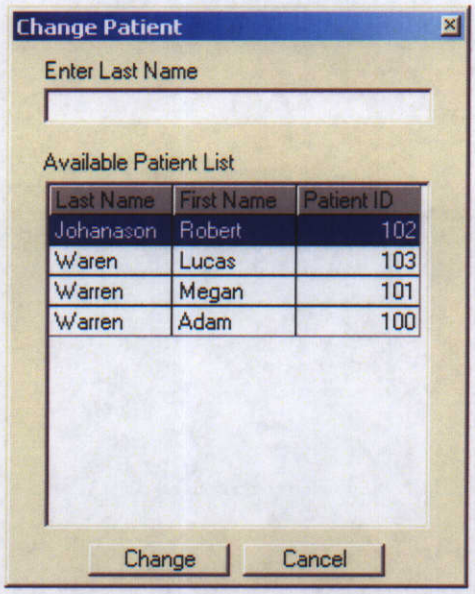
To move an image from one patient to another, in the Available Patient list double left click on the name of the patient who should have received the image, or type in the last name of the patient who should have received the image for TigerView to locate the patient for you, then left click on the name once to select the patient and click on the Change button.



To move an image from a patient who belongs to one provider to a patient who belongs to another provider, the Allow Access To Other Provider Images checkbox on the Security Options window of TigerView Administration must be checked. If that checkbox has a check in it, all of the patients in TigerView will appear in the Change Patient window Available Patient list.

Anatomical Region

When Anatomical Region is selected the following window will display:

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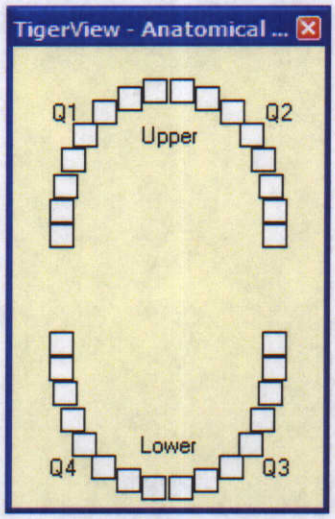
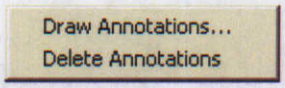


Click on the teeth in the diagram that correspond with the teeth in the image. Changes to this window are saved when the window's close box is clicked. For pan images click on the word "Upper" and the word "Lower" to mark all of the teeth. Clicking on Q1, Q2, Q3 or Q4 will mark individual quadrants of teeth.

Annotations

When Annotations is selected the following window will display:



Draw Annotations

Draw Annotations will display the selected image in the Image Viewer or Viewer window with the annotation tool bar open at the top. For instructions on how to use the Image Viewer window, please refer to the Image Viewer Window section of this manual. For instructions on how to use the Viewer window, please refer to the Viewer Window section of this manual.

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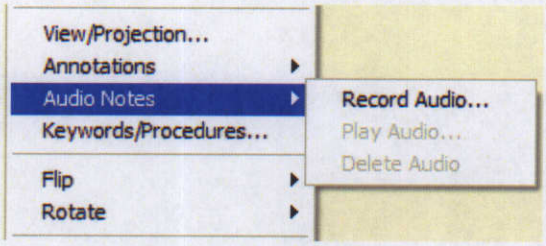
Delete Annotations

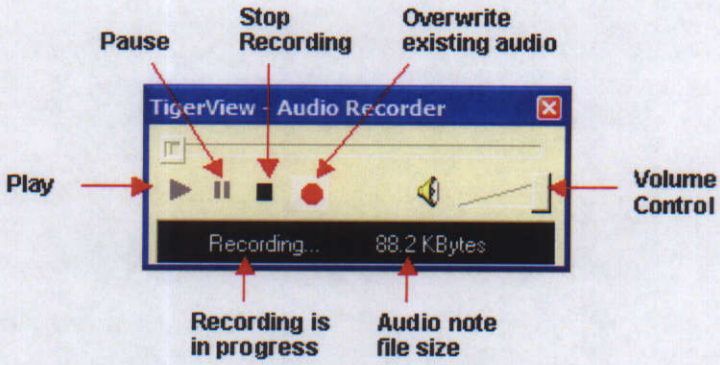
Delete Annotations will delete all of the annotations from an image. To delete individual annotations, use the annotation tool in the Image Viewer or Viewer window.

Audio Notes

If the computer TigerView is running on has a microphone plugged into a Mic In connection, audio notes can be recorded for an image. If a microphone is not used, or if the computer has a problem with either the microphone or the Mic In port, the audio notes will record silence.



Select Record Audio to record audio notes. The following window will display and TigerView will immediately begin recording the audio notes.



Stop

To stop recording or playing audio notes click the Stop button.

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Overwrite

To replace existing audio notes with new notes click the Overwrite button. Audio notes cannot be added to, they can only be replaced with new notes or deleted.

Play

To listen to audio notes click on the Play button.

Pause

Clicking on the Pause button while listening to audio notes will stop playing the notes. When the Play button is clicked after pausing, the notes will resume playing at the point they were paused at instead of starting the notes over at the beginning as they would if the Stop button were clicked instead of the Pause button.

Volume Control

Left click on the Volume Control bar and slide it left or right to set the volume level of the audio notes.

Click on the Close Window button to close the Audio Notes window.

When Audio Notes are saved on an image, the image will display the Audio Notes icon.

After audio notes have been saved to an image, the Audio Notes submenu will expand to include Play Audio and Delete Audio.

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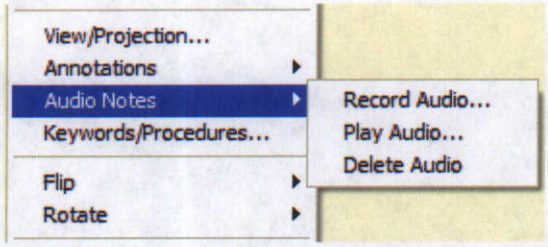
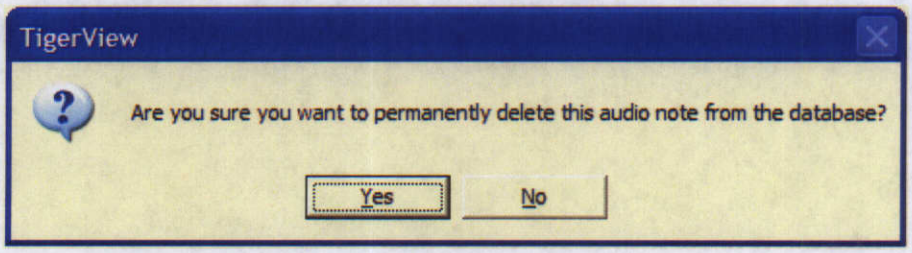
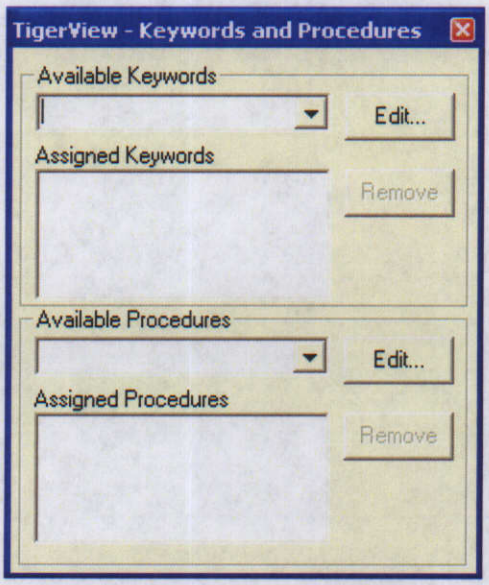


If Delete Audio is selected, the following window will display. If the Yes button is clicked the audio notes will be permanently erased.



Keywords/Procedures

When Keywords/Procedures is selected the Keywords and Procedures window will display:



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The Keywords/Procedures window allows four actions:

It allows Keywords to be added or deleted from the main Keywords List that supplies keywords to all of the images in TigerView.

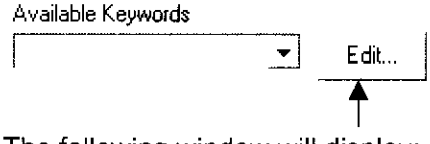
It allows Procedures to be added or deleted from the main Procedures List that supplies procedures to all of the images in TigerView.

Specific Keywords can be associated with the currently selected image

Specific Procedures can be associated with the currently selected image

Add Keywords To The Main Keyword List

To add or delete Keywords from the main Keywords List, click on the Edit button to the right of the Available Keywords drop down box.



The following window will display:

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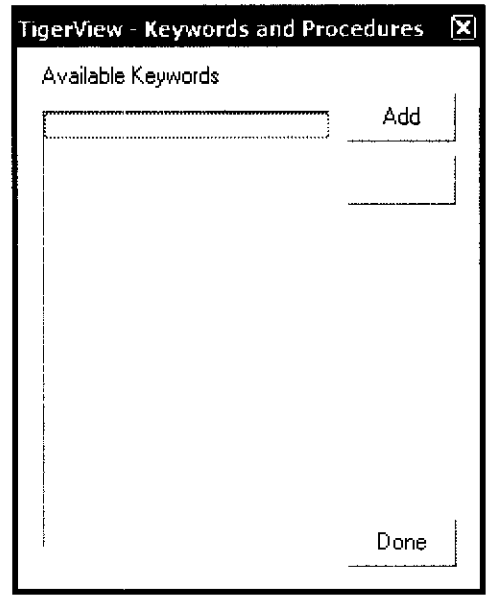
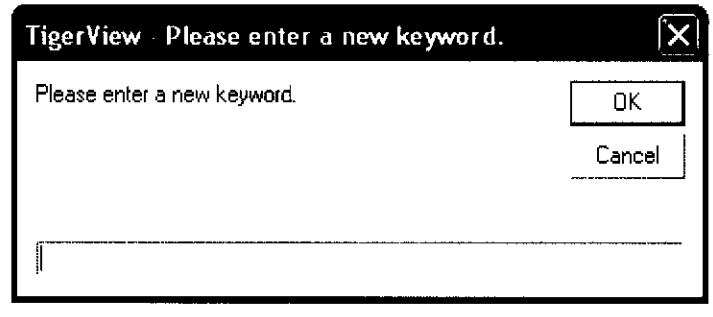


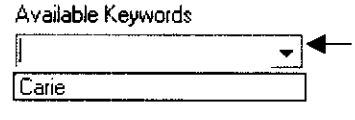
To Add a Keyword, click on the Add button at the top of the window then enter the keyword into the New Keyword window. Click on the OK button to save the new keyword.



Click on the Done button to close the Add Keyword window.

Assign A Keyword To An Image

To assign a keyword to a selected image, click on the down arrow of the Available Keywords drop down box



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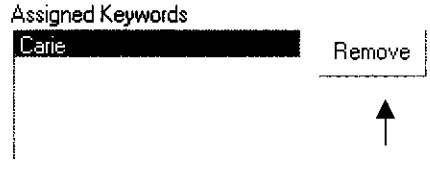
then select the keyword. The keyword must exist in the Main Keyword List before it can be assigned to an image.

Multiple Keywords can be assigned to an image. When all of the applicable Keywords have been assigned to the image, click on the window's Close button to close the Keyword and Procedures window. Note: If the keyword to assign does not appear in the drop down box, add the keyword to the main Keyword List following the Add Keywords To The Main Keyword List instructions above.

Remove a Keyword From An Image

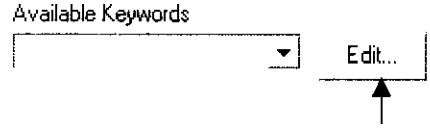
To Remove a Keyword that was assigned to an image, click on the Keyword then click the Remove Button.



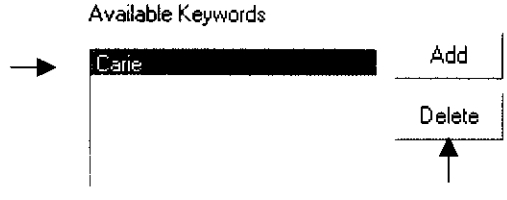
When finished, click on the window's Close button to close the Keywords and Procedures window.

Delete a Keyword From The Main Keyword List

To Delete a Keyword from the Main Keyword List, click on the Edit button on the Keyword and Procedure window,



click on the Keyword to delete, and then click on the Delete button.



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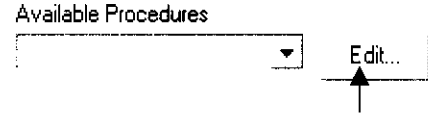
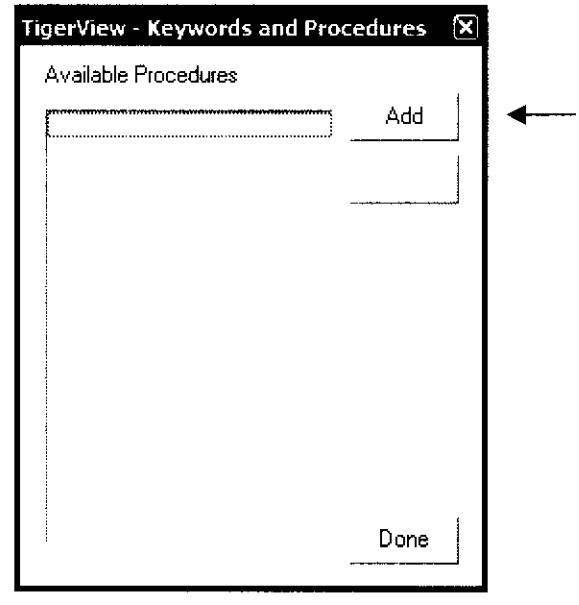
Click on the Done button to close the Edit Keywords and Procedures window then on the window's Close button ✕ to close the main Keywords and Procedures window.

Add Procedures To The Main Procedure List

To add or delete Procedures from the main Procedures List, click on the Edit button to the right of the Available Procedures drop down box.



The following window will display:



To Add a Procedure, click on the Add button at the top of the window then enter the procedure into the New Procedure window. Click on the OK button to save the new procedure.

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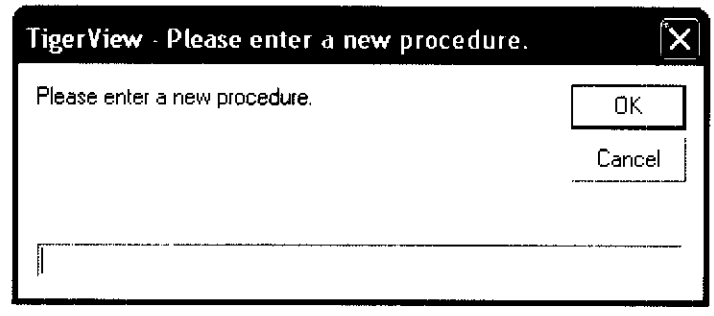
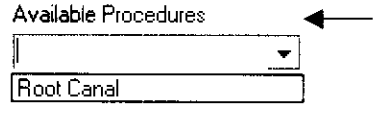


When the required procedures have been added to the Main Procedure List, click on the Done button to close the Add Procedure window. Click on the window's Close button to close the main Keywords and Procedures window.

Assign A Procedure To An Image

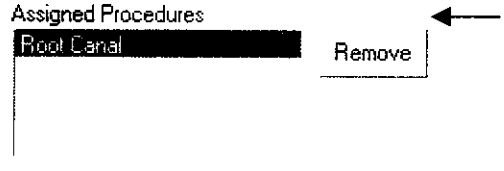
To assign a Procedure to an image, click on the down arrow of the Available Procedures drop down box then select the Procedure from the list that appears.



The Procedure must exist in the Main Procedure List before it can be assigned to an image. If the Procedure does not appear in the Available Procedures list, add the procedure to the list following the Add Procedures To The Main Procedure List instructions above. Multiple Procedures can be assigned to an image.

Remove A Procedure From An Image

To Remove a Procedure from an image, select the procedure from the Assigned Procedures box then click on the Remove button.



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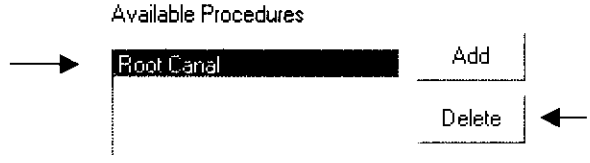
Delete A Procedure From The Main Procedure List

To Delete a Procedure from the Main Procedure List, click on the Edit button next to the Available Procedures box,

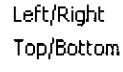
click on the Procedure to delete, and then click on the Delete button.



Click on the Done button to close the window then on the Close button to exit the Keywords/Procedures window.

Flip

When Flip is selected the following window will display:



Left/Right

Selecting Left/Right will cause the selected image to flip 180 degrees. If the image was facing left, it will now face right. If the image was facing right, it will now face left.

Top/Bottom

Selecting Top/Bottom will cause the selected image to flip from top to bottom. If the top of the image was right side up, after flipping it will be upside down. If the top of the image was upside down, it will change to right side up.

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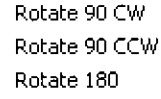
Rotate

When Rotate is selected the following window will display:



Rotate 90 CW

Selecting Rotate 90 CW will cause the selected image to spin 90 degrees clockwise (CW).

Rotate 90 CCW

Selecting Rotate 90 CCW will cause the selected image to spin 90 degrees counter clockwise (CCW).

Rotate 180

Selecting Rotate 180 will cause the selected image to rotate 180 degrees.

- If the front of the image was facing left it will now face right.
- If the front of the image was facing right it will now face left.
- If the top of the image was right side up it will now be upside down.
- If the top of the image was upside down it will now be right side up.

Special F/X

Special F/X is another way of opening the Image Viewer window. "F/X" stands for Effects, referring to the tools located in the Image Viewer or Viewer window.

Delete

Selecting Delete will remove the image from TigerView. Once deleted the image is not restorable.

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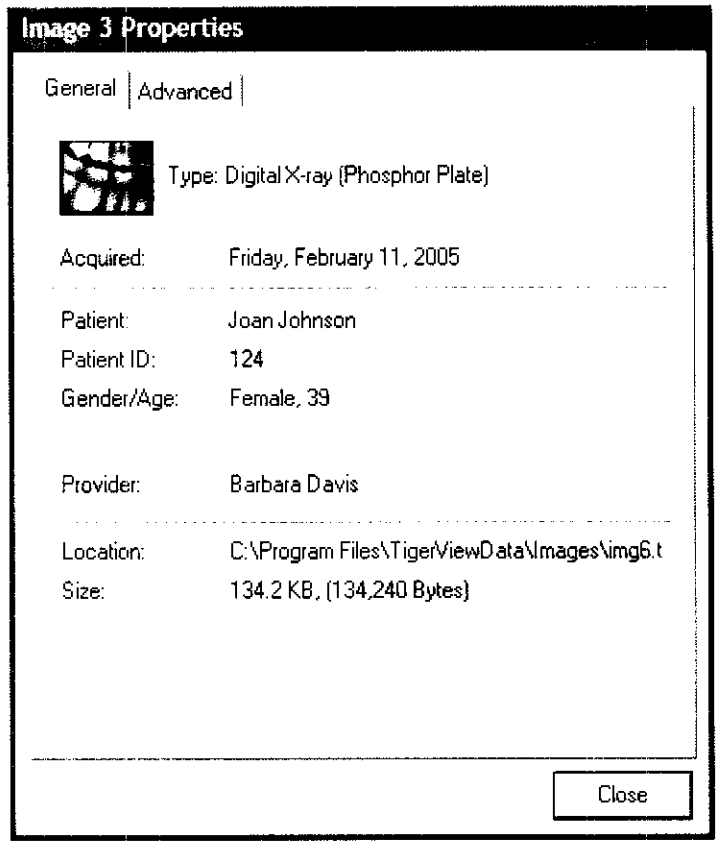
Properties

When Properties is selected the following window will display:



The information displayed on the General tab includes the type of equipment used to capture the currently selected image, the name, ID, gender and age of the patient the image was saved to, the name of the provider for this patient, the date the image was acquired, where the image is stored, what the stored image is called, and how large the image is.

Change the Acquire Date for Images acquired from a flatbed scanner

If the image was obtained from a flatbed scanner, an Edit button Edit... will appear on the Preferences window that will allow the Acquire Date for the image to be changed.

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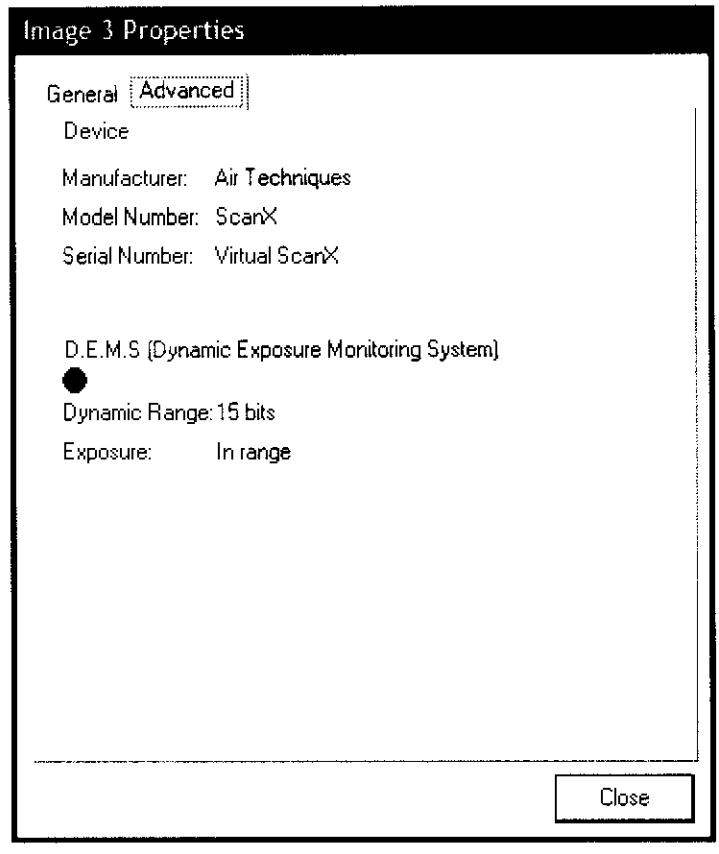

The information displayed on the Advanced tab includes the manufacturer, model number and serial number of the device used to capture the currently selected image, and the setting TigerView read the image at. The Advanced tab will not display for an image that was imported.

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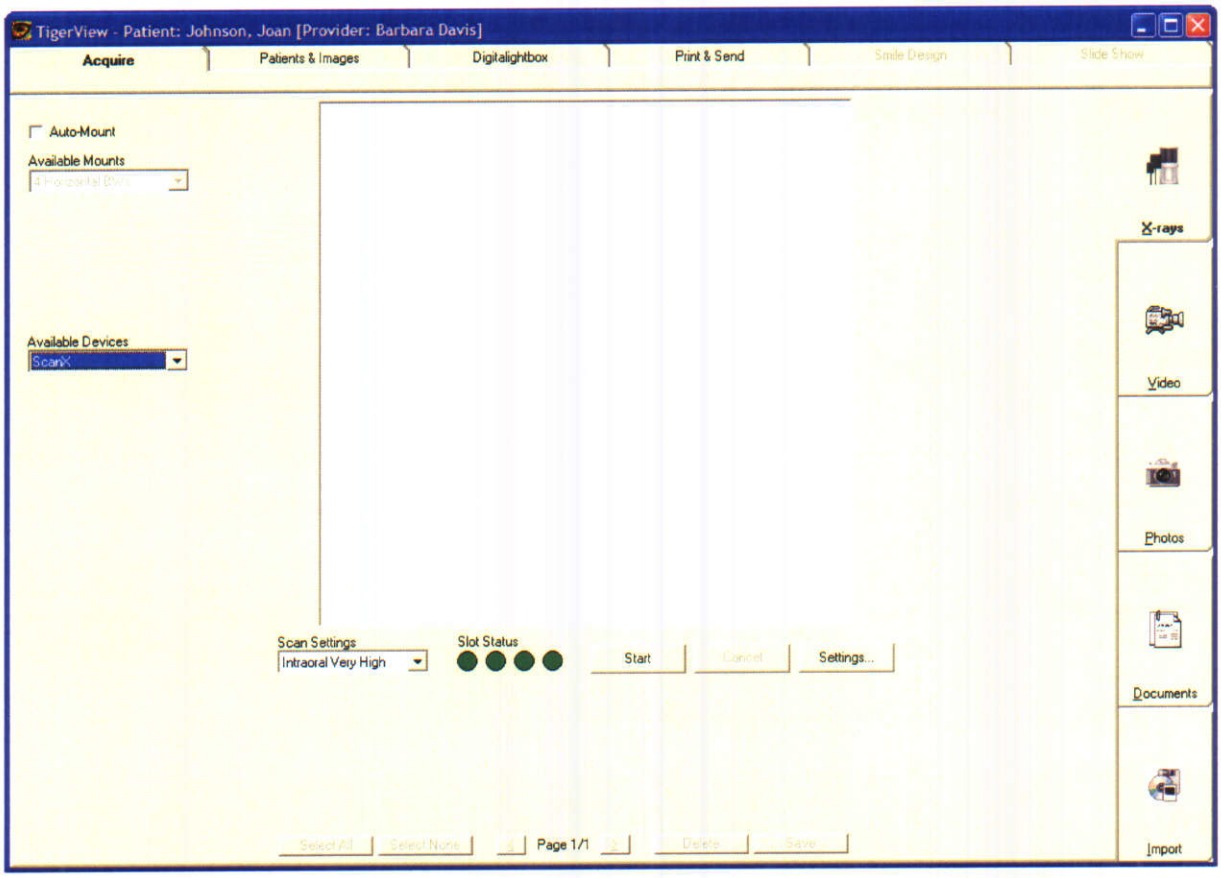
Acquire Window

X-rays tab - For a ScanX Scanner



Images are entered into TigerView through the Acquire Windows. The methods to bring the images in are listed on the tabs on the right side of the Acquire window. The input methods consist of X-rays, Video, digital Photos, Documents or other images acquired by a flatbed scanner, and images that have already been saved digitally and will be brought in by Importing them.

Available Devices

Click on the down arrow of the Available Devices drop down box to display the devices that TigerView can retrieve x-rays from.

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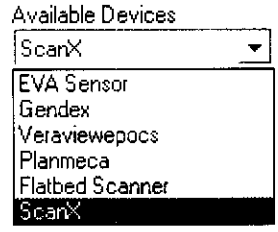
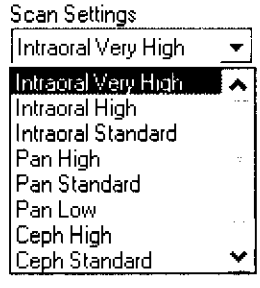


If a TigerView readable x-ray device is directly attached to a computer but does not display in the Available Devices drop down box on that computer, close TigerView, open TigerView Administration and add the device. See the TigerView Administration manual for instructions.

The Scan Settings drop down box and the windows that appear when the Settings button is clicked are different for different devices.

Scan Settings for a ScanX Scanner

Like traditional film, the scan settings for the ScanX phosphor plate scanner are set in line pair. Selecting a high or very high resolution setting with more line pair per millimeter will result in a greater amount of detail in the resulting image. It will also save a larger digital image requiring more hard drive space. For most x-rays, a Standard resolution scan setting is appropriate.



If, after viewing a standard resolution image, the viewer would like to see more detail, place the phosphor plate back into the ScanX scanner and rescan it at the High Resolution scan setting. The x-ray does not need to be retaken unless the person handling the phosphor plate exposed it to light or handled it improperly thus destroying part of the image on the plate.

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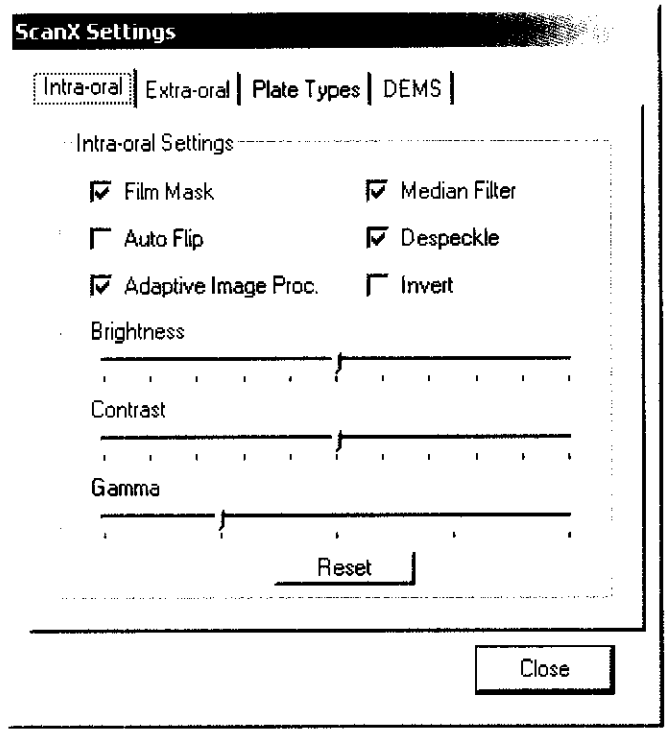
Settings Button for a ScanX Scanner

The Settings button will display windows that hold optional scanning settings for the ScanX scanner that is connected to this computer. These settings are advanced and will affect all future images acquired by this scanner.

Settings Button – Intra-Oral Window – ScanX scanner



The advanced options contained in this window are intended for doctors who want their images to have a more unique look. These fine-tuning options will apply to all of the future images acquired by this scanner. The Reset button on each window will change the settings for that window back to the original settings TigerView came with.

Film Mask

A Film Mask is a black border around the image that is similar to a mat around a picture. This border can make the edges of the image look sharper. A check mark indicates that a film mask will be placed on all future ScanX scanned images.

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Median Filter

When Median Filter is off, the image will have a more salt and pepper look (noise) but the edges of the image will be more defined.

When Median Filter is on, the image won't have as many unnecessary white dots but the edges of the image may not be as defined.

Auto Flip

When an image is Auto Flipped the view is as though sitting on the other side of the item being x-rayed looking at the x-ray head.

Despeckle

Despeckling an image removes the extra dots (noise) that are not actually part of the image.

Use Adaptive Image Processing (AIP)

Using Adaptive Image Processing captures images as 8-bit images allowing brightness and contrast to be adjusted. Not using Adaptive Image Processing saves images in 16-bit form and allows window leveling to be adjusted. The default in dentistry is to use Adaptive Image Processing.

Invert

Inverting an image causes the white areas to become black and the black areas to become white.

Brightness

Changing the Brightness setting can make up for an x-ray machine that shoots images with too much lightness or darkness. Brightness raises or lowers the lightness for every pixel in the image.

Contrast

Increasing the Contrast creates an image where the white areas are whiter and the black areas blacker. This causes

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the edges of a shape within the image to be more easily seen.

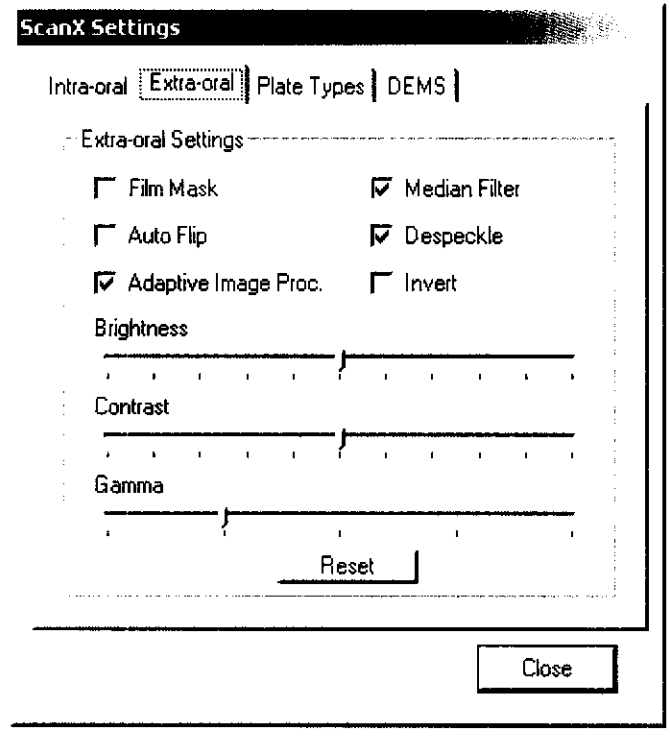
Gamma

A Gamma change leaves the whitest and blackest parts of an image alone as it makes the mid gray values lighter or darker. If the Gamma level gets moved up the Contrast level should be moved down. Changing the Gamma setting can make the image very dark.

Reset

Reset restores the default settings that came with TigerView.

Settings Button – Extra-oral Window – ScanX scanner



Extra-oral Settings

The Extra-oral settings are the same as the Intra-oral settings except, of course that they refer to Extra-oral images instead of Intra-oral images. For an explanation of

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each setting please refer to the Intra-oral settings explanations listed above this section.

Settings Button – Plate Types Window – ScanX scanner

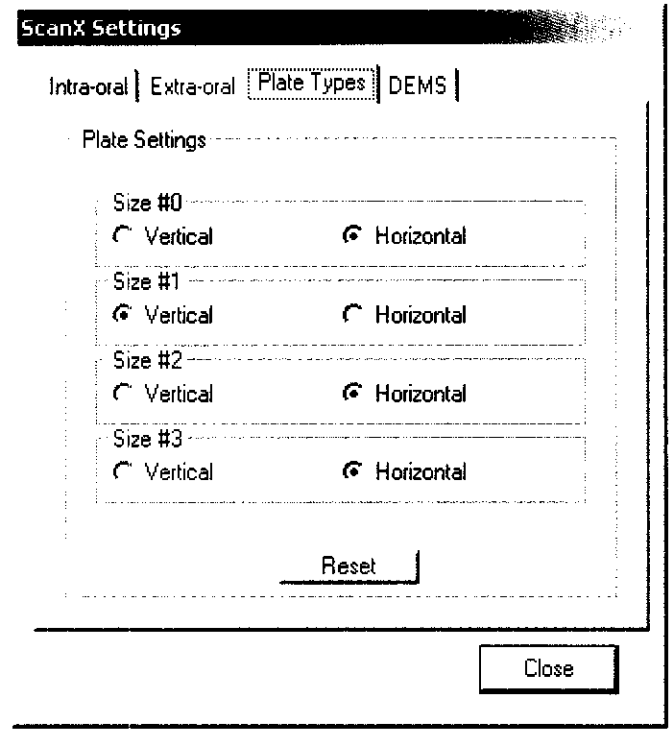

Plate Types

The Plate Types window lists each size of intra-oral phosphor plate and whether it is to be scanned into TigerView in either a vertical or horizontal position. No matter how an image is brought into TigerView, its orientation can always be changed later, from vertical to horizontal or from horizontal to vertical. Please refer to the Patients & Images Window, Right Click On An Image section of this manual for instructions on how to rotate and flip individual images.

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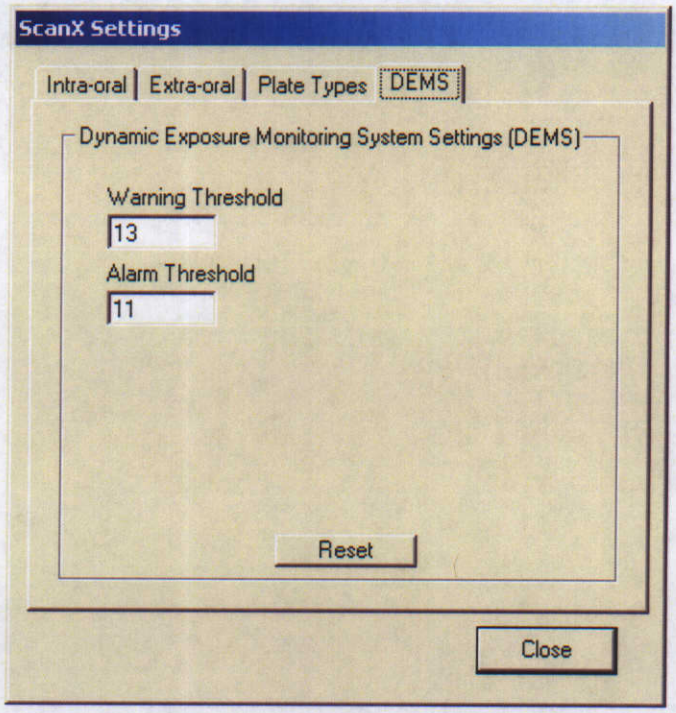
Settings Button – DEMS Window – ScanX scanner



DEMS

DEMS stands for Dynamic Exposure Monitoring System. The DEMS thresholds are an advanced feature that should never be altered by the user without the permission of a TigerView representative. If, for some reason, the DEMS settings are altered, clicking on the Reset button Reset will restore the original settings.

Auto-Mount

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Check the Auto-Mount checkbox to automatically place each scanned image into a previously created and saved mount. Click on the down arrow of the Available Mounts drop down box to select a mount. The selected mount will display in the black mount box underneath the Available Mounts drop down box.

Scanning Order

When using the Auto-Mount feature, images must be scanned in the order they are placed into the mount. For example, in the mount displayed above, the first scanned image would be placed in the image box with the number one on it, the second scanned image would be placed in the image box with the number two on it, etc. When mounting a large number of images, such as a full mouth series, taking the x-rays in the order specified by the mount can become a more complicated business.

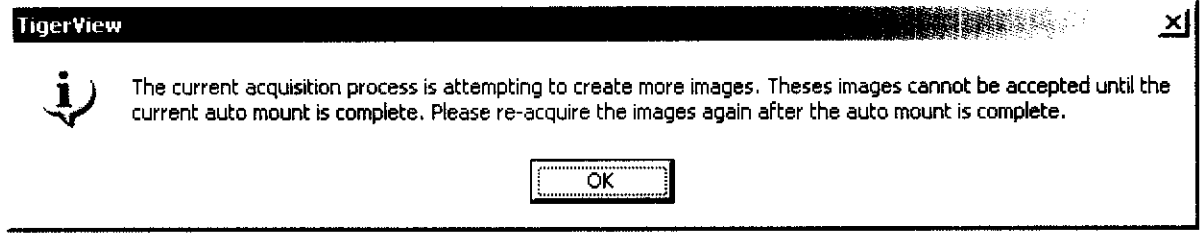
Skipping an Image in the Mount

There will be times when some of the image holders in a mount will need to be skipped because that particular x-ray was not taken. To skip an image holder, click on it before the scan begins. The image holder will turn black. Clicking on the image holder again will remove the black and allow the image holder to receive an image again.

Creating the Mount

When a mount is full it will flash three times. Clicking on the Create button at this time will save the mount without disrupting any scanning that is still going on. This allows further scans to be placed in a new, empty mount automatically.

If the Create button is not clicked on time, the following warning message will appear and scanning will stop.



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If the warning message appears, click on the OK button to close it, click on the Create button to save the mount, and then rescan any plates that did not have their image acquired.

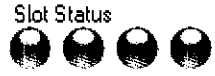
If an image used in the mount is deleted before the mount is saved the image will automatically be removed from the mount. The next image acquired will be placed in the open mount space that was created by removing the image.

Manually Mount Images

The alternative to Auto-Mount is to mount the images manually by dragging them onto a mount using the Mount window. For instructions on how to mount images manually, please refer to the Mount Window - Using The Mount Window To Mount Images section of this manual.

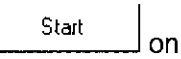
Slot Status

Before beginning the first scan make sure the four Slot Status lights on the Acquire window and the four slot scan lights on the ScanX scanner are colored green.



A green Slot Status light indicates that that phosphor plate entry slot on the ScanX is ready to feed a phosphor plate. If all four Slot Status lights are green an extra-oral plate may be fed.

Start button

Click on the Start button 

on the Acquire window to tell TigerView a scan is ready to begin.

At the ScanX Scanner

Load the phosphor plate or plates into the ScanX scanner according to the manufacturer's directions.

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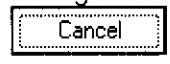
During the Scanning Process

TigerView will automatically capture the image from the ScanX scanner. As the phosphor plate or plates advance through the ScanX scanner they will drop down the TigerView Current Image box on the Acquire window in a waterfall effect. As the plate is being scanned the Slot light on the ScanX scanner and the corresponding light in TigerView will turn red. A red light indicates that an image is being processed in that slot. When both lights turn green another phosphor plate can be inserted in that slot to begin another scan. If the Cancel Button is clicked on during the scanning process, the scan will be aborted.



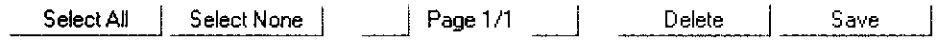
Please note that the Current Image box on the Acquire Window does not accurately display the scanned image. The Current Image box is only used to show the image's progression through the scanning device.

After the Scanning Process

Once an image has been scanned, a small version of it, called a thumbnail, will appear in the area under the Scan Settings drop down box. A DEMS light on each image will be green if TigerView is satisfied with the image, yellow if TigerView is not totally happy with the image, and red if the image should be checked.

To check an image, double click on the image to open it into the TigerView Image Viewer. If the image quality is acceptable, close the Image Viewer by clicking on the Close Window box in the upper right corner of the window and continue scanning. If the image quality is not acceptable, close the Image Viewer, and place the phosphor plate back into the ScanX scanner to rescan it. After rescanning check the image again. If the image is acceptable, select the image then click on the Save button to save the image into TigerView. If the image is still not acceptable consider retaking the x-ray.

Image Buttons



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Select an Image

To select an image, left click on it. To select multiple images, left click on multiple images. To select all of the images click on the Select All button at the bottom of the window. Select All A selected image will have a green box around it.

Deselect an Image

To deselect an image, left click on it again. To deselect all of the images click on the Select None button at the bottom of the window. Select None

Delete an Image

To delete an image, first select the image or images to be deleted, and then click on the Delete button at the bottom of the window. Delete Deleted images are not recoverable.

Save an Image

To save an image, first select the image or images to be saved, and then click on the Save button at the bottom of the Window. Save The image will save, no matter what color its DEMS light is, to the currently selected patient.

Open an Image into the Image Viewer or Viewer

To open an image into the Image Viewer or Viewer window, double click on the image using the left mouse button or right click on the image and select View from the Right Click Image Menu. For instructions on how to use the Image Viewer window, please refer to the Image Viewer Window section of this manual. For instructions on how to use the Viewer window, please refer to the Viewer Window section of this manual.

Mount an Image or include an image in a Report

To mount an image or to include an image in a report, click on the image then click on either the Mount tab or the Print & Send tab. Both tabs are located at the top of the TigerView window.

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Right Click Image Menu

To flip, rotate, add annotations, add keywords, add procedures, copy, archive, e-mail, export, print, etc before saving, right click on the image. This Right Click Image Menu can be accessed any time the image can be viewed outside of the TigerView Image Viewer. For instructions on how to use the Right Click Image Menu see Right Click On An Image in the Patient & Images Window – Images Tab section of this manual.

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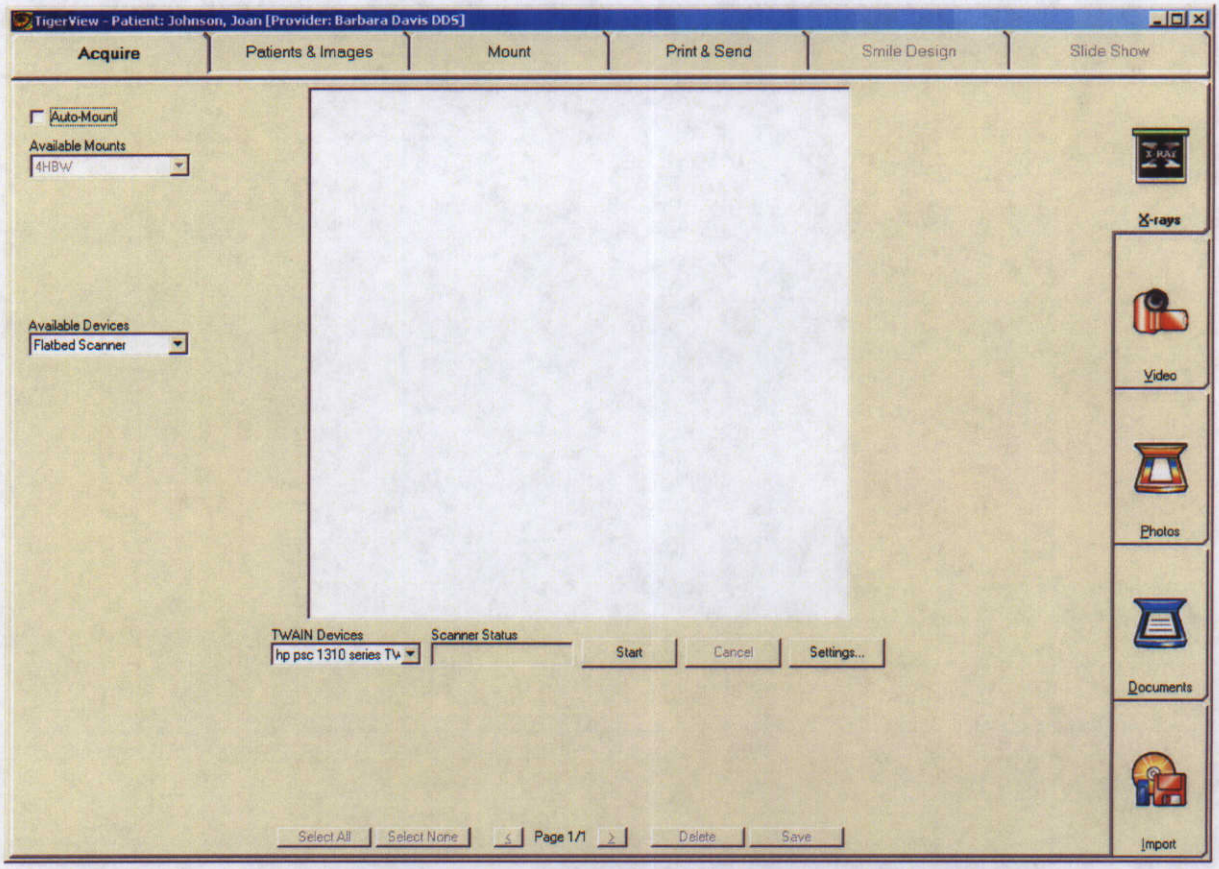
Acquire Window

X-rays tab - For a Flatbed Scanner



Images are entered into TigerView through the Acquire Windows. The methods to bring the images in are listed on the tabs on the right side of the Acquire window. The input methods consist of X-rays, Video, digital Photos, Documents or other images acquired by a flatbed scanner, and images that have already been saved digitally and will be brought in by Importing them.

Setting up Film on the Flatbed Scanner Bed

When scanning film, make sure the scanner's transparency cover – if it has one – is off. It will need to be replaced for scanning documents and photographs.

For the greatest efficiency, if the scanner will read negatives placed anywhere on the scanner bed, negatives should be lined up starting in the upper right corner angling

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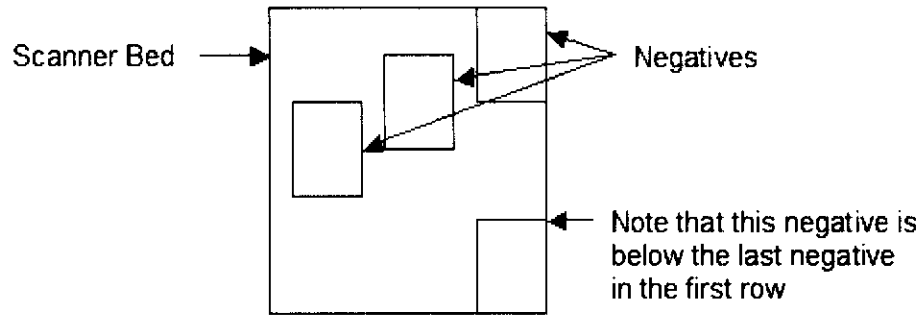
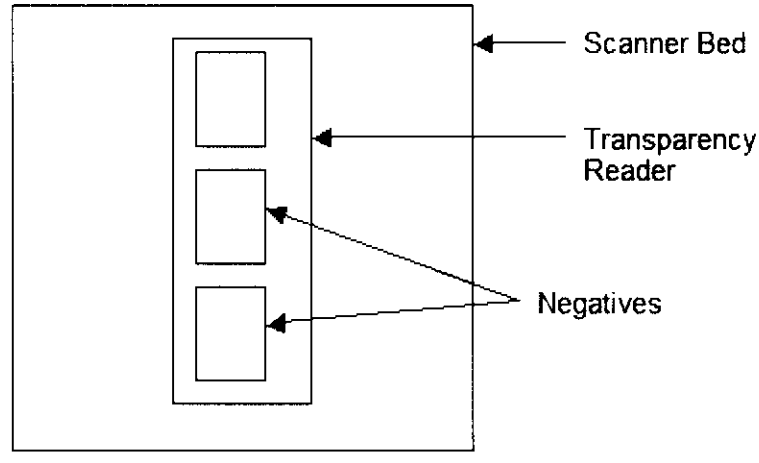
down to the lower left corner. The negatives should be placed film dot side down with each successive negative slightly below the negative in front of it in a stair step pattern.



If the scanner's transparency area does not include the entire scanner bed, line up the negatives under the area of the scanner bed that the transparency area does cover. For example, the Epson Perfection 1600 transparency area includes just an oblong section of the center of the scanner bed. In this case, negatives would be placed in a straight row within the oblong area.



In the Settings Button, Preferences tab, the Auto Segment should be checked to allow TigerView to automatically scan in each negative as a separate image, and the Allow Scan Edit should be checked to allow images to be input that TigerView doesn't recognize as film.

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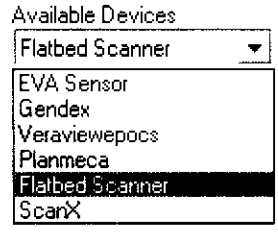
Available Devices

Click on the Available Devices drop down arrow to display the devices that TigerView can retrieve x-rays from.

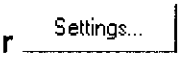


If a TigerView readable x-ray device is directly attached to the computer but does not display in the Available Devices drop down box on that computer, close TigerView, open TigerView Administration and add the device. See the TigerView Administration manual for instructions.

Select the Flatbed Scanner.

Twain Devices

Click on the Twain Devices drop down to display the Twain devices that TigerView can retrieve x-rays from. Select the appropriate device.

Settings Button for a Flatbed Scanner 

The Settings button will display windows that hold optional scanning settings for the scanner that is connected to this computer. These settings are advanced and will apply to all of the future images acquired by this scanner. The Reset button on each window will change the settings for that window back to the original settings TigerView came with.

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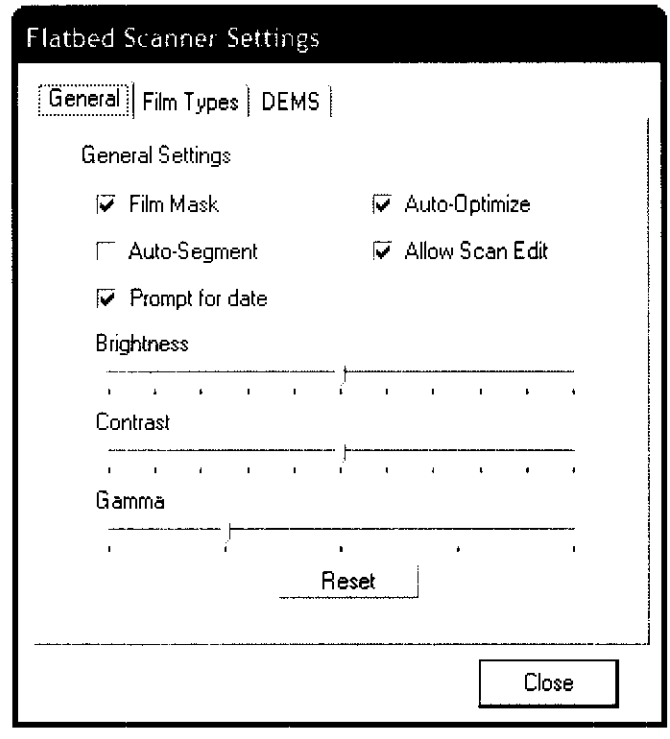
Settings Button – General Window – Flatbed scanner



Film Mask

A Film Mask is a black border that is placed around an image in the same way a colored mat surrounds a painting. This border can make the edges of the image look sharper. A check mark indicates that a film mask will be placed on all future flatbed scanned images.

Auto Optimize

Auto Optimize turns TigerView's Adaptive Image Processing (AIP) on or off. Adaptive Image Processing enhances the diagnostic quality of the scanned image. When the film being scanned is over exposed turn Auto Optimize off. A check mark indicates that Auto Optimize is on.

Auto-Segment

Auto-Segment is the ability to automatically recognize separate items on the scanner face as separate images. If four standard size negatives are placed on the scanner

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face and Auto-Segment is on (the Auto-Segment box has a check mark in it), TigerView should place a green box around each negative indicating that it recognizes four separate pieces of film to scan.

A green box indicates that TigerView recognizes the contents of the box as a standard size piece of film. A blue box indicates that TigerView does not recognize the item on the scanner face as standard film but does recognize the item as being something to scan. An item that does not have a box around it at all indicates that TigerView does not recognize the item as being something to scan.

If Auto-Segment is off (the box is not checked), the user must draw a box around each image manually by clicking and dragging a box around the image. Allow Scan Edit must be on (checked) to manually draw boxes. Auto-Segment and Allow Scan Edit should never both be off (unchecked).

Allow Scan Edit

After the flatbed scanner has scanned the objects on its face, TigerView either tries to automatically segment the objects into separate images, or waits for the user to separate the images manually by clicking and dragging boxes around the images. For the user to be able to manually draw boxes around each image, or for the user to be able to edit the boxes TigerView automatically drew around the images using Auto-Segment, Allow Scan Edit must be on (checked).

For instructions on how to add, edit and remove boxes please refer to the Add a Box Around an Item, Edit a Box Around an Item, and Remove a Green or Blue Box paragraphs coming up in this section of the manual.

Prompt for Date

If Prompt for Date is on (checked) TigerView will ask the user to enter the date the film was originally taken on. If Prompt for Date is off (unchecked) TigerView will save each scan using the current date.

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Brightness

Changing the Brightness setting can make up for an x-ray machine that shoots images with too much lightness or darkness. Brightness raises or lowers the lightness for every pixel in the image.

Contrast

Increasing the Contrast creates an image where the white areas are whiter and the black areas blacker. This causes the edges of a shape within the image to be more easily seen.

Gamma

A Gamma change leaves the whitest and blackest parts of an image alone as it makes the mid gray values lighter or darker. If the Gamma level gets moved up the Contrast level should be moved down. Changing the Gamma setting can make the image very dark.

Reset

Reset restores the default settings that came with TigerView.

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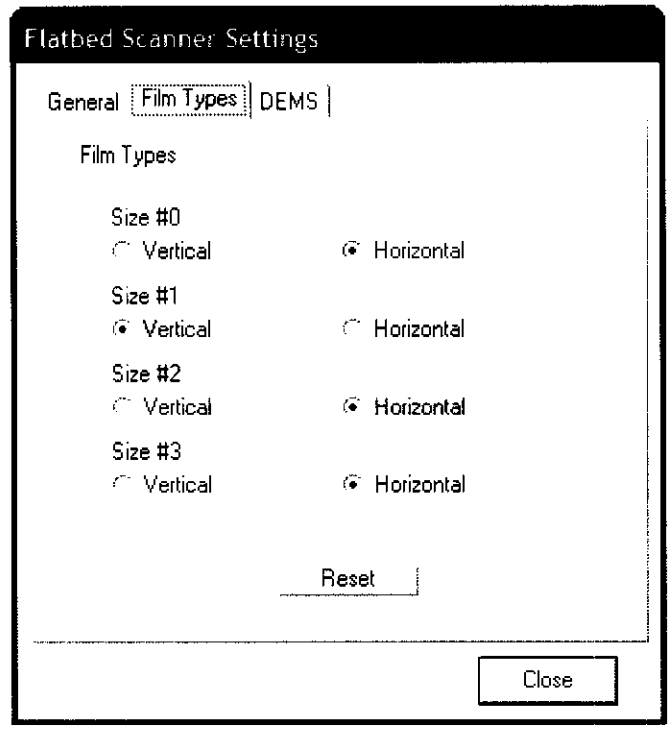
Settings Button – Film Types Window – Flatbed scanner



Film Types

The Film Types window lists each size of intra-oral film and whether it is to be scanned into TigerView in either a vertical or horizontal position. No matter how an image is brought into TigerView, its orientation can always be changed later, from vertical to horizontal or from horizontal to vertical. Please refer to the Patients & Images Window, Right Click On An Image section of this manual for instructions on how to rotate and flip individual images.

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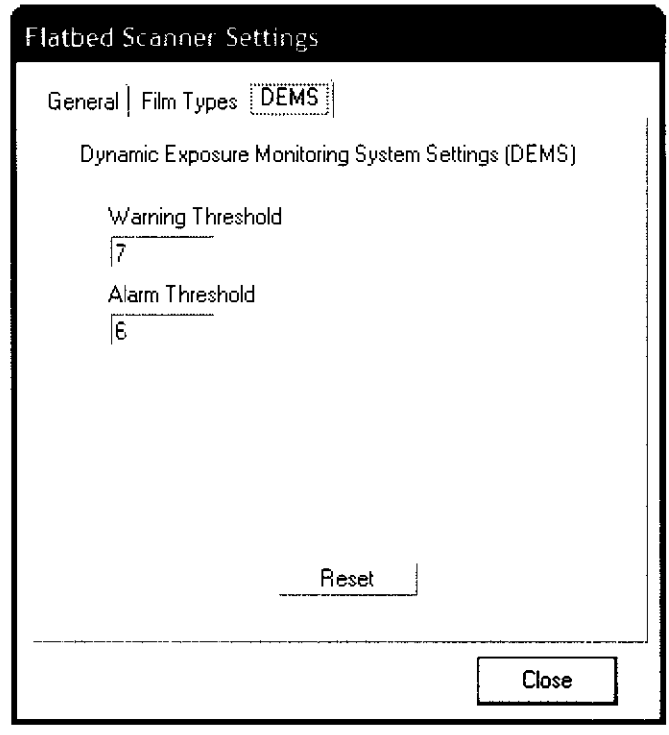
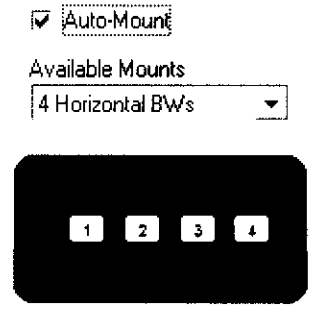
Settings Button – DEMS Window – Flatbed scanner



DEMS

DEMS stands for Dynamic Exposure Monitoring System. The DEMS thresholds are an advanced feature that should never be altered by the user without the permission of a TigerView representative. If, for some reason, the DEMS settings are altered, clicking on the Reset button Reset will restore the original settings.

Auto-Mount



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Check the Auto-Mount checkbox to automatically place each scanned image into a previously created and saved mount. Click on the down arrow of the Available Mounts drop down box to select a mount. The selected mount will display in the black mount box underneath the Available Mounts drop down box.

When using the Auto-Mount feature, images must be scanned in the order they are placed into the mount. For example, in the mount displayed above, the first scanned image would be placed in the image box with the number one on it, the second scanned image would be placed in the image box with the number two on it, etc. When mounting a large number of images, such as a full mouth series, taking the x-rays in the order specified by the mount can become a more complicated business.

When a mount is full the user will be asked if they want to create (save) the mount. If an image used in the mount is deleted before the mount is saved the image will automatically be removed from the mount. The next image acquired will be placed in the open mount space that was created by removing the image.

The alternative to Auto-Mount is to mount the images manually by dragging them onto a mount using the Mount window. For instructions on how to mount images manually, please refer to the Mount Window - Using the Mount Window to Mount Images section of this manual.

Start Button

Click on the Start button on the Acquire window to tell TigerView a scan is ready to begin.

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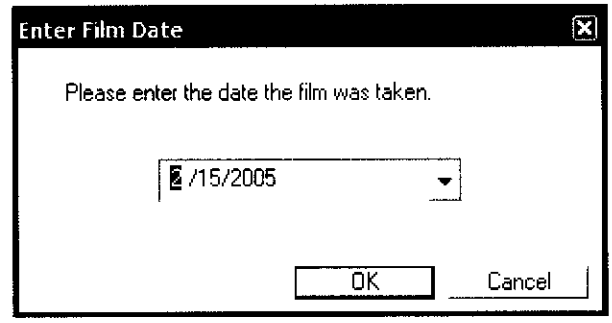
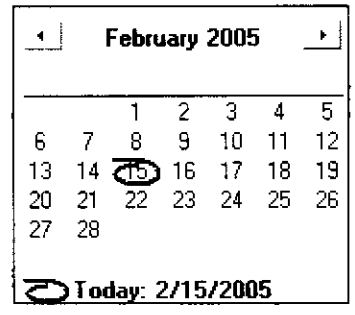
Enter Film Date



Enter the date that this film was taken then click on the OK button. If you are not sure of the date, click on the down arrow of the Enter Film Date drop down box to display a calendar.



Click on the left and right arrows that are on either side of the month and year to step backwards or forwards through the months. Click on a day to automatically insert that date into the Enter Film Date box and close the calendar.

After the scan date has been entered, the scanner's scanning software will open. For the following example, the Epson Perfection 3170 flatbed scanner will be used.

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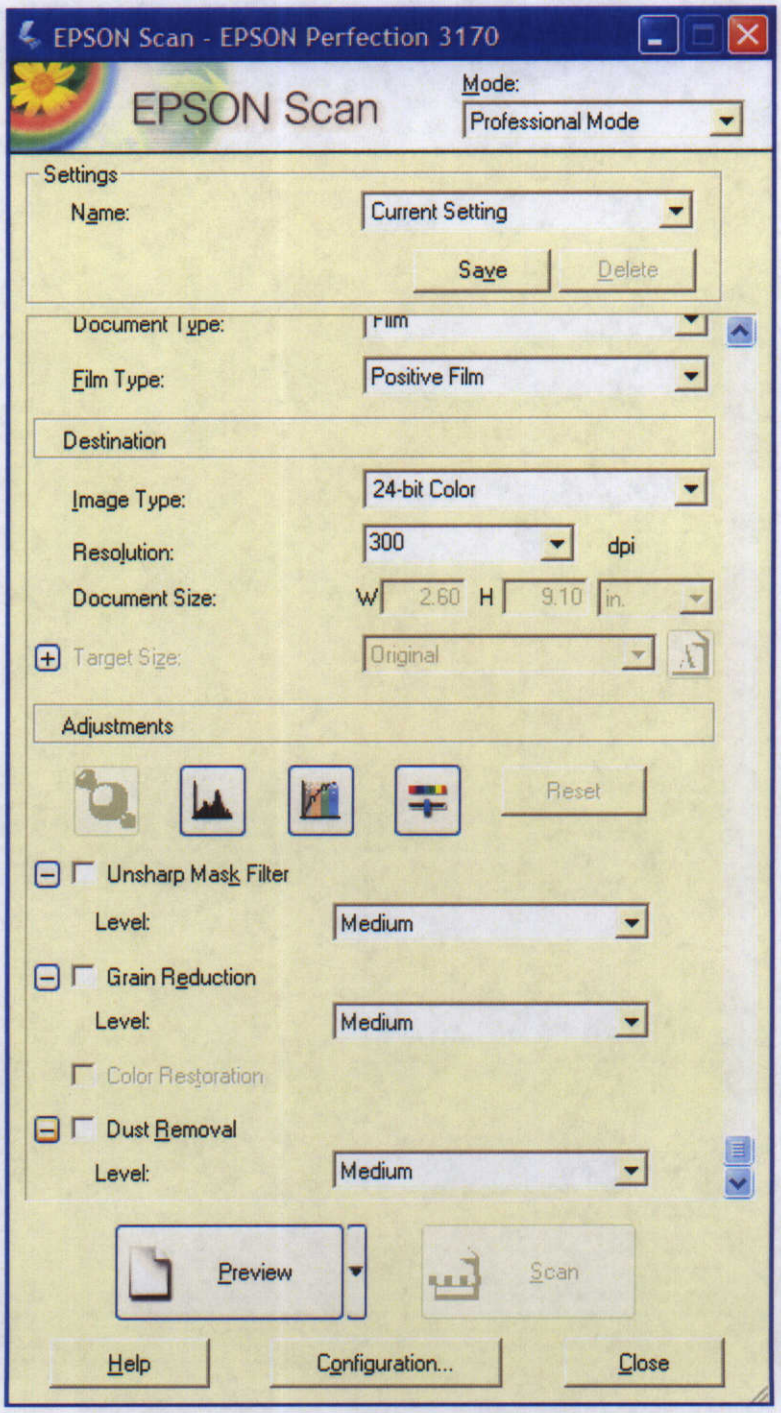
Epson Perfection 3170 Flatbed Scanner Setup



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Mode

If there is a choice of Modes, select Professional.

Document Type

Film refers to something that light can shine through, such as film or transparencies. For instructions on how to scan in something other than film, please refer to the Acquire Window - Photos Tab or the Acquire Window - Documents Tab sections of this manual.

Film Type

The selections consist of Positive, Color Negative and Black and White Negative. Most film is Positive.

Image Type

The selections for the Epson 3170 scanner include:

48-bit color
24-bit color
Color Smoothing
16-bit Grayscale
8-bit Grayscale
Black and White

Select 24-bit Color for color film or 8 bit Grayscale for black and white film.

Resolution

The Resolution setting for the picture that the Epson 3170 scanner will create starts at 50 dpi (dots per inch) and ends at 12,800 dpi. The suggested range is from 150 – 300.

Preview Button

Click on the Preview button to see a general image of the scanned film.

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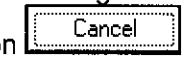
Scan Button

Click on the Scan button while the Preview window is open to actually scan the document.

During the Scanning Process

TigerView will automatically capture the image from the flatbed scanner. If the Cancel button 

is clicked on during the scanning process, the scan will be aborted.

After the Initial Scanning Process if Allow Scan Edit is on

Once an image has been scanned, if Allow Scan Edit is on (the Allow Scan Edit box is checked on the Settings Button – Preferences window), TigerView will pause to allow the user to add or edit boxes around each image. A green box around an item indicates that TigerView recognizes that item as a standard piece of film to be scanned. A blue box around an item indicates that TigerView recognizes that item as being something to scan but does not recognize it as a standard piece of film. If an item does not have a box around it TigerView will not attempt to scan it. Whatever is within the box will be what TigerView acquires as an image.

Add a Box Around an Item

Adding a box around an item will cause TigerView to scan that item. To add a box, left click on a corner of the item, hold the left mouse button down and drag the mouse to the opposite corner of the item to scan.

Edit a Box Around an Item

Editing a box involves using the resizing or rotating arrows on the box to change its size or orientation. The rotating arrows are located at the corners of the box. The resizing arrows are located in the middle of each side. Click and drag the appropriate arrow.

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Remove a Green or Blue Box

Removing a green or blue box from around an item prevents that item from being scanned. To remove a box, right click on the box and select Delete Outline.

After the Boxes have been Adjusted

Once the user is done adjusting boxes the OK button should be clicked to allow the final scanning processes to start.

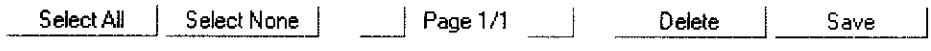
After the Final Scanning Process

The final scanning process involves rotating the images to make them straight and optimizing them to create the best images possible. The images will then be moved to the area under the TWAIN Devices drop down box as thumbnail images. The images still need to be selected and saved into TigerView.

A DEMS light on each image will be green if TigerView is satisfied with the amount of information in the image, yellow if TigerView is not totally happy, and red if the image should be checked.

To check an image, double click on the image to open it into the TigerView Image Viewer. If the image quality is acceptable, close the Image Viewer by clicking on the Close Window box in the upper right corner of the window and move on to selecting and saving the image. If the image quality is not acceptable, close the Image Viewer and rescan the film. After rescanning, if the DEMS light is still red, check the image again. If the image is acceptable, select the image then click on the Save button to save the image into TigerView. If the image is still not acceptable consider requesting that a new film x-ray be taken.

Image Buttons



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Select an Image

To select an image, left click on it. To select multiple images, left click on multiple images. To select all of the images click on the Select All button at the bottom of the window. Select All A selected image will have a green box around it.

Deselect an Image

To deselect an image, left click on it again. To deselect all of the images click on the Select None button at the bottom of the window. Select None

Delete an Image

To delete an image, first select the image or images to be deleted, and then click on the Delete button at the bottom of the window. Delete Deleted images are not recoverable.

Save an Image

To save an image, first select the image or images to be saved, and then click on the Save button at the bottom of the window. Save The image will save, no matter what color its DEMS light is, to the currently selected patient.

Open an Image into the Image Viewer or Viewer

To open an image into the Image Viewer or Viewer window, double click on the image using the left mouse button or right click on the image and select View from the Right Click Image Menu. For instructions on how to use the Image Viewer window, please refer to the Image Viewer Window section of this manual. For instructions on how to use the Viewer window, please refer to the Viewer Window section of this manual.

Mount an Image or include an image in a Report

To mount an image or to include an image in a report, click on the image then click on either the Mount tab or the Print & Send tab. Both tabs are located at the top of the TigerView window.

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Right Click Image Menu

To flip, rotate, add annotations, add keywords, add procedures, copy, archive, e-mail, export, print, etc before saving, right click on the image. This Right Click Image Menu can be accessed any time the image can be viewed outside of the TigerView Image Viewer window. For instructions on how to use the Right Click Image Menu see Right Click On An Image in the Patients & Images Window - Images Tab section of this manual.

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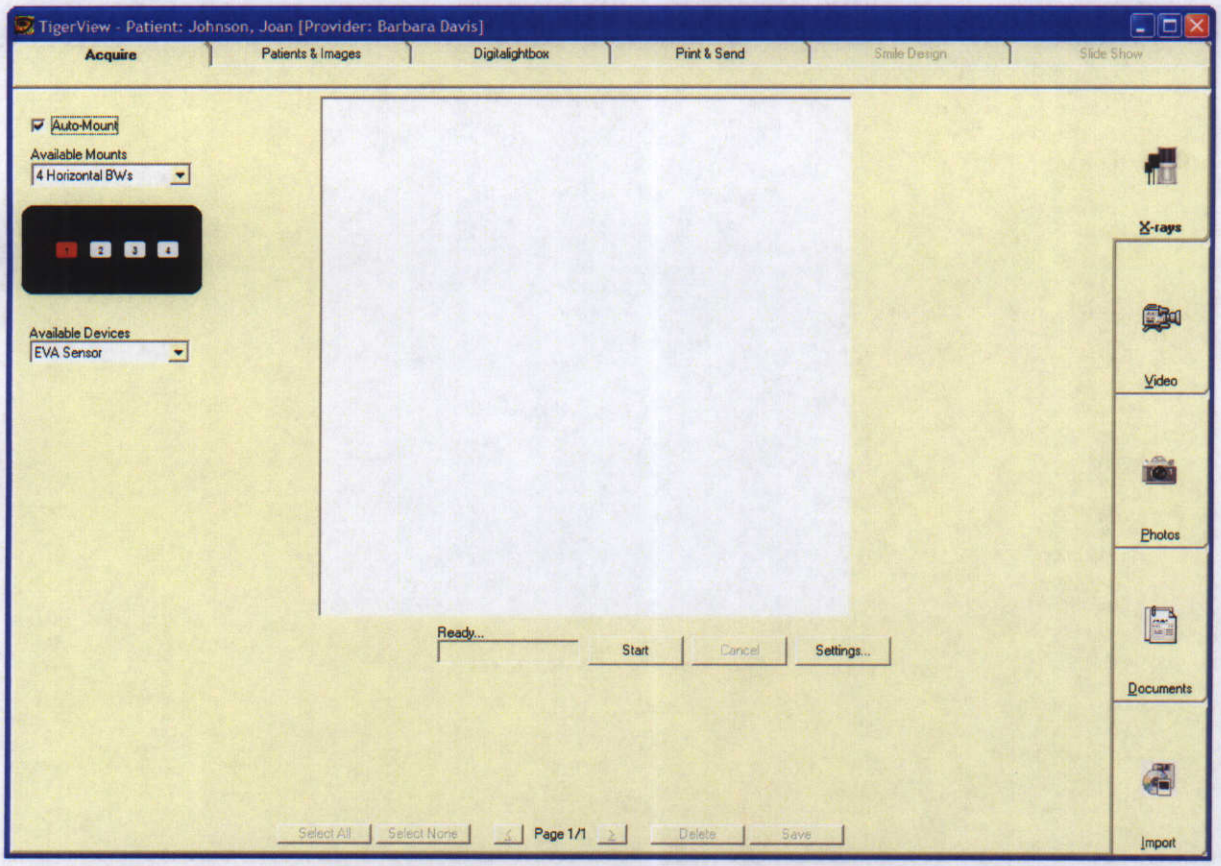
Acquire Window

X-rays tab – For an EVA Sensor



Images are entered into TigerView through the Acquire Windows. The methods to bring the images in are listed on the tabs on the right side of the Acquire window. The input methods consist of X-rays, Video, digital Photos, Documents or other images acquired by a flatbed scanner, and images that have already been saved digitally and will be brought in by Importing them.

Available Devices

Click on the Available Devices drop down arrow to display the devices that TigerView can retrieve x-rays from.

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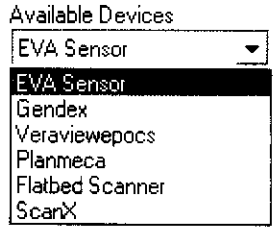
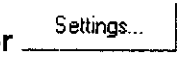


If a TigerView readable x-ray device is directly attached to the computer but does not display in the Available Devices drop down box on that computer, close TigerView, open TigerView Administration and add the device. See the TigerView Administration manual for instructions.

Select the EVA Sensor.

Settings Button for an EVA Sensor 

The Settings button will display windows that hold optional settings for the sensor that is connected to this computer. These settings are advanced and will apply to all of the future images acquired by this sensor. The Reset button on each window will change the settings for that window back to the original settings TigerView came with.

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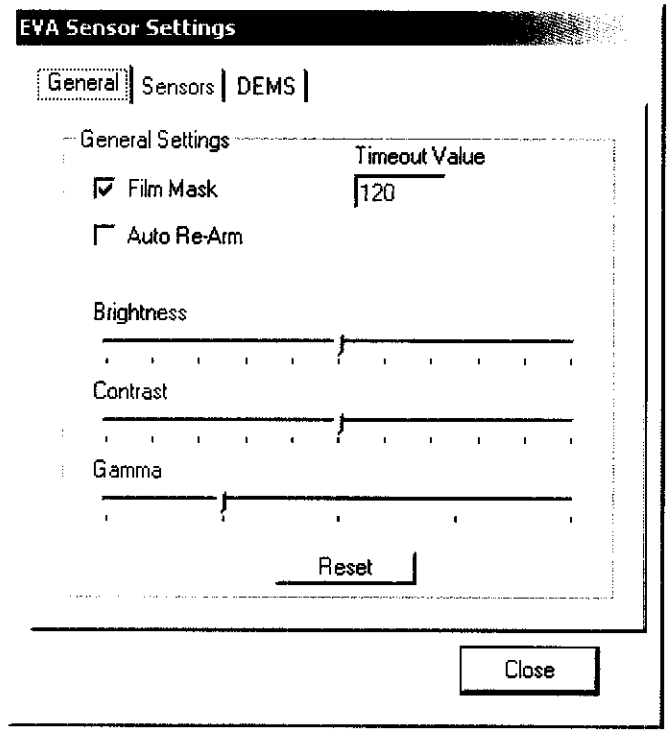
Settings Button – General Window – EVA Sensor



Film Mask

A Film Mask is a black border that is placed around an image in the same way a black mat surrounds a painting. This border can make the edges of the image look sharper. A check mark indicates that a film mask will be placed on all future EVA Sensor acquired images.

Auto Re-Arm

A check mark indicates that the sensor will automatically ready itself to acquire another image after it's finished acquiring the current image.

Timeout Value

The Timeout Value is the amount of time TigerView will wait for the EVA Sensor to finish initializing and become ready to accept information.

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Brightness

Changing the Brightness setting can make up for an x-ray machine that shoots images with too much lightness or darkness. Brightness raises or lowers the lightness for every pixel in the image.

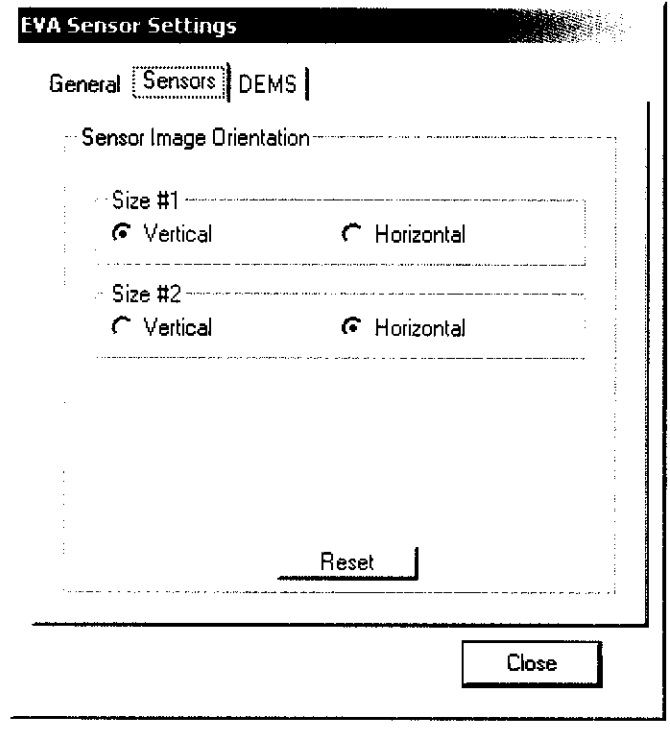
Contrast

Increasing the Contrast creates an image where the white areas are whiter and the black areas blacker. This causes the edges of a shape within the image to be more easily seen.

Gamma

A Gamma change leaves the whitest and blackest parts of an image alone as it makes the mid gray values lighter or darker. If the Gamma level gets moved up the Contrast level should be moved down. Changing the Gamma setting can make the image very dark.

Settings Button – Sensors Window – EVA Sensor



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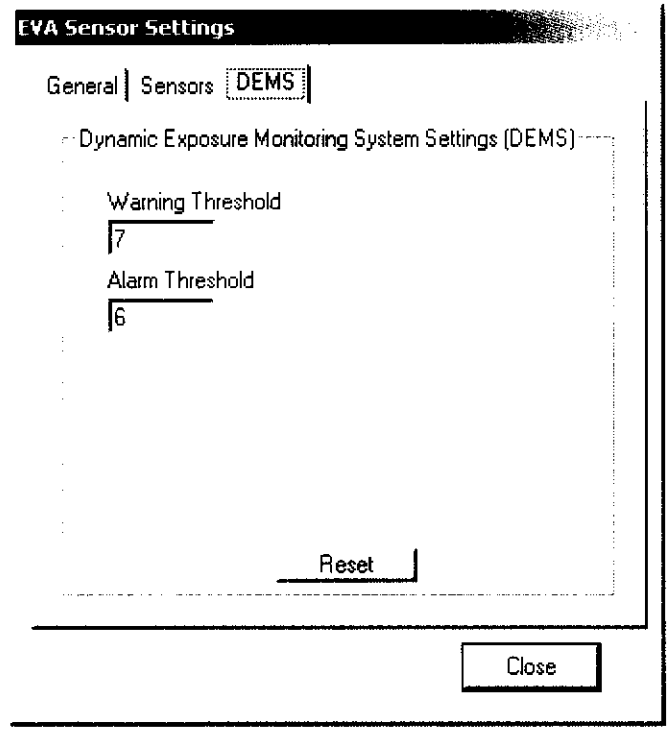
Sensor Image Orientation

The Sensors window lists the two sizes of EVA Sensors and whether the image taken by each size is to be scanned into TigerView in either a vertical or horizontal position. No matter how an image is brought into TigerView, its orientation can always be changed later, from vertical to horizontal or from horizontal to vertical. Please refer to the Patients & Images Window – Images Tab, Right Click On An Image section of this manual for instructions on how to rotate and flip individual images.

Settings Button – DEMS Window – EVA Sensor



DEMS

DEMS stands for Dynamic Exposure Monitoring System. The DEMS thresholds are an advanced feature that should never be altered by the user without the permission of a TigerView representative. If, for some reason, the DEMS settings are altered, clicking on the Reset button Reset will restore the original settings.

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Auto-Mount

Check the Auto-Mount checkbox to automatically place each image into a previously created and saved mount. Click on the down arrow of the Available Mounts drop down box to select a mount. The selected mount will display in the black mount box underneath the Available Mounts drop down box.

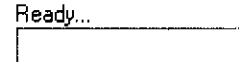
When using the Auto-Mount feature, images must be scanned in the order they are placed into the mount. For example, in the mount displayed above, the first scanned image would be placed in the image box with the number one on it, the second scanned image would be placed in the image box with the number two on it, etc. When mounting a large number of images, such as a full mouth series, taking the x-rays in the order specified by the mount can become a more complicated business.

When a mount is full the user will be asked if they want to create (save) the mount. If an image used in the mount is deleted before the mount is saved the image will automatically be removed from the mount. The next image acquired will be placed in the open mount space that was created by removing the image.

The alternative to Auto-Mount is to mount the images manually by dragging them onto a mount using the Mount window. For instructions on how to mount images manually, please refer to the Mount Window - Using the Mount Window to Mount Images section of this manual.

Initializing vs. Ready

During the time that the EVA Sensor is initializing, the box next to the Start button will display the word "Initializing". Once the EVA Sensor is ready to be used, the box will display the word "Ready".



Start Button

Once the EVA Sensor has finished initializing and is ready to be used, the Start button on the Acquire window can be clicked to tell TigerView an image is ready to be acquired.

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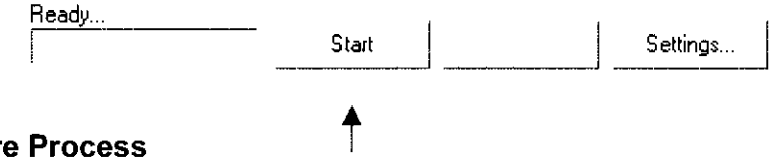
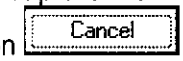


During the Acquire Process

TigerView will automatically capture the image from the sensor. If the Cancel button 

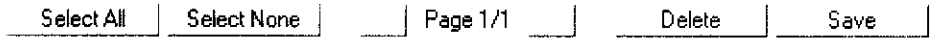
is clicked during the scanning process, the scan will be aborted.

After the Acquire Process

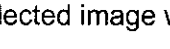
Once an image has been acquired it will appear in the area under the Start button. A DEMS light on each image will be green if TigerView is satisfied with the amount of information in the image, yellow if TigerView is not totally happy, and red if the image should be checked.

To check an image, double click on the image to open it into the TigerView Image Viewer. If the image quality is acceptable, close the Image Viewer by clicking on the Close Window box in the upper right corner of the window and either continue acquiring images or move on to selecting the images and saving them into TigerView. If the image quality is not acceptable, close the Image Viewer, and reacquire the image. Once the image is acceptable, select the image then click on the Save button to save the image into TigerView.

Image Buttons



Select an Image

To select an image, left click on it. To select multiple images, click on multiple images. To select all of the images click on the Select All button at the bottom of the window. 

A selected image will have a green box around it.

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Deselect an Image

To deselect an image, click on it again. To deselect all of the images click on the Select None button at the bottom of the window. Select None

Delete an Image

To delete an image, first select the image or images to be deleted, and then click on the Delete button at the bottom of the window. Delete Deleted images are not recoverable.

Save an Image

To save an image, first select the image or images to be saved, and then click on the Save button at the bottom of the window. Save The image will save, no matter what color its DEMS light is, to the currently selected patient.

Open an Image into the Image Viewer or Viewer

To open an image into the Image Viewer or Viewer window, double click on the image using the left mouse button or right click on the image and select View from the Right Click Image Menu. For instructions on how to use the Image Viewer window, please refer to the Image Viewer Window section of this manual. For instructions on how to use the Viewer window, please refer to the Viewer Window section of this manual.

Mount an Image or include an image in a Report

To mount an image or to include an image in a report, click on the image then click on either the Mount tab or the Print & Send tab. Both tabs are located at the top of the TigerView window.

Right Click Image Menu

To flip, rotate, add annotations, add keywords, add procedures, copy, archive, e-mail, export, print, etc before saving, right click on the image. This Right Click Image Menu can be accessed any time the image can be viewed outside of the TigerView Image Viewer. For instructions on how to use the Right Click Image Menu see Patients & Images Window, Right Click On An Image section of this manual.

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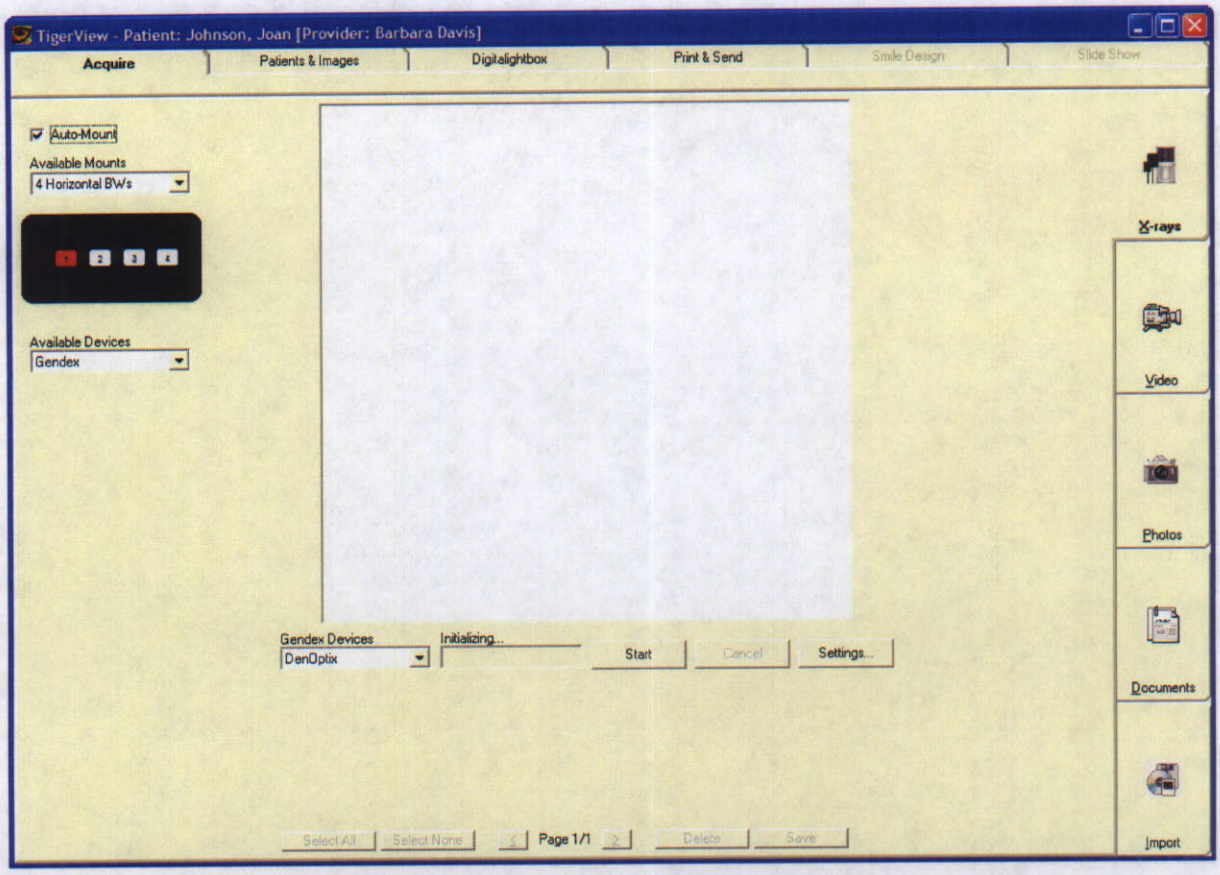
Acquire Window

X-rays tab – For a Gendex Device



Images are entered into TigerView through the Acquire Windows. The methods to bring the images in are listed on the tabs on the right side of the Acquire window. The input methods consist of X-rays, Video, digital Photos, Documents or other images acquired by a flatbed scanner, and images that have already been saved digitally and will be brought in by Importing them.

Available Devices

Click on the Available Devices drop down arrow to display the devices that TigerView can retrieve x-rays from.

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

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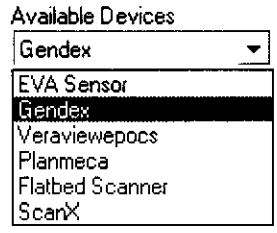
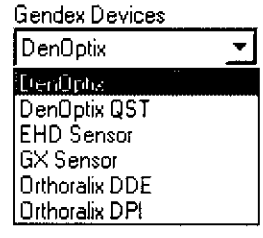


If a TigerView readable x-ray device is directly attached to the computer but does not display in the Available Devices drop down box on that computer, close TigerView, open TigerView Administration and add the device. See the TigerView Administration manual for instructions.

Select Gendex.

Gendex Devices

Click on the Gendex Devices down arrow to display the specific Gendex devices that TigerView can retrieve x-rays from.



Settings Button

The TigerView window for the different Gendex devices does not change much. One of the differences between the Gendex devices in TigerView lies in the windows of the Settings button. The Settings button displays windows that hold optional settings for the Gendex device that is connected to this computer. These settings are advanced and will apply to all of the future images acquired by this device. The Reset button on each window will change the settings for that window back to the original settings TigerView came with.

The following sections will explain each Settings window.

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

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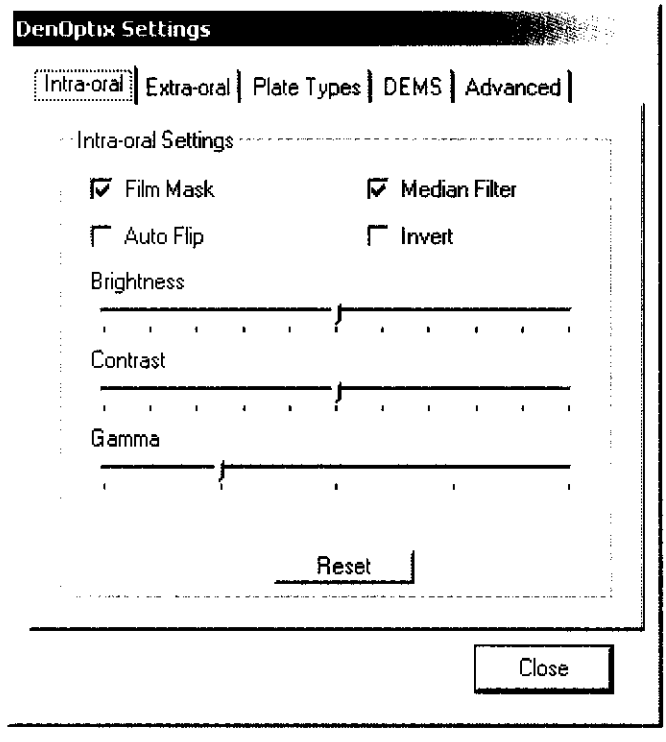
Settings Button for a DenOptix Phosphor Plate Scanner

Settings Button – Intra-oral Window – DenOptix



Film Mask

A Film Mask is a black border that is placed around an image in the same way a black mat surrounds a painting. This border can make the edges of the image look sharper. A check mark indicates that a film mask will be placed on all future DenOptix scanned images.

Median Filter

When Median Filter is off, the image will have a more salt and pepper (noise) look but the edges of the image will be more defined.

When Median Filter is on (checked), the image won't have as many unnecessary white dots but the edges of the image may not be as defined.

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

Records processed under FOIA Request # 2015-8521; Released by CDRH on 05-10-2016

Auto Flip

When an image is Auto Flipped the view is as though sitting on the other side of the item being x-rayed looking at the x-ray head.

Invert

Inverting an image causes the white areas to become black and the black areas to become white.

Brightness

Changing the Brightness setting can make up for an x-ray machine that shoots images with too much lightness or darkness. Brightness raises or lowers the lightness for every pixel in the image.

Contrast

Increasing the Contrast creates an image where the white areas are whiter and the black areas blacker. This causes the edges of a shape within the image to be more easily seen.

Gamma

A Gamma change leaves the whitest and blackest parts of an image alone as it makes the mid gray values lighter or darker. If the Gamma level gets moved up the Contrast level should be moved down. Changing the Gamma setting can make the image very dark.

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

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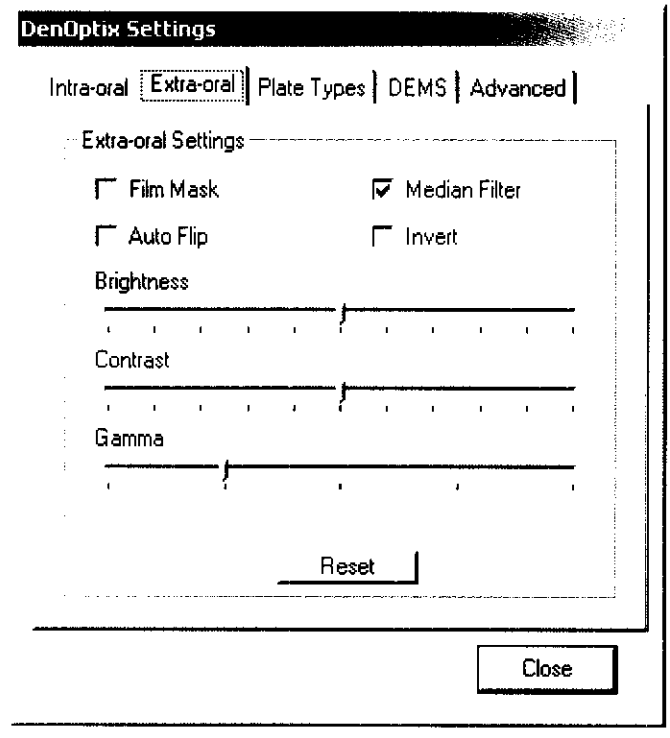
Settings Button – Extra-oral Window – DenOptix



Instructions for the Extra-oral settings are exactly the same as for the Intra-oral settings. For instructions, please refer to the Intra-oral Settings section above.

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Settings Button – Plate Types Window – DenOptix

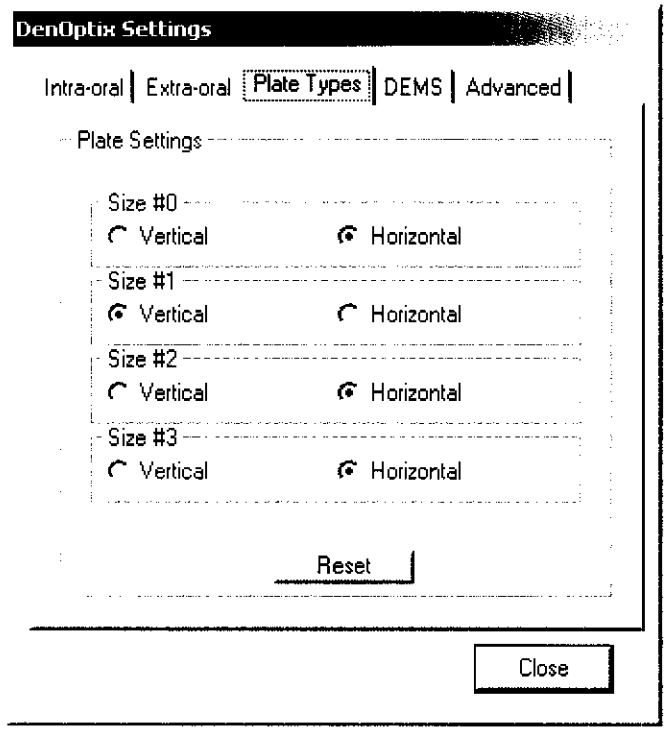

Plate Types

The Plate Types window lists each size of intra-oral phosphor plate and whether it is to be scanned into TigerView in either a vertical or horizontal position. No matter how an image is brought into TigerView, its orientation can always be changed later, from vertical to horizontal or from horizontal to vertical. Please refer to the Patients & Images Window – Images Tab, Right Click On An Image section of this manual for instructions on how to rotate and flip individual images.

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

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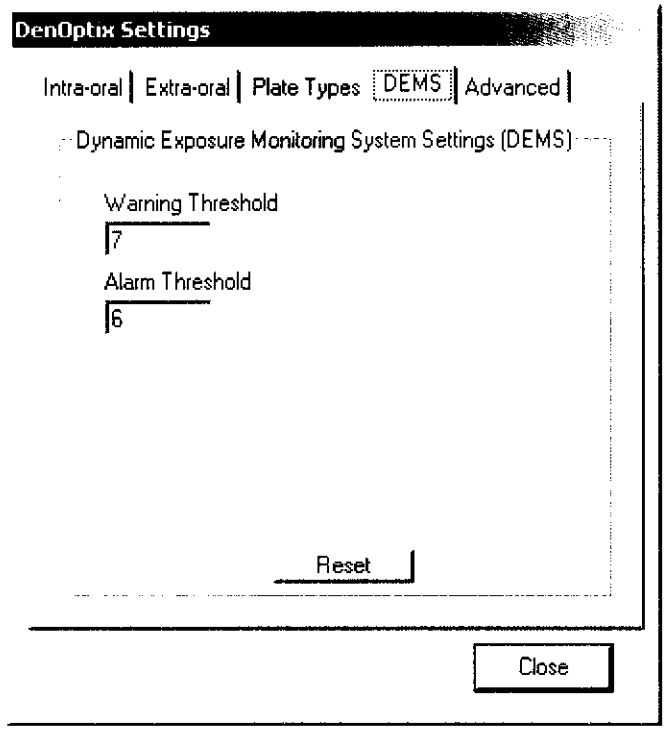
Settings Button – DEMS Window – DenOptix



DEMS

DEMS stands for Dynamic Exposure Monitoring System. The DEMS thresholds are an advanced feature that should never be altered by the user without the permission of a TigerView representative. If, for some reason, the DEMS settings are altered, clicking on the Reset button Reset will restore the original settings.

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

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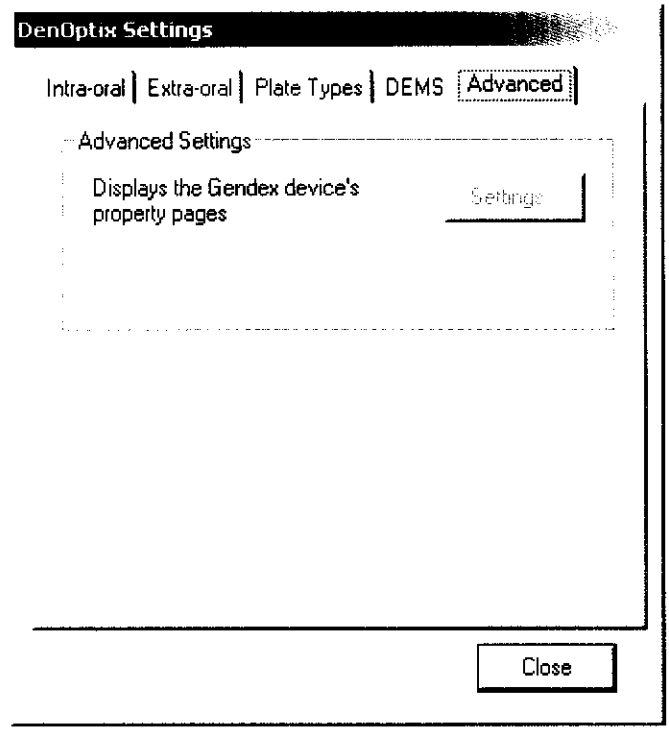
Settings Button – Advanced Window – DenOptix



Advanced Settings

Click on the Settings button on the Advanced Settings window to display the property pages for the DenOptix.

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

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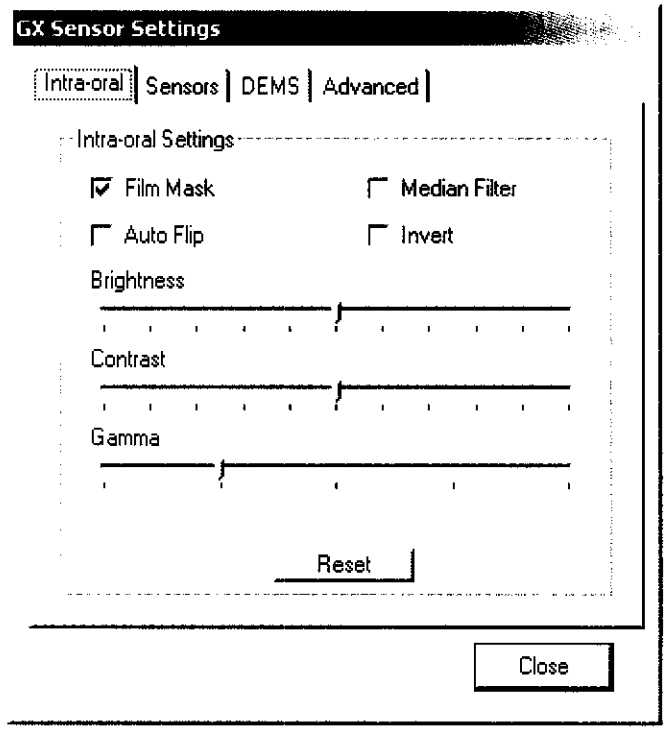
Settings Button for a GX Sensor

Settings Button – Intra-oral Window – GX & EHD Sensors



Film Mask

A Film Mask is a black border that is placed around an image in the same way a black mat surrounds a painting. This border can make the edges of the image look sharper. A check mark indicates that a film mask will be placed on all future GX Sensor images.

Median Filter

When Median Filter is off, the image will have a more salt and pepper look but the edges of the image will be more defined.

When Median Filter is on (checked), the image won't have as many unnecessary white dots but the edges of the image may not be as defined.

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Auto Flip

When an image is Auto Flipped the view is as though sitting on the other side of the item being x-rayed looking at the x-ray head.

Invert

Inverting an image causes the white areas to become black and the black areas to become white.

Brightness

Changing the Brightness setting can make up for an x-ray machine that shoots images with too much lightness or darkness. Brightness raises or lowers the lightness for every pixel in the image.

Contrast

Increasing the Contrast creates an image where the white areas are whiter and the black areas blacker. This causes the edges of a shape within the image to be more easily seen.

Gamma

A Gamma change leaves the whitest and blackest parts of an image alone as it makes the mid gray values lighter or darker. If the Gamma level gets moved up the Contrast level should be moved down. Changing the Gamma setting can make the image very dark.

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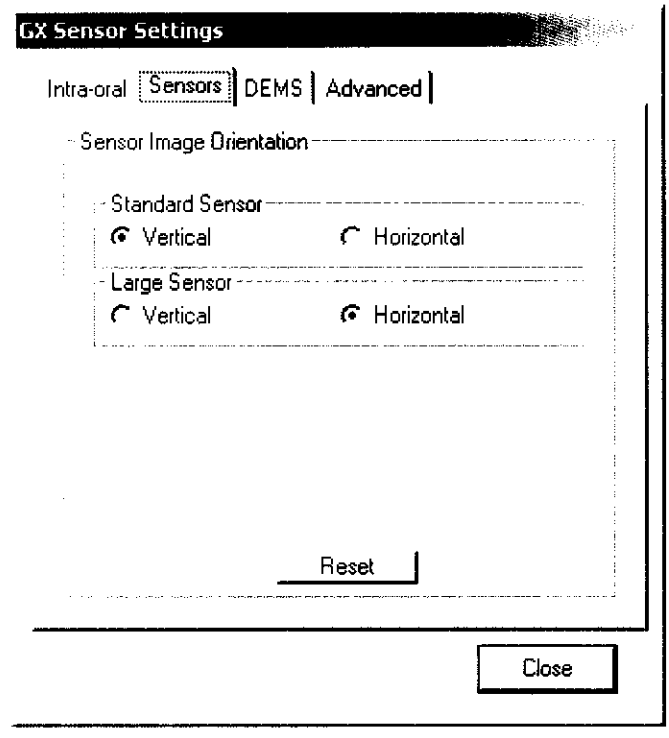
Settings Button – Intra-oral Window – GX & EHD Sensors



Sensors Image Orientation

The Sensors window lists the two sizes of GX Sensors and whether the image taken by each size is to be scanned into TigerView in either a vertical or horizontal position. No matter how an image is brought into TigerView, its orientation can always be changed later, from vertical to horizontal or from horizontal to vertical. Please refer to the Patients & Images Window – Images Tab, Right Click On An Image section of this manual for instructions on how to rotate and flip individual images.

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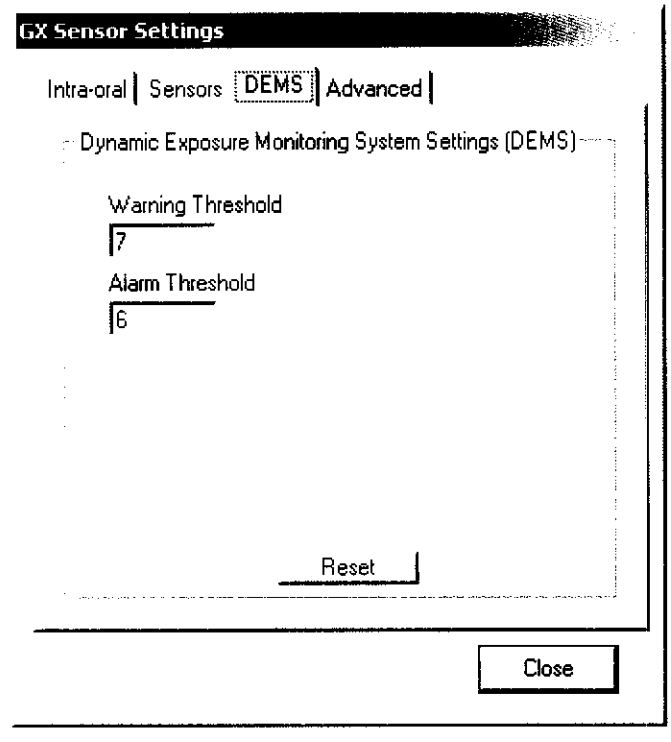
Settings Button – Intra-oral Window – GX & EHD Sensors



DEMS

DEMS stands for Dynamic Exposure Monitoring System. The DEMS thresholds are an advanced feature that should never be altered by the user without the permission of a TigerView representative. If, for some reason, the DEMS settings are altered, clicking on the Reset button Reset will restore the original settings.

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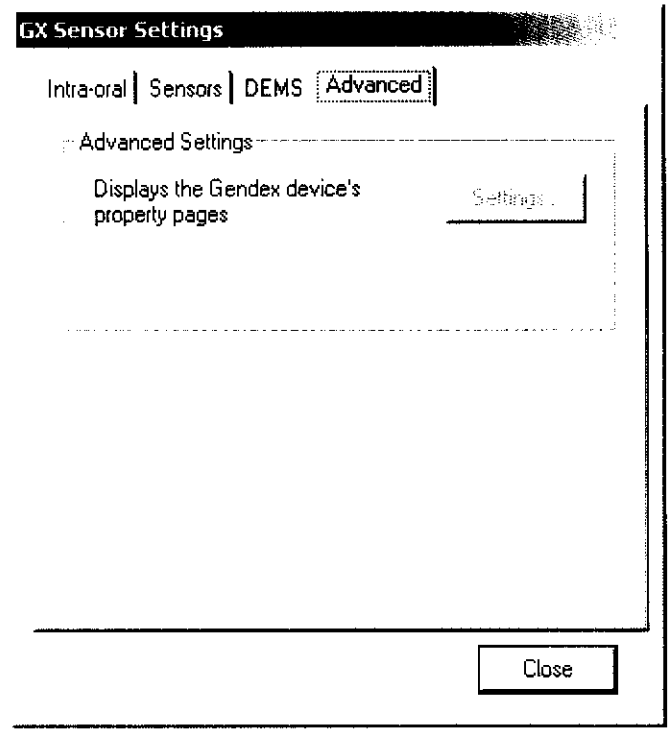
Settings Button – Intra-oral Window – GX & EHD Sensors



Advanced Settings

Click on the Settings button on the Advanced Settings window to display the property pages for the GX Sensor.

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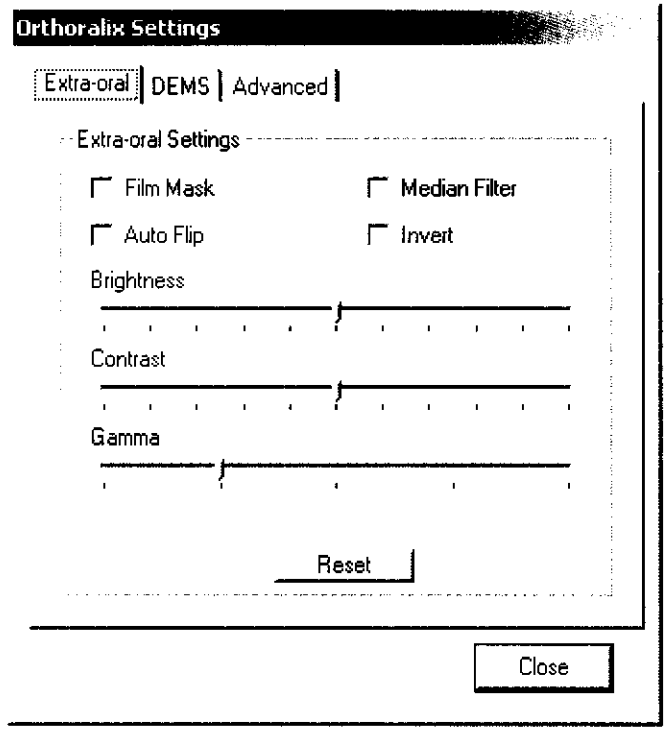
Settings Button for a Orthoralix DDE or Orthoralix DPI Pan Device

Settings Button – Extra-oral Window – Orthoralix



Film Mask

A Film Mask is a black border that is placed around an image in the same way a black mat surrounds a painting. This border can make the edges of the image look sharper. A check mark indicates that a film mask will be placed on all future Orthoralix images.

Median Filter

When Median Filter is off, the image will have a more salt and pepper look but the edges of the image will be more defined.

When Median Filter is on (checked), the image won't have as many unnecessary white dots but the edges of the image may not be as defined.

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

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Auto Flip

When an image is Auto Flipped the view is as though sitting on the other side of the item being x-rayed looking at the x-ray head.

Invert

Inverting an image causes the white areas to become black and the black areas to become white.

Brightness

Changing the Brightness setting can make up for an x-ray machine that shoots images with too much lightness or darkness. Brightness raises or lowers the lightness for every pixel in the image.

Contrast

Increasing the Contrast creates an image where the white areas are whiter and the black areas blacker. This causes the edges of a shape within the image to be more easily seen.

Gamma

A Gamma change leaves the whitest and blackest parts of an image alone as it makes the mid gray values lighter or darker. If the Gamma level gets moved up the Contrast level should be moved down. Changing the Gamma setting can make the image very dark.

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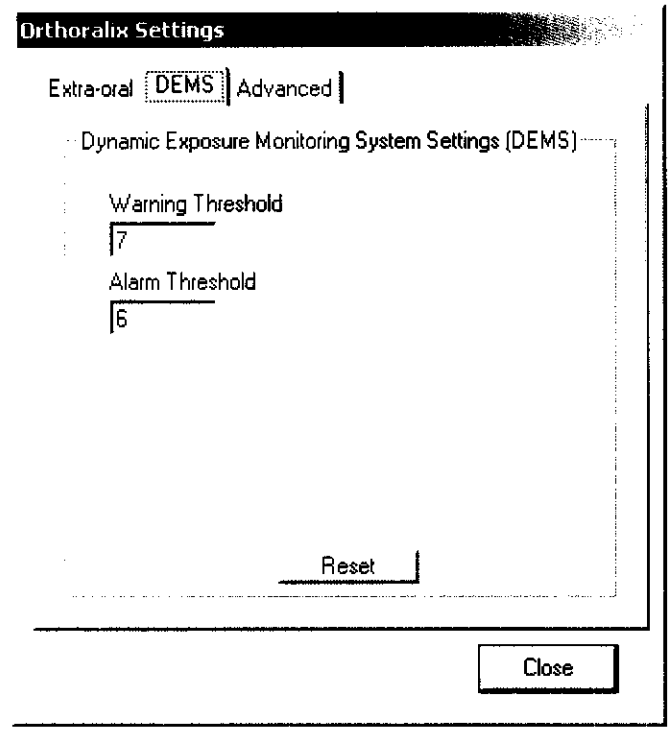
Settings Button – DEMS Window – Orthoralix



DEMS

DEMS stands for Dynamic Exposure Monitoring System. The DEMS thresholds are an advanced feature that should never be altered by the user without the permission of a TigerView representative. If, for some reason, the DEMS settings are altered, clicking on the Reset button Reset will restore the original settings.

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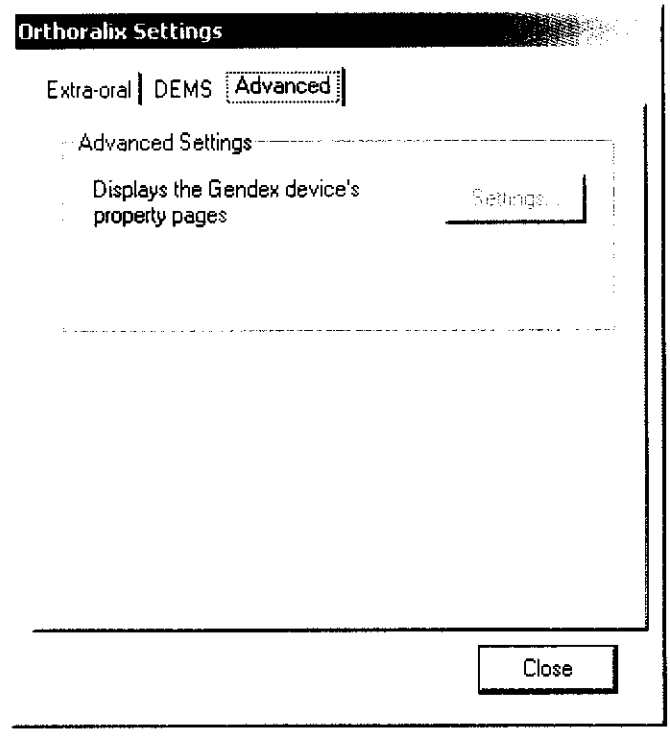
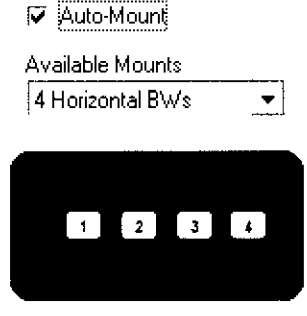
Settings Button – Advanced Window – Orthoralix



Advanced Settings

Click on the Settings button to display the property pages for the Orthoralix pan device.

Auto-Mount



Check the Auto-Mount checkbox to automatically place each scanned image into a previously created and saved mount. Click on the down arrow of the Available Mounts drop down box to select a mount. The selected mount will

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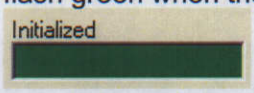
display in the black mount box underneath the Available Mounts drop down box.

When using the Auto-Mount feature, images must be scanned in the order they are placed into the mount. For example, in the mount displayed above, the first scanned image would be placed in the image box with the number one on it, the second scanned image would be placed in the image box with the number two on it, etc. When mounting a large number of images, such as a full mouth series, taking the x-rays in the order specified by the mount can become a more complicated business.

When a mount is full the user will be asked if they want to create (save) the mount. If an image used in the mount is deleted before the mount is saved the image will automatically be removed from the mount. The next image acquired will be placed in the open mount space that was created by removing the image.

The alternative to Auto-Mount is to mount the images manually by dragging them onto a mount using the Mount window. For instructions on how to mount images manually, please refer to the Mount Window - Using the Mount Window To Mount Images section of this manual.

Device Ready Bar

The Device Ready Bar changes slightly depending on which Gendex device is used. If an Orthoralix or a Sensor is used the bar will flash green when the device is ready to acquire an image. 

Push the button on the Orthoralix or the Sensor while the bar is flashing green to acquire the image. Once the image is acquired the bar will flash red once

and a thumbnail version of the image will appear at the bottom of the TigerView window.

If a Denoptix is used, load the plates onto the carousel, place the carousel inside the Denoptix, then click on the Start button in TigerView.

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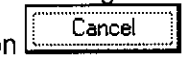
The bar will tell you when the Denoptix is scanning the plates

. As the images are acquired a thumbnail of each will appear at the bottom of the TigerView window.

Gendex Devices

For more specific instructions on how to use each Gendex device please refer to the manufacturer's instructions that came with it.

During the Scanning Process

TigerView will automatically capture the image from the Gendex device. If the Cancel button 

is clicked during the scanning process, the scan will be aborted.

After the Scanning Process

Once an image has been acquired it will appear in the area under the Start button. A DEMS light on each image will be green if TigerView is satisfied with the amount of information in the image, yellow if TigerView is not totally happy, and red if the image should be checked.

To check an image, double click on the image to open it into the TigerView Image Viewer. If the image quality is acceptable, close the Image Viewer by clicking on the Close Window box ☒ in the upper right corner of the window and move on to selecting and saving the image. If the image quality is not acceptable, close the Image Viewer, and rescan the image. If the image is acceptable, select the image then click on the Save button to save the image into TigerView. If the image is still not acceptable, consider retaking the x-ray then using the DenOptix to scan it again.

The image must be selected and saved before it is loaded into TigerView

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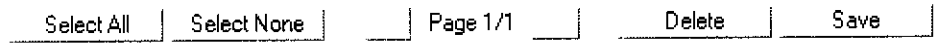
Image Buttons



Select an Image

To select an image, left click on it. To select multiple images, click on multiple images. To select all of the images click on the Select All button at the bottom of the window. Select All A selected image will have a green box around it.

Deselect an Image

To deselect an image, click on it again. To deselect all of the images click on the Select None button at the bottom of the window. Select None

Delete an Image

To delete an image, first select the image or images to be deleted, and then click on the Delete button at the bottom of the window. Delete A deleted image is not recoverable.

Save an Image

To save an image, first select the image or images to be saved, and then click on the Save button at the bottom of the window. Save The image will save, no matter what color its DEMS light is, to the currently selected patient.

Open an Image into the Image Viewer or Viewer

To open an image into the Image Viewer or Viewer window, double click on the image using the left mouse button or right click on the image and select View from the Right Click Image Menu. For instructions on how to use the Image Viewer window, please refer to the Image Viewer Window section of this manual. For instructions on how to use the Viewer window, please refer to the Viewer Window section of this manual.

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Mount an Image or include an image in a Report

To mount an image or to include an image in a report, click on the image then click on either the Mount tab or the Print & Send tab. Both tabs are located at the top of the TigerView window.

Right Click Image Menu

To flip, rotate, add annotations, add keywords, add procedures, copy, archive, e-mail, export, print, etc before saving, right click on the image. This Right Click Image Menu can be accessed any time the image can be viewed outside of the TigerView Image Viewer. For instructions on how to use the Right Click Image Menu see Right Click On An Image in the Patients & Images Window - Images Tab section of this manual.

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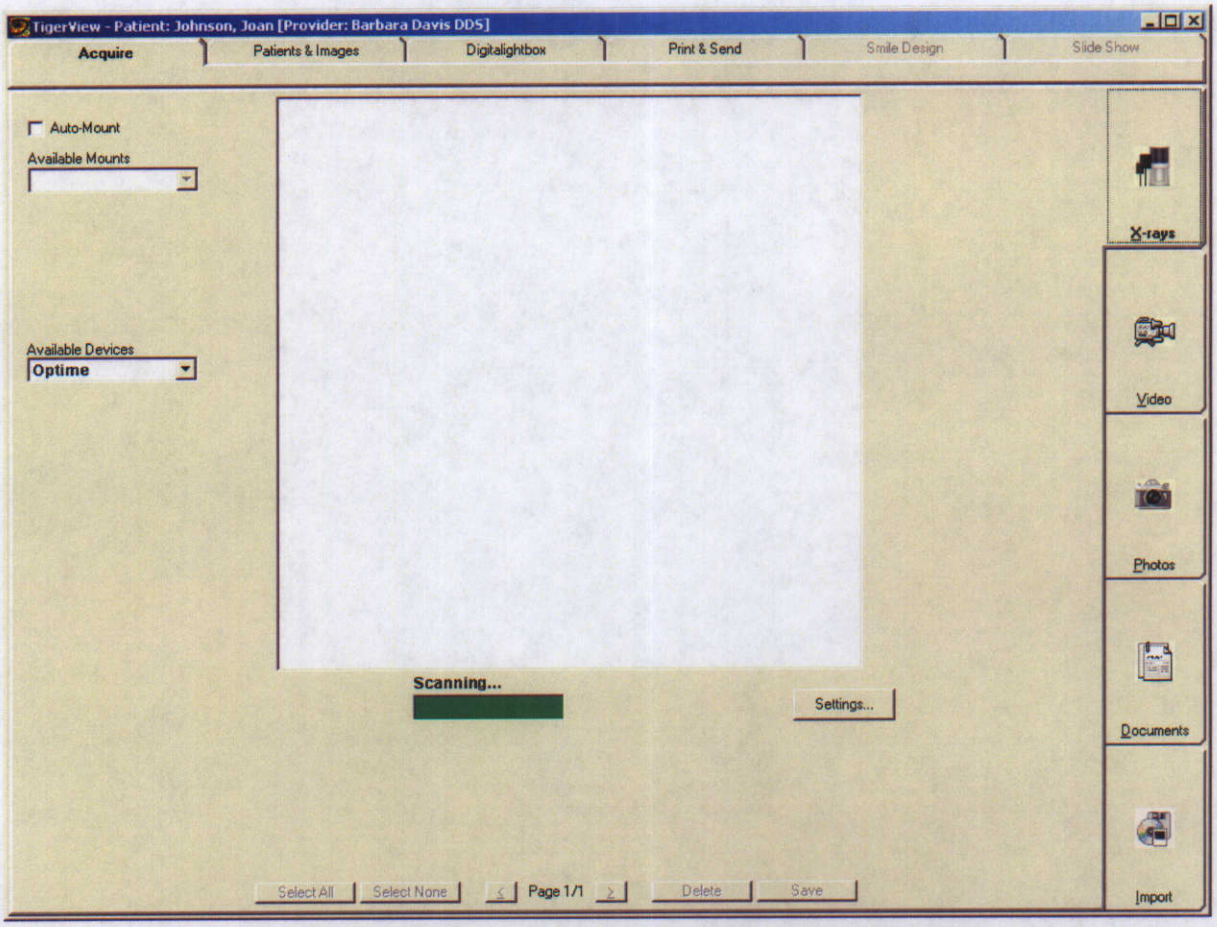
Acquire Window

X-rays tab – For an Optime Scanner Device



Images are entered into TigerView through the Acquire Windows. The methods to bring the images in are listed on the tabs on the right side of the Acquire window. The input methods consist of X-rays, Video, digital Photos, Documents or other images acquired by a flatbed scanner, and images that have already been saved digitally and will be brought in by Importing them.

Available Devices

Click on the Available Devices drop down arrow to display the devices that TigerView can retrieve x-rays from.

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

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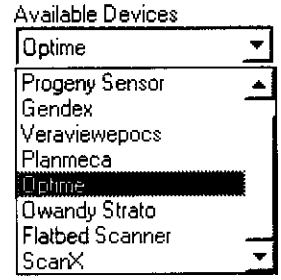
If a TigerView readable x-ray device is directly attached to the computer but does not display in the Available Devices drop down box on that computer, close TigerView, open TigerView Administration and add the device. See the TigerView Administration manual for instructions.



Select the Optime device.

Settings Button for an Optime

The Settings button will display windows that hold optional settings for the Veraviewepocs that is connected to this computer. These settings are advanced and will apply to all of the future images acquired by this device. The Reset button, where available, will change the settings for that window back to the original settings TigerView came with.

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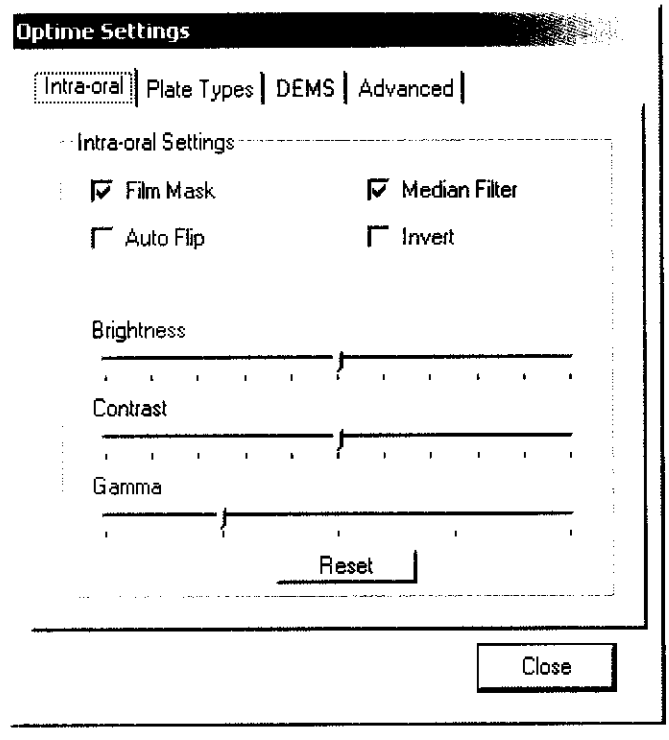
Settings Button – Intra-oral Window – Optime Scanner



The advanced options contained in this window are intended for doctors who want their images to have a more unique look. These fine-tuning options will apply to all of the future images acquired by this scanner. The Reset button on each window will change the settings for that window back to the original settings TigerView came with.

Film Mask

A Film Mask is a black border around the image that is similar to a mat around a picture. This border can make the edges of the image look sharper. A check mark indicates that a film mask will be placed on all future ScanX scanned images.

Median Filter

When Median Filter is off, the image will have a more salt and pepper look (noise) but the edges of the image will be more defined.

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

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When Median Filter is on, the image won't have as many unnecessary white dots but the edges of the image may not be as defined.

Auto Flip

When an image is Auto Flipped the view is as though sitting on the other side of the item being x-rayed looking at the x-ray head.

Invert

Inverting an image causes the white areas to become black and the black areas to become white.

Brightness

Changing the Brightness setting can make up for an x-ray machine that shoots images with too much lightness or darkness. Brightness raises or lowers the lightness for every pixel in the image.

Contrast

Increasing the Contrast creates an image where the white areas are whiter and the black areas blacker. This causes the edges of a shape within the image to be more easily seen.

Gamma

A Gamma change leaves the whitest and blackest parts of an image alone as it makes the mid gray values lighter or darker. If the Gamma level gets moved up the Contrast level should be moved down. Changing the Gamma setting can make the image very dark.

Reset

Reset restores the default settings that came with TigerView.

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Settings Button – Plate Types Window – Optime Scanner

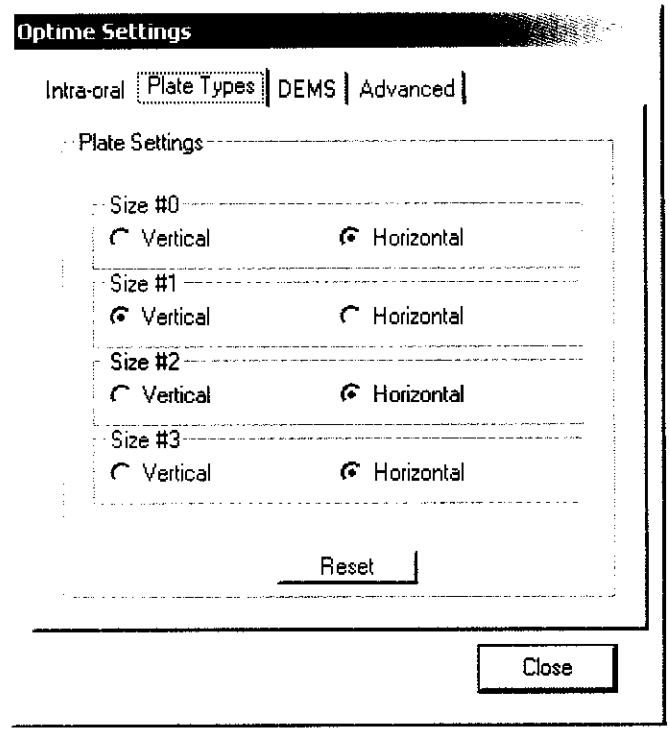

Plate Types

The Plate Types window lists each size of intra-oral phosphor plate and whether it is to be scanned into TigerView in either a vertical or horizontal position. No matter how an image is brought into TigerView, its orientation can always be changed later, from vertical to horizontal or from horizontal to vertical. Please refer to the Patients & Images Window, Right Click On An Image section of this manual for instructions on how to rotate and flip individual images.

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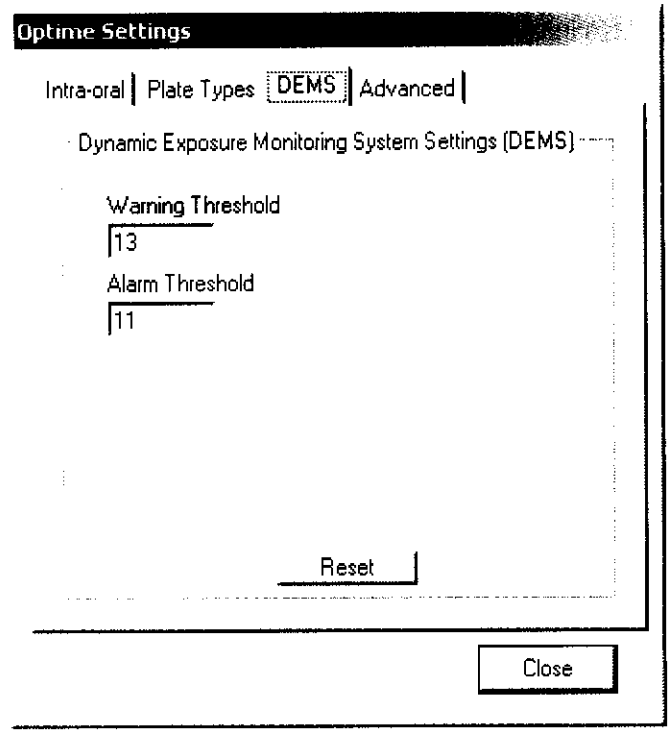
Settings Button – DEMS Window – Optime scanner



DEMS

DEMS stands for Dynamic Exposure Monitoring System. The DEMS thresholds are an advanced feature that should never be altered by the user without the permission of a TigerView representative. If, for some reason, the DEMS settings are altered, clicking on the Reset button Reset will restore the original settings.

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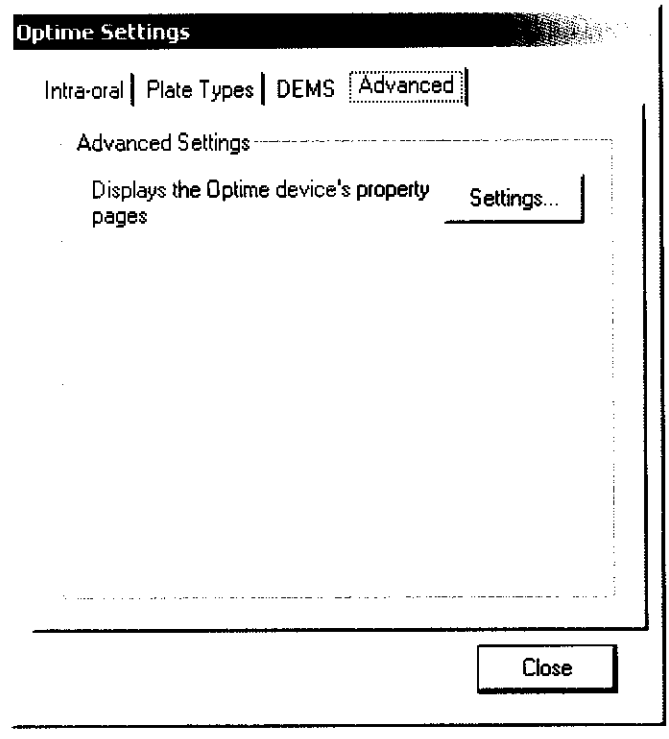
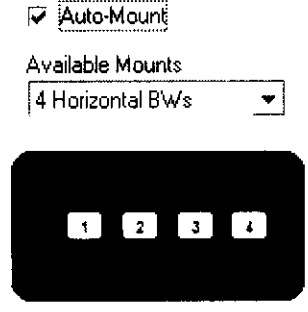
Settings Button – Advanced Window – Optime scanner



Advanced Settings

Click on the Settings button to display the property pages for the Optime scanner.

Auto-Mount



Check the Auto-Mount checkbox to automatically place each scanned image into a previously created and saved mount. Click on the down arrow of the Available Mounts drop down box to select a mount. The selected mount will

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display in the black mount box underneath the Available Mounts drop down box.

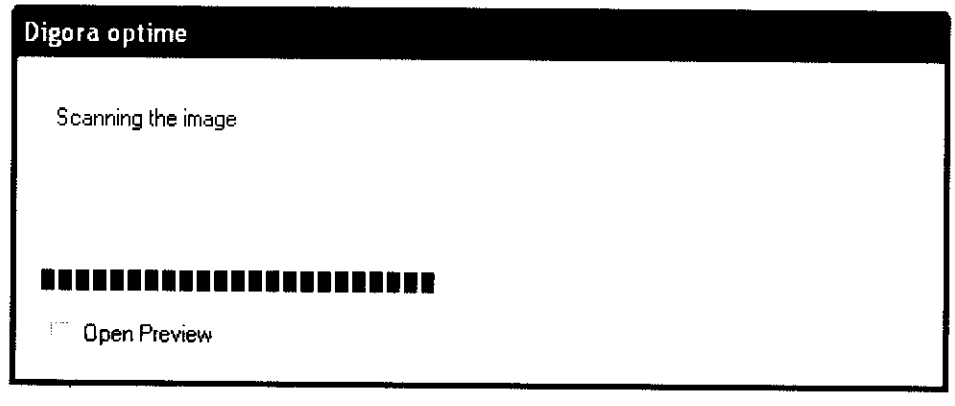
When using the Auto-Mount feature, images must be scanned in the order they are placed into the mount. For example, in the mount displayed above, the first scanned image would be placed in the image box with the number one on it, the second scanned image would be placed in the image box with the number two on it, etc. When mounting a large number of images, such as a full mouth series, taking the x-rays in the order specified by the mount can become a more complicated business.

When a mount is full the user will be asked if they want to create (save) the mount. If an image used in the mount is deleted before the mount is saved the image will automatically be removed from the mount. The next image acquired will be placed in the open mount space that was created by removing the image.

The alternative to Auto-Mount is to mount the images manually by dragging them onto a mount using the Mount window. For instructions on how to mount images manually, please refer to the Mount Window - Using the Mount Window To Mount Images section of this manual.

During the Scanning Process

After the Optime is selected from the Available Devices drop down the green scanning bar will flash and the door on the Optime will open. Place the phosphor plate in the Optime following the manufacturer's instructions.



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The blue progress bar will indicate how far along the Optime is on scanning the phosphor plate. When the Optime has completed the scan the image will appear at the bottom of the TigerView Acquire window and the Optime will release the phosphor plate into the holding tray.

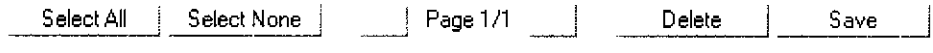
After the Scanning Process

Once an image has been acquired it will appear in the area under the Start button. A DEMS light on each image will be green if TigerView is satisfied with the amount of information in the image, yellow if TigerView is not totally happy, and red if the image should be checked.

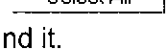
To check an image, double click on the image to open it into the TigerView Image Viewer or View window. If the image quality is acceptable, close the Image Viewer of Viewer by clicking on the Close Window box in the upper right corner of the window and move on to selecting and saving the image. If the image quality is not acceptable, close the Image Viewer or Viewer, and rescan the image. If the image is acceptable, select the image then click on the Save button to save the image into TigerView. If the image is still not acceptable, consider retaking the x-ray then using the DenOptix to scan it again.

The image must be selected and saved before it is loaded into TigerView

Image Buttons



Select an Image

To select an image, left click on it. To select multiple images, click on multiple images. To select all of the images click on the Select All button at the bottom of the window. 

A selected image will have a green box around it.

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Deselect an Image

To deselect an image, click on it again. To deselect all of the images click on the Select None button at the bottom of the window. Select None

Delete an Image

To delete an image, first select the image or images to be deleted, and then click on the Delete button at the bottom of the window. Delete Deleted images are not recoverable.

Save an Image

To save an image, first select the image or images to be saved, and then click on the Save button at the bottom of the window. Save The image will save, no matter what color its DEMS light is, to the currently selected patient.

Open an Image into the Image Viewer or Viewer

To open an image into the Image Viewer or Viewer window, double click on the image using the left mouse button or right click on the image and select View from the Right Click Image Menu. For instructions on how to use the Image Viewer window, please refer to the Image Viewer Window section of this manual. For instructions on how to use the Viewer window, please refer to the Viewer Window section of this manual.

Mount an Image or include an image in a Report

To mount an image or to include an image in a report, click on the image then click on either the Mount tab or the Print & Send tab. Both tabs are located at the top of the TigerView window.

Right Click Image Menu

To flip, rotate, add annotations, add keywords, add procedures, copy, archive, e-mail, export, print, etc before saving, right click on the image. This Right Click Image Menu can be accessed any time the image can be viewed outside of the TigerView Image Viewer. For instructions on how to use the Right Click Image Menu see Right Click On An Image in the Patients & Images Window - Images Tab section of this manual.

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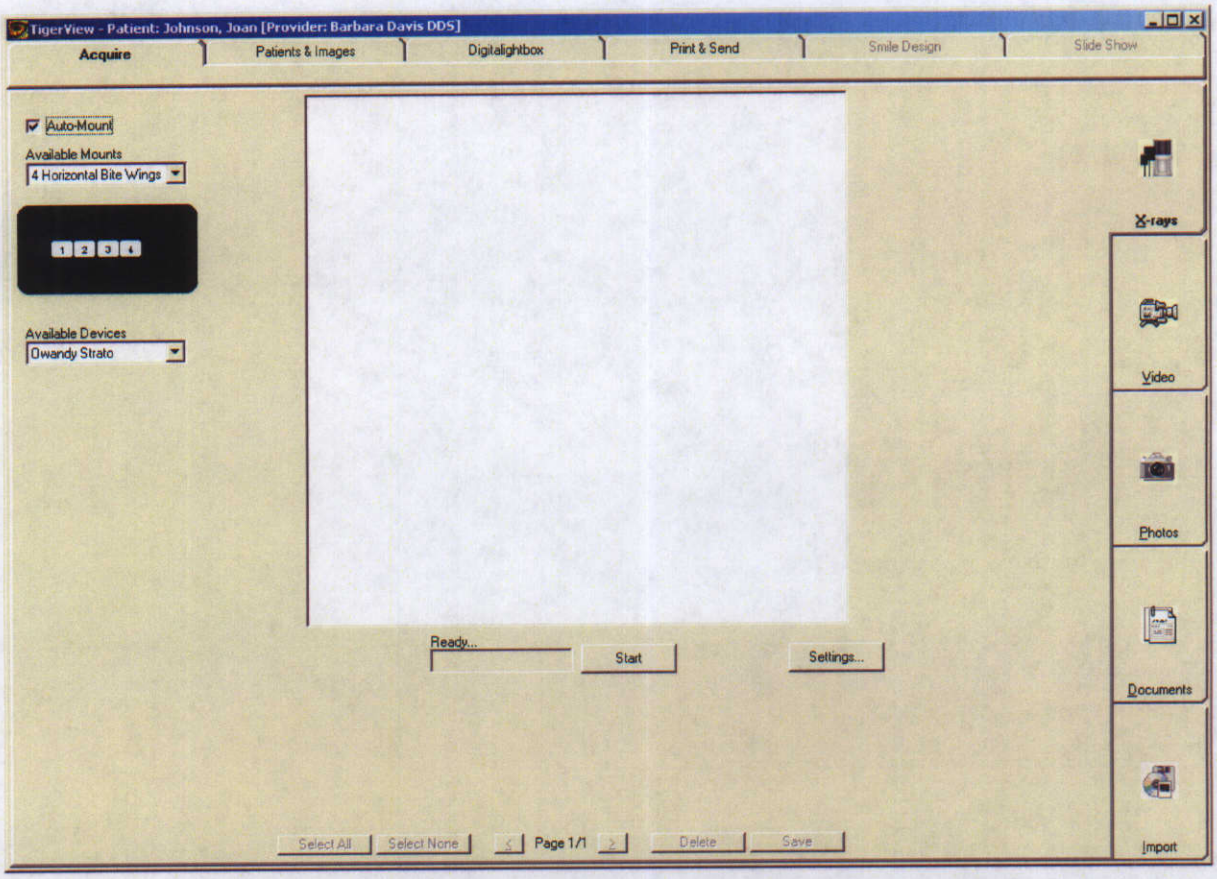
Acquire Window

X-rays tab – For an Owandy Strato Pan Device



Images are entered into TigerView through the Acquire Windows. The methods to bring the images in are listed on the tabs on the right side of the Acquire window. The input methods consist of X-rays, Video, digital Photos, Documents or other images acquired by a flatbed scanner, and images that have already been saved digitally and will be brought in by Importing them.

Available Devices

Click on the Available Devices drop down arrow to display the devices that TigerView can retrieve x-rays from.

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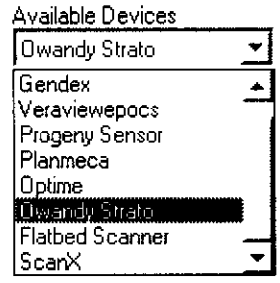
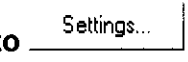


If a TigerView readable x-ray device is directly attached to the computer but does not display in the Available Devices drop down box on that computer, close TigerView, open TigerView Administration and add the device. See the TigerView Administration manual for instructions.

Select the Owandy Strato device.

Settings Button for a Strato 

The Settings button will display windows that hold optional settings for the Strato that is connected to this computer. These settings are advanced and will apply to all of the future images acquired by this Strato. The Reset button on each window will change the settings for that window back to the original settings TigerView came with.

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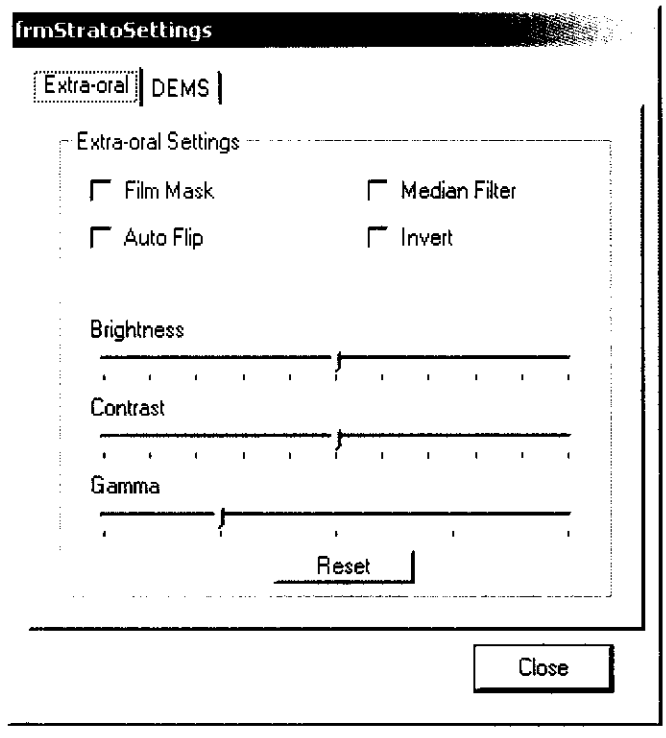
Settings Button – Extra-oral Window – Strato



Film Mask

A Film Mask is a black border that is placed around an image in the same way a black mat surrounds a painting. This border can make the edges of the image look sharper. A check mark indicates that a film mask will be placed on all future Strato images.

Median Filter

When Median Filter is off, the image will have a more salt and pepper (noisy) look but the edges of the image will be more defined.

When Median Filter is on (checked), the image won't have as many unnecessary white dots but the edges of the image may not be as defined.

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Auto Flip

When an image is Auto Flipped the view is as though sitting on the other side of the item being x-rayed looking at the x-ray head.

Invert

Inverting an image causes the white areas to become black and the black areas to become white.

Brightness

Changing the Brightness setting can make up for an x-ray machine that shoots images with too much lightness or darkness. Brightness raises or lowers the lightness for every pixel in the image.

Contrast

Increasing the Contrast creates an image where the white areas are whiter and the black areas blacker. This causes the edges of a shape within the image to be more easily seen.

Gamma

A Gamma change leaves the whitest and blackest parts of an image alone as it makes the mid gray values lighter or darker. If the Gamma level gets moved up the Contrast level should be moved down. Changing the Gamma setting can make the image very dark.

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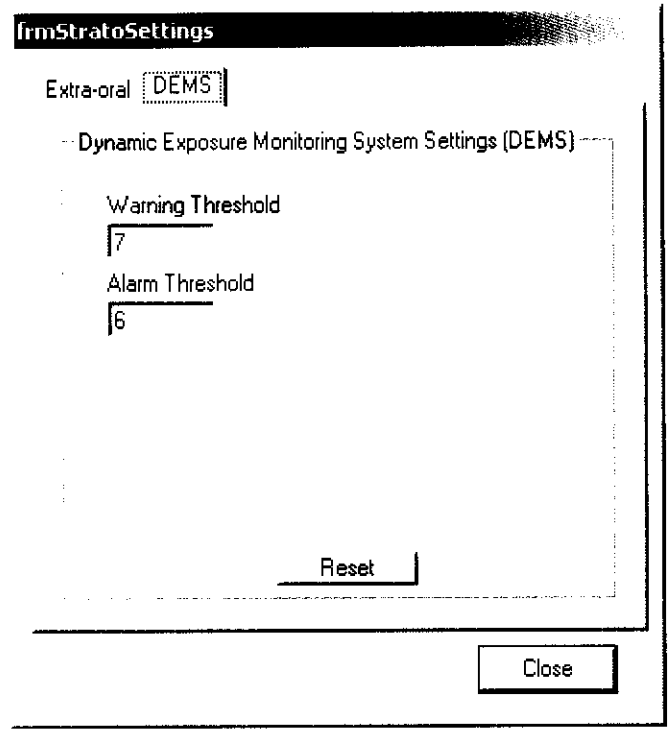
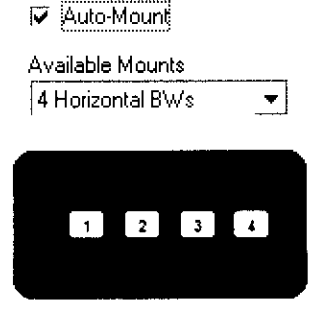
Settings Button – DEMS Window – Strato



DEMS

DEMS stands for Dynamic Exposure Monitoring System. The DEMS thresholds are an advanced feature that should never be altered by the user without the permission of a TigerView representative. If, for some reason, the DEMS settings are altered, clicking on the Reset button Reset will restore the original settings.

Auto-Mount



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Check the Auto-Mount checkbox to automatically place each scanned image into a previously created and saved mount. Click on the down arrow of the Available Mounts drop down box to select a mount. The selected mount will display in the black mount box underneath the Available Mounts drop down box.

When using the Auto-Mount feature, images must be scanned in the order they are placed into the mount. For example, in the mount displayed above, the first scanned image would be placed in the image box with the number one on it, the second scanned image would be placed in the image box with the number two on it, etc. When mounting a large number of images, such as a full mouth series, taking the x-rays in the order specified by the mount can become a more complicated business.

When a mount is full the user will be asked if they want to create (save) the mount. If an image used in the mount is deleted before the mount is saved the image will automatically be removed from the mount. The next image acquired will be placed in the open mount space that was created by removing the image.

The alternative to Auto-Mount is to mount the images manually by dragging them onto a mount using the Mount window. For instructions on how to mount images manually, please refer to the Mount Window - Using the Mount Window To Mount Images section of this manual.

Operating the Strato

After the Strato is selected from the Available Devices drop down box and the patient has been positioned correctly the Start button should be clicked on to display the Strato keyboard. The Strato keyboard on the screen is the same as the keyboard on the Strato itself except that not all of the keys can be accessed on the screen.

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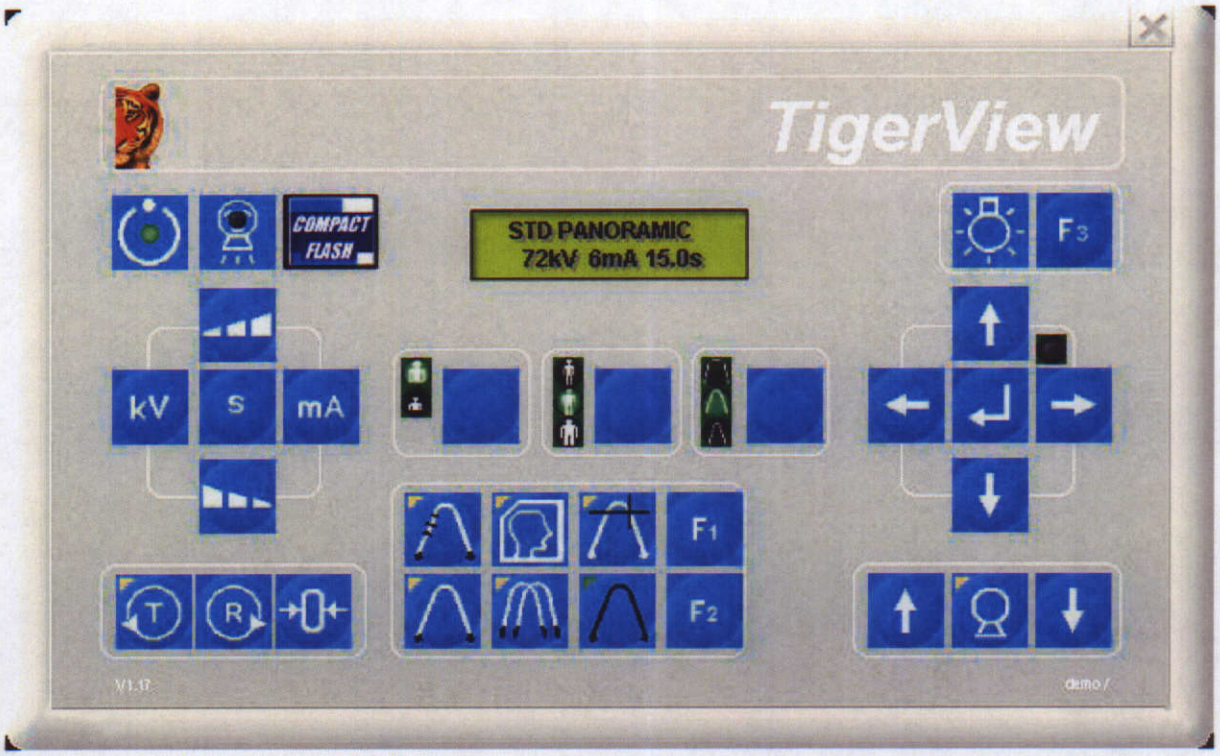
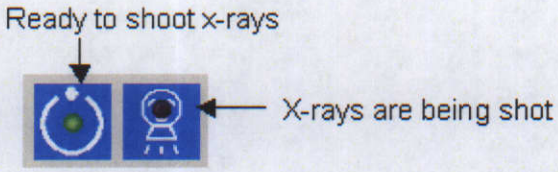


When the Strato keyboard opens on the computer screen a Notepad file named Config is created on the desktop. This file is not deleted when the virtual keyboard is closed. If the file is deleted manually the keyboard will simply create another one the next time it is opened.

Signal LEDs



Press the x-ray button once and the light on the left will be lit to indicate that the Strato is ready to shoot x-rays. Press the x-ray button a second time to actually shoot the x-ray. While the x-ray is being shot the light on the right is lit.

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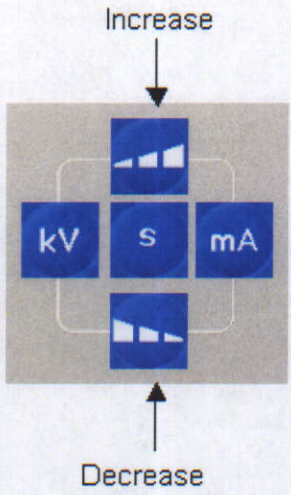
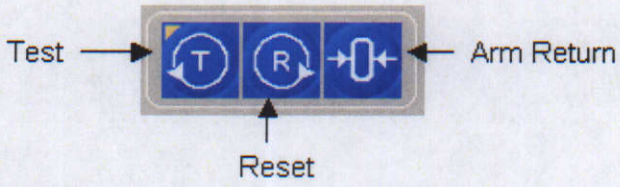
Exposure Settings



Click on one of the middle row buttons – kv, s(time), or ma – then on the increase or decrease button to change the value. KV values range from 50 – 80. MA values range from 4 –12. S values (time) are only used for cephs.

Control Keys



The Control keys function only on the actual Strato keyboard. They do not work on the Strato keyboard that appears on the computer screen. The Test key disables x-rays before the Strato arm is moved. The Reset key is pressed if the x-ray button was accidentally pressed or if it was released too early. The Arm Return key is pressed to get the system ready for the next patient.

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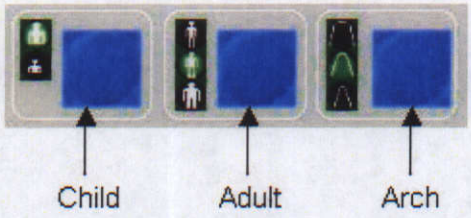
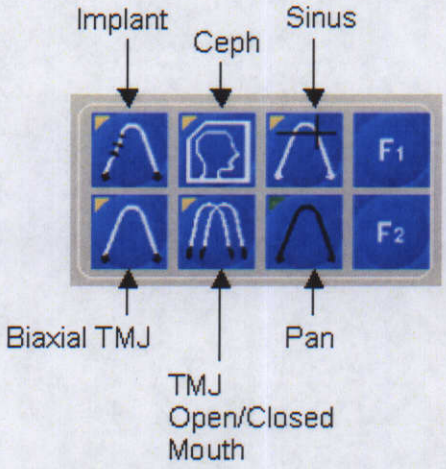
Anatomical Selection for Preset Exposure Settings



Press the blue buttons to select a small child, a large child, a small adult, a medium adult or a large adult. Press the blue Arch button to select a small, medium or large mouth.

Examination Mode



Select the type of x-ray being taken. Note that the implant and the F1 and F2 keys are not enabled at this time.

Centering the Strato

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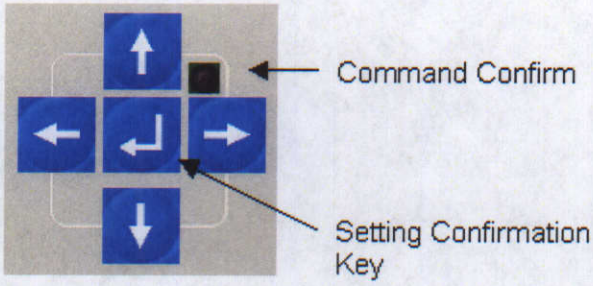
This button functions only on the actual Strato keyboard. It will not work on the Strato keyboard that appears on the computer screen. The Centering key shines a light on the patient that the operator can use to precisely place the patient in the correct position. The F3 key is not in use at this time.

Carriage Movement



To move the arm of the Strato press the arrow buttons. These buttons function only on the actual Strato keyboard. They do not work on the Strato keyboard that appears on the computer screen. When the Command Confirm light is lit the Setting Confirmation Key must be pressed to confirm the action that was entered. When the Strato is turned on the Setting Confirmation Key should be pressed to calibrate the Strato.

Column Movement

To move the column of the Strato the center button must be pushed at the same time as one of the directional arrow buttons. These buttons function only on the actual Strato keyboard. They do not work on the Strato keyboard that appears on the computer screen.

During the Scanning Process

The image will appear in sections, from left to right, in a small window. When the Strato has completed the scan the image will appear at the bottom of the TigerView

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Acquire window and both the small scanning window and the Strato virtual keyboard window will close.

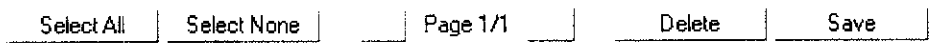
After the Scanning Process

A DEMS light on each image will be green if TigerView is satisfied with the amount of information in the image, yellow if TigerView is not totally happy, and red if the image should be checked.

To check an image, double click on the image to open it into the TigerView Image Viewer. If the image quality is acceptable, close the Image Viewer by clicking on the Close Window box in the upper right corner of the window and move on to selecting and saving the image. If the image quality is not acceptable, close the Image Viewer, and retake the x-ray.

Once the image is acceptable, select the image then click on the Save button to save the image into TigerView. The image must be selected and saved before it is loaded into TigerView

Image Buttons



Select an Image

To select an image, left click on it. To select multiple images, click on multiple images. To select all of the images click on the Select All button at the bottom of the window. Select All A selected image will have a green box around it.

Deselect an Image

To deselect an image, click on it again. To deselect all of the images click on the Select None button at the bottom of the window. Select None

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Delete an Image

To delete an image, first select the image or images to be deleted, and then click on the Delete button at the bottom of the window. [Delete] A deleted image is not recoverable.

Save an Image

To save an image, first select the image or images to be saved, and then click on the Save button at the bottom of the window. [Save] The image will save, no matter what color its DEMS light is, to the currently selected patient.

Open an Image into the Image Viewer or Viewer

To open an image into the Image Viewer or Viewer window, double click on the image using the left mouse button or right click on the image and select View from the Right Click Image Menu. For instructions on how to use the Image Viewer window, please refer to the Image Viewer Window section of this manual. For instructions on how to use the Viewer window, please refer to the Viewer Window section of this manual.

Mount an Image or include an image in a Report

To mount an image or to include an image in a report, click on the image then click on either the Mount tab or the Print & Send tab. Both tabs are located at the top of the TigerView window.

Right Click Image Menu

To flip, rotate, add annotations, add keywords, add procedures, copy, archive, e-mail, export, print, etc before saving, right click on the image. This Right Click Image Menu can be accessed any time the image can be viewed outside of the TigerView Image Viewer. For instructions on how to use the Right Click Image Menu see Right Click On An Image in the Patients & Images Window - Images Tab section of this manual.

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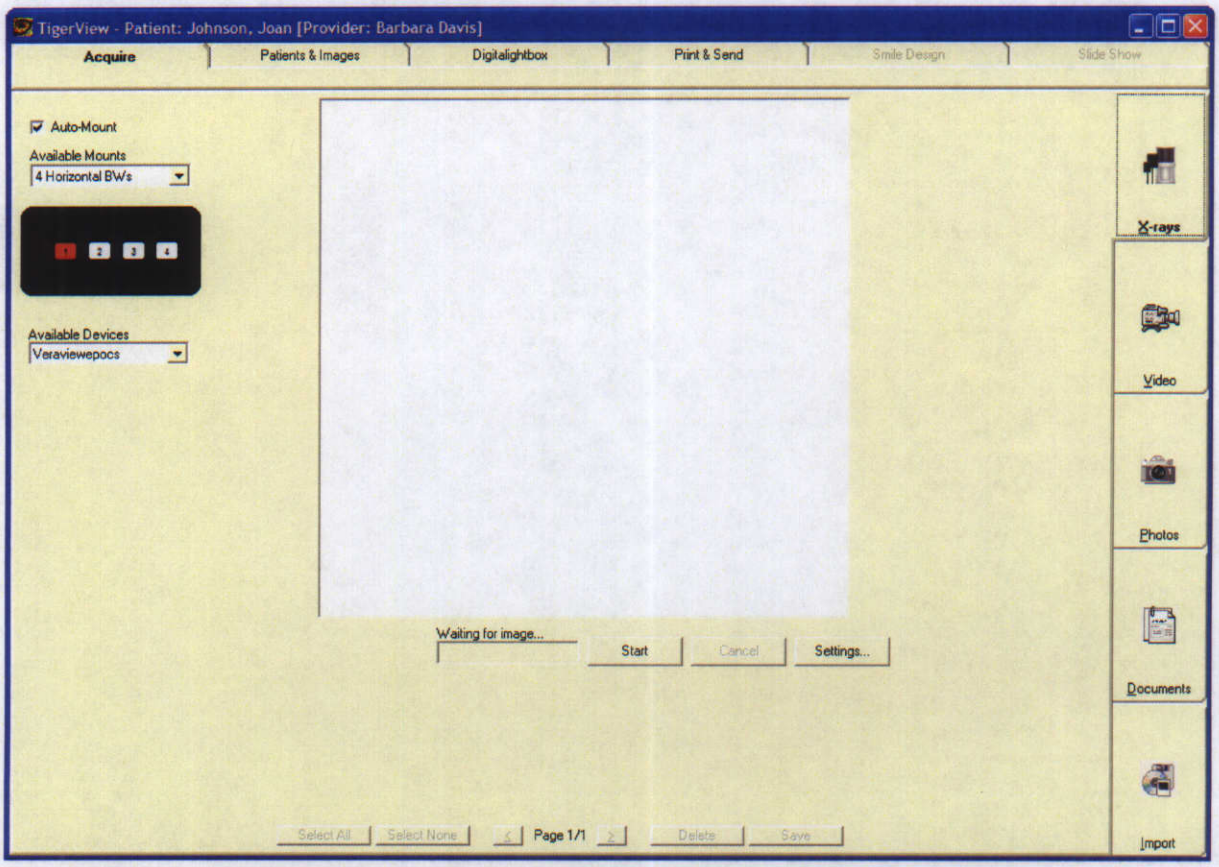
Acquire Window

X-rays tab – For a Veraviewepocs Pan Device



Images are entered into TigerView through the Acquire Windows. The methods to bring the images in are listed on the tabs on the right side of the Acquire window. The input methods consist of X-rays, Video, digital Photos, Documents or other images acquired by a flatbed scanner, and images that have already been saved digitally and will be brought in by Importing them.

Available Devices

Click on the Available Devices drop down arrow to display the devices that TigerView can retrieve x-rays from.

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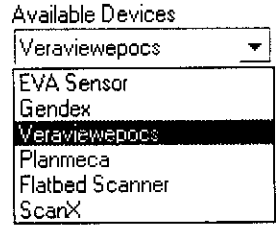
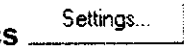


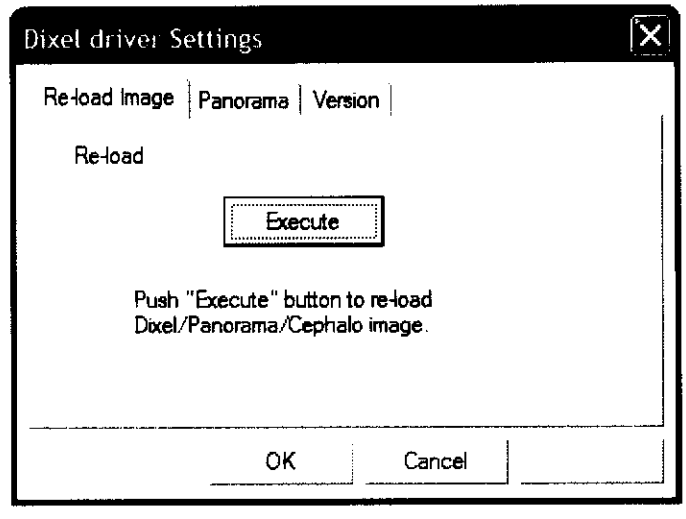
If a TigerView readable x-ray device is directly attached to the computer but does not display in the Available Devices drop down box on that computer, close TigerView, open TigerView Administration and add the device. See the TigerView Administration manual for instructions.

Select the Veraviewepocs device.

Settings Button for a Veraviewepocs 

The Settings button will display windows that hold optional settings for the Veraviewepocs that is connected to this computer. These settings are advanced and will apply to all of the future images acquired by this Veraviewepocs. The Reset button on each window will change the settings for that window back to the original settings TigerView came with.

Settings Button – Re-load Image Window – Veraviewepocs



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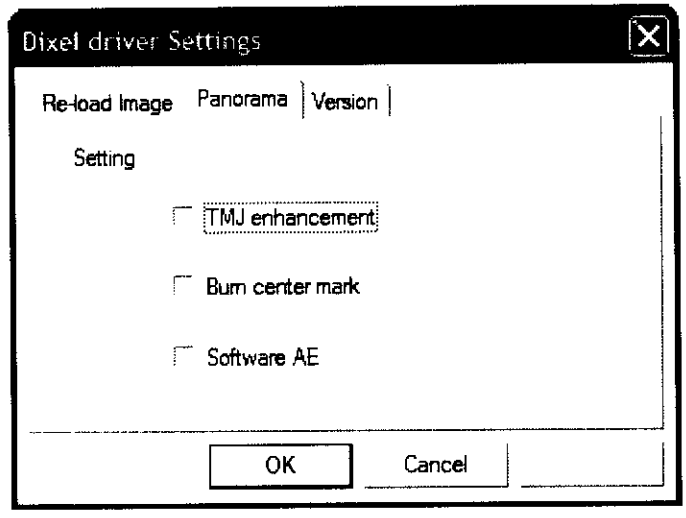
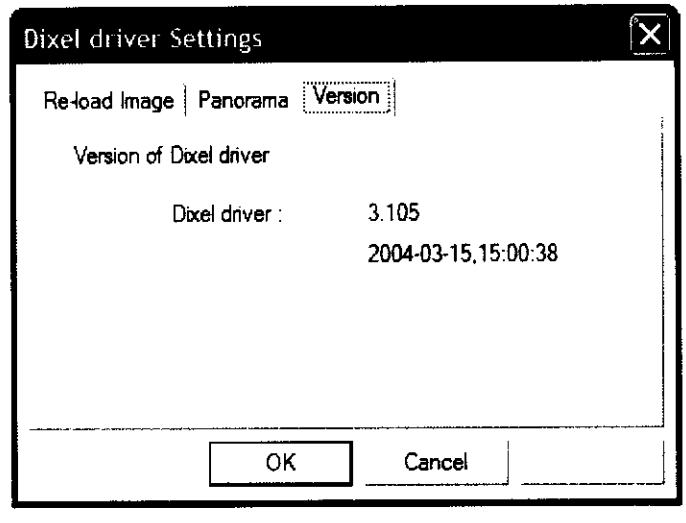
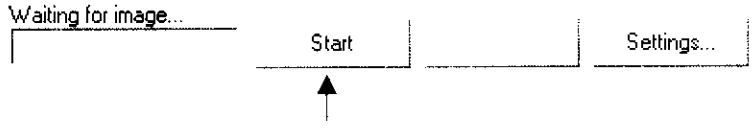
Settings Button – Panorama Window – Veraviewepocs



Settings Button – Version Window – Veraviewepocs



Start Button



Once the Veraviewepocs is ready to be used, the Start button on the Acquire window can be clicked to tell TigerView a scan is ready to begin.

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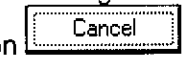
Veraviewepocs Software

After the Start button has been clicked, the software that comes with the Veraviewepocs will open. For instructions on how to use the Veraviewepocs software please refer to the manufacturer's information that came with it.

During the Scanning Process

TigerView will automatically capture the image from the Veraviewepocs. If the Cancel button 

is clicked during the scanning process, the scan will be aborted.

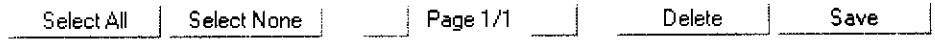
After the Scanning Process

Once an image has been scanned it will appear in the area under the Start button. A DEMS light on each image will be green if TigerView is satisfied with the amount of information in the image, yellow if TigerView is not totally happy, and red if the image should be checked.

To check an image, double click on the image to open it into the TigerView Image Viewer. If the image quality is acceptable, close the Image Viewer by clicking on the Close Window box ☒ in the upper right corner of the window and move on to selecting and saving the image. If the image quality is not acceptable, close the Image Viewer, and retake the image.

The image must be selected and saved before it is loaded into TigerView

Image Buttons



Select an Image

To select an image, left click on it. To select multiple images, click on multiple images. To select all of the images click on the Select All button at the bottom of the

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window. Select All A selected image will have a green box around it.

Deselect an Image

To deselect an image, click on it again. To deselect all of the images click on the Select None button at the bottom of the window. Select None

Delete an Image

To delete an image, first select the image or images to be deleted, and then click on the Delete button at the bottom of the window. Delete A deleted image is not recoverable.

Save an Image

To save an image, first select the image or images to be saved, then click on the Save button at the bottom of the window. Save The image will save, no matter what color its DEMS light is, to the currently selected patient.

Open an Image into the Image Viewer or Viewer

To open an image into the Image Viewer or Viewer window, double click on the image using the left mouse button or right click on the image and select View from the Right Click Image Menu. For instructions on how to use the Image Viewer window, please refer to the Image Viewer Window section of this manual. For instructions on how to use the Viewer window, please refer to the Viewer Window section of this manual.

Mount an Image or include an image in a Report

To mount an image or to include an image in a report, click on the image then click on either the Mount tab or the Print & Send tab. Both tabs are located at the top of the TigerView window.

Right Click Image Menu

To flip, rotate, add annotations, add keywords, add procedures, copy, archive, e-mail, export, print, etc before saving, right click on the image. This Right Click Image Menu can be accessed any time the image can be

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viewed outside of the TigerView Image Viewer. For instructions on how to use the Right Click Image Menu see Right Click On An Image in the Patients & Images Window - Images Tab section of this manual.

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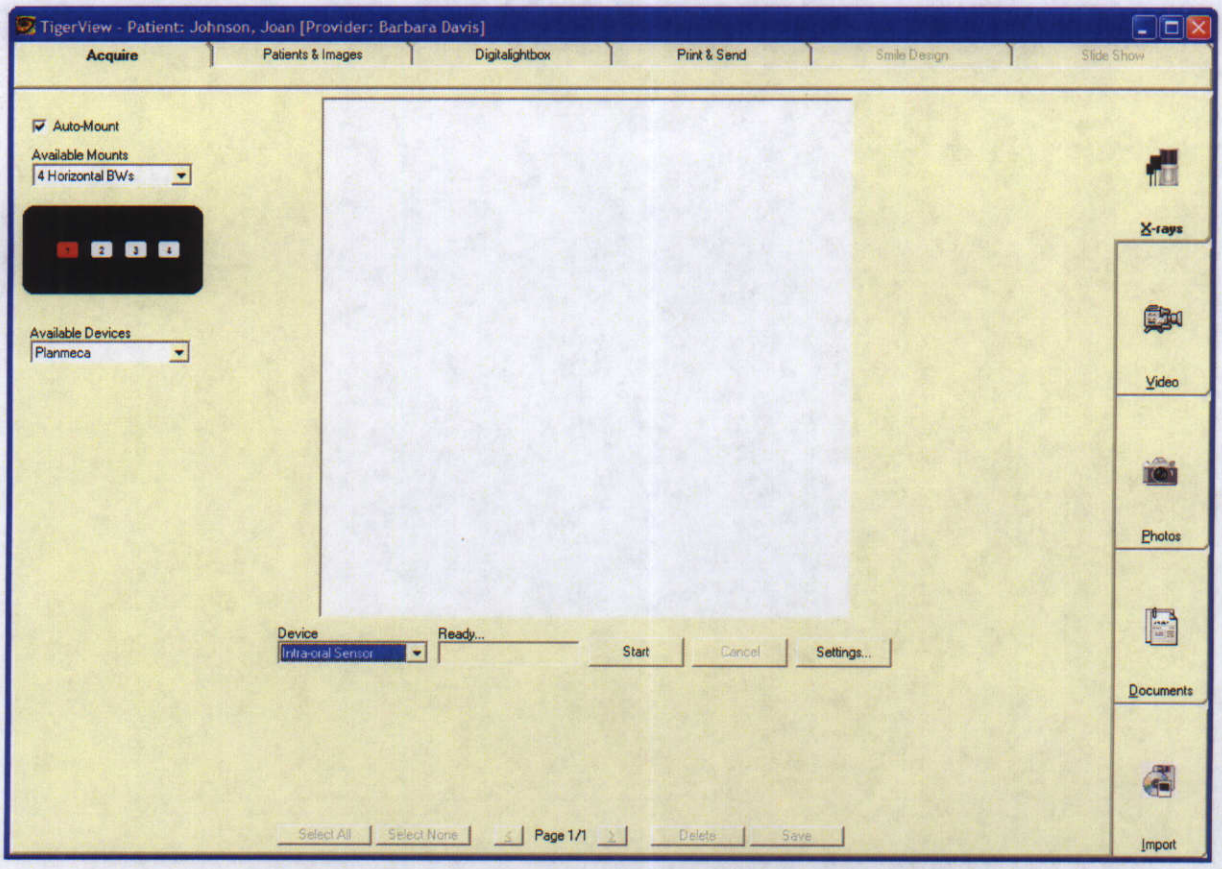
Acquire Window

X-rays tab – For a Planmeca Device



Images are entered into TigerView through the Acquire Windows. The methods to bring the images in are listed on the tabs on the right side of the Acquire window. The input methods consist of X-rays, Video, digital Photos, Documents or other images acquired by a flatbed scanner, and images that have already been saved digitally and will be brought in by Importing them.

Available Devices

Click on the Available Devices drop down arrow to display the devices that TigerView can retrieve x-rays from.

If a TigerView readable x-ray device is directly attached to the computer but does not display in the Available Devices drop down box on that computer, close TigerView, open

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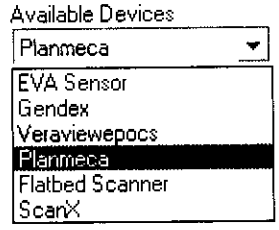
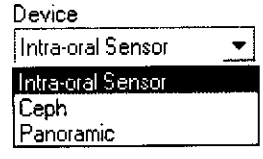
TigerView Administration and add the device. See the TigerView Administration manual for instructions.

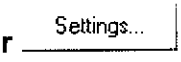


Select the Planmeca device.

Device

Click on the Device drop down arrow to display the Planmeca devices that TigerView can retrieve x-rays from. Select the device that is attached to this computer.



Settings Button for a Planmeca Intra-oral Sensor 

The Settings button will display windows that hold optional settings for the device that is connected to this computer. These settings are advanced and will apply to all of the future images acquired by this Veraviewepocs. The Reset button on each window will change the settings for that window back to the original settings TigerView came with.

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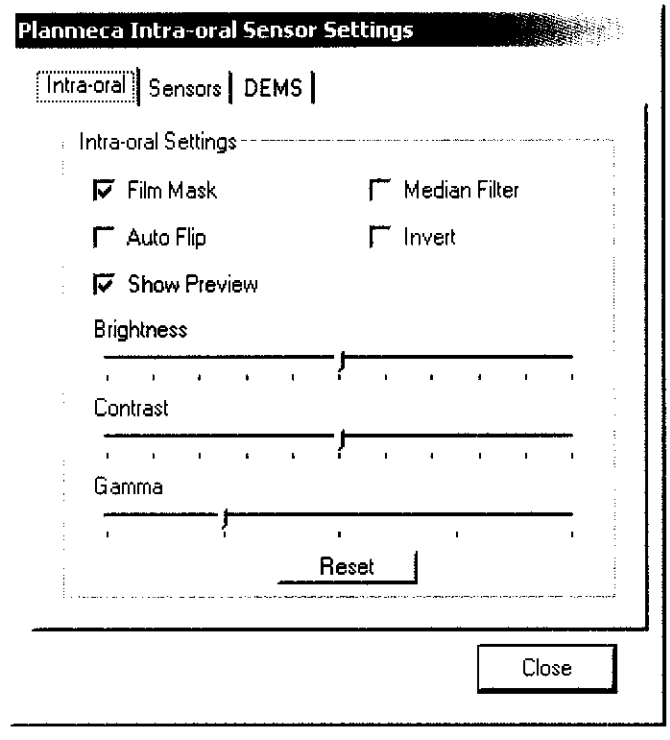
Settings Button – Intra-oral Window – Planmeca Sensor



Film Mask

A Film Mask is a black border that is placed around an image in the same way a black mat surrounds a painting. This border can make the edges of the image look sharper. A check mark indicates that a film mask will be placed on all future sensor images.

Median Filter

When Median Filter is off (unchecked), the image will have a more salt and pepper look (noise) but the edges of the image will be more defined.

When Median Filter is on, the image won't contain as many unnecessary white dots but the edges of the image may not be as defined.

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Auto Flip

When an image is Auto Flipped the view is as though sitting on the other side of the item being x-rayed looking at the x-ray head.

Invert

Inverting an image causes the white areas to become black and the black areas to become white.

Show Preview

Click on Show Preview to have the Preview window open during the scanning process with a preview of the image displayed.

Brightness

Changing the Brightness setting can make up for an x-ray machine that shoots images with too much lightness or darkness. Brightness raises or lowers the lightness for every pixel in the image.

Contrast

Increasing the Contrast creates an image where the white areas are whiter and the black areas blacker. This causes the edges of a shape within the image to be more easily seen.

Gamma

A Gamma change leaves the whitest and blackest parts of an image alone as it makes the mid gray values lighter or darker. If the Gamma level gets moved up the Contrast level should be moved down. Changing the Gamma setting can make the image very dark.

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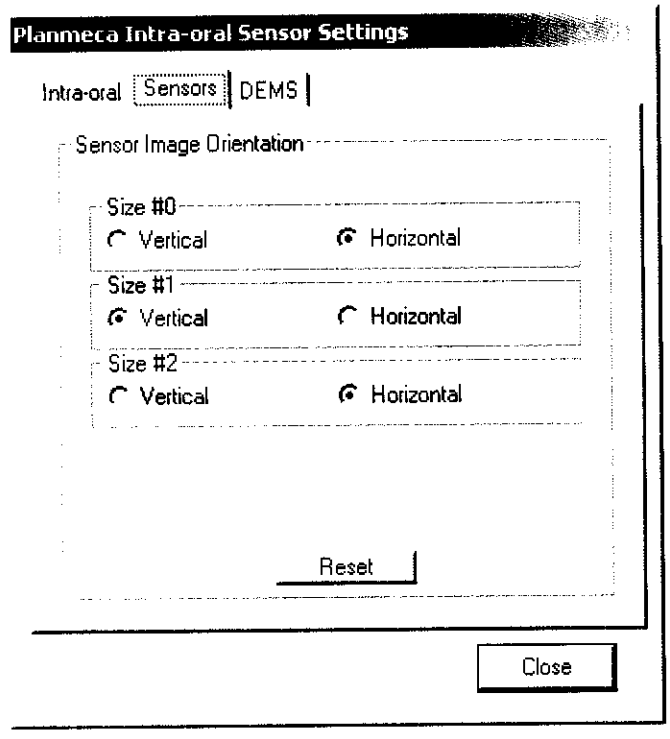
Settings Button – Sensors Window – Planmeca Sensor



Sensors Image Orientation

The Sensors window lists the three sizes of Planmeca Sensors and whether the image taken by each size is to be scanned into TigerView in either a vertical or horizontal position. No matter how an image is brought into TigerView, its orientation can always be changed later, from vertical to horizontal or from horizontal to vertical. Please refer to Right Click On An Image in the Patients & Images Window – Image Tab section of this manual for instructions on how to rotate and flip individual images.

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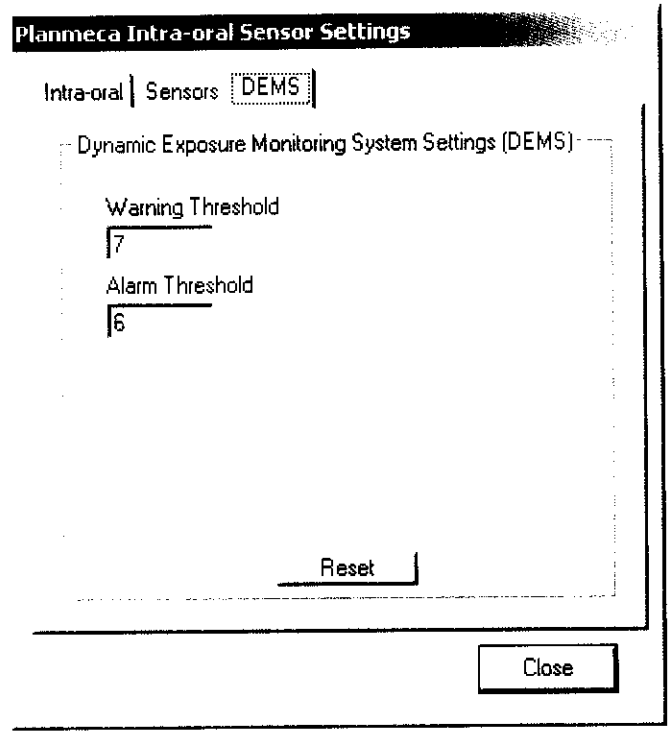
Settings Button – DEMS Window – Planmeca Sensor



DEMS

DEMS stands for Dynamic Exposure Monitoring System. The DEMS thresholds are an advanced feature that should never be altered by the user without the permission of a TigerView representative. If, for some reason, the DEMS settings are altered, clicking on the Reset button Reset will restore the original settings.

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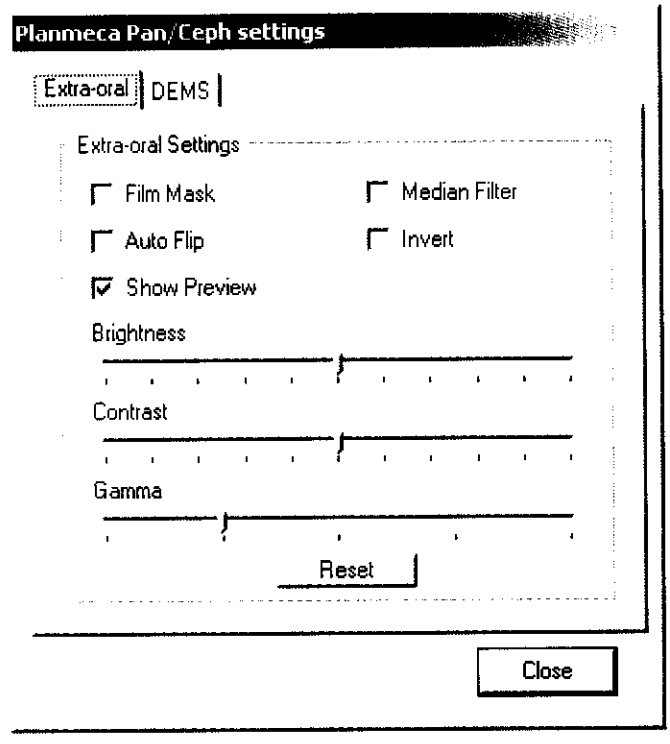
Settings Button for a Planmeca Panoramic or Ceph Device

Settings Button – Extra-oral Window – Planmeca Pan/Ceph



Film Mask

A Film Mask is a black border that is placed around an image in the same way a black mat surrounds a painting. This border can make the edges of the image look sharper. A check mark indicates that a film mask will be placed on all future pan or ceph images.

Median Filter

When Median Filter is off (unchecked), the image will have a more salt and pepper look (noise) but the edges of the image will be more defined.

When Median Filter is on, the image won't have as many unnecessary white dots but the edges of the image may not be as defined.

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Auto Flip

When an image is Auto Flipped the view is as though sitting on the other side of the item being x-rayed looking at the x-ray head. A check mark indicates that each image should be automatically flipped.

Invert

Inverting an image causes the white areas to become black and the black areas to become white.

Show Preview

Brightness

Changing the Brightness setting can make up for an x-ray machine that shoots images with too much lightness or darkness. Brightness raises or lowers the lightness for every pixel in the image.

Contrast

Increasing the Contrast creates an image where the white areas are whiter and the black areas blacker. This causes the edges of a shape within the image to be more easily seen.

Gamma

A Gamma change leaves the whitest and blackest parts of an image alone as it makes the mid gray values lighter or darker. If the Gamma level gets moved up the Contrast level should be moved down. Changing the Gamma setting can make the image very dark.

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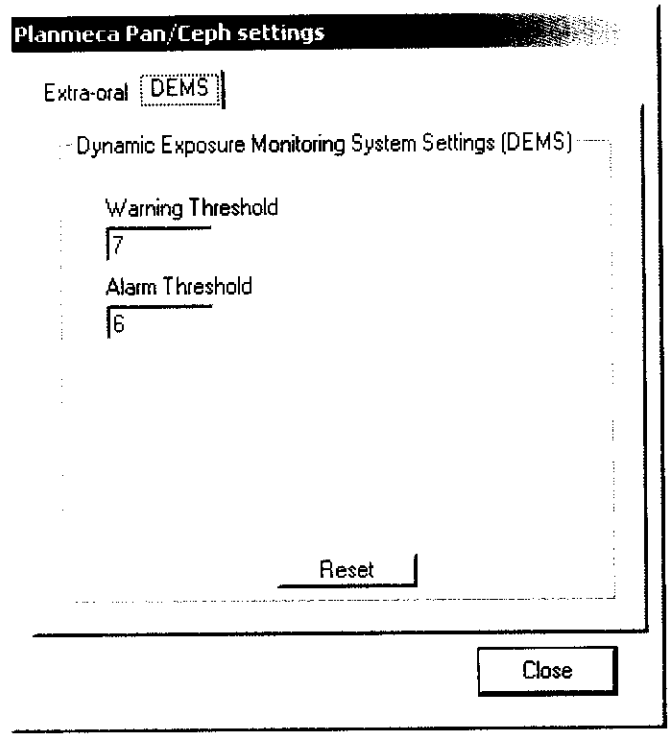
Settings Button – DEMS Window – Planmeca Pan/Ceph

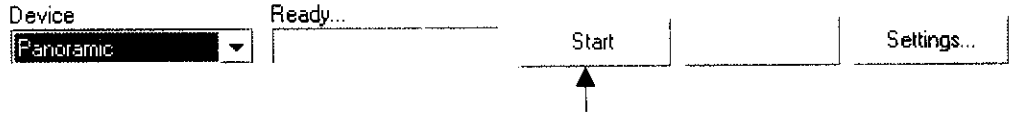


DEMS

DEMS stands for Dynamic Exposure Monitoring System. The DEMS thresholds are an advanced feature that should never be altered by the user without the permission of a TigerView representative. If, for some reason, the DEMS settings are altered, clicking on the Reset button [Reset] will restore the original settings.

Start Button

Once the Planmeca device is ready to be used, the Start button on the Acquire window can be clicked to tell TigerView a scan is ready to begin.



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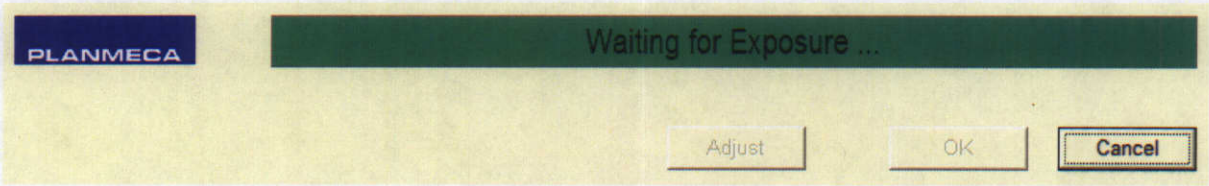
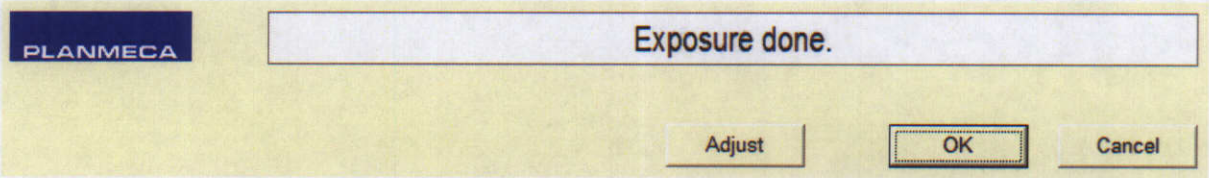
Waiting for Exposure

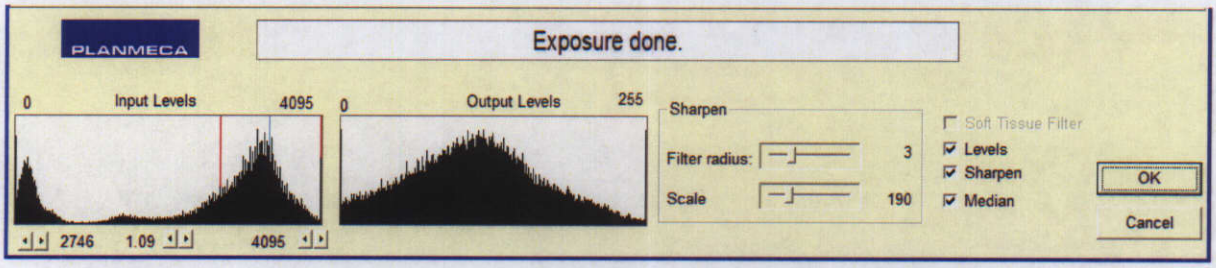
After clicking on Start, the Dixi Exposure software will open, displaying a Waiting for Exposure bar at the bottom of the window.

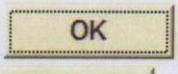


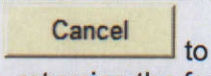
At this point, the Planmeca hardware button is pressed, the x-ray is taken, the Waiting for Exposure bar changes to the Exposure done bar, and the image appears on the screen.



If the Adjust button beneath the Exposure done bar is clicked, the Planmeca adjustment tools become available. Please refer to Planmeca documentation for instructions on how to use these tools. Adjustments can also be made within TigerView.



Click the OK button 

to accept the image or the Cancel button 

to reject it. The Planmeca software will close, returning the focus to TigerView.

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Sensor, Pan and Ceph Capture Differences

The Planmeca software functions basically the same whether the x-ray is from a sensor, pan or ceph. The only difference is in how the x-ray initially appears on the screen. X-rays taken with a sensor will appear on the screen all at once. Pan and ceph x-rays will scroll across the screen from right to left. Please note that the scrolling image is not an accurate representation of the scan. It is only intended to show the user the progression of the image through the Planmeca equipment.

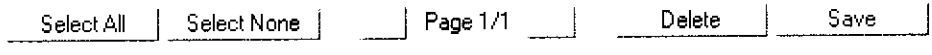
After the Scanning Process

Once the OK button has been clicked, the image will appear in the area under the Start button in TigerView. A DEMS light on each image will be green if TigerView is satisfied with the amount of information in the image, yellow if TigerView is not totally happy, and red if the image should be checked.

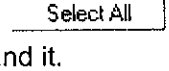
To check an image, double click on the image to open it into the TigerView Image Viewer. If the image quality is acceptable, close the Image Viewer by clicking on the Close Window box ☒ in the upper right corner of the window and either continue taking x-rays or move on to selecting and saving the images. If the image quality is not acceptable, close the Image Viewer, right click on the image and select Delete to erase it, and retake the x-ray.

The image must be selected and saved before it is loaded into TigerView

Image Buttons



Select an Image

To select an image, left click on it. To select multiple images, click on multiple images. To select all of the images click on the Select All button at the bottom of the window. 

A selected image will have a green box around it.

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Deselect an Image

To deselect an image, click on it again. To deselect all of the images click on the Select None button at the bottom of the window. Select None

Delete an Image

To delete an image, first select the image or images to be deleted, and then click on the Delete button at the bottom of the window. Delete A deleted image is not recoverable.

Save an Image

To save an image, first select the image or images to be saved, then click on the Save button at the bottom of the window. Save The image will save, no matter what color its DEMS light is, to the currently selected patient.

Open an Image into the Image Viewer or Viewer

To open an image into the Image Viewer or Viewer window, double click on the image using the left mouse button or right click on the image and select View from the Right Click Image Menu. For instructions on how to use the Image Viewer window, please refer to the Image Viewer Window section of this manual. For instructions on how to use the Viewer window, please refer to the Viewer Window section of this manual.

Mount an Image or include an image in a Report

To mount an image or to include an image in a report, click on the image then click on either the Mount tab or the Print & Send tab. Both tabs are located at the top of the TigerView window.

Right Click Image Menu

To flip, rotate, add annotations, add keywords, add procedures, copy, archive, e-mail, export, print, etc before saving, right click on the image. This Right Click Image Menu can be accessed any time the image can be viewed outside of the TigerView Image Viewer. For instructions on how to use the Right Click Image Menu see Right Click On An Image in the Patients & Images Window - Images Tab section of this manual.

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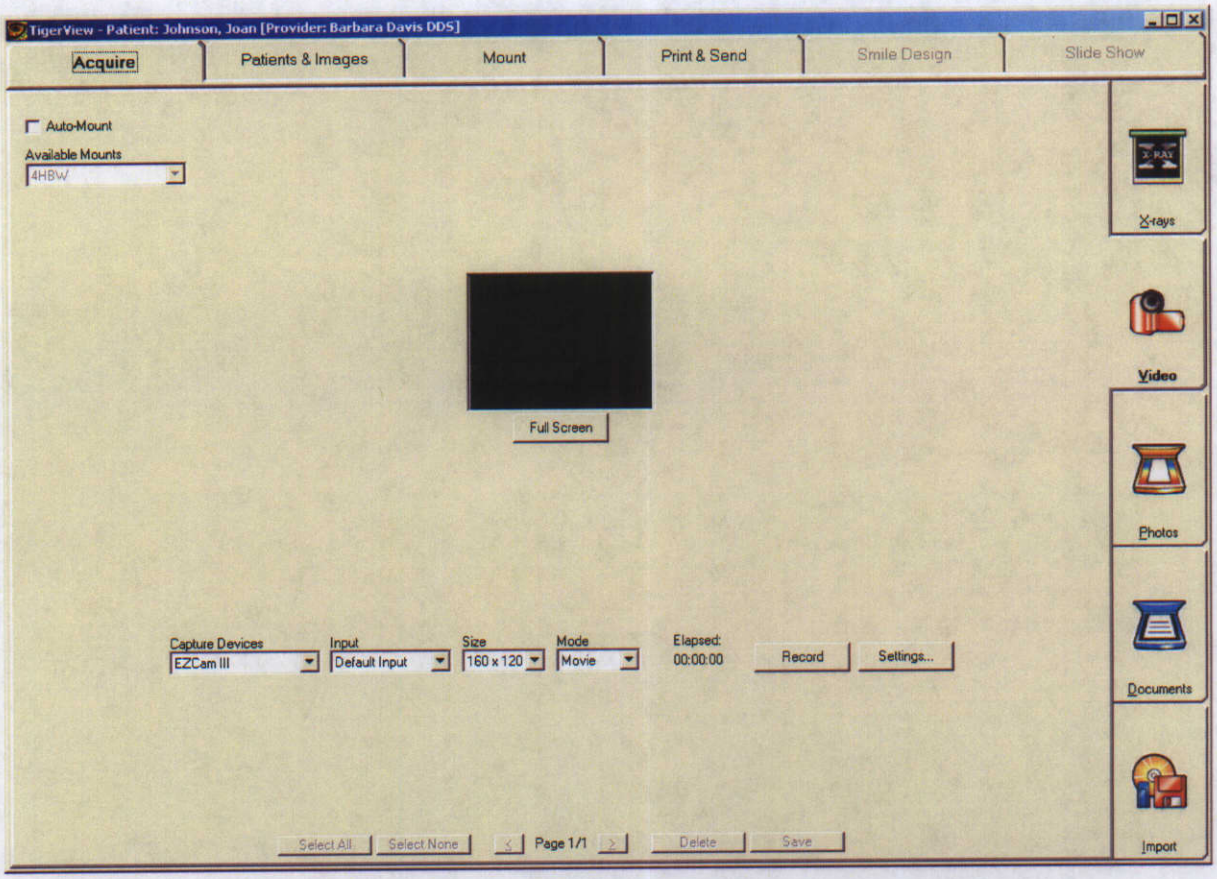
Acquire Window

Video tab



Images are entered into TigerView through the Acquire Windows. The methods to bring the images in are listed on the tabs on the right side of the Acquire window. The input methods consist of X-rays, Video, digital Photos, Documents or other images acquired by a flatbed scanner, and images that have already been saved digitally and will be brought in by Importing them.

Capture Devices

Click on the down arrow of the Capture Devices drop down box to display the devices TigerView can retrieve video clips and still images from. Select a device.

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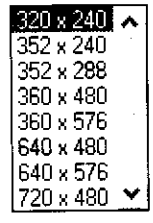
Input

Click on the down arrow of the Input drop down box to display the Input methods TigerView can retrieve video clips and still images from. Select an Input method.

Size

Click on the down arrow of the Size drop down box to display the dpi (dots per inch) settings to display the video in. A few of the available dpi settings are pictured below.



Select a dpi size.

Mode

Click on the down arrow of the Mode drop down box and select either Still Frame to capture individual pictures, or Movie to capture a video clip.

Still Frames can only be captured from a movie before the movie is saved into TigerView. After the movie is saved, separate, individual still images can no longer be taken from it.

Some video cameras, such as the Acclaim camera from Air Techniques, have buttons on them to handle capturing the images. If the camera that is being used does not have Freeze and Capture buttons, use the buttons on the screen to record the video clip or to freeze an individual image. The video will display on the Current Image Box in the center of the window.

Freeze / Live

If the Mode is set to Still Frame the Freeze button is used to capture a single image from the video that is being displayed on the window. After Freeze is clicked on either click on Save to put the image in the thumbnail row at the bottom of the window or click on the Live button to wait for

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another image to freeze. The picture still needs to be selected and saved to bring it into TigerView.

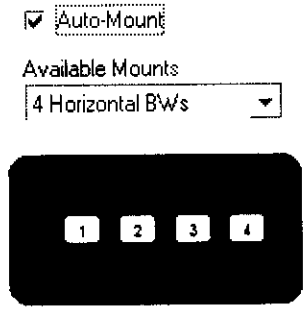
Record / Stop

If the Mode is set to Movie the Record button is used to capture the video that is being displayed on the window. Once enough video has been captured click on the Stop button to have a copy of the movie appear in the thumbnail row at the bottom of the window. The video still needs to be selected and saved to bring it into TigerView.

Settings Button for a Video Camera

Please refer to the camera manufacturer's instructions for an explanation of the video camera's settings. Please be aware that any changes made here will affect every future image and video taken by this camera.

Auto-Mount



Check the Auto-Mount checkbox to automatically place each still image into a previously created and saved mount. Click on the down arrow of the Available Mounts drop down box to select a mount. The selected mount will display in the black mount box underneath the Available Mounts drop down box.

When using the Auto-Mount feature, images must be taken in the order they are placed into the mount. For example, in the mount displayed above, the first still image would be placed in the image box with the number one on it, the second still image would be placed in the image box with the number two on it, etc.

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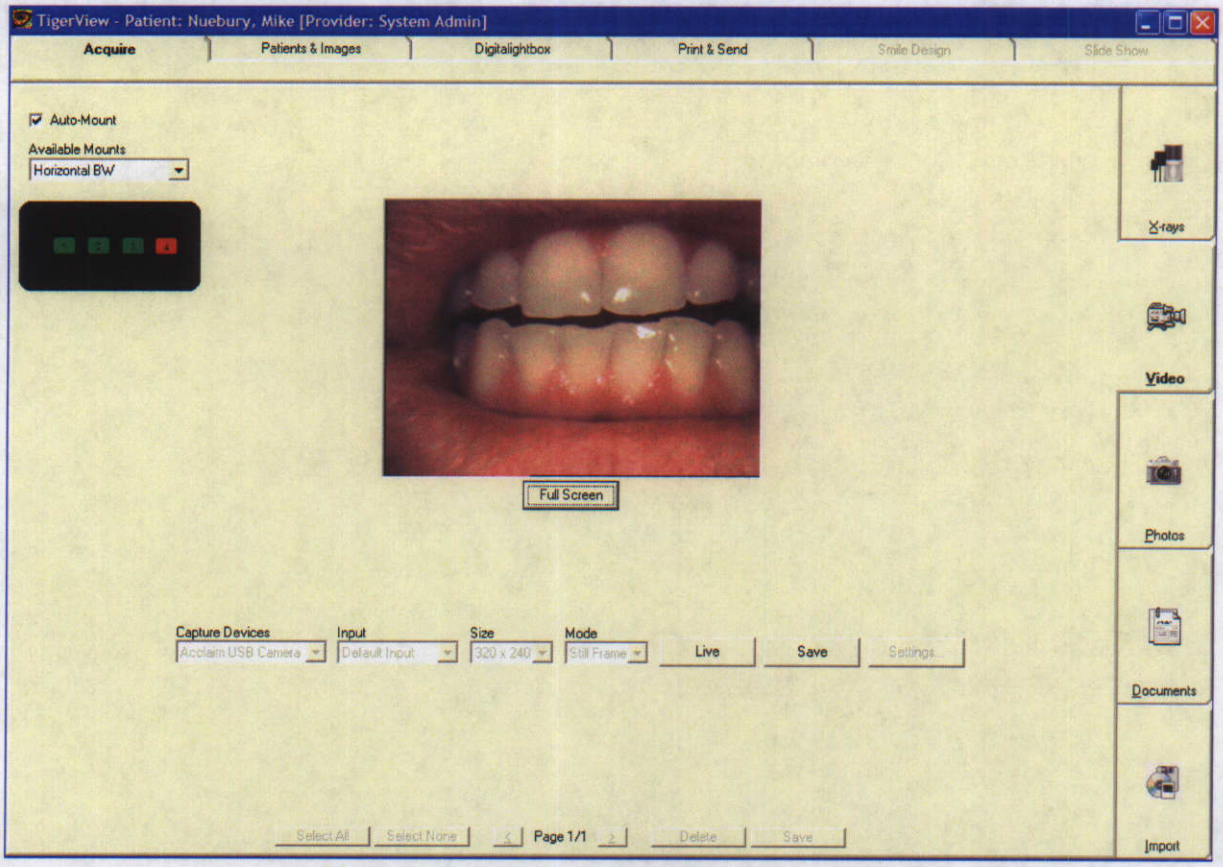
When a mount is full the user will be asked if they want to create (save) the mount. If an image used in the mount is deleted before the mount is saved the image will automatically be removed from the mount. The next image acquired will be placed in the open mount space that was created by removing the image.

The alternative to Auto-Mount is to mount the images manually by dragging them onto a mount using the Mount window. For instructions on how to mount images manually, please refer to the Mount Window - Using the Mount Window To Mount Images section of this manual.



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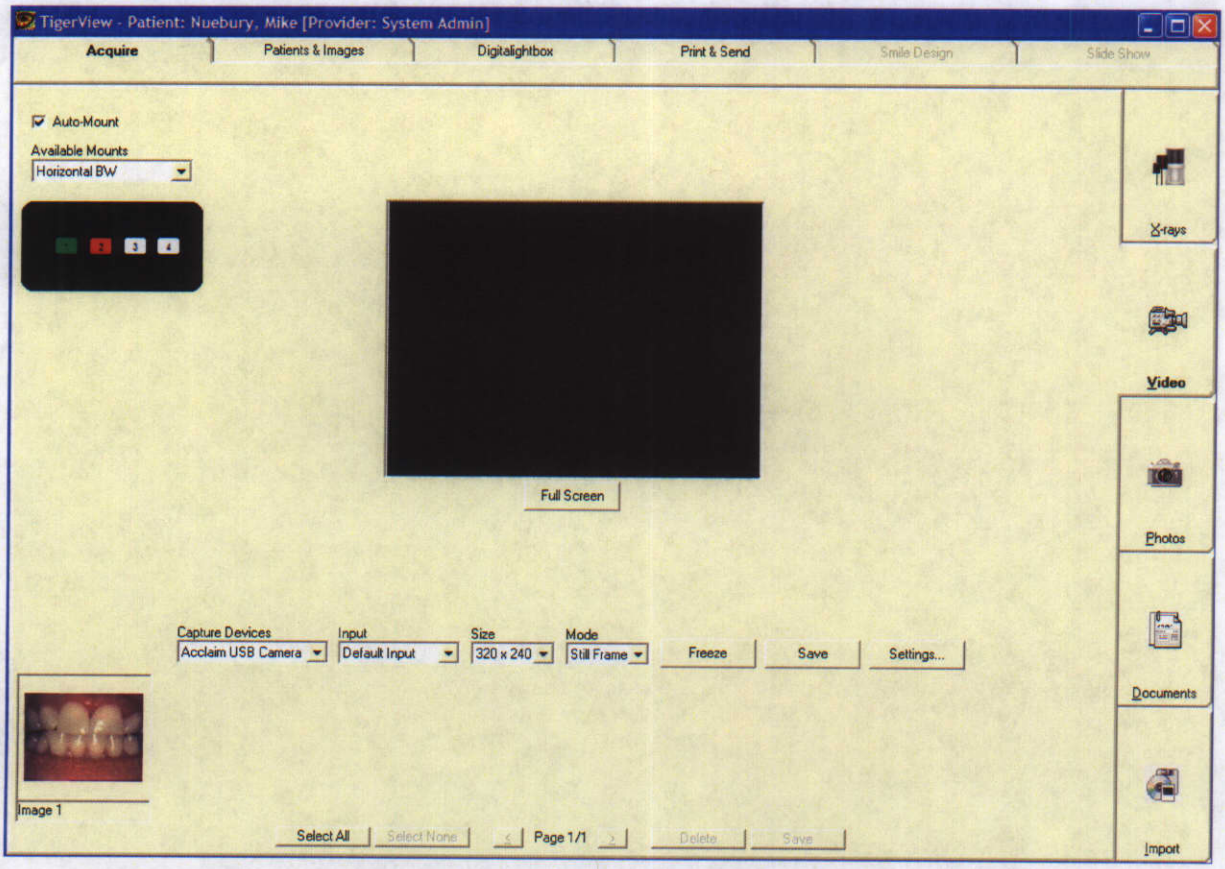

Image Buttons

Select All | Select None | < | Page 1/1 | > | Delete | Save

Select an Image

To select an image, left click on it. To select multiple images, left click on multiple images. To select all of the images click on the Select All button at the bottom of the window. Select All A selected image will have a green box around it.

Deselect an Image

To deselect an image, left click on it again. To deselect all of the images click on the Select None button at the bottom of the window. Select None

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Delete an Image

To delete an image, first select the image or images to be deleted, and then click on the Delete button at the bottom of the window. [Delete] A deleted image is not recoverable.

Save an Image

To save an image, first select the image or images to be saved, then click on the Save button at the bottom of the window. [Save] The image will save, no matter what color its DEMS light is, to the currently selected patient.

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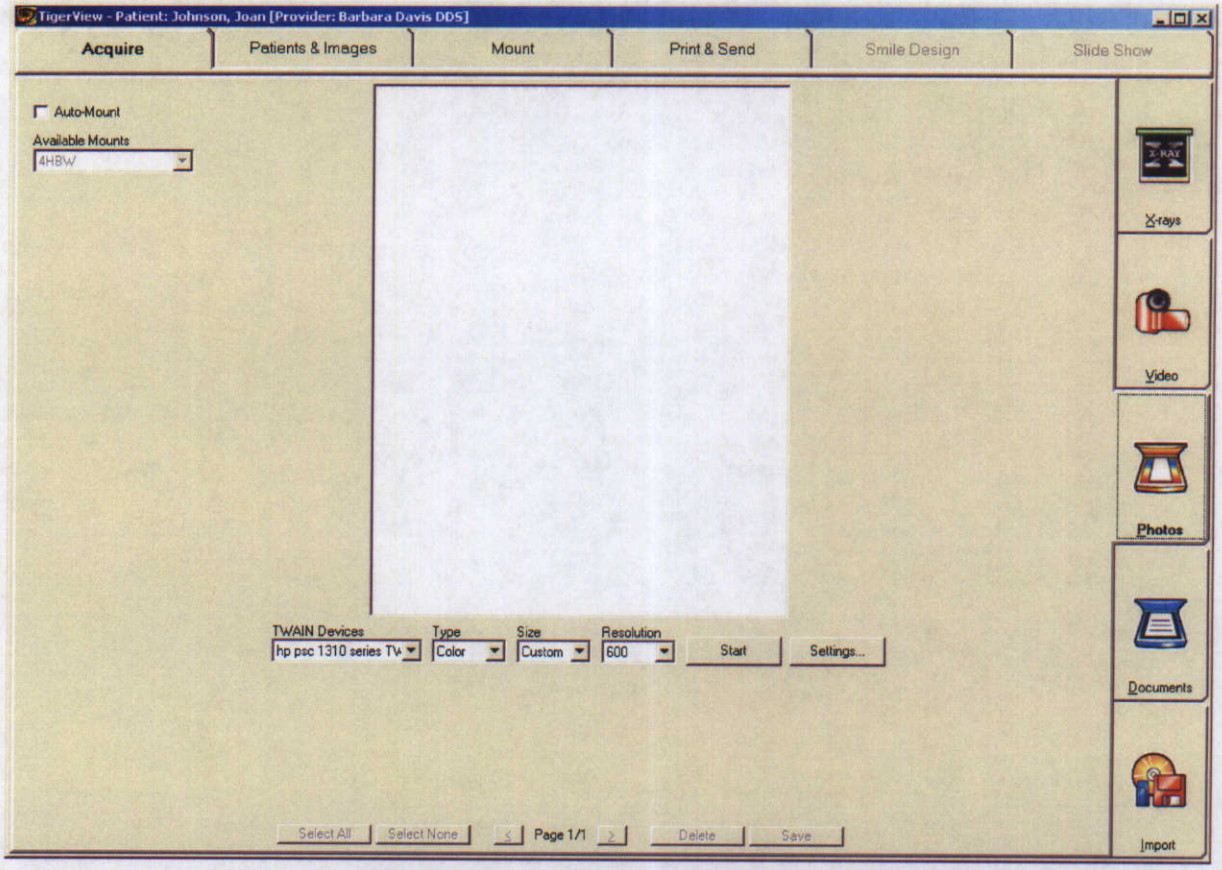
Acquire Window

Photos Tab



Images are entered into TigerView through the Acquire Windows. The methods to bring the images in are listed on the tabs on the right side of the Acquire window. The input methods consist of X-rays, Video, digital Photos, Documents or other images acquired by a flatbed scanner, and images that have already been saved digitally and will be brought in by Importing them.

Setting up a Photograph on a Flatbed Scanner Bed

When scanning photographs, make sure the scanner's transparency cover – if it has one – is on. The photograph should be placed in the upper right corner of the scanning bed.

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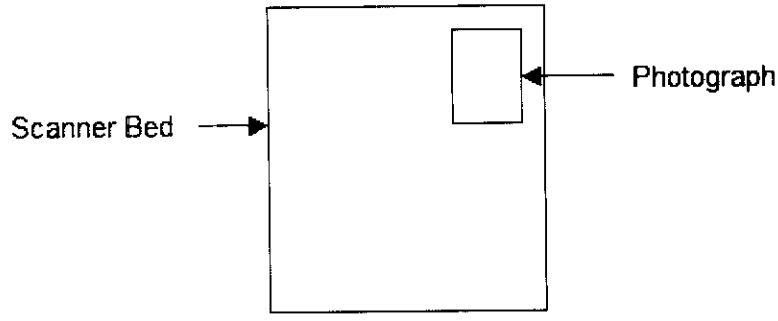


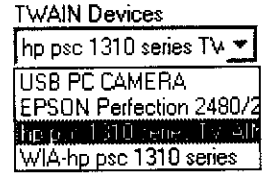
Acquiring Pictures from a Digital Camera

To acquire pictures directly from a digital camera, the camera must be viewed by the computer as a camera, and not as a removable hard drive. If the camera is viewed as a removable hard drive the pictures will need to be acquired through the Acquire Window - Import Tab instead of this window.

Install the camera and connect it to the computer according to the manufacturer's directions. If the image transfer software that comes with the camera opens, close it. Before the Photos window is opened in TigerView make sure the camera is connected to the computer and turned on.

TWAIN Devices

Click on the down arrow of the TWAIN Devices drop down box to display the devices that TigerView can retrieve images from.



Select the camera or scanner to receive images from.

If a TigerView readable scanner is directly attached to the computer but does not display in the Twain Devices drop down box check the manufacturer's instructions to make

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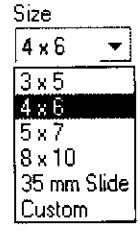
sure the scanner has been installed correctly on the computer.

Type

Select the type of image that will be acquired.

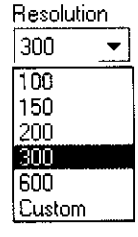
Size

For photographs that will be scanned select either the specific size of the photograph or Custom for photographs that are not a standard size. For photographs that come from a digital camera select Custom.



Resolution

Select the resolution of the photographs.



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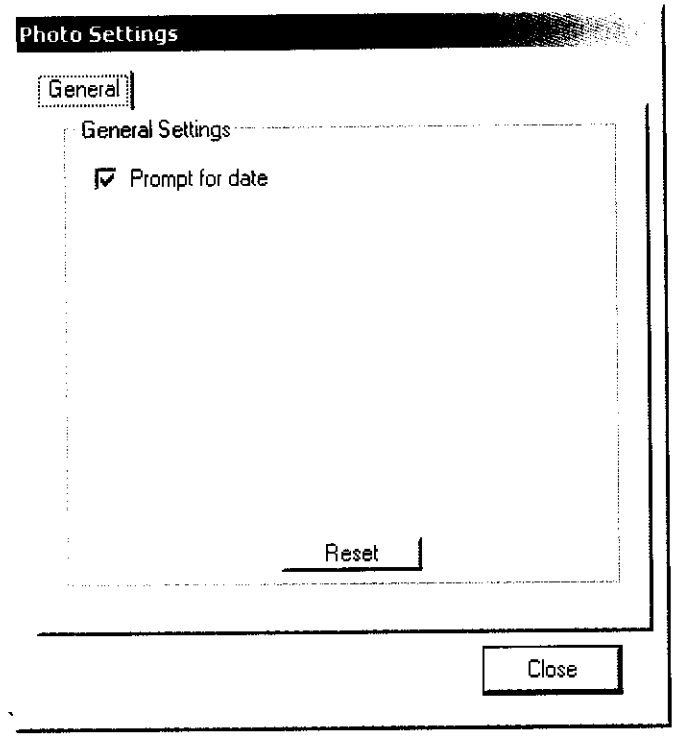
Settings Button for Scanning in Photographs

Settings Button – Photographs



Prompt for Date

If Prompt for Date is on (checked) TigerView will ask the user to enter the date the photograph was originally taken on. If Prompt for Date is off (unchecked) TigerView will save each scan using the current date.

Settings Button for a Digital Camera

There are no optional settings for a digital camera that is connected to this computer. Any image adjustments that need to be made will occur in the Image Viewer window.

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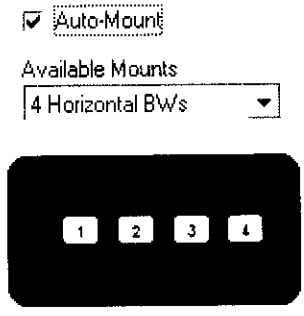
Auto-Mount



Check the Auto-Mount checkbox to automatically place each acquired image into a previously created and saved mount. Click on the down arrow of the Available Mounts drop down box to select a mount. The selected mount will display in the black mount box underneath the Available Mounts drop down box.

When using the Auto-Mount feature, images must be acquired in the order they are placed into the mount. For example, in the mount displayed above, the first scanned image would be placed in the image box with the number one on it, the second scanned image would be placed in the image box with the number two on it, etc.

When a mount is full the user will be asked if they want to create (save) the mount. If an image used in the mount is deleted before the mount is saved the image will automatically be removed from the mount. The next image acquired will be placed in the open mount space that was created by removing the image.

The alternative to Auto-Mount is to mount the images manually by dragging them onto a mount using the Mount window. For instructions on how to mount images manually, please refer to the Mount Window - Using the Mount Window To Mount Images section of this manual.

Start

Click on the Start button on the Acquire window to tell TigerView to start acquiring the images.

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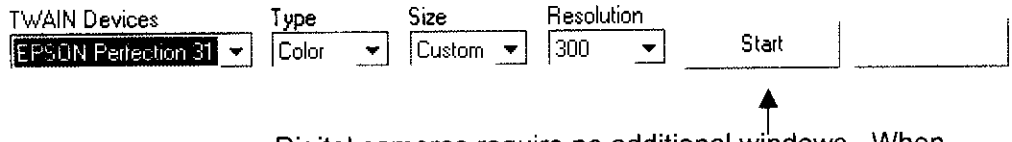
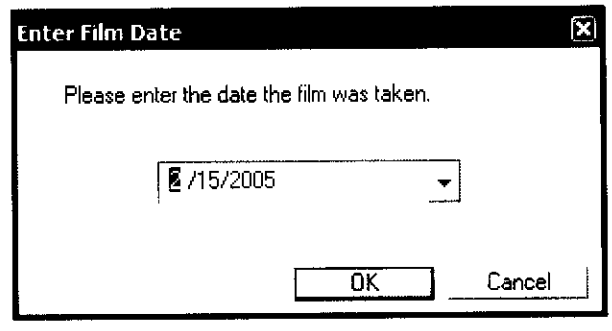


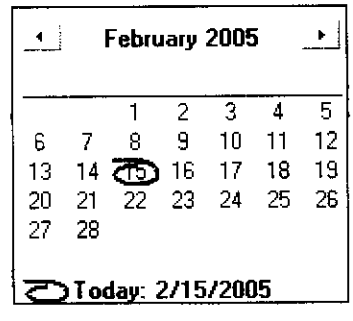
Digital cameras require no additional windows. When using a digital camera skip to "During the Acquire Process" section below.

When using a flatbed scanner continue on with this section.

Enter Film Date



Enter the date that this photo was taken then click on the OK button. If you are not sure of the date, click on the down arrow of the Enter Film Date drop down box to display a calendar.



Click on the left and right arrows that are on either side of the month and year to step backwards or forwards through the months. Click on a day to automatically insert that date into the Enter Film Date box and close the calendar.

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During the Acquire Process

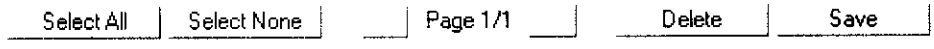
After the scan date has been entered, TigerView will automatically capture the image from the scanner.

After the Acquire Process

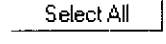
Once an image has been acquired it will be moved to the area under the TWAIN Devices drop down box as a thumbnail image.

To check an image, double click on the image to open it into the TigerView Image Viewer or Viewer window. If the image quality is acceptable, close the Image Viewer or Viewer by clicking on the Close Window box in the upper right corner of the window and move on to selecting and saving the image. If the image quality is not acceptable, close the Image Viewer and reacquire the image from the camera or scanner. After reacquiring, check the image again. Once the image is acceptable, select the image then click on the Save button to save the image into TigerView.

Image Buttons



Select an Image

To select an image, left click on it. To select multiple images, click on multiple images. To select all of the images click on the Select All button at the bottom of the window. 

A selected image will have a green box around it.

Deselect an Image

To deselect an image, click on it again. To deselect all of the images click on the Select None button at the bottom of the window.

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Delete an Image

To delete an image, first select the image or images to be deleted, and then click on the Delete button at the bottom of the window. [Delete] A deleted image is not recoverable.

Save an Image

To save an image, first select the image or images to be saved, then click on the Save button at the bottom of the window. [Save] The image will save, no matter what color its DEMS light is, to the currently selected patient.

Open an Image into the Image Viewer or Viewer

To open an image into the Image Viewer or Viewer window, double click on the image using the left mouse button or right click on the image and select View from the Right Click Image Menu. For instructions on how to use the Image Viewer window, please refer to the Image Viewer Window section of this manual. For instructions on how to use the Viewer window, please refer to the Viewer Window section of this manual.

Mount an Image or include an image in a Report

To mount an image or to include an image in a report, click on the image then click on either the Mount tab or the Print & Send tab. Both tabs are located at the top of the TigerView window.

Right Click Image Menu

To flip, rotate, add annotations, add keywords, add procedures, copy, archive, e-mail, export, print, etc before saving, right click on the image. This Right Click Image Menu can be accessed any time the image can be viewed outside of the TigerView Image Viewer. For instructions on how to use the Right Click Image Menu see Right Click On An Image in the Patients & Images Window - Images Tab section of this manual.

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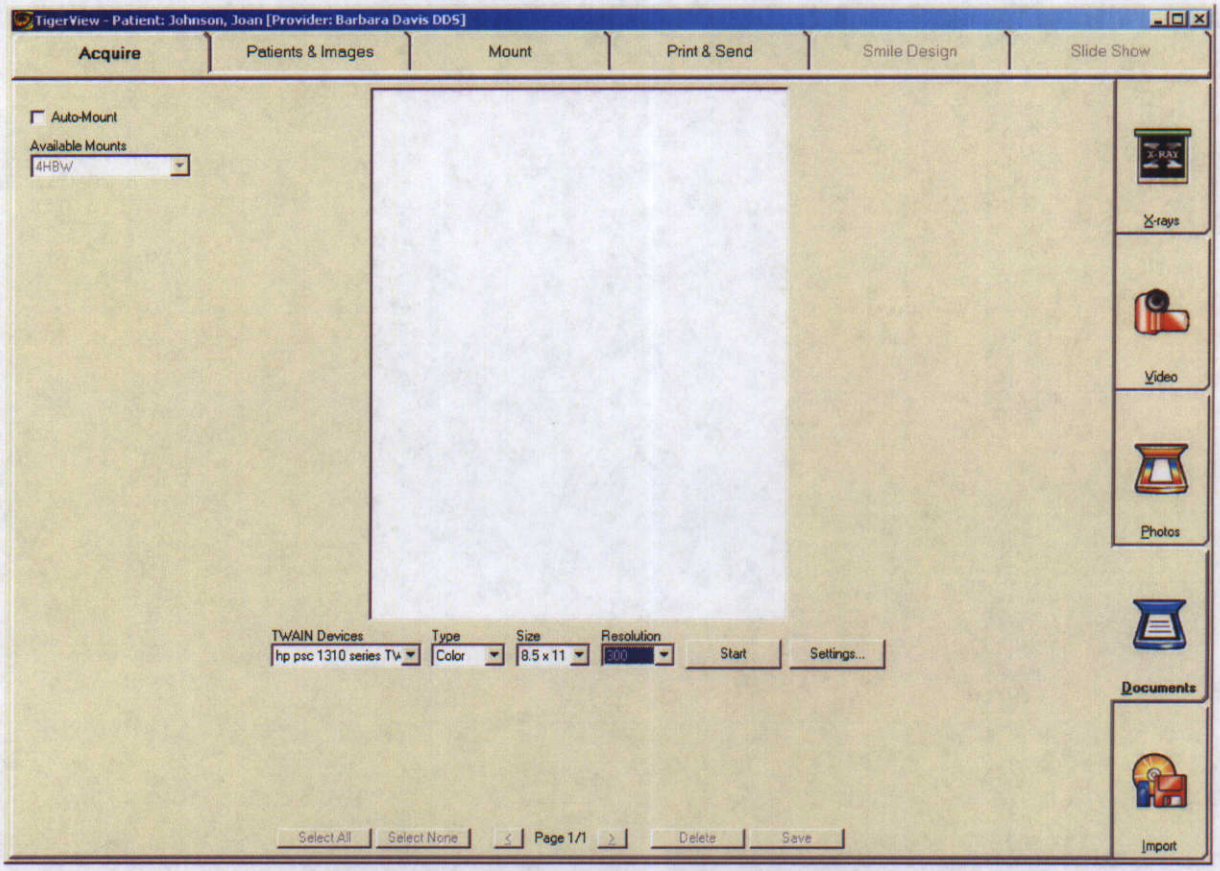
Acquire Window

Documents Tab



Images are entered into TigerView through the Acquire Windows. The methods to bring the images in are listed on the tabs on the right side of the Acquire window. The input methods consist of X-rays, Video, digital Photos, Documents or other images acquired by a flatbed scanner, and images that have already been saved digitally and will be brought in by Importing them.

The Acquire Window Documents Tab is used to scan documents, such as forms and letters, into TigerView using a flatbed scanner.

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TWAIN Devices

Click on the down arrow of the TWAIN Devices drop down box to display the devices that TigerView can retrieve images from.

Select the scanner to receive images from.

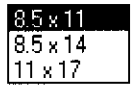
If a TigerView readable device is directly attached to the computer but does not display in the Available Devices drop down box on that computer, close TigerView, open TigerView Administration and make sure the device has been installed. See the TigerView Administration manual for instructions.

Type

Select the type of image that will be acquired from the scanner.

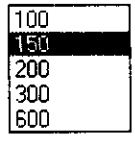
Size

Select the size of the document that will be imported from the scanner.



Resolution

Select the resolution to save the image at.



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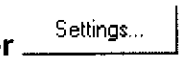
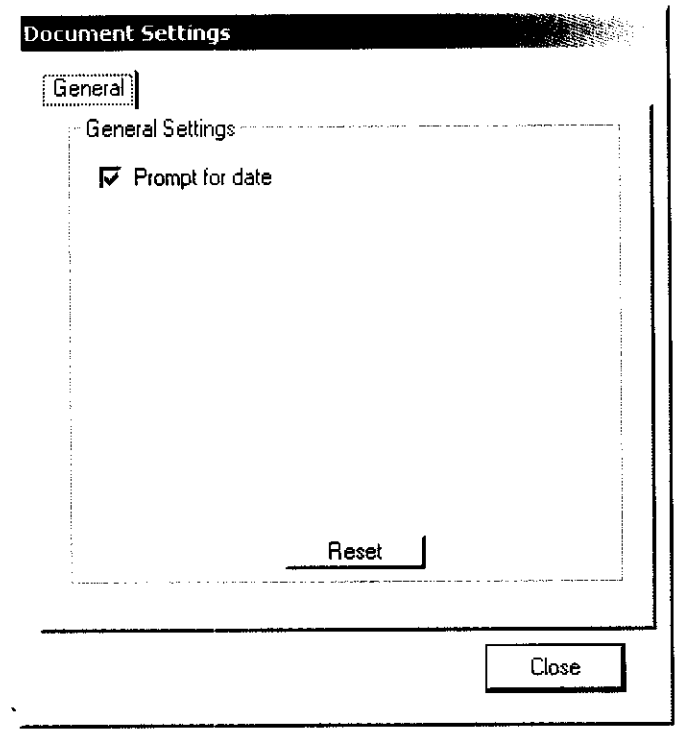
Settings Button for a Flatbed Scanner 

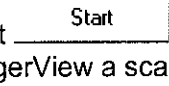
Settings Button – Documents



Prompt for Date

If Prompt for Date is on (checked) TigerView will ask the user to enter the date the film was originally taken on. If Prompt for Date is off (unchecked) TigerView will save each scan using the current date.

Start Button

Click on the Start 

button on the Acquire window to tell TigerView a scan is ready to begin.

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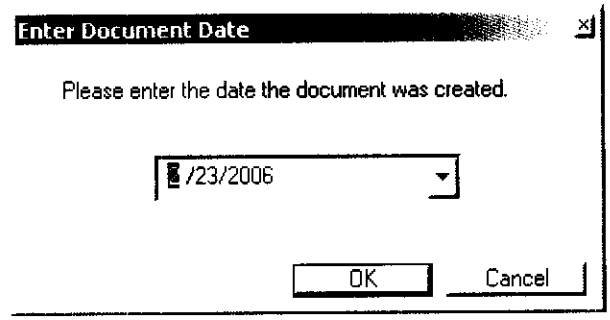
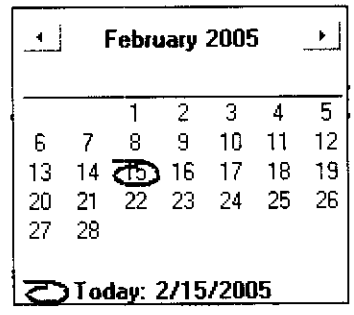
Enter Document Date



Enter the date that this document was printed then click on the OK button. If you are not sure of the date, click on the down arrow of the Enter Document Date drop down box to display a calendar.



Click on the left and right arrows that are on either side of the month and year to step backwards or forwards through the months. Click on a day to automatically insert that date into the Enter Film Date box and close the calendar.

During the Acquire Process

After the scan date has been entered, TigerView will automatically capture the image from the scanner.

After the Acquire Process

Once an image has been acquired it will be moved to the area under the TWAIN Devices drop down box as a thumbnail image.

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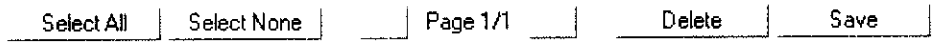
To check an image, double click on the image to open it into the TigerView Image Viewer. If the image quality is acceptable, close the Image Viewer by clicking on the Close Window box ☒ in the upper right corner of the window and move on to selecting and saving the image. If the image quality is not acceptable, close the Image Viewer and rescan the document. After rescanning, check the image again. Once the image is acceptable, select the image then click on the Save button to save the image into TigerView.

Image Buttons

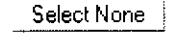


Select an Image

To select an image, left click on it. To select multiple images, click on multiple images. To select all of the images click on the Select All button at the bottom of the window.

A selected image will have a green box around it.

Deselect an Image

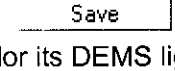
To deselect an image, click on it again. To deselect all of the images click on the Select None button at the bottom of the window. 

Delete an Image

To delete an image, first select the image or images to be deleted, and then click on the Delete button at the bottom of the window.

A deleted image is not recoverale.

Save an Image

To save an image, first select the image or images to be saved, then click on the Save button at the bottom of the window. 

The image will save, no matter what color its DEMS light is, to the currently selected patient.

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Open an Image into the Image Viewer or Viewer

To open an image into the Image Viewer or Viewer window, double click on the image using the left mouse button or right click on the image and select View from the Right Click Image Menu. For instructions on how to use the Image Viewer window, please refer to the Image Viewer Window section of this manual. For instructions on how to use the Viewer window, please refer to the Viewer Window section of this manual.

Mount an Image or include an image in a Report

To mount an image or to include an image in a report, click on the image then click on either the Mount tab or the Print & Send tab. Both tabs are located at the top of the TigerView window.

Right Click Image Menu

To flip, rotate, add annotations, add keywords, add procedures, copy, archive, e-mail, export, print, etc before saving, right click on the image. This Right Click Image Menu can be accessed any time the image can be viewed outside of the TigerView Image Viewer. For instructions on how to use the Right Click Image Menu see Right Click On An Image in the Patients & Images Window - Images Tab section of this manual.

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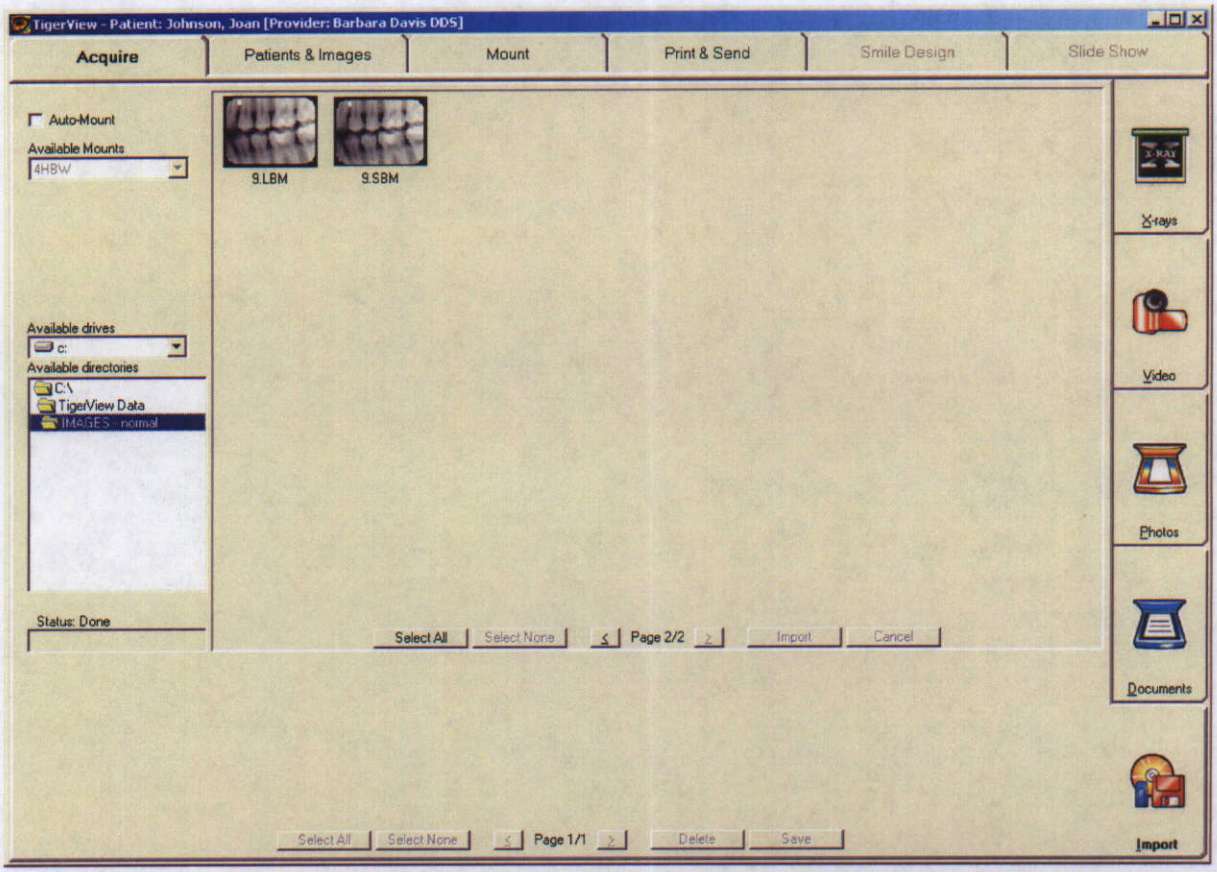
Acquire Window

Import Tab



Images are entered into TigerView through the Acquire Windows. The methods to bring the images in are listed on the tabs on the right side of the Acquire window. The input methods consist of X-rays, Video, digital Photos, Documents or other images acquired by a flatbed scanner, and images that have already been saved digitally and will be brought in by Importing them.

Importing is the process by which an image, document or video file can be copied into TigerView from a file that is outside of TigerView.

Available Drives

Click on the drop down box arrow to display the list of drives this computer can access. If this computer is on a

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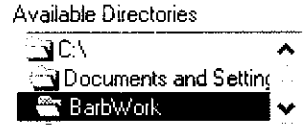
network and has network drives mapped, the network drives will also display.

Select the drive where the imported images can be found. Note that the computer views many digital cameras as removable hard drives.

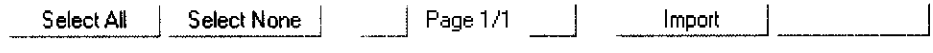
Available Directories

After the drive is selected, a list of the folders (also called Directories) on that drive will display.



Select the folder where the imported images can be found. Any images in the selected folder (directory) on the selected drive will display in the Current Image box on the Acquire window. To import an image, the image must be selected then imported, then selected and saved.

Image Buttons in the Current Image Box



Select an Image

To select an image, left click on it. To select multiple images, click on multiple images. To select all of the images click on the Select All button at the bottom of the window. A selected image will have a green box around it.

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Deselect an Image

To deselect an image, click on it again. To deselect all of the images click on the Select None button at the bottom of the window. Select None

Import an Image

To import an image, first select the image or images that require importing then click on the Import button at the bottom of the Current Image box. Import

Stop the Import

If, during the import operation, the image is no longer desired, click on the Cancel button at the bottom of the Current Image box. Cancel The Cancel button will abort the import operation.

After the Import

Once an image has been selected and imported it will move to the area under the Available Directories box as a thumbnail image. The image still needs to be selected and saved into TigerView.

To check an image, double click on the image to open it into the TigerView Image Viewer.

Image Buttons Below the Current Image Box

Select an Image

To select an image, left click on it. To select multiple images, left click on the first image, then hold the Control (ctrl) key down and left click on the rest of the desired images. To select all of the images click on the Select All button at the bottom of the window. Select All A selected image will have a green box around it.

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Deselect an Image

To deselect an image, click on the Select None button at the bottom of the window. Select None

Delete an Image

To delete an image, first select the image or images to be deleted, and then click on the Delete button at the bottom of the window. Delete A deleted image is not recoverable.

Save an Image

To save an image, first select the image or images to be saved, then click on the Save button at the bottom of the window. Save.

Open an Image into the Image Viewer or Viewer

To open an image into the Image Viewer or Viewer window, double click on the image using the left mouse button or right click on the image and select View from the Right Click Image Menu. For instructions on how to use the Image Viewer window, please refer to the Image Viewer Window section of this manual. For instructions on how to use the Viewer window, please refer to the Viewer Window section of this manual.

Mount an Image or include an image in a Report

To mount an image or to include an image in a report, click on the image then click on either the Mount tab or the Print & Send tab. Both tabs are located at the top of the TigerView window.

Right Click Image Menu

To flip, rotate, add annotations, add keywords, add procedures, copy, archive, e-mail, export, print, etc before saving, right click on the image. This Right Click Image Menu can be accessed any time the image can be viewed outside of the TigerView Image Viewer. For instructions on how to use the Right Click Image Menu see Right Click On An Image in the Patients & Images Window - Images Tab section of this manual.

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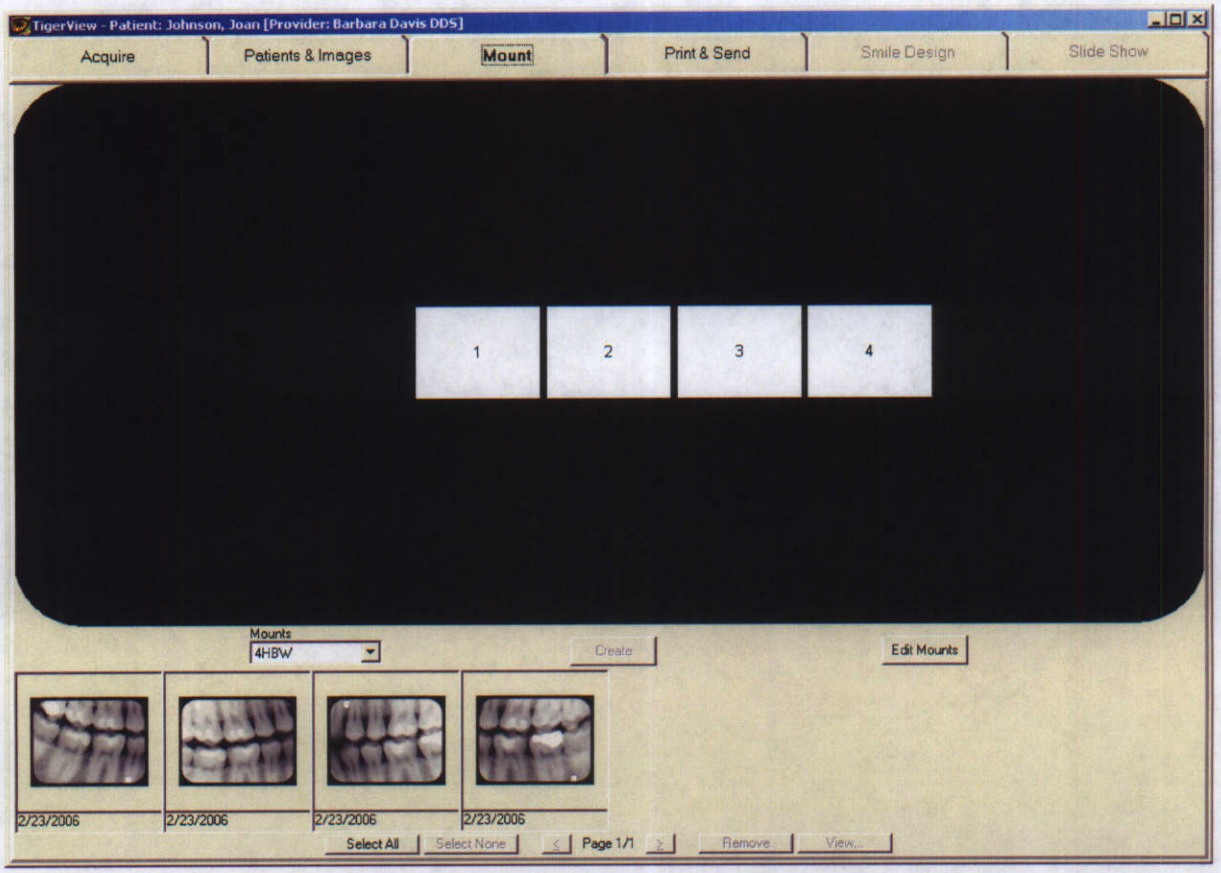
Mount Window



Digital images can be viewed, and/or mounted, from the Mount window. Any image, except for those inside the Current Image box on the Acquire window, can be brought to the Mount window.

Bring an Image to the Mount Window

To bring an image to the Mount window, click on it from any location except inside the Current Image box on the Acquire window then click on the Mount tab at the top of the TigerView window.

To move multiple images to the Mount window, click on each or click on the Select All button at the bottom of the window then click on the Mount tab. The images will appear on the Mount window below the black Mount box.

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Using the Mount window to view an image

To use the Mount window like a view box, click on the down arrow of the Mounts drop down box and select Free Form. Then drag the images, one at a time, from the bottom of the Mount window onto the black Mount box. The larger the number of images displayed on the Mount box, the smaller the images will appear.

Using the Mount window to Mount Images

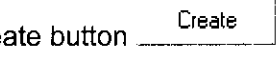
Mounting images is similar to placing existing photographs inside a mat that has multiple openings. The mounted photographs are now grouped together and can be viewed as one large picture. In the same way images can be placed into the same mount then viewed, e-mailed, exported, etc. as a single image.

Create Mounted Images Using Existing Mounts

Move the images that need to be mounted to the Mount window by clicking on them then clicking on the Mount tab. Click on the down arrow of the Mounts drop down box and select a mount. The Free Form mount is used more often to view images than to mount them. If Free Form is the only mount available, consider moving on to the Create A New Mount section below.

The white boxes that appear in the black Mount box are meant to hold the images. Drag the images, one at a time, onto a white box. The order that the images are dragged onto the white boxes does not matter.

To move an image within the mount, drag the image from its current location in the mount to an empty white box. To remove an image from the mount, right click on the image in the mount and select Remove from the Right Click Menu that appears. To change the orientation of an image in the mount from vertical to horizontal or from horizontal to vertical, the orientation of the white box that holds the image must be changed. For instructions on how to change the orientation of a white box on an existing mount please refer to the Edit An Existing Mount section below.

When the images have been correctly placed in the mount, click on the Create button 

to save them as a single mounted image

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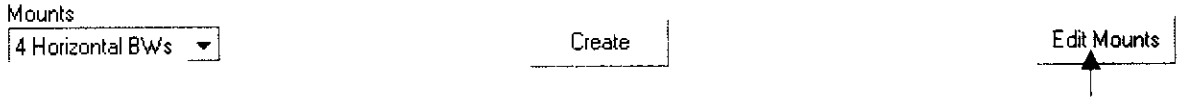
Create a New Mount

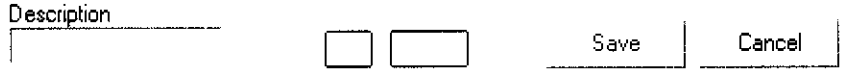
To create a new mount, in the Mount window click on the Edit Mounts button.



The area of the window underneath the Mount box will change.

Click on the Add button to setup a new mount.

The area of the window underneath the Mount box will again change.



To create a new mount, drag one of the two boxes onto the Mount box to create an image holder. The boxes that are dragged onto the Mount box cannot touch each other. The larger oblong box, when dragged onto the Mount box, will expand to hold a pan or ceph image. Notice that the Image Holder boxes are numbered. The numbers are important only if the mount is going to be used with TigerView's Auto-Mount feature.

Creating a Mount that will be used with for Auto-Mounting

If the Auto-Mount feature is going to be used with this mount, the Image Holders must be placed on the mount in the same order that the images coming into TigerView will be loaded into the mount. For example:

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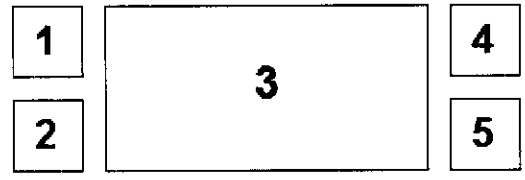
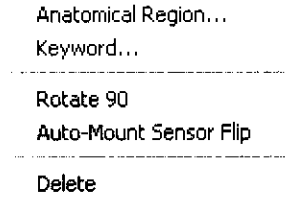


In the mount above, two bitewings are located on each side of a pan. Using a phosphor plate scanner for this example, the first plate that is scanned will be placed into the Image Holder with the number 1 on it, the second plate that is scanned will be placed into the Image Holder with the number 2 on it, the third plate that is scanned will be placed into the Image Holder with the number 3 on it (the pan), etc. If the plates are fed into the scanner in the wrong order the pan may end up in a bitewing sized Image Holder.

Image Holder Right Click Menu

To change one of the image holders on the Mount box, right click on it. The Image Holder Right Click Menu will appear.



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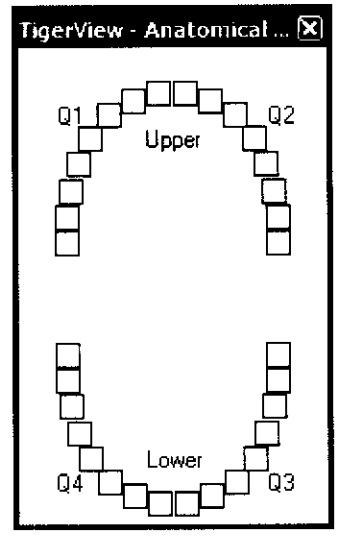
Anatomical Region



If images of the same tooth, or group of teeth, will always be placed in this image holder, the anatomical region represented can be preset. This Anatomical Region will be automatically assigned to the image that is placed in this Image Holder. For instructions on how to use the Anatomical Region window, please refer to the Patients&Images / Right Click On An Image / Anatomical Region section of this manual.

Keyword

When Keyword is selected the Keywords and Procedures window will display with only the Keywords section available for use:

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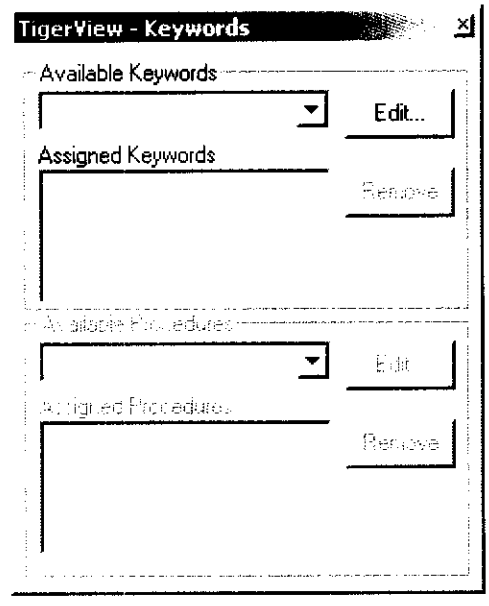

Any Keywords assigned to this Image Holder will be automatically assigned to the image that is placed inside this Image Holder. For instructions on how to use the Keywords window please refer to the Patients&Images / Right Click on an Image / Keywords/Procedures section of this manual.

Rotate 90

Select Rotate 90 to rotate the Image Holder 90 degrees.

Auto-Mount Sensor Flip

If selected, any image obtained from a sensor that is placed in this Image Holder will be automatically flipped.

Delete

Select Delete to remove the Image Holder from the mount.

Complete the New Mount

When the Image Holders are adjusted correctly in the mount, click in the Description box and enter a descriptive title for this mount, then click on the Save button to save the new mount.

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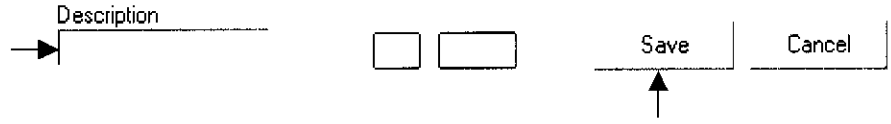


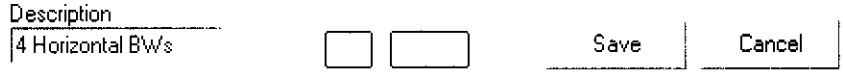
Edit an Existing Mount

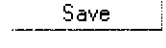
To change an existing mount, in the Mount window click on the Edit Mounts button.

The area of the window underneath the Mount box will change.

Click on the down arrow of the Mounts drop down box to select the mount to edit, then click on the Edit button to edit the selected mount.

The area of the window underneath the Mount box will again change.



Anything on the mount, including its description, can be changed. If the mount is being used with the Auto-Mount feature be cautious about adding and deleting Image Holders. You may affect the order that the digital images should come into TigerView (see Creating A Mount That Will Be Used With The Auto-Mount Feature above). When all of the changes have been made, click on the Save button  to save the mount.

Right Click Menu for Images in the Mount Box

Placing the cursor on an image that has been dragged onto an Image Holder in the Mount box, then clicking the

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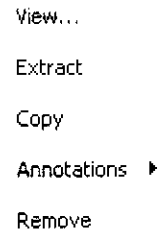
right mouse button once accesses the Right Click Image Menu displayed below.



View

To view an image in the Image Viewer, right click on the image in the Mount box and select View from the menu that appears. In the Image Viewer the image can be magnified, rotated, flipped, colorized, embossed, annotated, measured and inverted.

Extract

To copy an image from the Mount box to the area underneath the Mount box, right click on the image in the Mount Box and select Extract from the menu that appears. This feature is meant to replace an image that was mistakenly removed from the Mount window. If multiple copies of the same image are created, the images will act as a synchronous group, performing all operations together as if they were one image instead of multiple copies of one image.

Copy

To copy an image from the Mount box, right click on the image in the Mount box and select Copy from the menu that appears. The image will be copied to the clipboard.

Annotations

To add annotations to an image in the Mount box, right click on the image in the Mount box and select annotations from the menu that appears. The Annotations submenu will appear:

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Draw Annotations...
Show Annotations
Delete Annotations

Draw Annotations

Draw Annotations will display the selected image in the Image Viewer window with the annotation tools open at the top. For instructions on how to use the Image Viewer window, please refer to the Image Viewer section of this manual.

Show Annotations

Show Annotations will cause the annotations to display on the thumbnail version of the image. Selecting Show Annotations when the annotations already display will cause the annotations to be hidden. When annotations are present on an image an annotation icon will display on the thumbnail version of the image.

Delete Annotations

Delete Annotations will delete all of the annotations from an image.

Remove

To remove an image from the Mount box but leave it on the Mount window under the Mount box where it can be used again, right click on the image in the Mount box and select Remove from the menu that appears.

Image Buttons

Select an Image

To select an image, left click on it. To select multiple images, left click on the first image, then hold the Control (ctrl) key down and left click on the rest of the desired images. To select all of the images click on the Select All button at the bottom of the window. Select All A selected image will have a green box around it.

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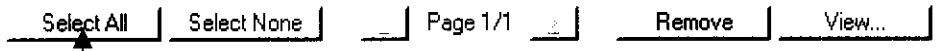
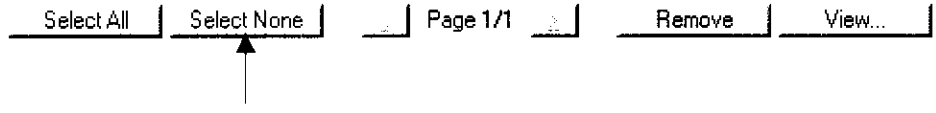


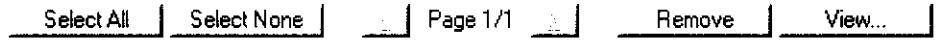
Deselect an Image

To deselect an image, click on the Select None button at the bottom of the window. Select None



Remove an Image from the Mount Window

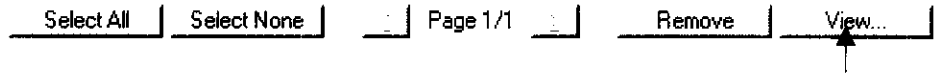
To remove an image from the Mount window, right click on the image under the Mount box and click on the Remove button on the bottom of the Mount window.



If a copy of the image is in a mount on the Mount box the copy will not be erased. If an image was mistakenly removed from the Mount window right click on the image in the mount and select Extract. A copy of the image will be placed under the Mount box.

View an Image

To view an image in the Image Viewer or Viewer window, select the image or images then click on the View button at the bottom of the Mount window.



For instructions on how to use the Image Viewer or Viewer window, please refer to those sections of this manual.

Right Click Menu for Images Underneath the Mount box

Placing the cursor on an image below the Mount box then clicking the right mouse button once accesses the following Right Click Menu.

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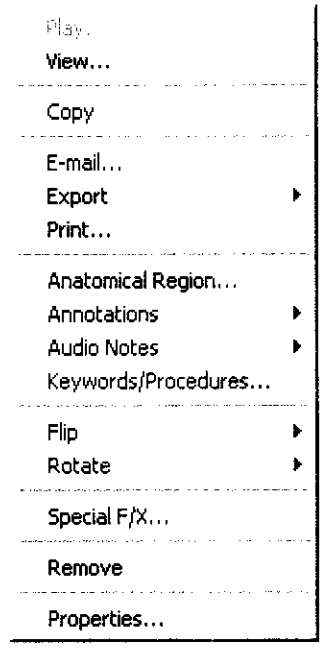

For instructions on how to use the Right Click Image Menu see Right Click On An Image in the Patients & Images Window - Images Tab section of this manual.

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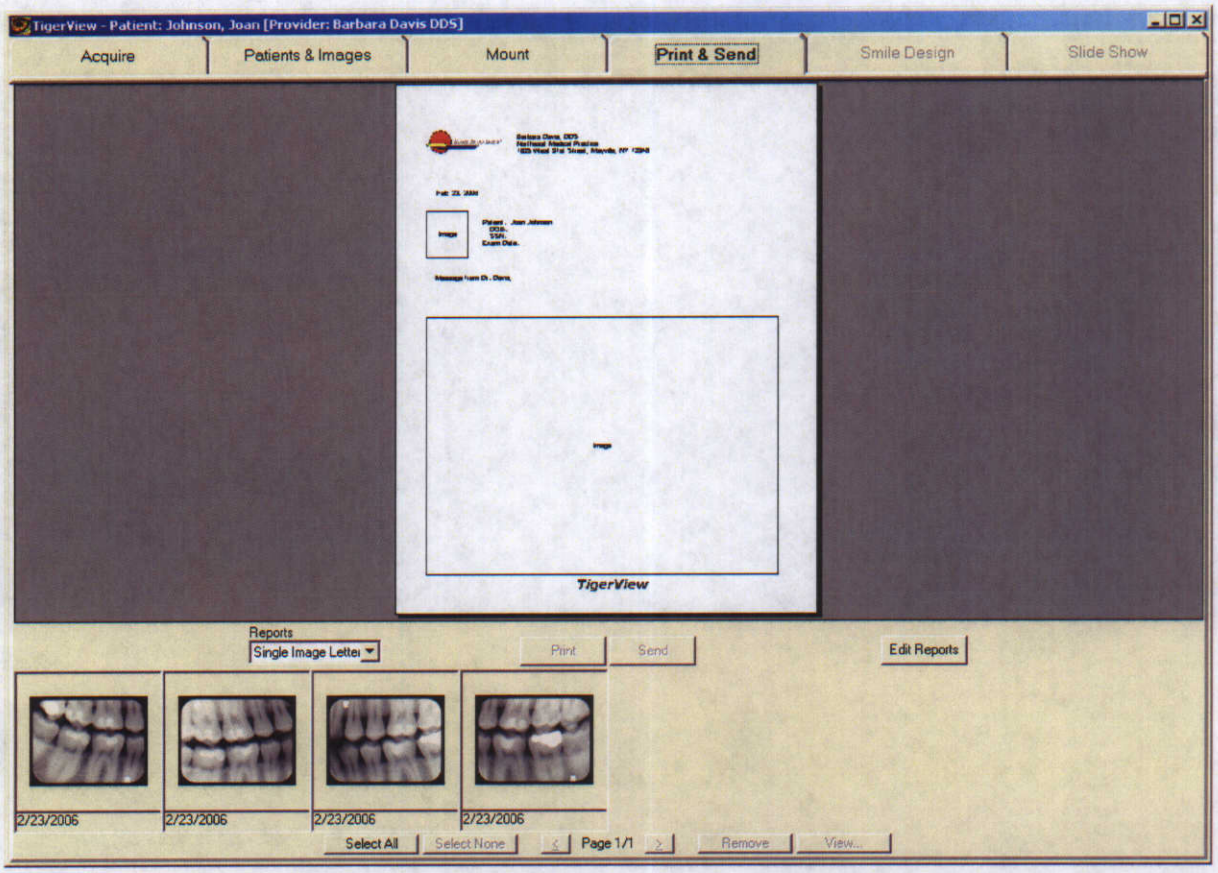
Print & Send Window



TigerView comes with several predefined reports. These reports can be used as is, edited to add, delete or change information, or deleted if the user is certain the report will never be needed.

New reports can be added to TigerView. Reports are created using:

- Fixed text that is the same for everyone the report prints for.
- Patient and provider information that changes depending on the patient selected.
- Fixed graphics such as clip art.
- Patient images that are placed on the report at the time the report is generated. The patient images available change depending on the patient selected.

Viewing Size of the Report

At any time, the report that is displayed in the Current Report box can be resized. The report can be viewed in Normal size, where the text can be

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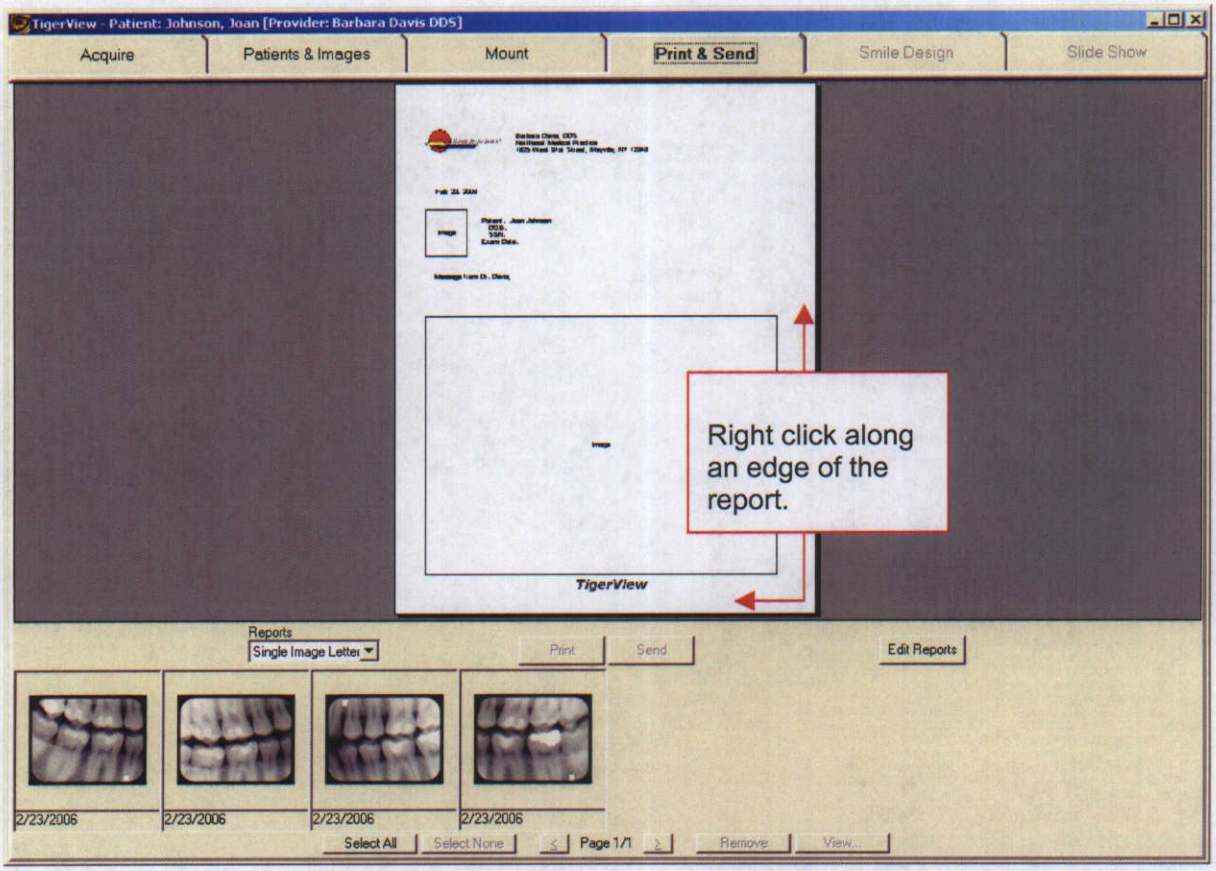
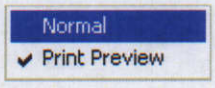
easily read, or in Print Preview size where the entire page is viewable at once.

To change the size of the report, right click outside a Text, Image or Graphic box, close to an edge of the report.



The Report Right Click Menu will appear.



Select Normal to allow the text to be read by displaying the report at 100% of its size, or Print Preview to view the entire report at once by displaying the page at 50% of its size.

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Print or Send an Existing Report

Before printing a report from TigerView, the images needed for the report must be brought to the Print & Send window.

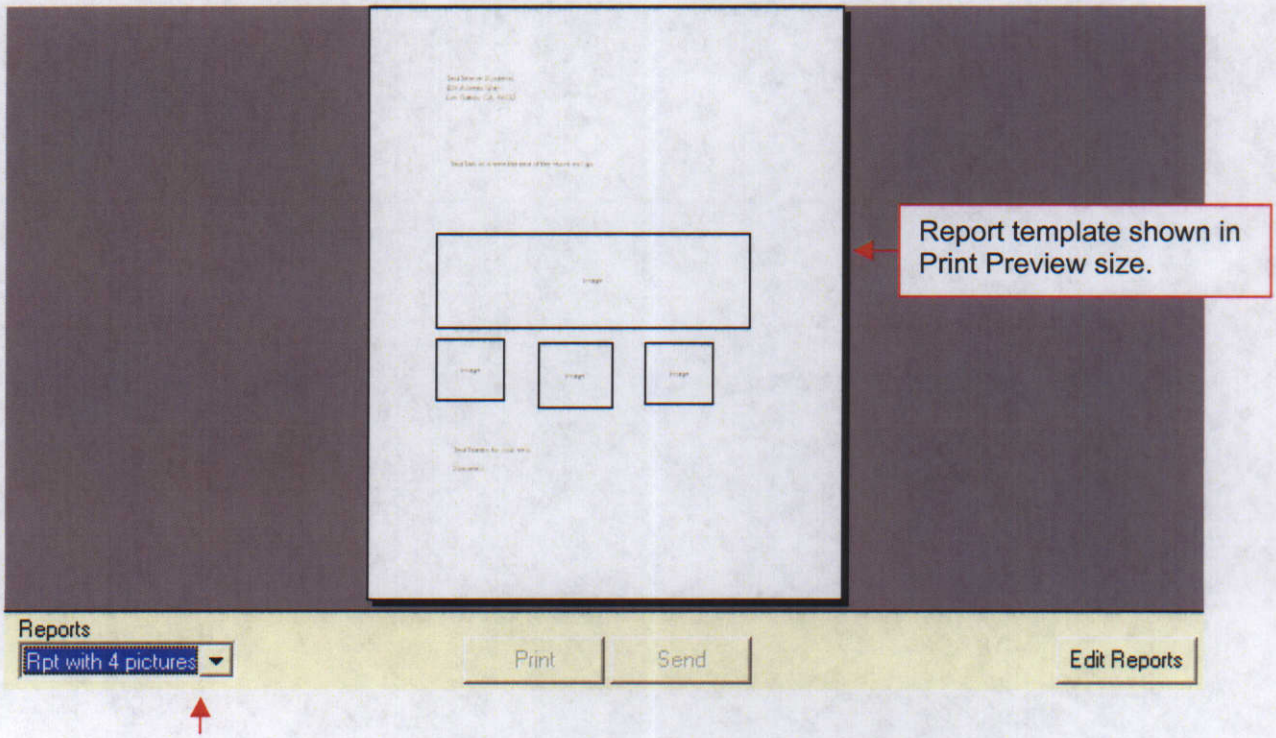
Bring Images to the Print & Send window

To bring an image to the Print & Send window, select it from anywhere in TigerView except inside the Current Image box on the Acquire window then click on the Print & Send tab at the top of the TigerView window. The image will appear at the bottom of the Print & Send Window beneath the Reports drop down box.

To print and send multiple images, select all of the images by left clicking on them then click on the Print & Send tab at the top of the TigerView window.

Select an Existing Report to Print

Click the down arrow on the Reports drop down box to display existing TigerView reports. Select a report. The template for the selected report will display in the Current Report box.



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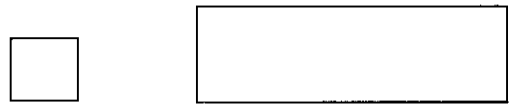
Place an Image on a Report

The images copied to the Print & Send tab will display at the bottom of the Print & Send window. To move an image onto the report, drag the image onto a box that displays on the report template in the Current Report box. Below are several examples of Image boxes.

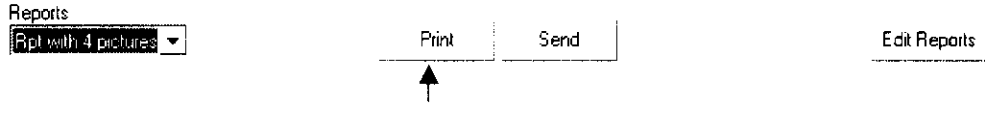


Drag each image onto a box that is sized appropriately for the image. For example, in the above two boxes a larger image would display better in the box on the right than in the box on the left.

The image will be automatically resized to match the size of that box. If a square image is placed in an oblong box the image will be sized so that its edges touch either the oblong's horizontal sides or the oblong's vertical sides but not both. If an oblong image is placed in a square box the image will remain oblong but sized so that its edges touch either the square's horizontal sides or the square's vertical sides but not both. In either case, the image may be reduced or enlarged until it meets at least two of the sides of the Image box it is placed in.

Print the Report

After the images are dragged onto the report, click on the Print button to print the report.



The Microsoft Windows Print window will display, allowing the user to specify which device to print to.

Send the Report

After the images are dragged onto the report, click on the Send button to send the report by e-mail.

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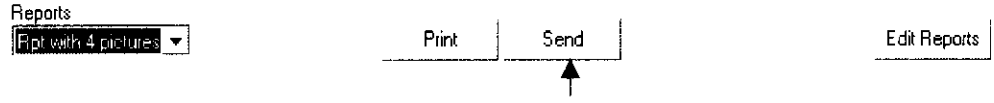
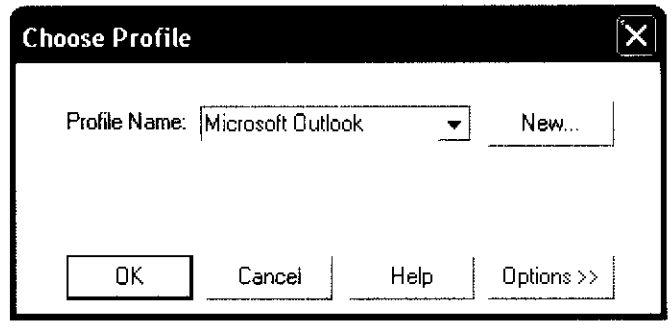


If the computer being used has an email software package set up to use as its default email software that software will open. If the computer being used does not have an e-mail software package setup as its default e-mail software the Microsoft Profile window will display, allowing the user to select which e-mail software to use.



The selected e-mail program will open with the report already attached and a subject line created. Enter the e-mail address to send to, and a message, if desired, then click on the e-mail screen Send button to send the e-mail.

Microsoft Outlook e-mail window is used as an example

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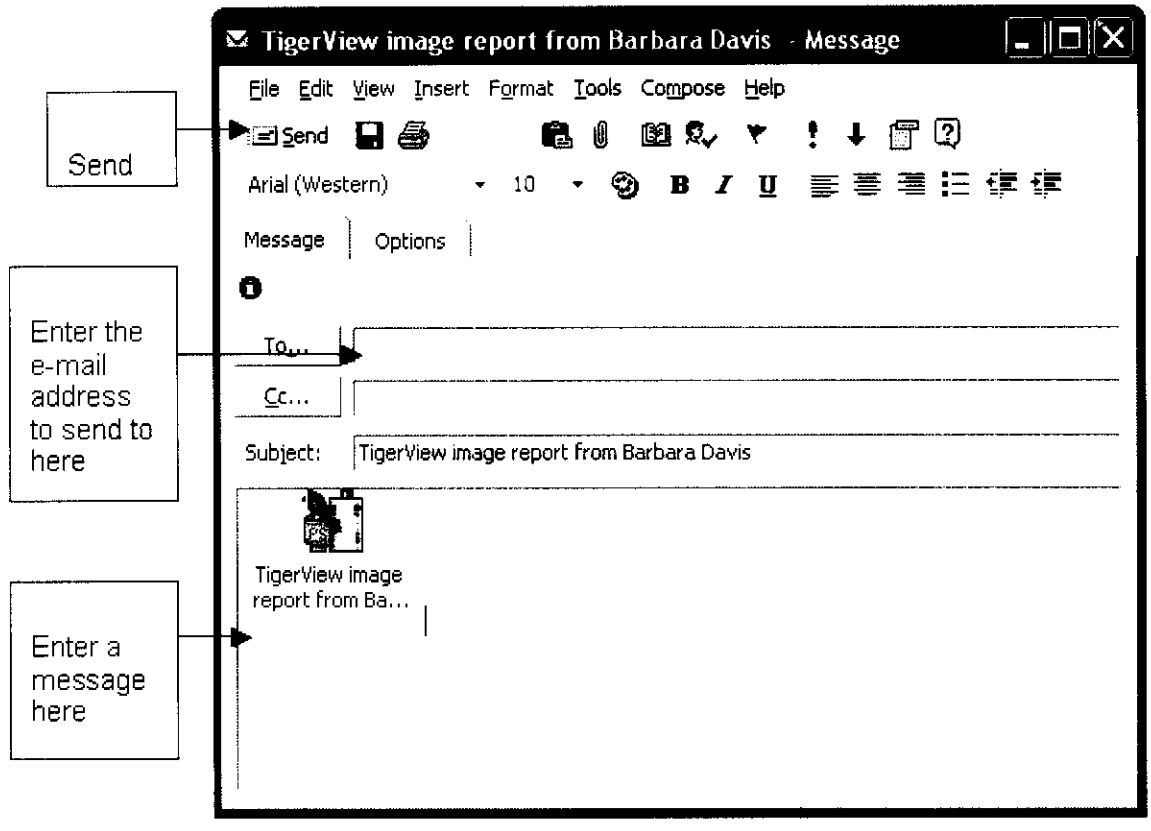
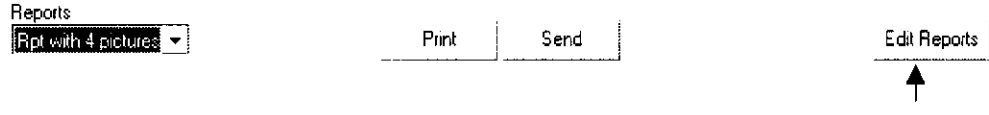


For more complete instructions on how to send e-mail, refer to the manufacturer's instructions for the selected e-mail program.

Create a New Report

The Print & Send window opens with the last report that was accessed displayed in the Current Report box. To create a new report, click on the Edit Reports button.



The lower portion of the Print & Send window will change to one row of buttons plus the drop down box that displays the existing reports.

Click on the Add button to start a new report.

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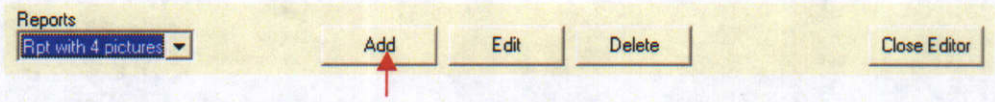
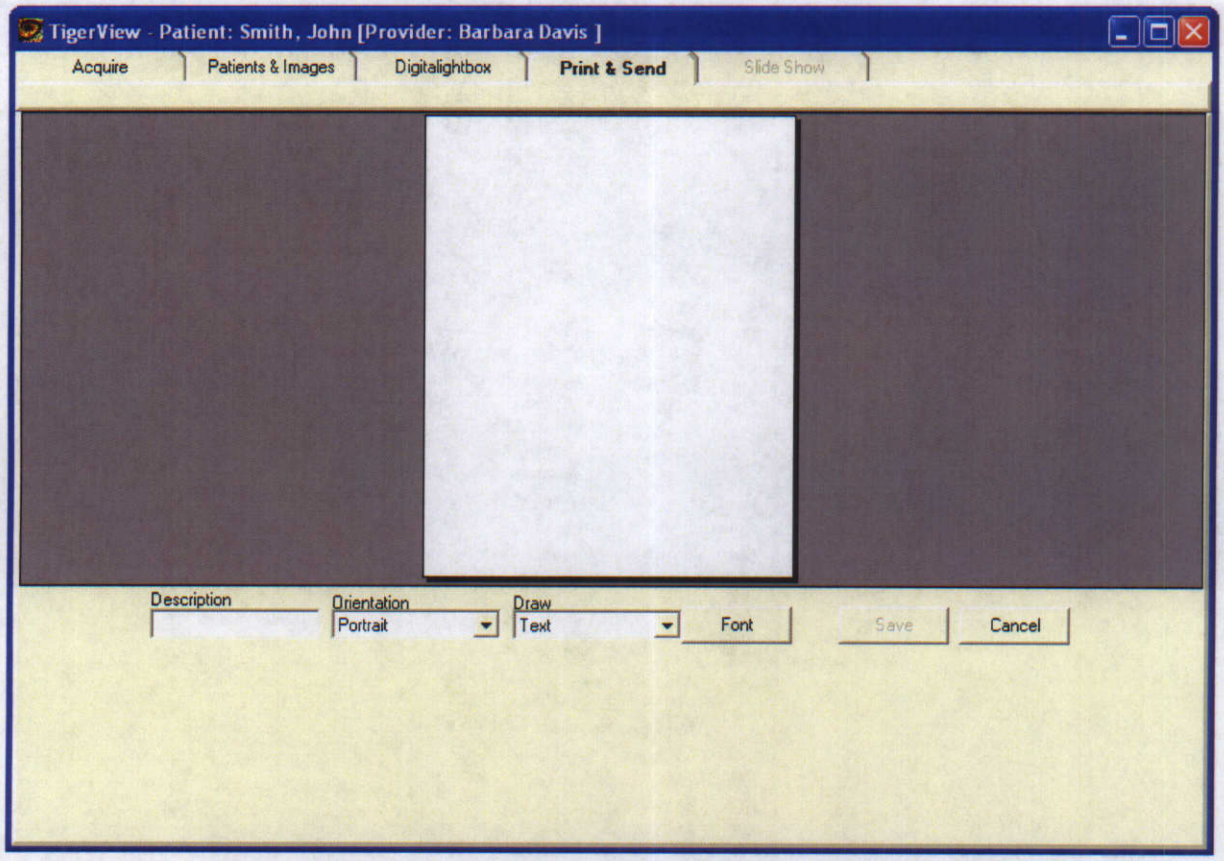


The Print & Send window will change as follows:



A blank document now displays in the Current Report box and the row of drop down boxes and buttons has changed.

Description

In the box labeled "Description" enter the name for this report. Approximately 23 characters of the report description will be viewable by the user.

Orientation

Click on the down arrow of the Orientation drop down box to select either a Portrait (vertical) or Landscape (horizontal) paper orientation for the

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report. The orientation of the report is the one feature of the report that cannot be changed after the report has been saved.

Draw

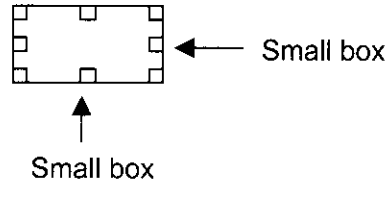
Reports are set up as series of boxes. A box can be a Text box to hold text, an Image box to hold an image, or a Graphic box to hold a graphic such as a piece of clip art. Click on the down arrow of the Draw drop down box to select a Text box, Image box, or Graphic box to place on the report.

On the blank document in the Current Report box, click and drag diagonally to create the Text, Image, or Graphic box. The box can be created anywhere on the document then moved to its intended location.

The cursor icon will change depending on where it is in regards to the Text, Image or Graphic box.

The cursor will change to a hand when it touches an edge of the box. When the cursor is a hand, the Text, Image or Graphic box can be moved.

The cursor will change to a two-headed arrow when it touches one of the small boxes along an edge of a Text, Image or Graphic box. The small boxes are used to resize the Text, Image or Graphic box. Resize the main box by clicking and dragging a small box. Clicking on the Text, Image or Graphic box will cause the small boxes to display if they don't already.



The cursor will change to an I beam when it is inside a Text box where text can be inserted, edited or deleted. Most of the normal word processing abilities exist inside a Text box.

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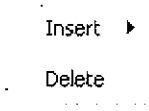
Note that when a Text box is created the word "Text" appears inside it. Remove this word using either the Backspace or Delete key. If not removed, the word will appear with the rest of the text placed inside the Text box.

The words "Graphic" and "Image" appear inside Graphic and Image boxes. These words do not need to be deleted. The graphic or image ultimately dragged into each box will overlay them.

Each box – Text, Image or Graphic – has its own individualized right click menu.

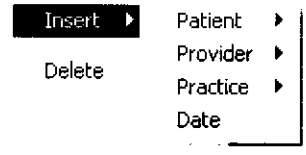
Text Box Right Click Menu

The first Right Click Menu to appear is the Insert or Delete Menu.



Insert

Select Insert to display the Insert Submenu.



Patient

Select Patient to automatically display the currently selected patient's first or last name, patient ID, date of birth or social security number on the report. If the first name and last name will both be used, place either a space or a comma between them for ease of viewing.

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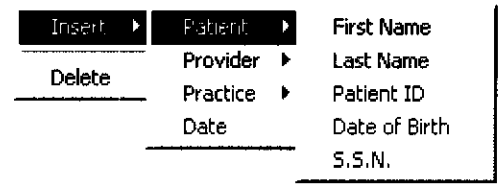
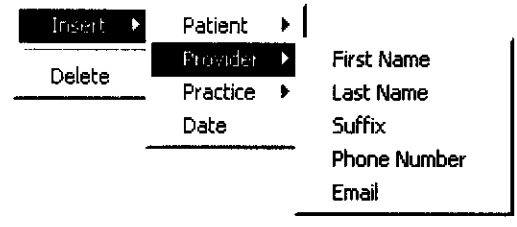


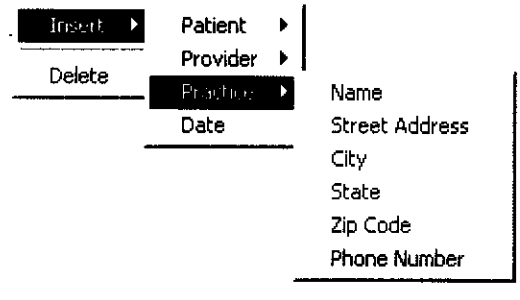
Provider

Select Provider to automatically display information about the currently selected patient's provider. Provider information includes his or her first name, last name, suffix, phone number and email address. Place each piece of information either on its own line or separated from the other information by a space, comma, or other separator for ease of viewing.



Practice

Select Practice to automatically display the name, street address, city, state, zip and phone number of the practice. Place each piece of information either on its own line or separated from the other information by a space, comma, or other separator for ease of viewing.



Date

Select Date to display the current date.

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Delete

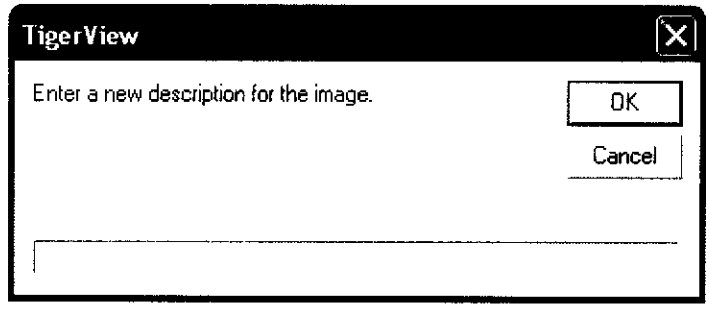
Select Delete from the first Text box right click menu to delete the Text box.

Image Box Right Click Menu

There is only one right click menu for an Image box.

Edit Description

Select Edit Description to change the text that appears inside the Image box.



Delete

Select Delete to remove the Image box from the report.

Graphic Box Right Click Menu

There is only one right click menu for a Graphic box.

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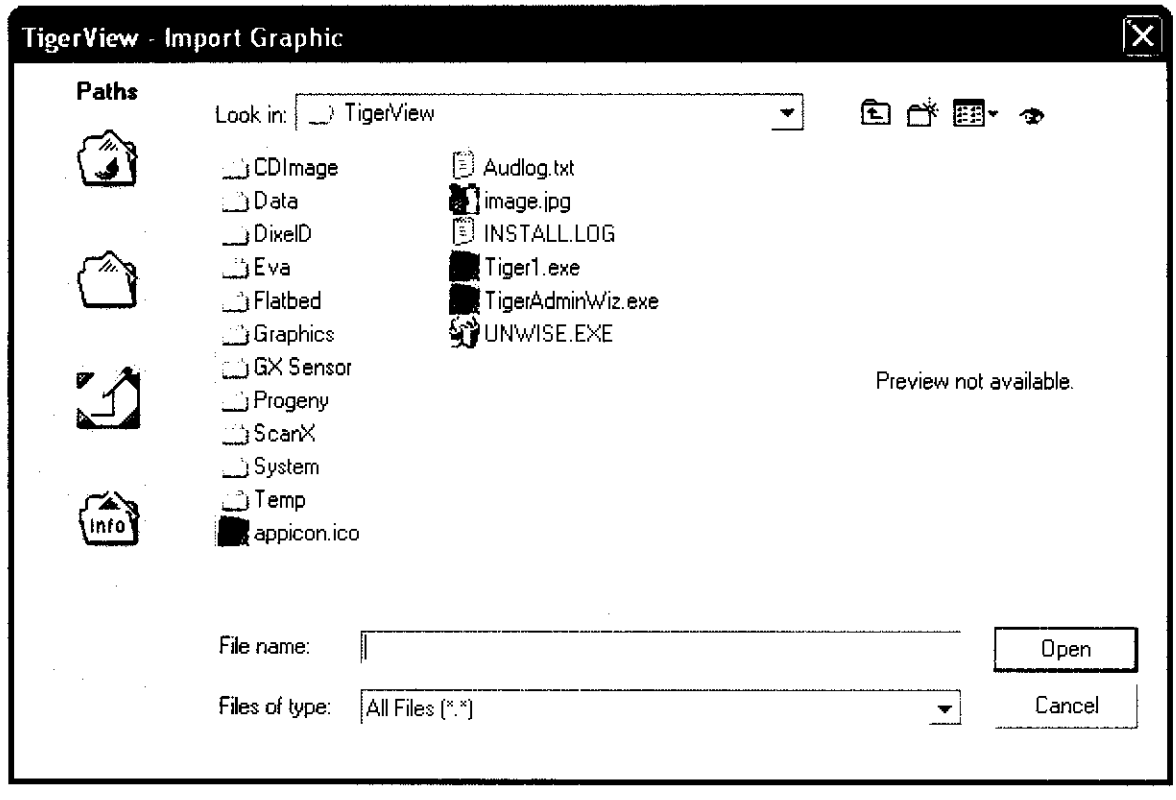
Graphic

Select Graphic to either add a graphic to, or delete a graphic from, the Graphic box.

Add

Selecting Add will allow the user to browse the computer's drives to locate a graphic file.



Once the graphic file is selected it will appear in the Graphic box. The graphic is selected and placed on the report when the report is created or updated. Unlike an image, the user does not select the graphic at the time the report is run.

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The Graphic box does not have to be the same size as the graphic. The graphic will be placed in the Graphic box fitting the box's width or height but not both unless the graphic happens to have exactly the same shape as the box.

To resize a graphic, click and drag on one of the small boxes located along the edge of the main Graphic box until the graphic becomes the necessary size.

Delete

Select Delete to remove the graphic from the Graphic box without removing the box itself.

Delete

Select Delete from the first Graphic box right click menu to delete both the graphic and the Graphic box.

Font

Click on the Font button to display the Font window.

Use the Font window to make font changes to a Text box. The font change must be made before the text is entered.

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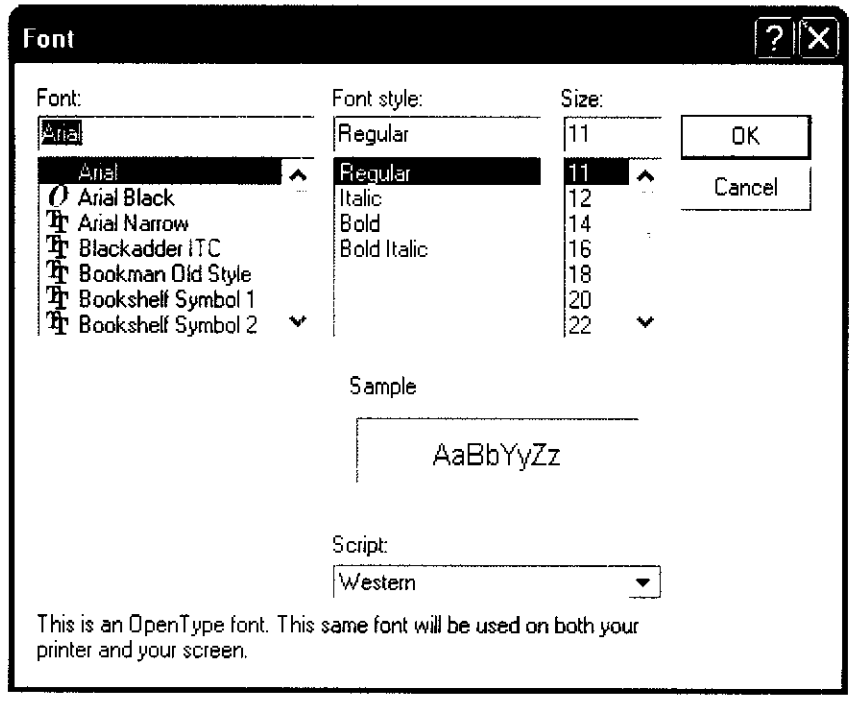
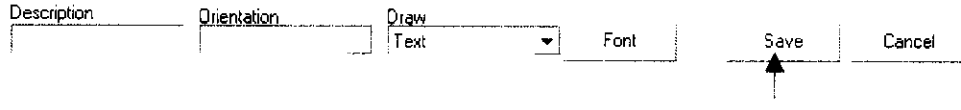
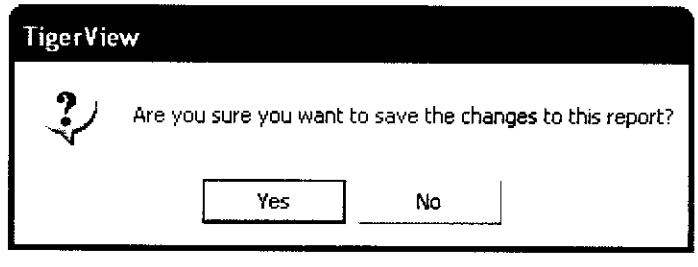


Save

Click on the Save button to save any changes made to the current report.



The Save window will display.



Click on Yes to save the report or No to leave the Add Report or Edit Report mode, discarding all changes made since the last time the Save button was clicked and the "Are you sure" question answered by clicking the Yes button. Clicking No has the same effect as clicking the Cancel button.

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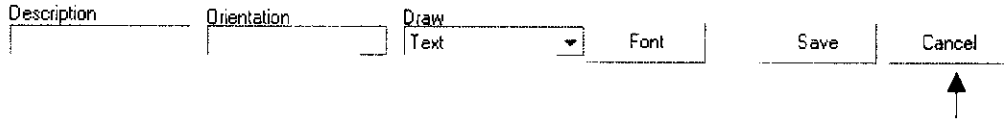
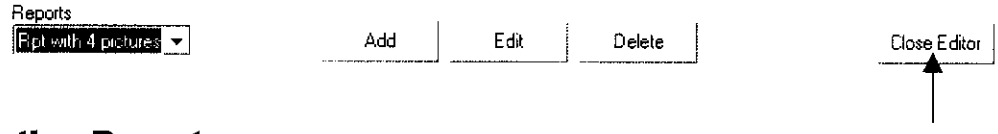
Cancel

Click on the Cancel button to leave the Add Report or Edit Report mode, discarding all changes made since the last time the report was saved.



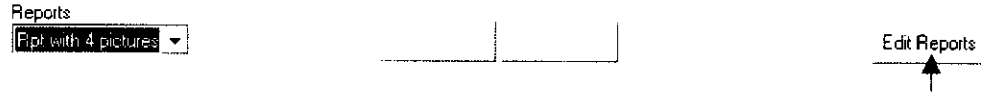
Close the Report Editor

To leave the current edit session, click the Close Editor button



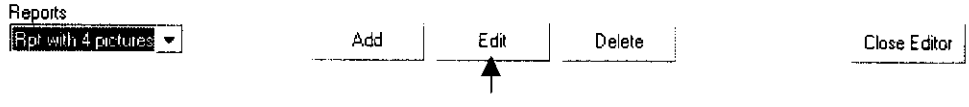
Edit an Existing Report

As explained in the Print & Send Window, Create A New Report section of this manual, the Print & Send window opens with the last report that was accessed displayed on the window. To edit an existing report, click on the Edit Reports button.



The lower portion of the Print & Send window will change to one row of buttons plus the drop down box that displays the currently created reports.

Select the report to be changed from the Reports drop down box, then click on the Edit button.



The screen that displays will be the same screen that displays when a new report is created except that the report that was selected from the Reports drop down box will display in the Current Report box.

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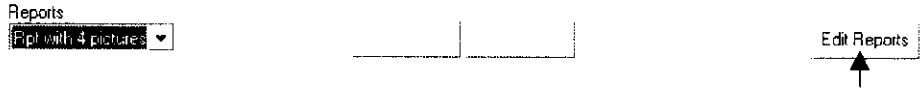
The only feature of the existing report that cannot be changed is the orientation (portrait or landscape) of the paper. Every other feature, including the name, can be changed.

For an explanation of how to use all of the features of this window, refer to the Print & Send Window, Create A New Report section of this manual. Ignore the paragraph on paper orientation since that cannot be changed.

Once the changes to the report have been saved or canceled, close the Report Editor by clicking the Close Editor button.

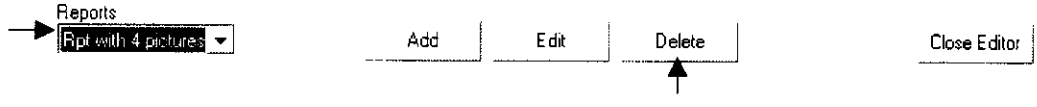
Delete an Existing Report

As explained previously, the Print & Send window opens with the last report that was accessed displayed on the window. To delete an existing report, click on the Edit Reports button.



The lower portion of the Print & Send window will change to one row of buttons plus the drop down box that displays the currently created reports.

Select the report to be deleted from the Reports drop down box, then click on the Delete button.



The Delete window will display.

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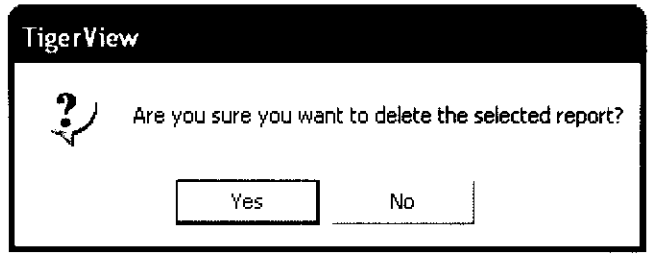

Click on Yes to delete the selected report or No to leave the report alone. A deleted report is not recoverable.

To leave the Report Editor, click the Close Editor button

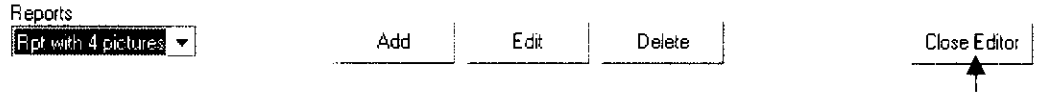

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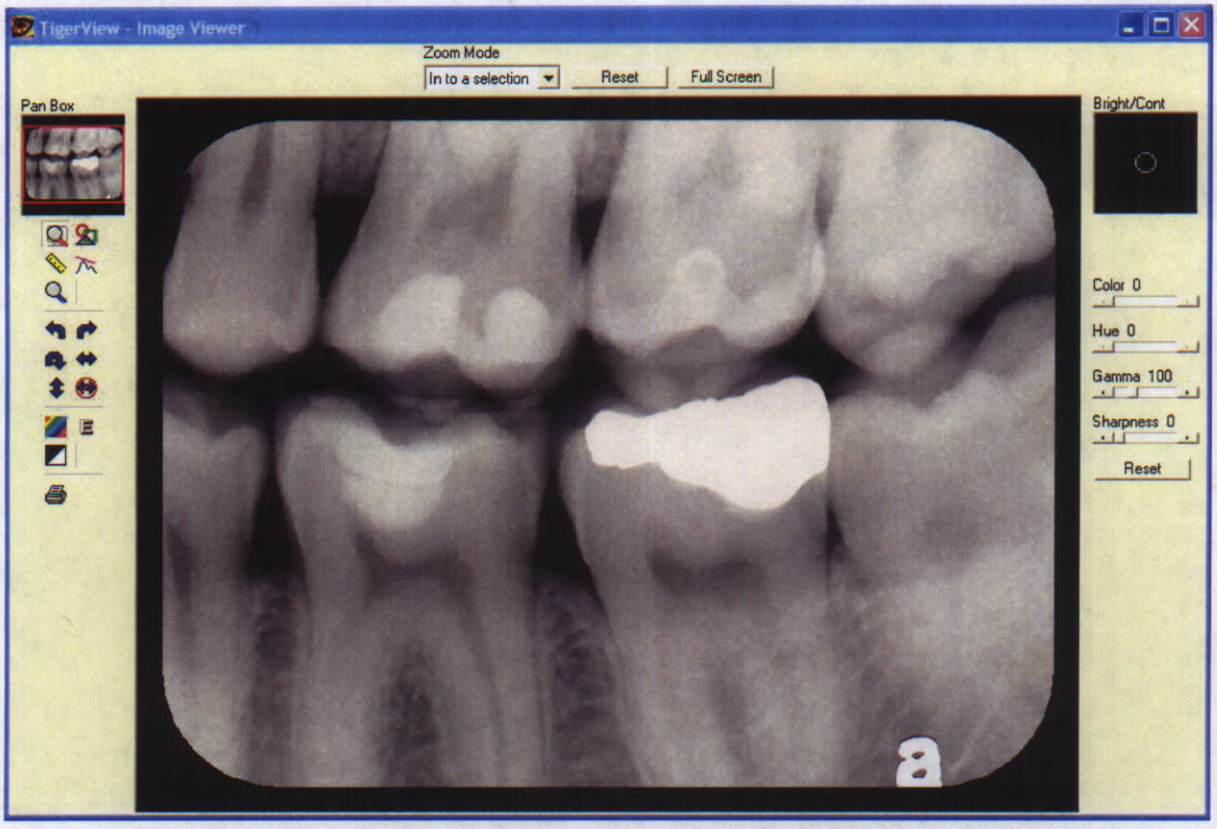
Image Viewer Window (Basic Viewer)



The Image Viewer window can be accessed by double clicking on any image except one that appears in the Current Image box on the Acquire window. The Image Viewer is used to examine and manipulate an image, through measurements of angles and lines, flipping, rotating, colorizing, zooming, changes in brightness and contrast, magnifying, annotations, etc.

Sections of the Image Viewer Window

The box where the image appears is the Current Image box. To the left of the Current Image box are the tools available to examine and manipulate the image. At the top of the Current Image box are any settings and requirements needed for the currently selected tool. To the right of the Current Image box are image settings that adjust the brightness, contrast and color of the image to the user's personal preferences.

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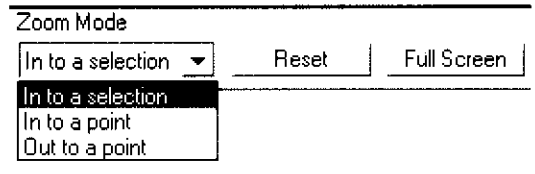
Image Viewer Tools

Pan Box

When viewing an image that has been zoomed in on, the Pan Tool can be used to move the area being displayed. Click and drag the red Pan Box to change the section of the zoomed in image that is currently displayed in the Image Viewer.

Zoom Tool

When the Zoom Tool is clicked, the Zoom Tool options appear above the Current Image box.



Zoom In to a Selection

Click and drag a box on the image around the area to zoom in to. The area selected will be magnified.

Zoom In to a Point

When the user clicks on the image, the area around the point clicked on will be magnified. Continue clicking to continue zooming in on the selected point.

Zoom Out to a Point

When the user clicks on the image, the area clicked on is reduced in size. Continue clicking to continue pulling back from the selected point.

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Reset

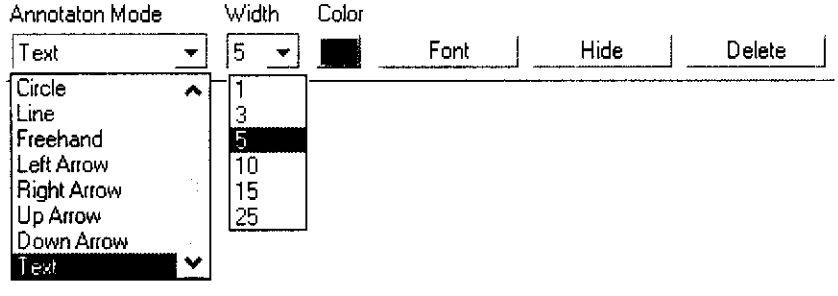
Clicking the Reset button returns the image to its original size.

Full Screen

Clicking the Full Screen button displays the image on a black screen. The light colored image can be more easily viewed if the area around it is black. To end the Full Screen display, click on the Close button in the lower right corner of the window.

Annotation Tool

When the Annotation Tool is clicked, the Annotation Tool options appear above the Current Image box. Annotations on an image cannot be moved or changed in any way. To move or change an annotation, the annotation must be deleted and reentered. Note that clicking the Delete button to delete an annotation actually deletes all of the annotations on the image. The necessary annotations must then be reentered.



Annotation Mode

Rectangle

Select the line width and color of the rectangle first, then click and drag a rectangle on the image.

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Circle

Select the line width and color of the circle first, then click and drag a circle on the image.

Line

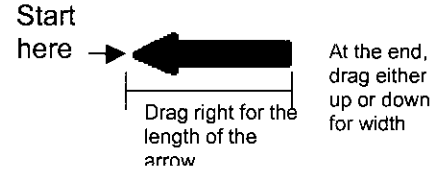
Select the line width and color of the line first, then left click on the image on one end of the line, left click on the other end of the line, and right click to stop the line drawing. A series of connected lines (for example, to draw a triangle) can be drawn by left clicking at each corner and right clicking only when all of the lines have been drawn.

Freehand

Select the line width and color of the line first, then hold down the left mouse button and draw.

Arrows

Select the line width and color of the arrow first, then left click where the tip of the arrowhead should be, drag the length of the arrow, and then drag in a perpendicular direction until the arrow has width and the arrowhead appears.



Text

Select the text color and font first then click on the point at which the first letter of the text should be placed. The Text Entry window will display allowing the text to be entered.

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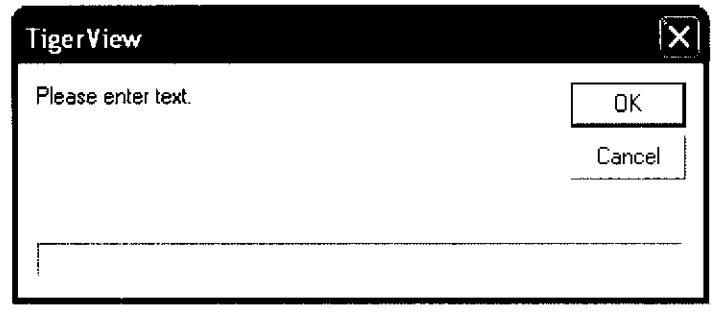

Width

Select the width of the line for a shape, line or arrow.

Color

Select the color the annotation will display in.

Font

Select the font, font style and font size for the text.

Hide

Annotations that are hidden will not display on the screen.

Delete

Delete all of the annotations.

Measurement Tool

When the Measurement Tool is clicked, the Measurement tool options appear above the Current Image box. The Measurement tool must be calibrated before it can be used. After calibrating, the width and color of the line should also be selected before beginning to measure.

Note: For accurate measurements, not only does the calibration need to be precise, but also the patient positioning and the acquisition device positioning needs to be precise to avoid images that are taken on an angle. Images taken on an angle will have measurements that are slightly different from reality.

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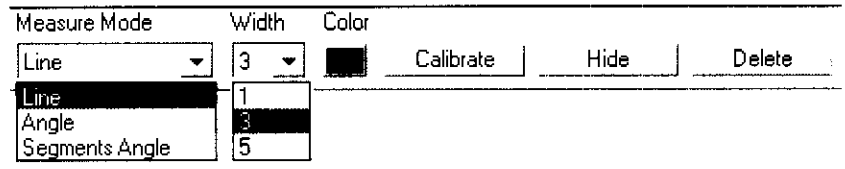

Measure Mode

Line

Left click on one end of the line, left click on the other end of the line, and then right click to stop the line drawing.

Angle

Left click on one end of the line, left click on the point of the angle, left click on the far end of the second line, then right click to stop the line drawing.

Segments Angle

Left click on both ends of one leg of the angle, left click on both ends of the other leg of the angle then right click to stop the line drawing. This allows angles to be measured when the tip of the angle is at a point that is off the image.

Width

Select 1 for a skinny line, 3 for a line of medium width and 5 for a wide line. The width must be selected before the line is drawn.

Color

Select the color of the line. The color must be selected before the line is drawn.

Calibrate

Calibrate before attempting to measure anything.

To calibrate, something that has a known length in millimeters must be on the image. Click the Calibrate button, click on one end of the object to measure, then

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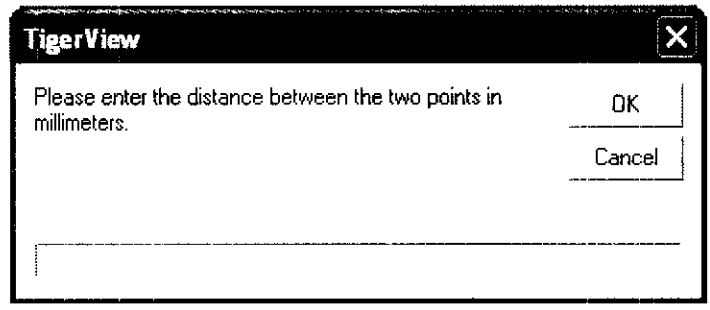
click on the opposite end of the object to measure. The Calibrate window will appear.



Enter the length of the object in millimeters. For example, if the object is 20 millimeters long enter 20 then click on the OK button. Do not enter "mm" for millimeters. Once the system is calibrated, angles and lines can be measured.

Note: Be as precise as possible when drawing the calibration line. Try to start and end the calibration line exactly on the edges of the object that is being used for calibration. In addition, try to keep the calibration line as straight as possible, avoiding the tiny jogs in the line that the computer adds to create a line that angles across the screen.

Hide

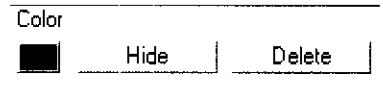
Allow the measurement lines to remain on the image but not display.

Delete

Delete the measurement lines from the image.

Line Profile Tool

When the Line Profile Tool is clicked, the Line Profile Tool options appear above the Current Image box.



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To draw a Line Profile, select a color for the line, click on one end of the area to be profiled then click on the other end of the area to be profiled. The histogram that appears will display the gray scale deviations of the area it is profiling.

A use of the Line Profile Tool is to determine when a titanium implant has osteointegrated into the bone. A line drawn through bone, then the implant, then bone again should look like a plateau. When the implant is first inserted there will be a region of low density around the implant until the bone grows in. A line drawn through this region will have a low spike just before and just after the implant.

Color

The color the Line Profile will display in.

Hide

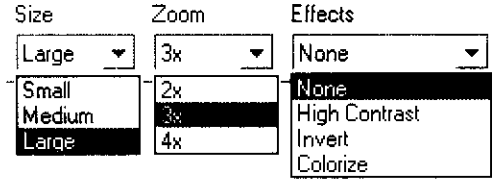
Allow the Line Profile to remain on the image but not display.

Delete

Delete the Line Profile from the image.

Magnifying Glass Tool

When the Magnifying Glass Tool is clicked, the Magnifying Glass Tool options appear above the Current Image box.



Size

Select the size of the round magnifying area.

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Zoom

Select the number of times to magnify the area.

Effects

None

Just magnify the area.

High Contrast

Make the dark colors on the image darker and the light colors on the image lighter within the round magnified area.

Invert

Make the black colors white and the white colors black on the image within the round magnified area.

Colorize

Apply colors to the image within the round magnified area.

Rotate 90 Degrees Left Tool

Turn the image 90 degrees counterclockwise.

Rotate 90 Degrees Right Tool

Turn the image 90 degrees clockwise.

Rotate 180 Degrees Tool

Turn the image 180 degrees.

Flip Left to Right Tool

Flip the image over from left to right.

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Flip Top to Bottom Tool

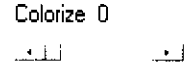
Flip the image over from top to bottom.

Restore Orientation Tool

Return the image to its original orientation.

Colorize Tool

When the Colorize Tool is clicked, the Colorize Tool option appears above the Current Image box. Colorizing substitutes colors for the grayscale values of an image. The default colors change black to purple and white to red. As the Colorize slider is moved, the grayscale values circle through the different colors allowing greater contrasts to appear anywhere in an image. The progression of colors starting with red, for this example, is red, pink, light blue, dark blue, purple, dark green, light green, yellow then back to red. Certain colors, such as yellow to red, transition slowly and smoothly. Other colors, such as blue to purple to dark green, transition more quickly and dramatically with greater contrast. The Colorize Tool is not available for use with a color image.



Click on the arrows to change the colors used.

Emboss Tool

When the Emboss Tool is clicked, the Emboss Tool options appear above the Current Image box. Embossing gives a 3-D effect to an image.

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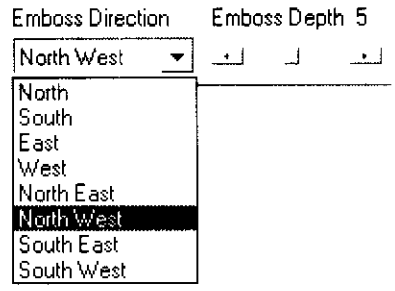

Emboss Direction

The Emboss Direction indicates the direction the light that is shining on the image is coming from.

Emboss Depth

The Emboss Depth sets the amount of difference there is between grayscale values. A large Emboss Depth number will cause the image to look more 3-D than a small Emboss Depth.

Black to White Tool

When the Invert Tool is clicked, the image areas that were black become white, and the image areas that were white become black.

Print Image Tool

When the Print Image Tool is clicked, the Microsoft Print window is opened to select the device to print to, the number of copies to print, etc. The image displayed in the Current Image box will print. The patient's name, ID, gender and date of birth will be displayed under the printed image, as will the provider's name and phone number and the date the image was taken.

Brightness and Contrast Tool

The cursor will change to a hand when it is placed on the small white circle on the Bright/Cont tool. When the cursor is a hand the circle can be moved. Moving the circle causes changes in the brightness (overall lightness) and

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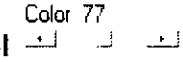
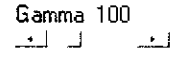
contrast (the whites become whiter and the blacks become blacker) of the image.

Color Slide Bar Tool 

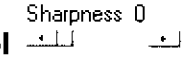
The Color Slide Bar Tool is only usable when the Image Viewer holds a color image. Slide the bar to the left into the negative color range and the image gradually turns into a grayscale image. A Color Slide Bar number of zero indicates the image has its original colors.

Hue Slide Bar Tool

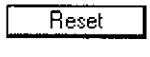
The Hue Slide Bar Tool is only usable when the Image Viewer holds a color image. Sliding the bar moves all of the colors on the image through the color scale.

Gamma Slide Bar Tool 

Gamma will not change the whitest and blackest grayscale values in the image. It will, however, change the in-between colors – the different shade of gray. When the Gamma Slide Bar is slid to the right, the in-between colors are lightened. When the Gamma Slide Bar is slid to the left, the in-between colors are darkened.

Sharpness Slide Bar Tool 

Sharpness looks for the boundaries between the light and dark areas of an image. When a boundary is found, it will make the first few pixels on the dark side darker and the first few pixels on the white side whiter. This causes more contrast at the edges and makes the image appear sharper. Making an image too sharp can make the image appear grainy.

Reset Button 

When clicked, the Reset Button will return the image to its original look at the time the Image Viewer was opened.

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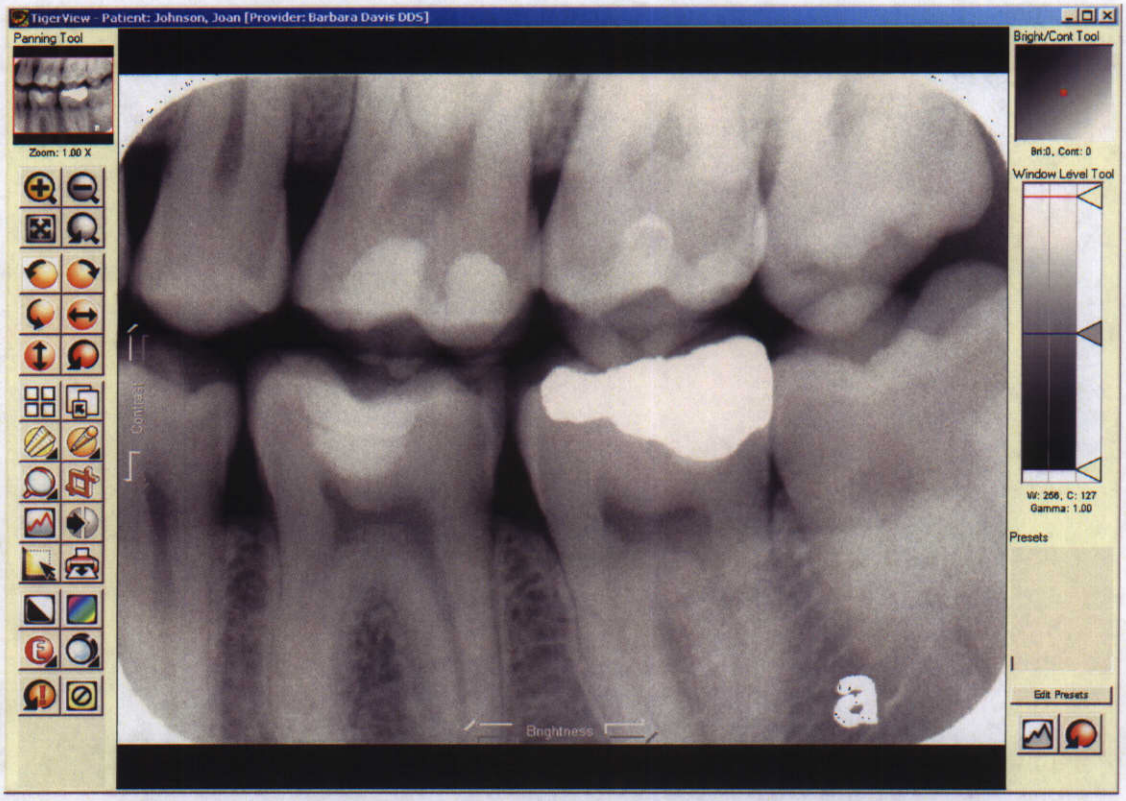
Viewer Window (Advanced Viewer)



The Viewer window can be accessed by double clicking on any image except one that appears in the Current Image box on the Acquire window. The Viewer is used to examine and manipulate an image, through measurements of angles and lines, flipping, rotating, colorizing, zooming, changes in brightness and contrast, magnifying, annotations, etc.

The Viewer window will be used if the Viewer Type selection on the Program Configuration window in the TigerView Administration program has a check next to "Advanced". If the Viewer Type selection on the Program Configuration window in the TigerView Administration program has a check next to "Basic" the Image Viewer window will be used instead of the Viewer window. For instructions on how to use the Image Viewer window, please refer to the Image Viewer Window section of this manual.

Note that only one image at a time can be examined using the Image Viewer window (the basic viewer). Multiple images can be examined at the same time using the Viewer window (the advanced viewer).

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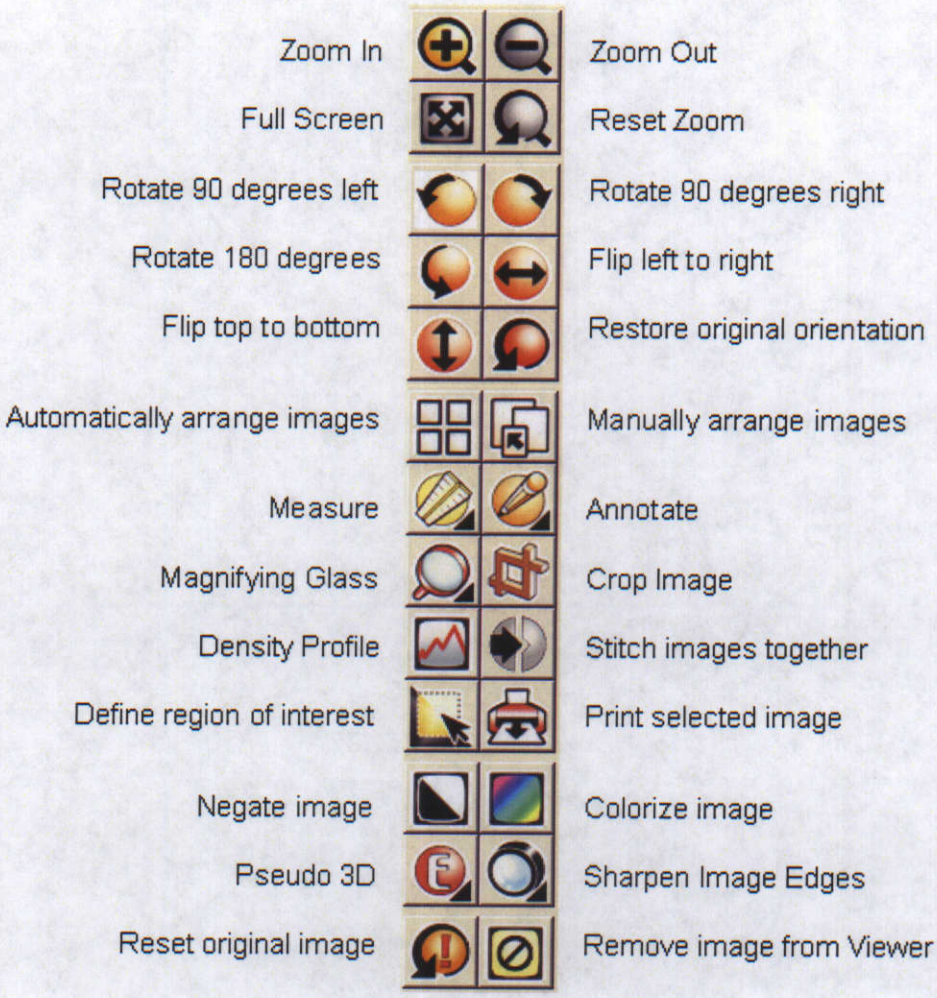
Sections of the Viewer Window

The box where the image appears is the Current Image box. To the left of the Current Image box are the tools available for examining and manipulating the image. At the top of the Current Image box are any settings and requirements needed for the currently selected tool. To the right of the Current Image box are image settings that adjust the brightness and contrast, window leveling, and image sharpness to the user's personal preferences.

Viewer Toolbar



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Viewer Tools

The tools will affect the selected image on the Viewer window. Left click once on an image to select it. The selected image on the Viewer window will have a green box around it.

Pan Tool

When viewing an image that has been zoomed in on, the Pan Tool can be used to move the area being displayed. Click and drag the red Pan Box to change the section of the zoomed in image that is currently displayed in the Image Viewer.

Zoom In

Each click on the Zoom In tool will make the image a little larger.

Zoom Out

Each click on the Zoom Out tool will make the image a little smaller until it's restored to its original size.

Full Screen

If more than one image is open in the Viewer, clicking on the Full Screen tool will make the selected image (the image with the green box around it) fill the entire Viewer window. Click on Full Screen again to return the image to its original size.

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Reset Zoom

Click on the Reset Zoom tool to return the image to its original size.

Rotate 90 Degrees Counter Clockwise

Click on this tool to turn the image 90 degrees to the left.

Rotate the Image 90 Degrees Clockwise

Click on this tool to turn the image 90 degrees to the right.

Rotate the Image 180 Degrees

Click on this tool to turn the image 180 degrees so that what had been at the top of the image is now at the bottom of the image.

Flip the Image from Left to Right

Click on this tool to flip the image over from left to right.

Flip the Image from Top to Bottom

Click on this tool to flip the image over from top to bottom.

Reset the Image to its Original Orientation

Click on the Reset tool to return the image to the direction it was facing at the time the Viewer was opened.

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Automatically Arrange Images

Click on the Auto Arrange Images tool to move the images in the Viewer to the position they were in when the Viewer was opened.

Manually Arrange Images

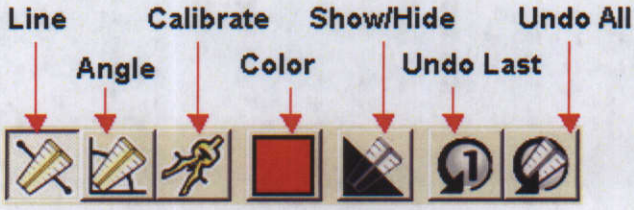
Click on the Manually Arrange Images tool to allow the images to be moved to any position on the Viewer window. To move an image, click on the image and drag it to a new location.

Measure

Click on the Measure tool to open the Measure Options window. The Measure tool must be calibrated before it can be used. After calibrating, if the color the lines will be drawn in needs to be changed, click on the Line Color button and select a new color. At this point, measurements may be taken.

Note: For accurate measurements, not only does the calibration need to be precise, but also the patient positioning and the acquisition device positioning needs to be precise to avoid images that are taken on an angle. Images taken on an angle will have measurements that are slightly different from reality.

To close the Measure options window click on the Measure tool again.



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Line

Click on the Line option to measure a line. Left click on one end of the line then left click on the other end of the line. Right click to stop measuring lines.

Angle

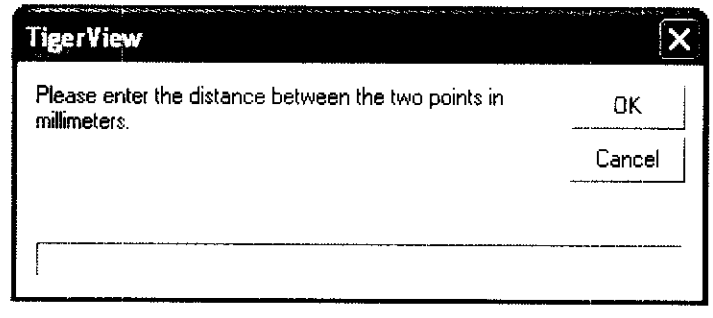
Click on the Angle option to measure an angle. Click on the end of one leg, then at the point of the angle, and finally on the end of the second leg. Right click to stop measuring angles.

Calibrate

Calibrate before attempting to measure anything.

To calibrate, something that has a known length in millimeters must be on the image. Click the Calibrate button, click on one end of the object to measure, then click on the opposite end of the object to measure. Do not click and drag.

The Calibrate window will appear.



Enter the length of the object in millimeters. For example, if the object is 20 millimeters long enter 20 then click on the OK button. Do not enter "mm" for millimeters. Once the system is calibrated, angles and lines can be measured.

Note: Be as precise as possible when drawing the calibration line. Try to start and end the calibration line exactly on the edges of the object that is being used for calibration. In addition, try to keep the calibration line as straight as possible, avoiding the tiny jogs in the line that

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the computer adds to create a line that angles across the screen.

Line Color

Select the color of the line from the pallet window that opens. The color must be selected before the line is drawn.

Show/Hide

The when the Measure tool is opened the default for Show/Hide is to Show the lines. Click on the Show/Hide option to allow the measurement lines to remain on the image but not display. Click on the Show/Hide option again to display the lines.

Undo Last

Delete the last measurement made on the currently selected image.

Undo All

Delete all of the measurement from the currently selected image.

Annotate

When the Annotate tool is clicked, the Annotation options window appears above the Current Image box. Note that annotations on an image cannot be moved or changed in any way. To move or change an annotation, the annotation must be deleted and then reentered.

To close the Annotation options window click on the Annotate tool again.

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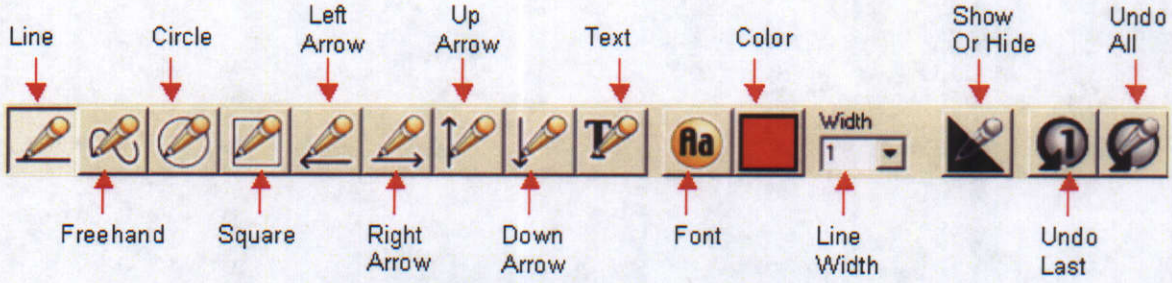

Line

Select the line width and color first, then left click on the image on one end of the line, left click on the other end of the line, and right click to stop the line drawing. A series of connected lines (for example, to draw a triangle) can be drawn by left clicking at each corner and right clicking only when all of the lines have been drawn.

Freehand

Select the line width and color first, then hold down the left mouse button and draw.

Circle

Select the line width and color, then click and drag a circle on the image.

Square

Select the line width and color first, then click and drag the square on the image.

Arrows

Select the left, right, up or down arrow option then left click where the tip of the arrowhead should be. Arrows and text are not affected by line width.

Text

Select the text color and font first then click on the point at which the first letter of the text should be placed. The Text

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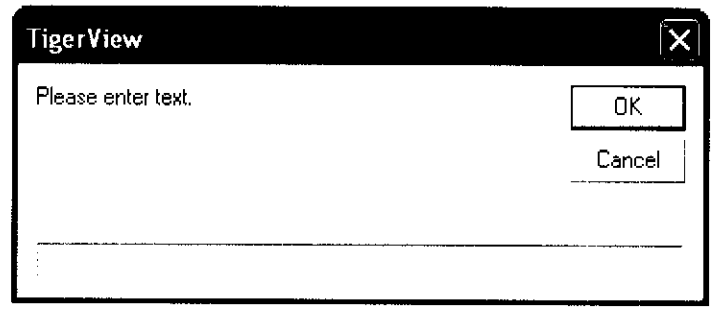
Entry window will display allowing the text to be entered. Arrows and text are not affected by line width.



Font

Select the font, font style and font size for the text before entering the text.

Color

Select the color the annotation will display in before creating the annotation.

Width

Select the width of the line for a line, freehand, circle or square before it is drawn.

Show/Hide

The when the Annotation tool is opened the default for Show/Hide is to Show the annotations. Click on the Show/Hide option to allow the annotations to remain on the image but not display. Click on the Show/Hide option again to display the annotations.

Undo Last

Delete the last annotation placed on the currently selected image.

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Undo All

Delete all of the annotations from the currently selected image.

Magnifying Glass

Click on the Magnifying Glass tool to open the Magnifying Glass Options window.

Click on the desired shape, size, magnification amount and special effect then hold the left mouse button down as the mouse is moved over the image. The area under the mouse will be affected.

Click on the Magnifying Glass tool again to close the Magnifying Glass Options window.

Crop Image

Click and drag a square around the section of the image that needs to be zoomed in on. The image will split into two images: the original image and the section of the image that was just marked. The cropped section will save as a separate image to the currently selected patient.

Density Profile

To draw a Density Profile click on one end of the area to be profiled then click on the other end of the area to be profiled. The Density Profile window will display the density variations in graph form of the section of the image that the line is bisecting.

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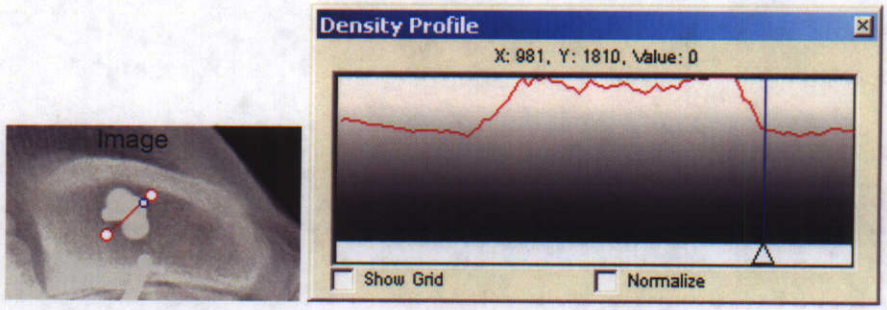
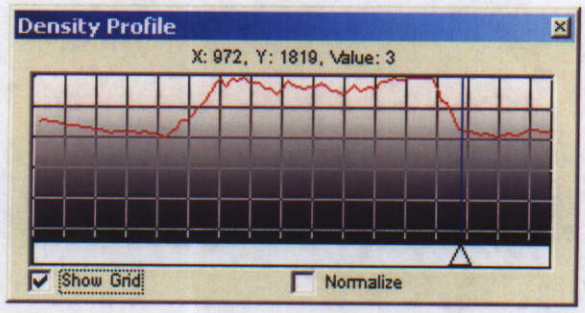
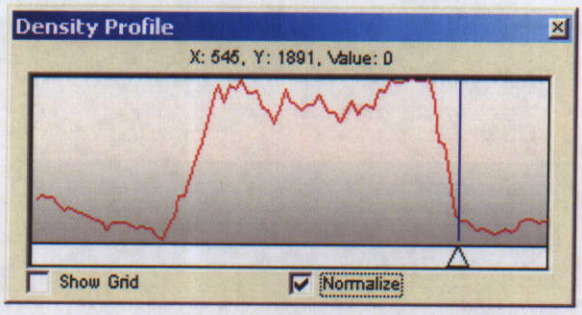


The density profile line is displayed on the image on the left with the corresponding density chart on the right. The blue line on the chart corresponds to the blue circle on the density profile line (on the image). Dragging the triangle at the base of the blue line will move the blue line. When the blue line moves, the blue circle on the image also moves.



Click on the Show Grid checkbox to have a grid placed over the density chart.



Click on the Normalize checkbox to increase the size of the profile line and make the line easier to view.

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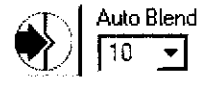
Another user of the Line Profile Tool is to determine when a titanium implant has osteointegrated into the bone. A line drawn through bone, then the implant, then bone again should look like a plateau. When the implant is first inserted there will be a region of low density around the implant until the bone grows in. A line drawn through this region will have a low spike just before and just after the implant.

Stitch Images Together

Stitching takes two separate images and merges them into one image. Open the two images to be stitched together into the Viewer and click on the Stitch tool . The Stitch options window will display above the image.



Drag the images into the correct alignment then click on them both. One image will have blue selection dots on the corners and the other image will have green selection dots on the corners. Click on the Auto Blend down arrow and select the amount of Auto Blend, then click on the Stitch button that is located next to the Auto Blend drop down box to join the images.

Auto Blend

Define Region of Interest

This feature is not yet available.

Print Selected Image

When the Print tool is clicked, the Microsoft Print window is opened to select the device to print to, the number of copies to print, etc. The selected image will print. The patient's name, species, breed, gender, age, and owner will be displayed with the printed image, as will the provider's name and the date the image was taken. The

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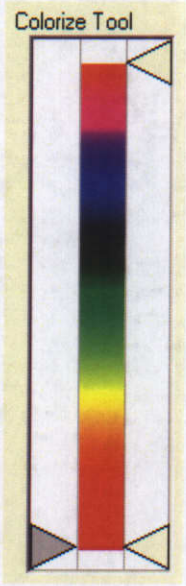
practice's name and phone number will display above the image.

Negate Image

When the Negate Image tool is clicked, the image areas that were black become white, and the image areas that were white become black. Click the Negate Image tool again to return the image to its previous appearance.

Colorize Image

When the Colorize Tool is clicked, the Colorize Slide Bar appears to the right of the Current Image box.



Colorizing substitutes colors for the grayscale values of an image. As an arrow on the Colorize Slide Bar is moved, the grayscale values circle through the different colors allowing greater contrasts to appear anywhere in an image. The progression of colors starting with red, for this example, is red, pink, light blue, dark blue, purple, dark green, light green, yellow then back to red. Certain colors, such as yellow to red, transition slowly and smoothly. Other colors, such as blue to purple to dark green, transition more quickly and dramatically with greater contrast. The Colorize Slide Bar is not available for use

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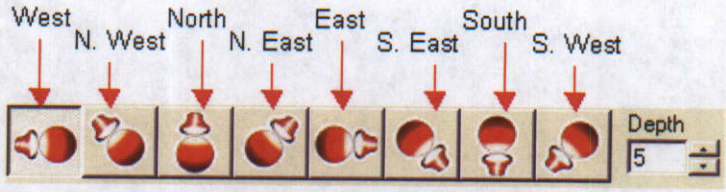
with a color image. To return an image to its non-color view, click on the Colorize Image tool again.

Pseudo 3D

When the Pseudo 3D tool is clicked, the Pseudo 3D options window appears below the Current Image box. To return the image to 2D and close the Pseudo 3D options window, click on the Pseudo 3D tool again.



Direction

The Direction indicates the direction the light that is shining on the image is coming from. Changing the direction that the light is coming from can cause different edges on the image to stand out more.

Depth

The Depth sets the amount of difference there is between grayscale values. A large Depth number will cause the image to look more 3-D than a small Depth number. Depth settings range from 1 to 10.

Sharpen Image Edges

Sharpness looks for the boundaries between the light and dark areas of an image. When a boundary is found, sharpening it will make the first few pixels on the dark side

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darker and the first few pixels on the white side whiter. This causes more contrast at the edges. Making an image too sharp can cause the image to appear grainy.

On the Sharpen options window that appears under the image click on Low to sharpen the image a little, on Medium to sharpen the image more, and on High to sharpen the image a lot.

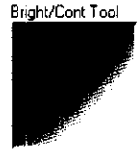
Click on the Sharpen Image Edges tool again to close the Sharpen options window.

Reset Original Image

When clicked, the Reset Original Image button will return the image to its original appearance at the time the Viewer was opened.

Remove From Viewer

Removing an image from the Viewer does not delete the image from TigerView; it simply takes the image off the Viewer window. Left click once on the image that needs to be removed to select the image. A green box displays around a selected image. Click on the Remove From Viewer button to take the image off the Viewer window.

Brightness and Contrast 

The cursor will change to a hand when it is placed on the small red circle on the Bright/Cont Tool. When the cursor is a hand the circle can be moved. Moving the circle causes changes in the brightness (overall lightness) and contrast (the whites become whiter and the blacks become blacker) of the image.

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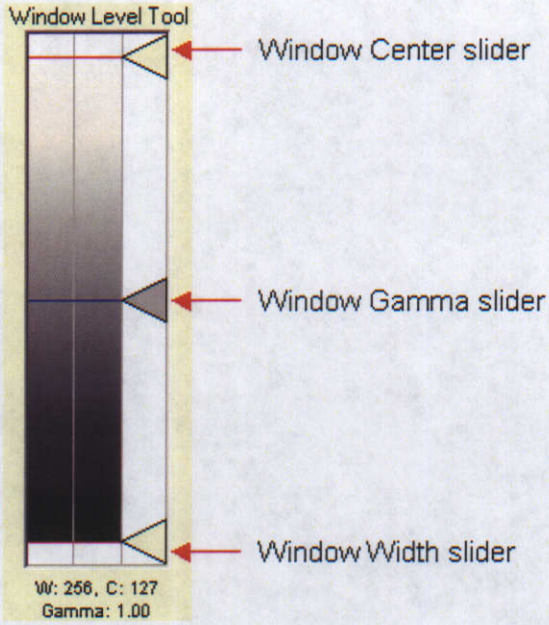
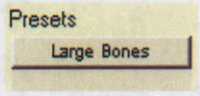
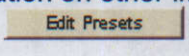
Window Level

Window leveling changes the focus of the image to either bone or flesh. Slide the Window Width slider up and the focus changes to the thicker bone. Slide the Window Center slider down and the focus changes to flesh. Use the Gamma slider to bring out the bone or flesh details.



Presets 

Presets allow the Brightness & Contrast, Window Leveling and Sharpness to be adjusted and then saved for later application on other images. Click on the Edit Preset button  to open the Edit Presets window.

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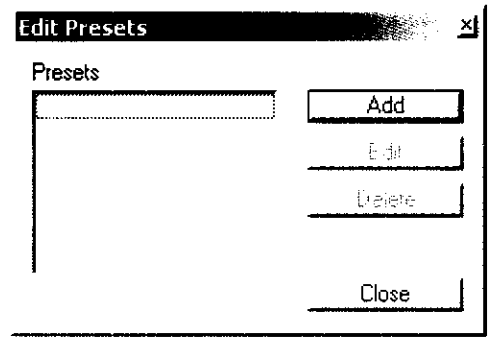
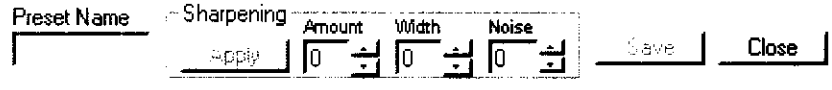


Add Preset

Click on the Add button to add a Preset. Preset options appear at the top of the Viewer window.



Preset Name

Enter a name for this Preset that contains 1-16 characters.

Sharpening Amount

Enter a Sharpening Amount of 1-300.

Sharpening Width

Enter a Width value of 1-25.

Sharpening Noise

Enter a Noise value of 1-25.

Additional Preset Settings

Brightness & Contrast and Window Leveling settings are saved with the Preset. Adjust them before clicking on the Preset Save button.

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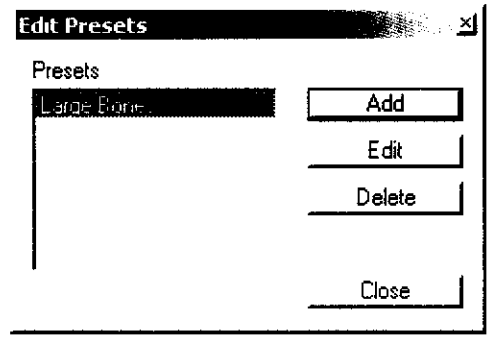
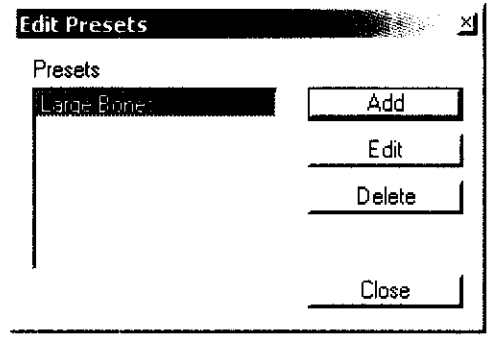
Edit Presets

Left click once on an existing Preset then click the Edit button to check and/or change the settings for that Preset.



Delete Presets

Left click once on an existing Preset then click the Delete button to erase that Preset.



Show/Hide Image Histogram

The Image Histogram window is used in conjunction with the Window Leveling tool. The Image Histogram displays a graphic representation of the level of each shade of gray in the image.

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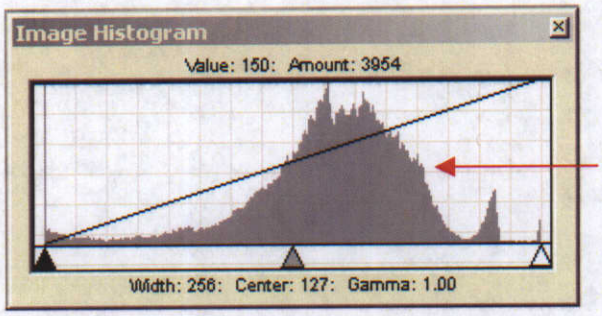

The three sliders on the Window Level tool correspond with the three triangles on the Image Histogram window. Slide one of the sliders on the Window Level tool and the corresponding triangle on the Image Histogram will move. In this fashion specific shades of gray can be focused on.

Reset Original Image Processing Settings

Restore the original settings for this image.

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How to Drag and Drop an Image

To drag an image

Place the cursor (the arrow that moves on the screen when the mouse is rolled on a flat surface) on top of the desired image. Press down and hold the left mouse button. While holding the left mouse button move the cursor by sliding the mouse on a flat surface.

To drop an image

To drop an image, release the left mouse button.

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A Few Recommendations from the maker of TigerView Professional . . .

Equipment

Make sure that the equipment used to run TigerView Professional at the very least meets the minimum requirements for TigerView Professional as well as for each acquisition device used. Remember that better computer equipment (including the monitor and the printer) and acquisition devices result in better images. Image printouts should be made on high quality color ink jet printers such as those made by HP and Epson.

Backups

Make a backup of your database and image files daily. We also strongly recommend that you use multiple backup media. For example, if you are backing up your files to disks, use a different disk for each day of the week plus a set of disks for each month end. By using multiple media in this way you reduce the risk of copying a damaged file over your only good backup.

Training

There is no substitute for investing in good hands-on training. As staff is added, make a practice of having the employee with the strongest knowledge of TigerView Professional completely train the new employee. In addition, make sure the TigerView Professional manual is easily accessible by all employees, and strongly consider purchasing a yearly support contract, which provides you with TigerView Professional support over the telephone.

Internet Access

Image files are large. If you intend to transfer them using the Internet (using, for example, email with the images sent as attachments) high speed Internet access is preferred.

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For questions about TigerView that are not answered in this manual, please call the TigerView support line at 1-800-385-9593 from 8:00 EST to 5:00 PST.

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Communicating with Images...

TigerView Professional Administration Manual

Medical Imaging Software

Televere Systems – 16275 Monterey Road, Suite K – Morgan Hill, CA 95037
(800) 385-9593

SOLD EXCLUSIVELY THROUGH QUALIFIED DEALERS

TigerView Pro 7.0.3

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Indications for Use

TigerView Professional is a clinical software application that receives images and data from various imaging sources (e.g., radiographic devices, digital video capture devices, and generic image devices such as scanners). In addition, TigerView Professional enables the storage of clinical notes, audio recordings, and clinical exam data.

It is intended to acquire, display, edit (e.g., resize, adjust contrast, crop, annotate, etc.), review, store, print, and distribute images using standard PC hardware.

Caution: Federal law restricts this device to sale by or on the order of a dentist or any other practitioner licensed by the law of the State in which he/she practices to use or order the use of the device.

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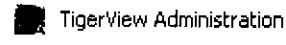
To Open TigerView Pro Administration

On your desktop, click on the Start button

Go to All Programs

Go to TigerView

Then click on TigerView Administration. 

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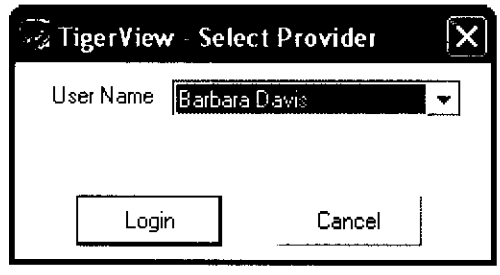
Select a Provider

The first TigerView window that opens is the Select Provider Window.



A provider is a doctor. If the name that displays is the correct provider click on the Login button. Otherwise, click on the User Name down arrow to display a drop down box of other providers that may be selected from. If the necessary provider does not appear in the drop down box, select a different one and use the Administration program to enter the missing provider.

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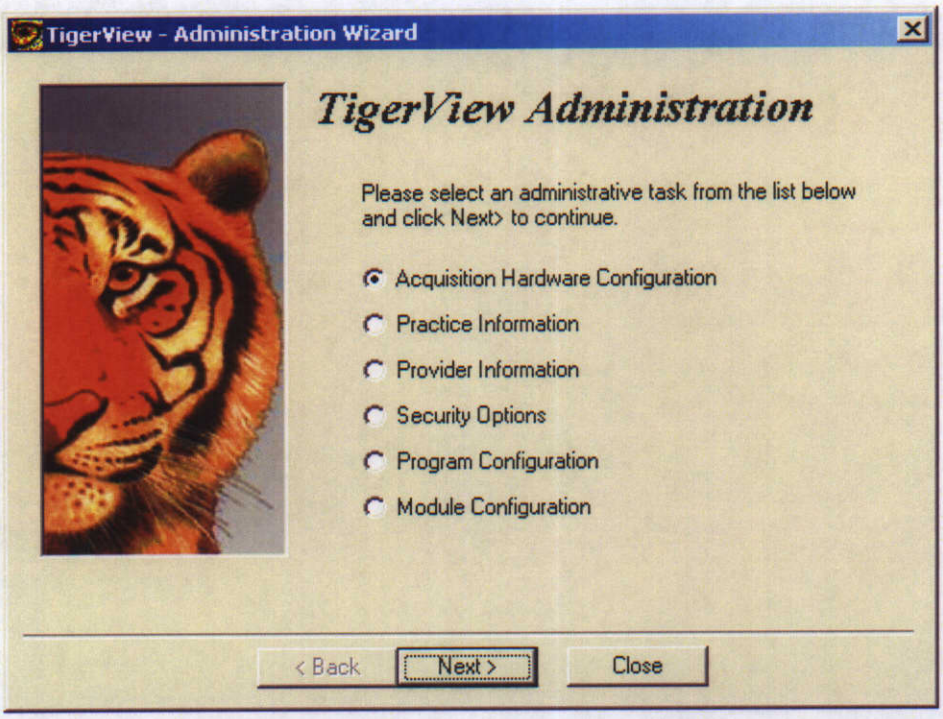
TigerView Administration Main Menu



To update administration information click on the radio button next to the information that requires updating then click on the Next button at the bottom of the window.

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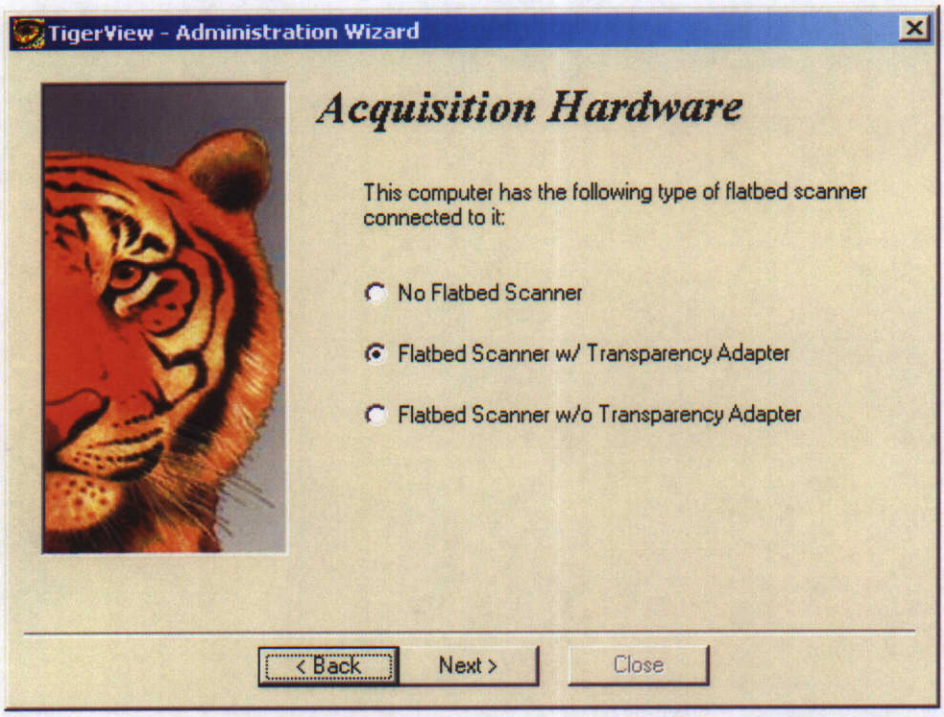
Acquisition Hardware Configuration



Modules, such as flatbed scanning, DICOM file conversion and ScanX scanners are entered into the Acquisition Hardware windows only after they have been installed in the Module Configuration section of TigerView Administration. For instructions on how to initially install add-on modules into TigerView please refer to the Module Configuration section of this manual.

To access the Acquisition Hardware windows click on the radio button next to Acquisition Hardware Configuration on the TigerView Administration Main Menu then click on the Next button at the bottom of the window.

The first Acquisition Hardware window that appears asks if TigerView will be acquiring images from a flatbed scanner. Click on No Flatbed Scanner if the office does not have a flatbed scanner, on Flatbed Scanner w/ Transparency Adapter if the office has a flatbed scanner and the scanner has a transparency adapter, or on Flatbed Scanner w/o Transparency Adapter if the office has a scanner but the scanner does not have a transparency adapter.

Click on the Next button at the bottom of the Acquisition Hardware window.

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The second Acquisition Hardware window asks if TigerView will be acquiring images from a video camera. Click on No Video Camera if the office does not have a video camera, or on Analog Video Camera or USB 2.0 Camera if the office does have a video camera.

Click on the Next button at the bottom of the Acquisition Hardware window.

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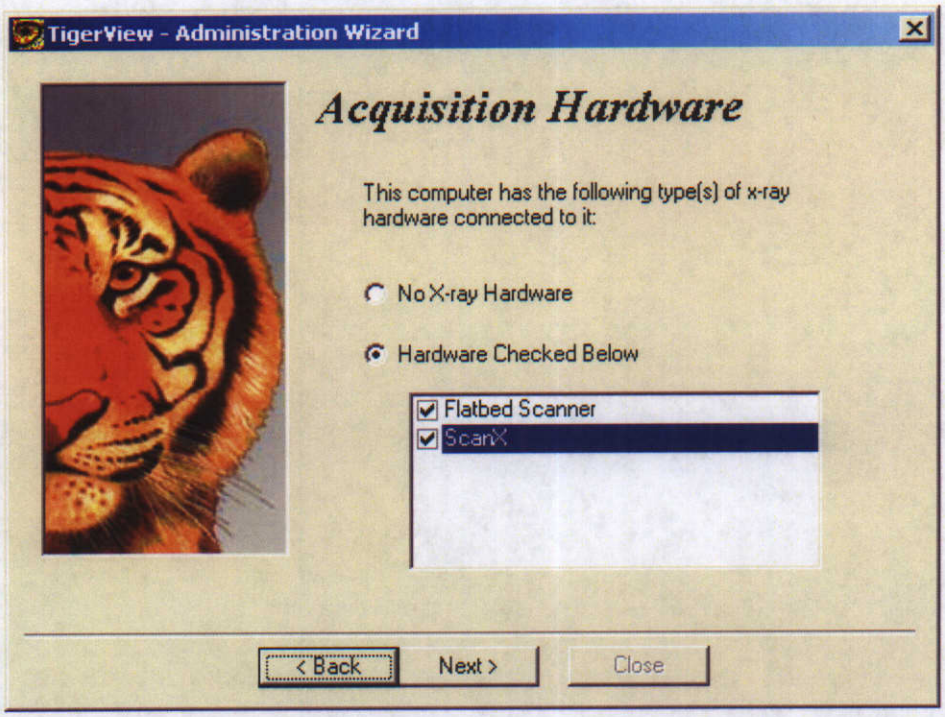

The third Acquisition Hardware window lists the specific devices TigerView will be acquiring images from. Click on No X-ray Hardware if TigerView will only acquire images through importing. Click on Hardware Checked Below if TigerView will be acquiring images through a device listed in the Device Window then also click on the checkbox next to the specific device. Devices TigerView will be acquiring images from must have checks next to them.

Click on the Next button at the bottom of the Acquisition Hardware window.

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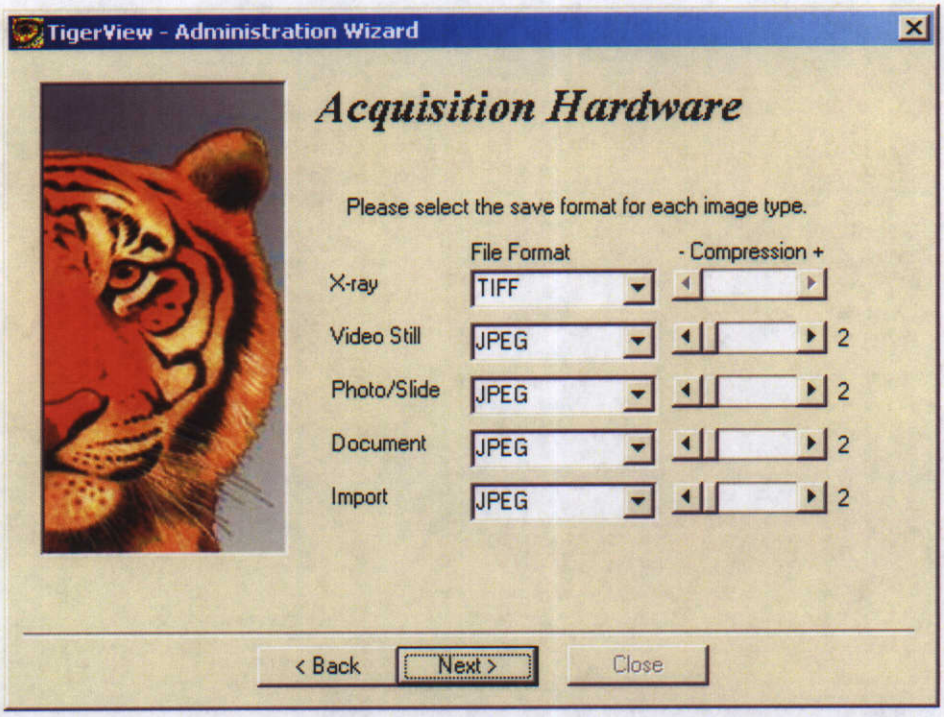

Jpeg image files can be compressed to make the size of the file smaller and save hard drive space. **The more an image file is compressed the less detail the image will contain.** If there is an issue with the amount of detail in acquired images consider lowering the compression value in this window for the acquisition device used. The default compression values should be fine.

A TIFF file format does not use compression and therefore contains a higher level of detail and a larger file size.

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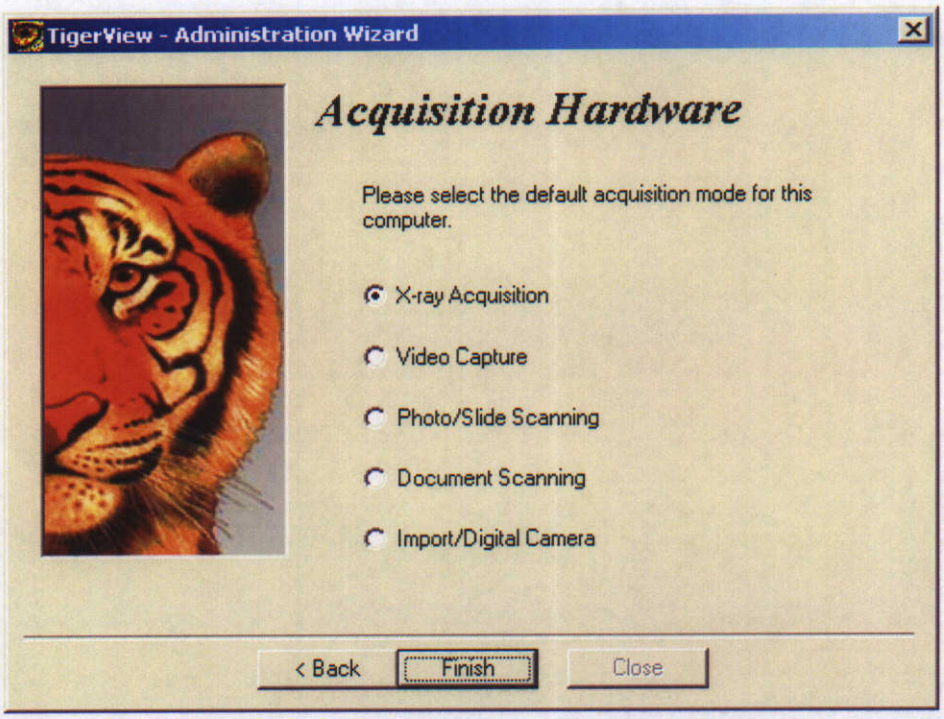
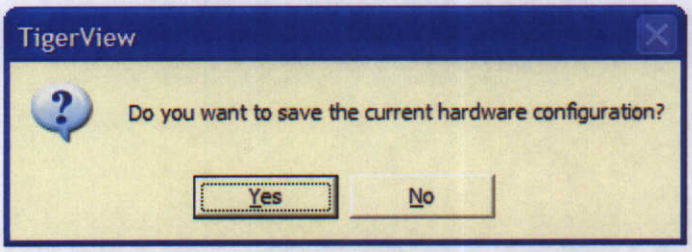


The fourth Acquisition Hardware window specifies which type of acquisition to display as a default when the Acquire Window is opened in TigerView. This should be the type of image acquisition the office normally performs.

Click on the Finish button at the bottom of the Acquisition Hardware window.



Click on Yes to save the Acquisition Hardware settings that were entered. Click on No if any changes that were made should be discarded.

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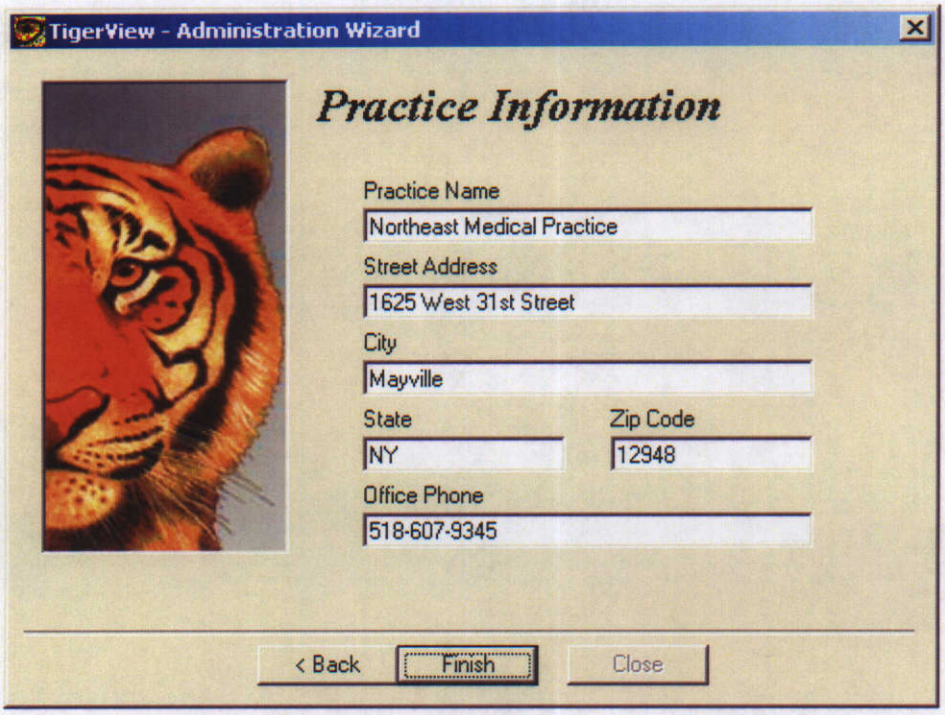
Practice Information



To access the Practice Information window click on the radio button next to Practice Information on the TigerView Administration Main Menu then click on the Next button at the bottom of the window.

Practice Name

Enter the business name of the practice.

Street Address

Enter the street address of the practice.

City

Enter the name of the city that the practice is located in.

State

Enter the state that the practice is located in.

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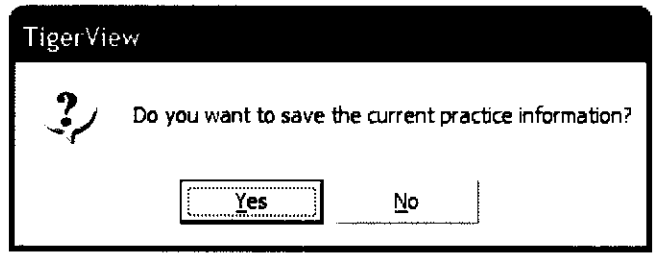
Zip Code

Enter the zip code that the practice is located in.

Office Phone

Enter the main phone number for the practice.

After the practice information has been entered click on the Finish button at the bottom of the window.



Click on Yes to save the practice information that was entered. Click on No if any changes that were made should be edited.

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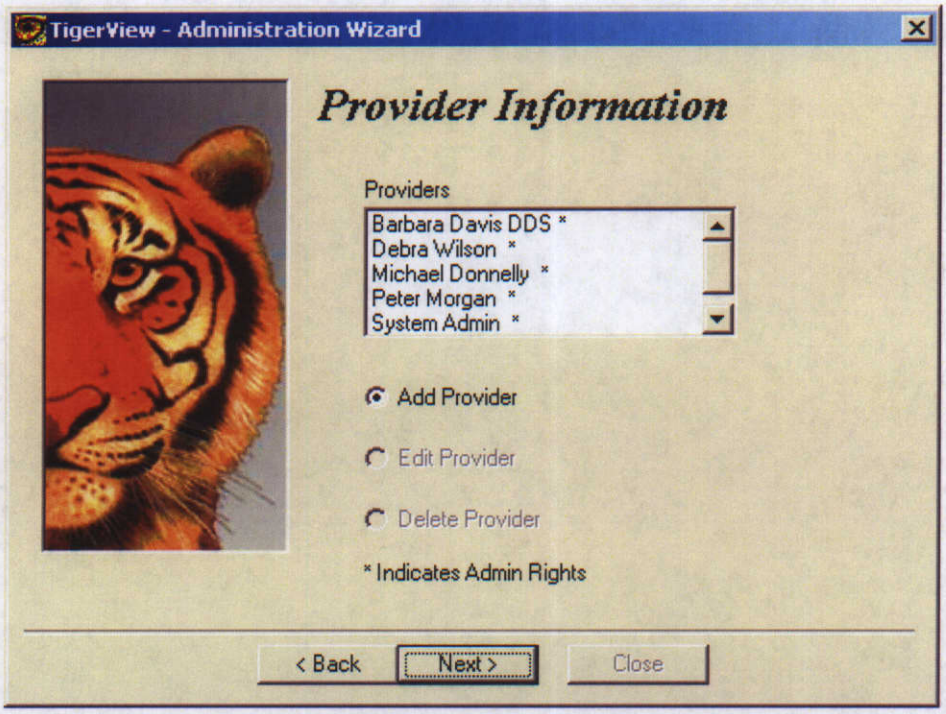
Provider Information



To access the Provider Information window click on the radio button next to Provider Information on the TigerView Administration Main Menu then click on the Next button at the bottom of the window.

Add a Provider

To add a provider (a doctor) click on the radio button next to Add Provider then click on the Next button at the bottom of the Provider Information window. The following window will display.

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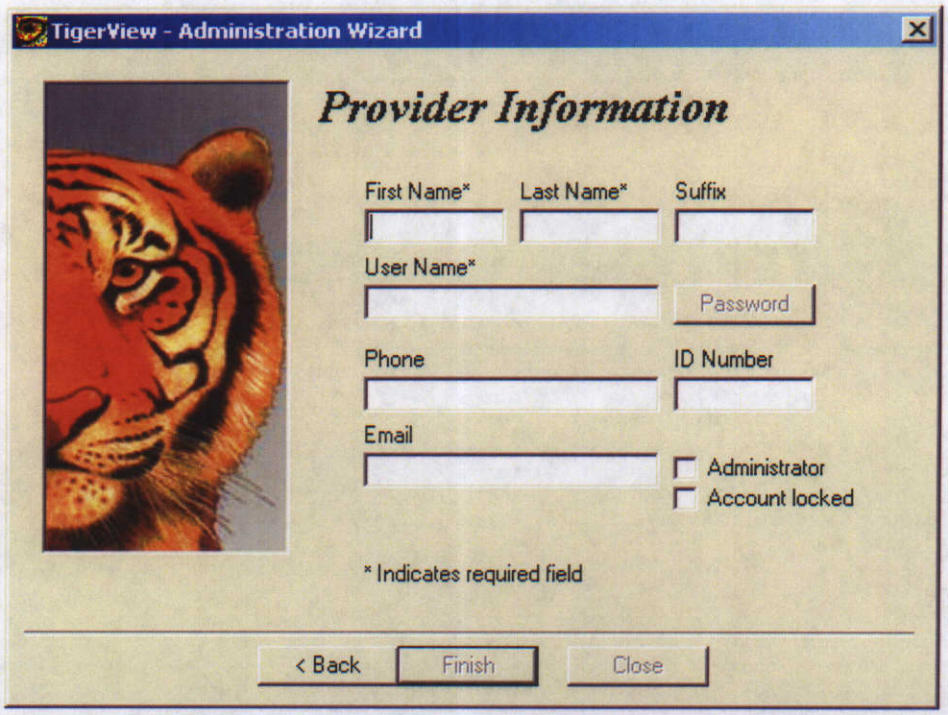

First Name

Enter the first name of the doctor. This information is required before the doctor's record can be saved.

Last Name

Enter the last name of the doctor. This information is required before the doctor's record can be saved.

Suffix

Enter any initials that should be placed at the end of the doctor's name.

User Name

Enter the first name of the provider. This information is required before the doctor's record can be saved.

Phone

Enter the provider's office phone number.

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ID Number

Enter the ID number assigned to this provider for use inside TigerView.

Email

Enter the email address for this provider

Administrator

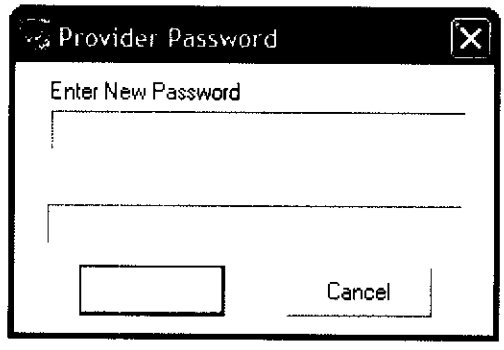
Put a check mark in the box by clicking on the box if this provider should have administrator rights in TigerView. To remove a check, click on it.

Account Locked

Put a check mark in the box by clicking on the box if this provider should not be allowed into either TigerView or TigerView Administration. To remove a check, click on it.

Password

Click on the Password button if this office requires a password to get into TigerView. The Password window will open.



The password must be at least 6 characters long. A combination of numbers and letters is best.

Enter the password then enter the password again in the Confirm Password box and click on the OK button.

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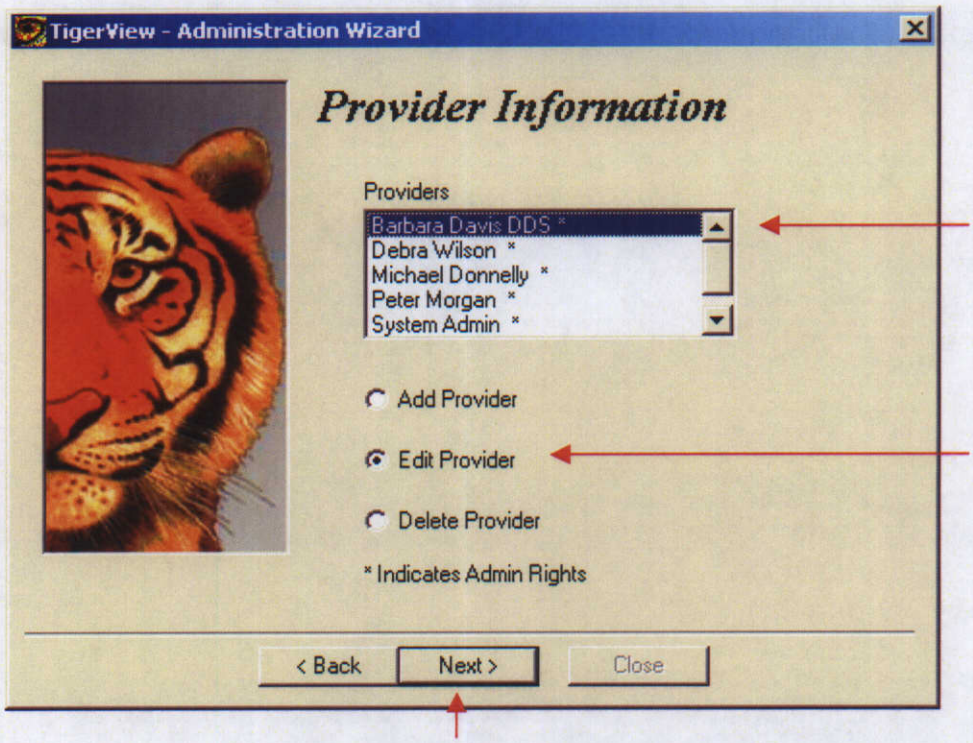
If the practice is going to use passwords, please impress upon the employees that the passwords are supposed to be secret. Passwords that are known by everyone make TigerView's security features insignificant.

Edit Provider

To edit provider information click on the provider's name in the first Provider Information window then click on the radio button next to Edit Provider and finally click on the Next button at the bottom of the window.



The same Provider Information window will display that displayed for Add Provider. Edit information as needed then click on the Finish button at the bottom of the window.

Delete Provider

To delete a provider click on the provider's name in the first Provider Information window then click on the radio button next to Delete Provider and finally click on the Next button at the bottom of the window.

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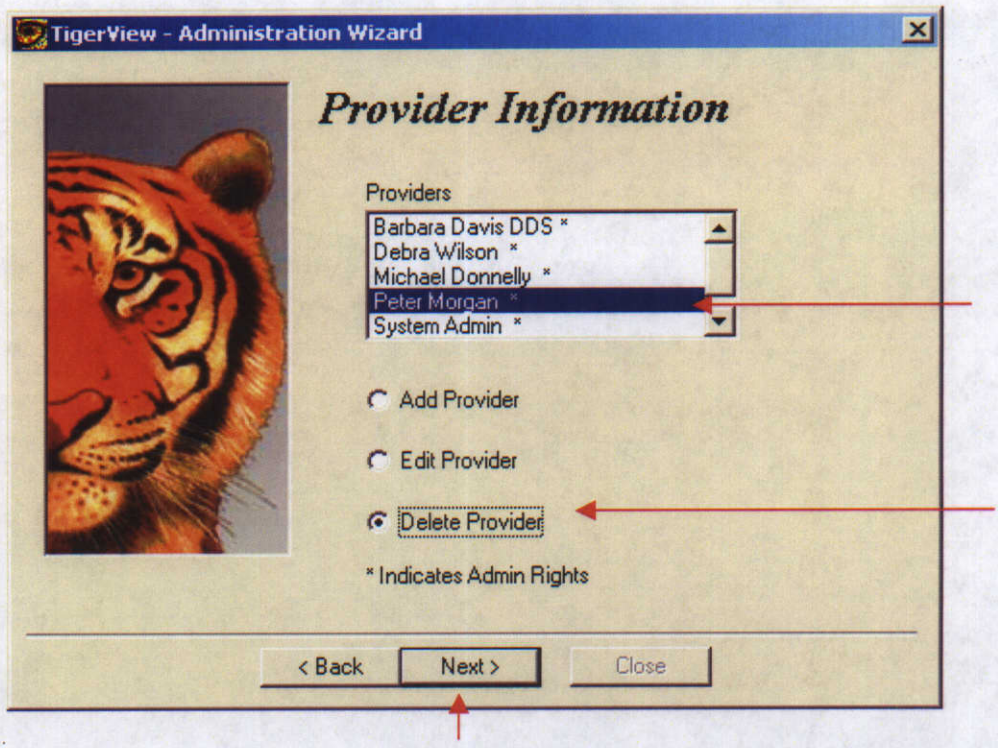
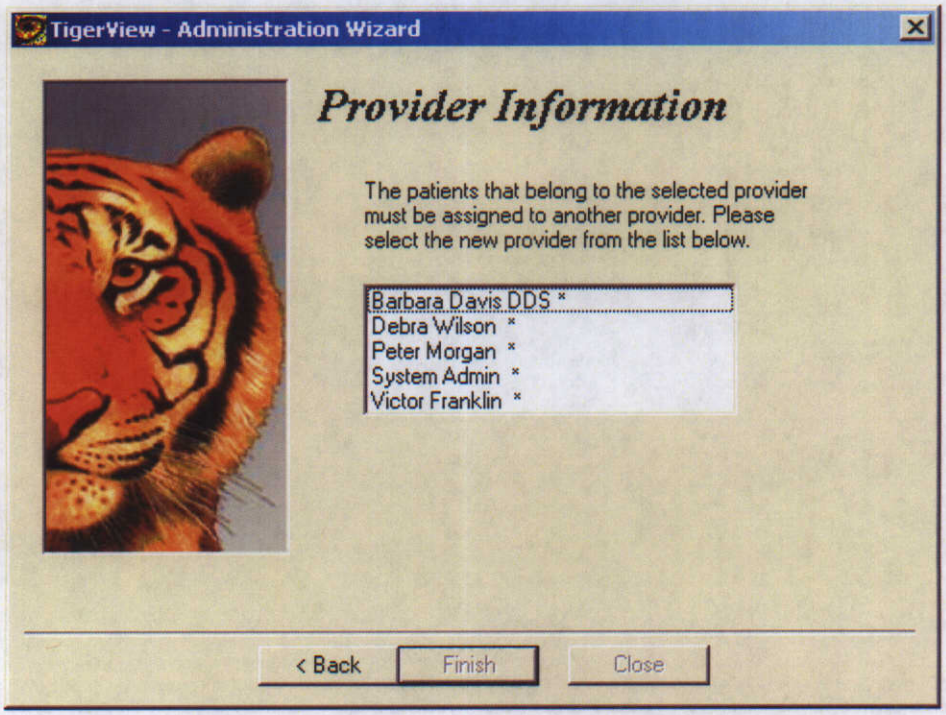


If the provider being deleted has patients, a window that asks which single provider to transfer the patients to will open.



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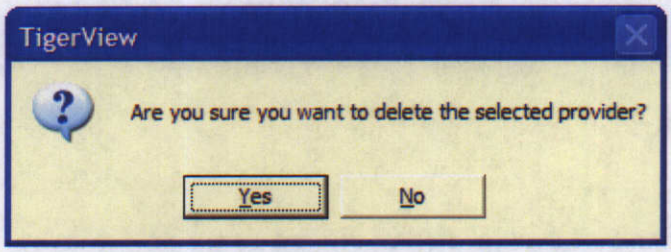
Click on the provider who will receive the patients then click on the Finish button.

Once the patients have been transferred the following screen will display:



Click on the Yes button to delete the provider.

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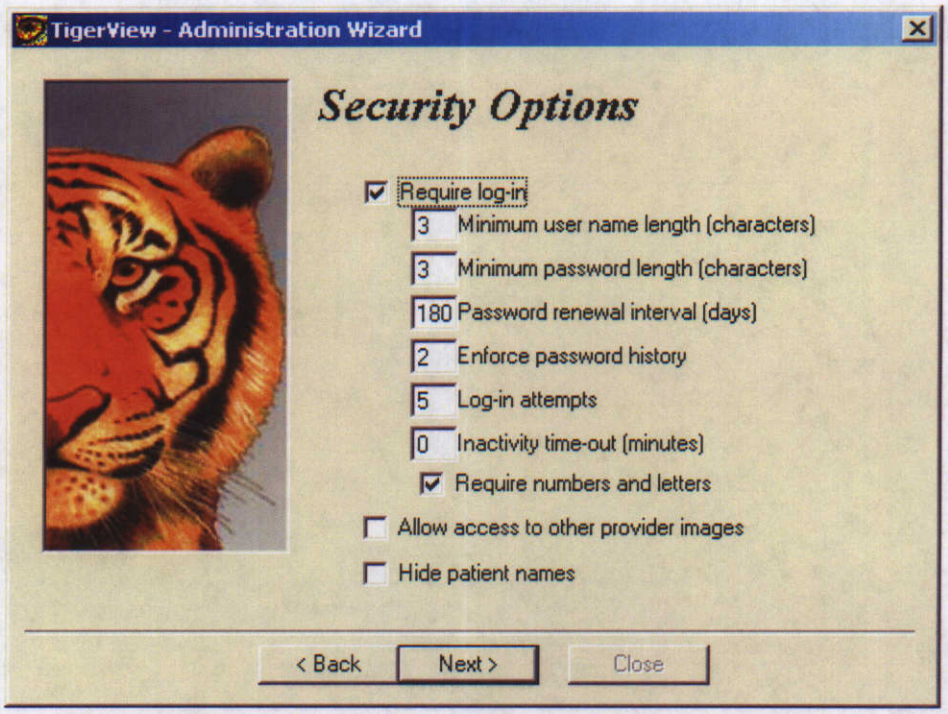
Security Options



To access the Security Options window click on the radio button next to Security Options on the TigerView Administration Main Menu then click on the Next button at the bottom of the window.

Require Log-in

The setup information under Require Log-in is accessible only when the Require Log-in check box has a check in it. A log-in is required to use the majority of TigerView's security features.

Minimum user name length

Enter the minimum number of characters (letters and numbers) that the user is required to use when creating a log-in name. The possible length for a log-in name can be as little as 3 characters up to as many as 16 characters long.

For example, if the minimum number of characters for a log-in name is 5 then the user could have jon01, jonathan or 1jondavis as a log-in name but not jon. jon has only 3

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characters whereas jon01, jonathan and 1jondavis have 5 or more characters but less than the maximum of 16.

The log-in name is not case sensitive.

Minimum password length

Enter the minimum number of characters (letters and numbers) that the user is required to use when creating a password. The possible length for a password can be as little as 3 characters up to as many as 16 characters long.

For example, if the minimum number of characters for a password is 5 then the user could have 12J13, 1jon32 or 1323145234J as a password but not EVA. EVA has only 3 characters whereas 12J13, 1jon32 or 1323145234J have 5 or more characters but less than the maximum of 16.

The password is case sensitive.

Password renewal interval

Enter the number of days that a TigerView user can use his present TigerView password before he is forced to enter a new TigerView password. The number of days must be between zero and 365.

Enforce password history

Enter the number of passwords the user has to use before he can repeat a password. For example, if 4 is entered and the first password used is 1lilly2, 1lilly2 could be reused for the fifth password. Allowable entries are 0-100.

Log-in attempts

Enter the number of times a user can try to log in to TigerView before he will be locked out. Allowable entries are 1 to 10.

To recover from being locked out, in the TigerView Administration program go to Provider Information, select the provider who has had their account locked, click on Edit Provider, click on the Next button, then uncheck the Account Locked checkbox and click the Finish button.

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Inactivity time-out

Enter the number of minutes that a computer can have TigerView open but with no activity before TigerView is closed. The number of minutes can be from 1 to 240.

Require numbers and letters

Enter a check into this box by clicking on the check box if passwords must use both letters and numbers.

Allow Access to other provider images

Enter a check into this box by clicking on the check box if providers can look at images from patients belonging to other providers.

Hide Patient Names

Enter a check into this box by clicking on the check box if patient names should not be displayed in the Patient List. The patient's initials will display instead of the patient's full name.

Next

Click on the Next button to access the final security window.

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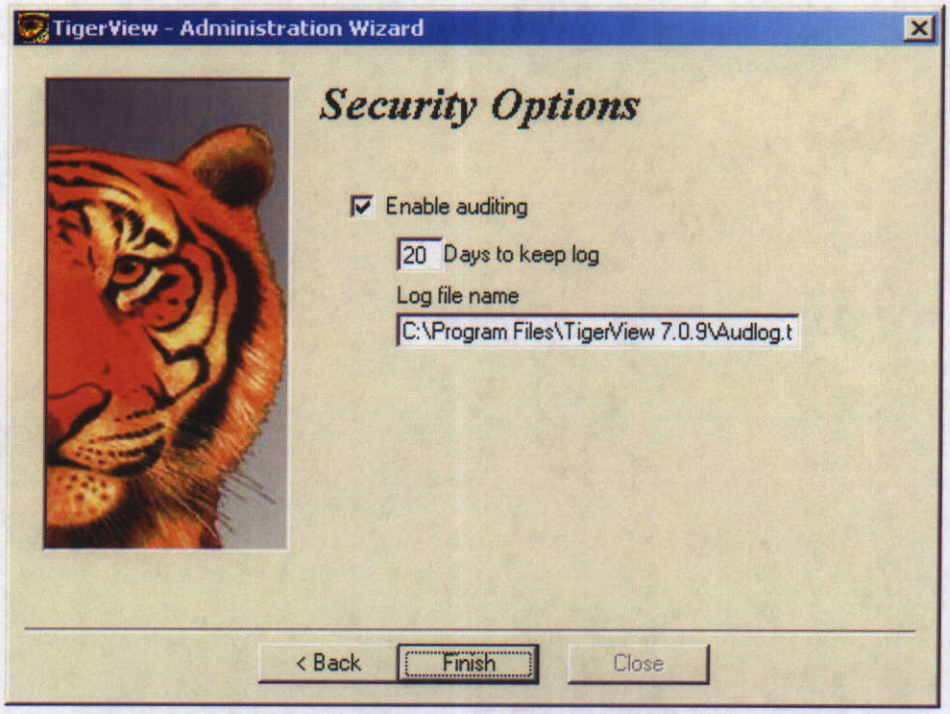

Enable auditing

The setup information under Enable Auditing is accessible only when the Enable Auditing check box has a check in it. To place a check in a check box, click on the box.

Days to keep log

Enter the number of days of information to keep in the log file. Valid entries are from 1 through 90 days.

Log file name

By default when TigerView is installed the Audit Log is named Audlog.txt and is located in C:\Program Files\TigerView. The name of the file and/or the location of the file can be changed to the user's specifications.

Finish

Click the Finish button to complete the security set up.

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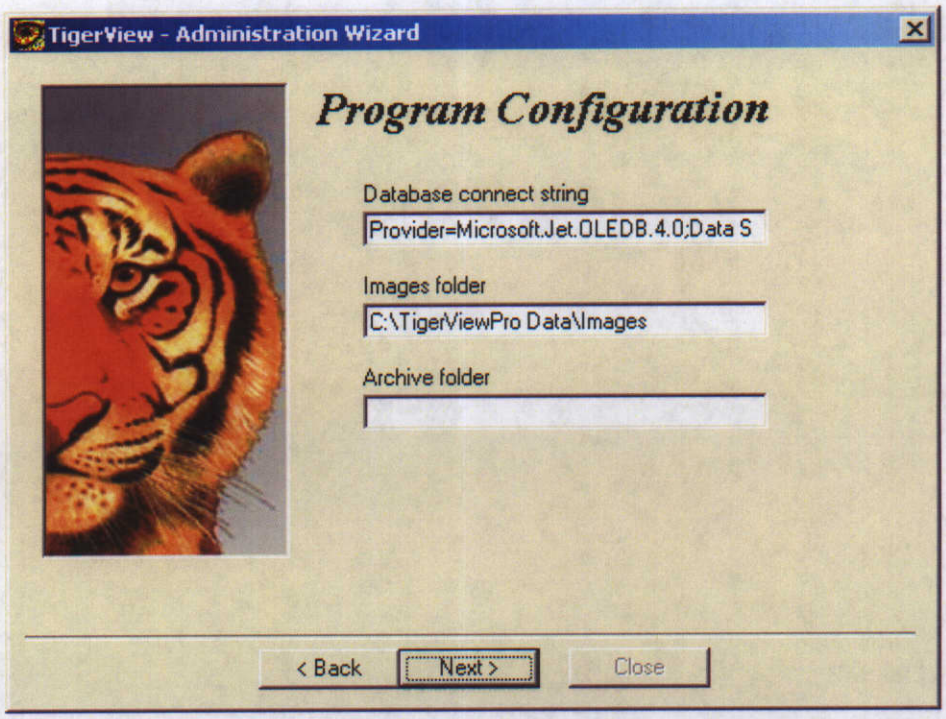
Program Configuration



To access the Program Configuration window click on the radio button next to Program Configuration on the TigerView Administration Main Menu then click on the Next button at the bottom of the window.

Database connect string

The Database Connect String specifies which version of the Microsoft Jet engine is used and the name and location of the TigerView Pro data file. Do not change this.

Images Folder

The Images Folder specifies the name and location of the folder where TigerView stores the image files. Do not change this.

Archive Folder

The Archive Folder specifies the name and location of the folder where TigerView will store its archive files. The

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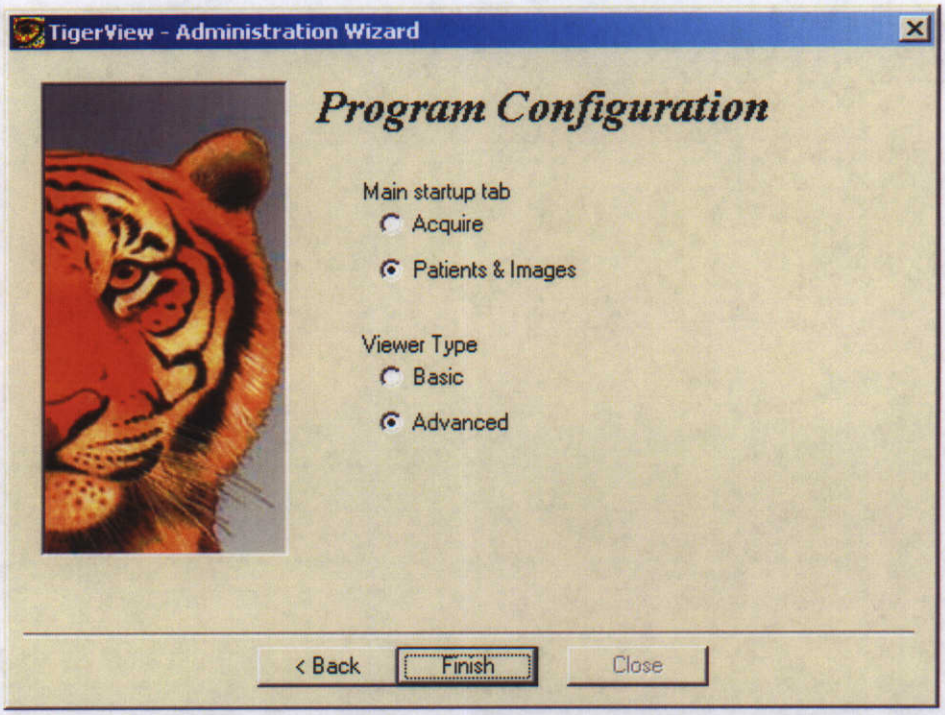
folder must be entered with its UNC path (\\computername\shared folder name).

Next

Click on the Next button to access the final Program Configuration window.



Main Startup Tab

Click on Acquire to display the Acquire window when TigerView is initially opened. Click on Patients & Images to display the Patients & Images window when TigerView is initially opened.

Viewer Type

Click on Basic to use the same Image Viewer window that previous versions of TigerView Pro used. Click on Advanced to use the new Viewer window, which has additional features.

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Finish

Click on the Finish Button to save the Program Configuration settings and return to the Administration Main Menu.

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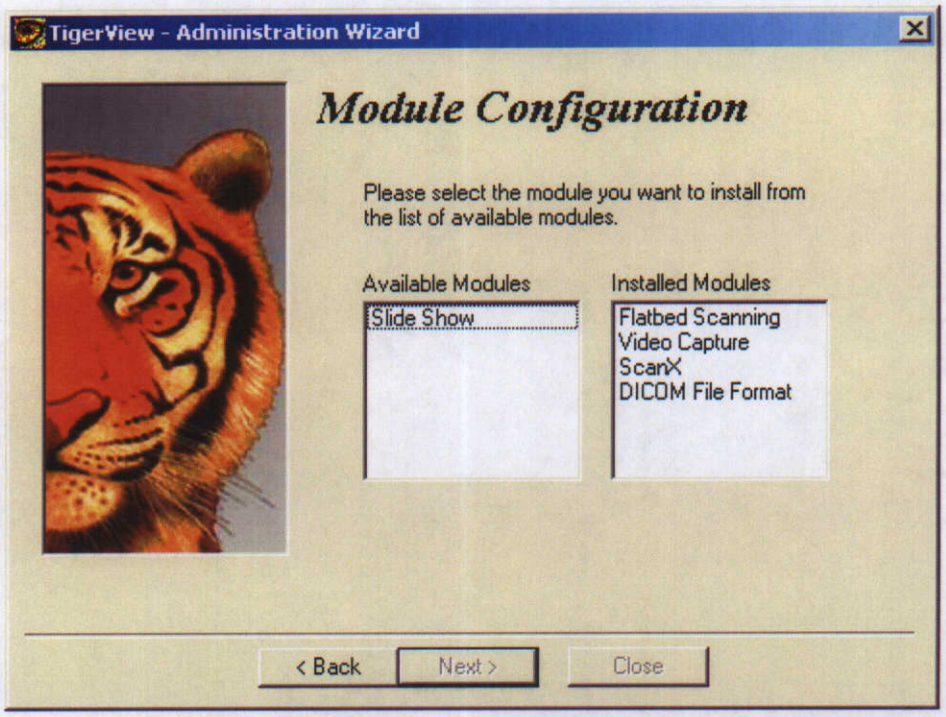
Module Configuration



To access the Module Configuration window click on the radio button next to Module Configuration on the TigerView Administration Main Menu then click on the Next button at the bottom of the window.

Available Modules

All of the modules available for use with TigerView Professional are listed in the Available Modules window. A module must be purchased, by either calling TigerView and providing credit card information or by sending TigerView a written order with a check attached, before it can be installed.

To install a module after it has been purchased click on the module in the Available Modules window then click on the Next button. A small window will open that asks for an activation code. Call the TigerView 800 number and ask a support technician for an activation code. The support technician will ask you to tell him the code that is displayed on your computer screen and will then give you a code to type in. This code will allow TigerView to install the

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requested module. The code needs to be typed in using upper case letters.

Once the module has been installed in this window it must be activated in the Acquisition Hardware Configuration section of TigerView Administration before TigerView can acquire images from it or send images to it automatically.

Installed Modules

All of the modules that have already been installed into TigerView are listed in this window.

Close Button

Click on the Close button to close the TigerView Administration program.

Back Button

Click on the Back button to return to the TigerView Administration Main Menu.

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For questions about TigerView that are not answered in this manual, please call the TigerView support line at 1-800-385-9593 from 8:00AM EST to 5:00PM PST.

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STERILIZATION AND SHELF LIFE

This section does not apply as the proposed device contains software only and does not require sterilization or have a shelf life identified.

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BIOCOMPATIBILITY

This section does not apply as the proposed device does not contain components that come into direct or indirect contact with patients.

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K061035

Televere Systems

Premarket Notification [510k]
TigerView Professional

April 14, 2006

Volume 2 of 2

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

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SOFTWARE

TigerView Professional (TigerView Pro) is a medical imaging software package that acquires, displays, enhances, stores, prints, and sends images. The images are acquired from various hardware sources such as scanners, digital cameras, digital video cameras, digital image files, digital sensors, etc.

Software Level of Concern:

According to the *Guidance for the Submission of Premarket Notifications for Medical Image Management Devices* dated July 27, 2000, software for most medical image management devices is considered a minor level of concern.

Based on the information provided for determining the level of concern in the *Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices* dated May 11, 2005, TigerView Pro is considered a minor level of concern and the following information is provided.

- A list and brief description of the functions performed by the software including revision history log;
- A description of the software development methods including changes and configuration management;
- A description of the software test methods;
- A list of hazards related to the functions performed by the software and the means taken to mitigate each of these hazards; and
- A certification statement regarding software.

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Functions:

The following is a list of the TigerView Pro functions with a brief description.

Function Number	Function	Description
1	Acquire Images	Save images taken by hardware device sources such as scanners, digital cameras, digital video cameras, digital image files, digital sensors, etc., or import digital image files that were saved on computer media such as hard drives, floppies, CDs, DVDs, the internet, thumb drives, etc.
2	Save images in a Searchable Image Library	Store images using cross referencing database information that allows images to be located later by such information as patient name, date, what hardware acquired the image, keywords, procedures, type of mount, tooth number, etc.
3	Display Images	Present images for viewing on either a computer or TV monitor, or a paper printout.
4	Enhance Images	Make minor, non-permanent image adjustments (e.g., rotate, zoom, flip, crop, annotate, etc.). to create the clearest and most detailed view possible of the image.
5	Link Information to Images	In database tables, link information such as the anatomical region represented by the image, keywords that describe an area on the image, the names of procedures that were performed on the area the image was taken of, audio and written notes describing the image, the date the image was taken, the hardware device used to acquire the image, and the patient that the image was taken of.
6	Delete Images	Remove images from both the TigerView Pro database and the computer media the image was stored on.
7	Create User Defined Reports	The user can set up reports that function in a mail merge fashion by loading the report with data specific to the patient that the report is being printed for. At print time, the user can add comments and additional information plus multiple user specified

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Function Number	Function	Description
		images to complete the report.
8	Send Image Copies out of TigerView	Save a copy of an image plus optional image information such as image annotations and audio notes, to a CD, DVD, another computer on the network, or using email, to a remote computer.

Revision History Log:

(b)(4)

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(b)(4) Software Modifications

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(b)(4) Software Modifications

[redacted]

Software Development Methods:

(b)(4)

[redacted]

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Figure 1. TigerView Pro Design Change or Request Form:

Televere Systems
TigerView Pro Design Change or Request Form

Version of TigerView Pro this form applies to: _____

Submitted On: ____/____/_____

Submitted By: _____

Change or Request Made by	Description of Change or Request	Engineering Response: Put In Current Version	Put in Future Version	Reject	Dup Request
		Comments:			
		Comments:			

The software development process is summarized below.

Development Step	Explanation	Step Performed By
(b)(4)		

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Development Step	Explanation	Step Performed By
(b)(4)		

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Development Step	Explanation	Step Performed By
(b)(4)		

Configuration Management

(b)(4)

Software Testing Methods

(b)(4)

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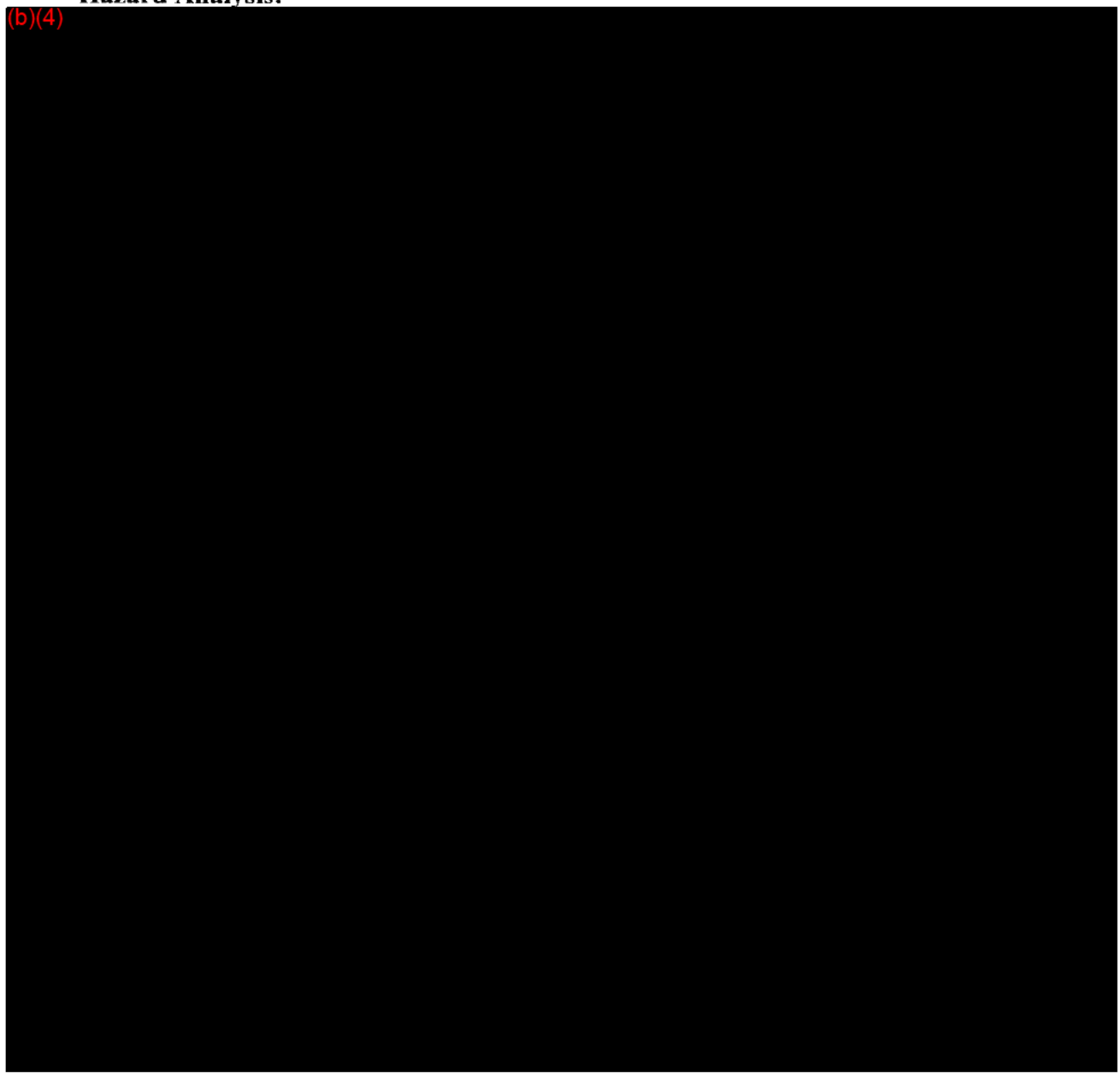
Hazard Analysis:

(b)(4)



Software Certification:

The software certification statement immediately follows this page.

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TigerView Professional Hazard Analysis

(b)(4)

[redacted]

Version 1.0

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(b)(4) Hazard Analysis

(b)(4) Hazard Analysis

(b)(4) Hazard Analysis

(b)(4) Hazard Analysis

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I hereby certify that the software development process was followed for the TigerView Professional software, good quality assurance procedures were adhered to, and test results demonstrate functional requirements were met.

Randell Quaal
General Manager
Televere Systems

April 14, 2006
Date

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

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ELECTROMAGNETIC COMPATIBILITY AND ELECTRICAL SAFETY

This section does not apply as the proposed device is software only and does not contain an electronic component.

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PERFORMANCE TESTING—BENCH

(b)(4)

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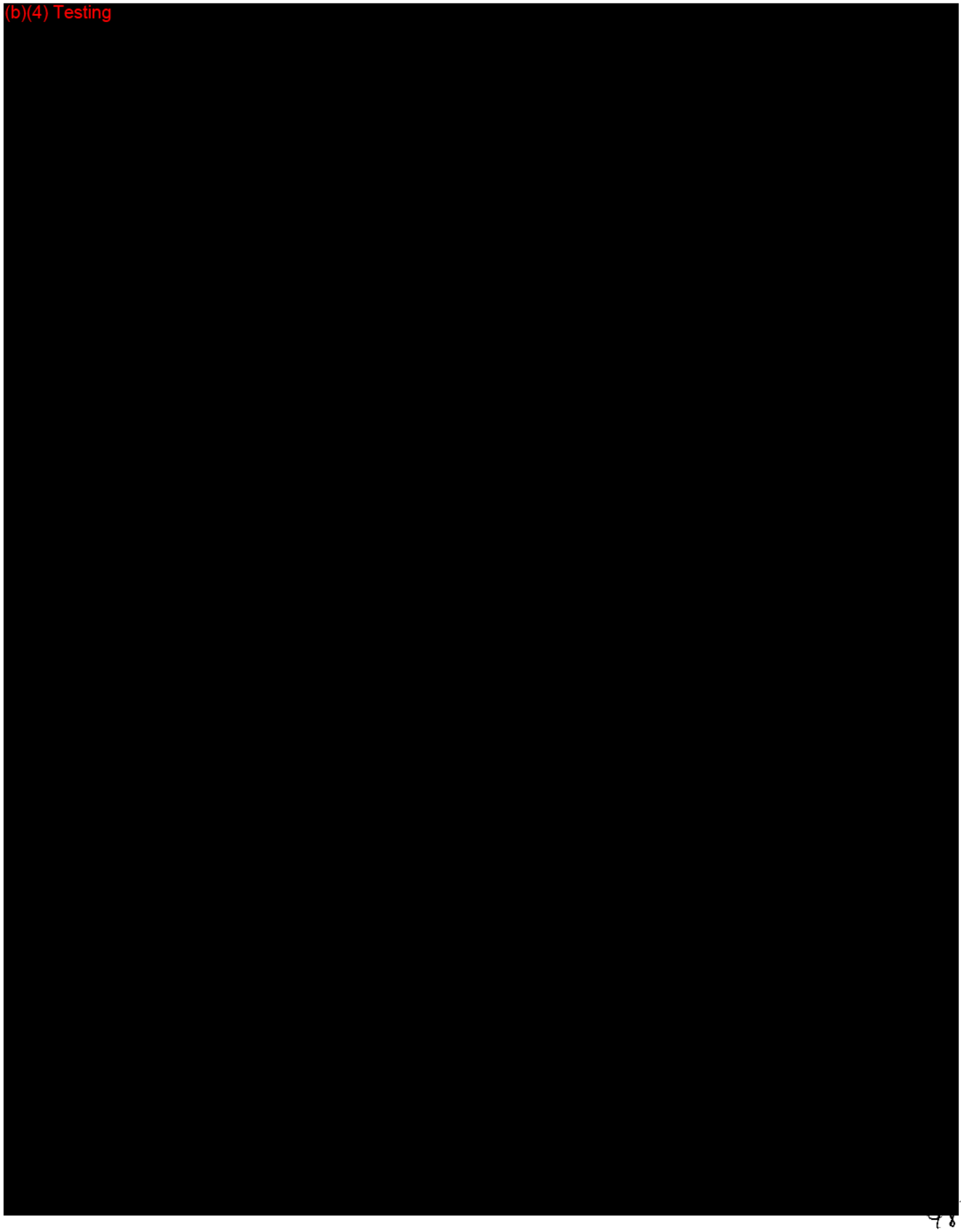
Summary Results File

(b)(4) Testing



(b)(4) Summary Results

(b)(4) Summary Results

(b)(4) Summary Results

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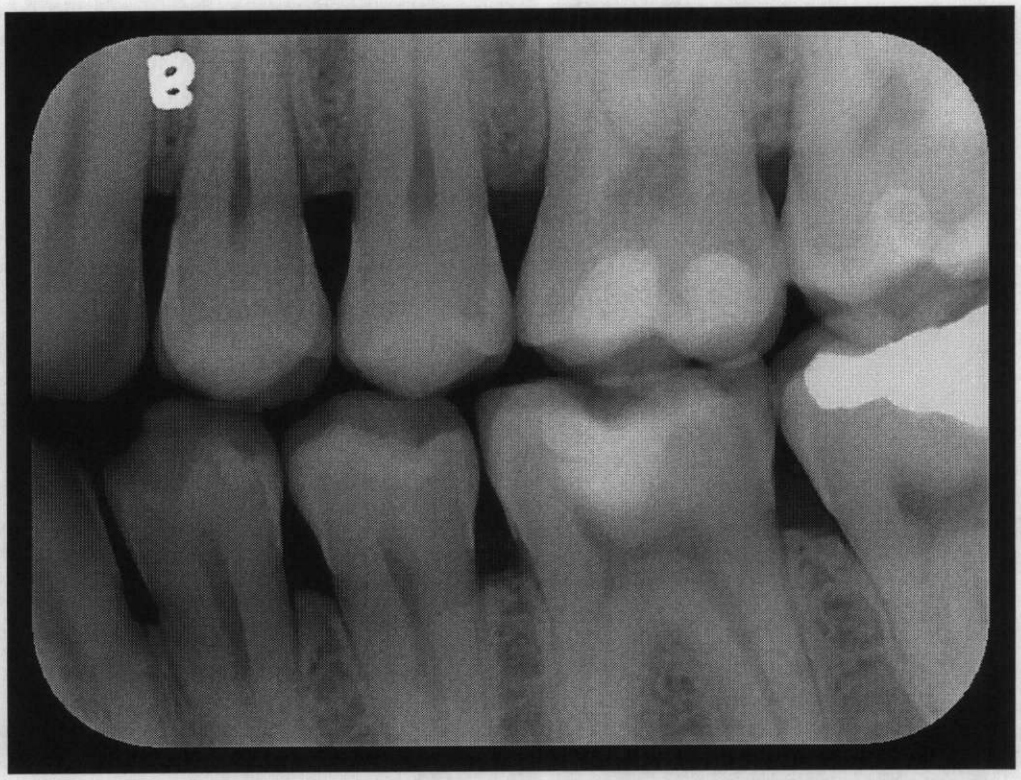
TigerView Professional
Sample Clinical Images



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

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TigerView Professional
Sample Clinical Images

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

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PERFORMANCE TESTING—ANIMAL

This section does not apply as no animal studies were necessary to support this 510(k) submission.

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

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PERFORMANCE TESTING—CLINICAL

This section does not apply as no clinical studies were necessary to support this 510(k) submission.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118 491

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
Memorandum

From: Reviewer(s) - Name(s) LOREN A. ZAREMBA

Subject: 510(k) Number K061035

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

NA ☐ 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: 90 - LLZ, Class II

Additional Product Code(s) with panel (optional):

Review: [signature] (Branch Chief) NAMS (Branch Code) 5/24/06 (Date)

Final Review: [signature] (Division Director) 6/2 (Date)

Revised:4/2/03

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

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REVISED:3/14/95

THE 510(K) DOCUMENTATION FORMS ARE AVAILABLE ON THE LAN UNDER 510(K) BOILERPLATES TITLED "DOCUMENTATION" AND MUST BE FILLED OUT WITH EVERY FINAL DECISION (SE, NSE, NOT A DEVICE, ETC.).

"SUBSTANTIAL EQUIVALENCE" (SE) DECISION MAKING DOCUMENTATION

K 041035

Reviewer: Zaremba

Division/Branch: DRARD/RDB

Device Name: TigerVision Professional

Product To Which Compared (510(K) Number If Known): K982422

	YES	NO	
1. Is Product A Device	✓		If NO = Stop
2. Is Device Subject To 510(k)?	✓		If NO = Stop
3. Same Indication Statement?	✓		If YES = Go To 5
4. Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?			If YES = Stop NE
5. Same Technological Characteristics?	✓		If YES = Go To 7
6. Could The New Characteristics Affect Safety Or Effectiveness?			If YES = Go To 8
7. Descriptive Characteristics Precise Enough?	✓		If NO = Go To 10 If YES = Stop SE
8. New Types Of Safety Or Effectiveness Questions?			If YES = Stop NE
9. Accepted Scientific Methods Exist?			If NO = Stop NE
10. Performance Data Available?			If NO = Request Data
11. Data Demonstrate Equivalence?			Final Decision: SE

Note: In addition to completing the form on the LAN, "yes" responses to questions 4, 6, 8, and 11, and every "no" response requires an explanation.

6

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

Records processed under FOIA Request # 2015-8521; Released by CDRH on 05-10-2016

1. Intended Use: Acquisition, processing & display of medical images

2. Device Description: Provide a statement of how the device is either similar to and/or different from other marketed devices, plus data (if necessary) to support the statement. Is the device life-supporting or life sustaining? Is the device implanted (short-term or long-term)? Does the device design use software? Is the device sterile? Is the device for single use? Is the device over-the-counter or prescription use? Does the device contain drug or biological product as a component? Is this device a kit? Provide a summary about the devices design, materials, physical properties and toxicology profile if important.

EXPLANATIONS TO "YES" AND "NO" ANSWERS TO QUESTIONS ON PAGE 1 AS NEEDED

1. Explain why not a device:

2. Explain why not subject to 510(k):

3. How does the new indication differ from the predicate device's indication:

4. Explain why there is or is not a new effect or safety or effectiveness issue:

5. Describe the new technological characteristics:

6. Explain how new characteristics could or could not affect safety or effectiveness:

7. Explain how descriptive characteristics are not precise enough:

8. Explain new types of safety or effectiveness questions raised or why the questions are not new:

9. Explain why existing scientific methods can not be used:

10. Explain what performance data is needed:

11. Explain how the performance data demonstrates that the device is or is not substantially equivalent:

ATTACH ADDITIONAL SUPPORTING INFORMATION

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510(K) Review

K06-1035

GENERAL INFORMATION

Company Name: Televere Systems, LLC
Address: 16275 S. Monterey Road, Ste. K
Morgan Hill, CA 95037

Dated: April 14, 2006
Received: April 14, 2006

Contact: Melissa Mahall, Director, Regulatory Affairs
Bio-Reg Associates, Inc.
6304 Belmont Circle, Bldg. 2
Mount Airy, MD 21771
Phone: 301-829-2468, Email: mmahall@bioreg.com

Tradename: TigerView Professional

Common Name: PACS

Intended Use: Display, editing, review, storage, printing and distribution of medical images

Device to Which Equivalence is Claimed:

Manufacturer: EagleSoft
Tradename: EagleSoft ChairSide Software Application
510(k) Number: K982422

Manufacturer: Tau Corp.
Tradename: TigerScan/TigerView
510(k) Number: K955237

Applicable Guidance: Medical Image Management Devices

Standard Questions:

1. Is the device subject to postmarket surveillance? No
2. Is a summary or certification of safety and effectiveness included? Summary
3. Is the device life supporting or life sustaining? No

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

Records processed under FOIA Request # 2015-8521; Released by CDRH on 05-10-2016

4. Is the device implanted? (short term or long term) No
5. Does the device use software? Yes
6. Is the device sterile? No
7. Is the device for single, home or prescription use? Prescription
8. Does the device contain drug or biological products? No
9. Is the device subject to the Radiation Control Act or other Standards? DICOM, JPEG

DETAILED REVIEW

Device Description:

Indications –

TigerView Professional is a clinical software application that receives images and data from various imaging sources (e.g. radiographic devices, digital video capture devices, and generic image devices such as scanners). In addition, it enables the storage of clinical notes, audio recordings, and clinical exam data. It is intended to acquire, display, edit (e.g. rsize, adjust contrast, crop, annotate, etc.), review, store, print and distribute images using standard PC hardware.

Technical Characteristics –

TigerView Professional is comprised of four main tabs: Patient and Images, Acquire, Mount, and Print and Send. In addition, there is an Image Viewer Window and an Export Image Function. The system includes functionality to compress images called Adaptive Image Processing, as well as software logic called Dynamic Exposure Monitoring System to aid in the acquisition of high quality images. Images are entered through the Acquire Window. The input methods consist of x-rays, video, digital photos, documents or images acquired on a flatbed scanner, and digital images acquired through the Import function.

The Viewer can be used to examine, manipulate and perform measurements on the image. It provides advanced image manipulation tools including image stitching, colorizing and pseudo 3D. The pseudo 3D applies a 3D effect to the image plus the addition of a light source. Customizable options include the location of the light source along with a depth value indicating the difference in grayscale values used for the effect. The Adaptive Image Processing feature can be used to compress images. It can remove unnecessary information such as information relating to the cheek in front of the teeth being x-rayed. The user has the option to choose a standard compression format (lossy JPEG) or lossless compression. Dynamic Exposure Monitoring provides a green, yellow or red light to indicate the amount of data available in the image to render the object being imaged. The amount of data in terms of bits acquired to meet the criteria is specific to each hardware device.

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

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Based on the user's manual the device appears to be principally intended for dental applications.

Laboratory and Clinical Data:

Laboratory or clinical data are not required to demonstrate substantial equivalence of a device of this type. Testing was conducted on a variety of computer platforms to demonstrate the performance of each feature and compliance with DICOM. Sample reports were included in the submission.

Labeling:

A user's manual entitled "TigerView Professional Manual Dentistry" was included in the submission. It provides instructions for image acquisition with a ScanX scanner, flatbed scanner, EVA sensor (Gendex, DenOptix, GX, Orthoralix, Optime, Owandy Strato Pan, Veraviewepocs and Planmeca). Instructions for the image viewer are also provided in the manual. The "TigerView Professional Administration Manual" was also included in the submission.

Software:

A list and description of the software functions was provided. The software is considered minor level of concern. A description of the software development methods was included. The development steps include function definition, requirements definition, design, implementation, module testing, project assembly, testing, system integration testing, beta testing and maintenance. A hazard analysis and software certification were provided.

Substantial Equivalence:

TigerView Professional utilizes the same programming routines to capture images as the original version (K955237). It is compatible with similar types of hardware (e.g. scanners, digital sensors, digital cameras, digital video, etc.) and has similar options for displaying, editing and printing/sending images as the predicates. A tabular comparison of features and performance was provided. All of these devices are software applications that have similar indications for use, overall functionality, provide similar image processing functions, and are compatible with similar hardware. All three appear to be aimed at dental applications. The previous version of TigerView could not acquire video or photographic data.

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

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Recommendation:

I believe that this device is substantially equivalent to:

90 – LLZ – Picture Archiving and Communications System

Classification should be based on:

892.2050 – Picture Archiving and Communications System

Class: II

Loren A. Zaremba

5-18-06

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SCREENING CHECKLIST
FOR ALL PREMARKET NOTIFICATION [510(k)] SUBMISSIONS

510(k) Number: K061035

The cover letter clearly identifies the type of 510(k) submission as **(Check the appropriate box)**:

☐ Special 510(k) - Do Sections 1 and 2

☐ Abbreviated 510(k) - Do Sections 1, 3 and 4

☑ Traditional 510(k) or no identification provided - Do Sections 1 and 4

Section 1: Required Elements for All Types of 510(k) submissions:

	Present or Adequate	Missing or Inadequate
Cover letter, containing the elements listed on page 3-2 of the Premarket Notification [510)] Manual.	✓	
Table of Contents.	✓	
Truthful and Accurate Statement.	✓	
Device's Trade Name, Device's Classification Name and Establishment Registration Number.	✓	
Device Classification Regulation Number and Regulatory Status (Class I, Class II, Class III or Unclassified).	✓	
Proposed Labeling including the material listed on page 3-4 of the Premarket Notification [510)] Manual.	✓	
Statement of Indications for Use that is on a separate page in the premarket submission.	✓	
Substantial Equivalence Comparison, including comparisons of the new device with the predicate.	✓	
510(k) Summary or 510(k) Statement.	✓	
Description of the device (or modification of the device) including diagrams, engineering drawings, photographs or service manuals.	✓	
Identification of legally marketed predicate device. *	✓	
Compliance with performance standards. * [See Section 514 of the Act and 21 CFR 807.87 (d).]	✓	
Class III Certification and Summary. **	NA	
Financial Certification or Disclosure Statement for 510(k) notifications with a clinical study. * [See 21 CFR 807.87 (i)]	NA	
510(k) Kit Certification ***	NA	

* - May not be applicable for Special 510(k)s.

** - Required for Class III devices, only.

*** - See pages 3-12 and 3-13 in the Premarket Notification [510)] Manual and the Convenience Kits Interim Regulatory Guidance.

Section 2: Required Elements for a SPECIAL 510(k) submission:

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	Present	Inadequate or Missing
Name and 510(k) number of the submitter's own, unmodified predicate device.		
A description of the modified device and a comparison to the sponsor's predicate device.		
A statement that the intended use(s) and indications of the modified device, as described in its labeling are the same as the intended uses and indications for the submitter's unmodified predicate device.		
Reviewer's confirmation that the modification has not altered the fundamental scientific technology of the submitter's predicate device.		
A Design Control Activities Summary that includes the following elements (a-c):		
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 required verification and validation activities, including the methods or tests used and the acceptance criteria to be applied.		
c. A Declaration of Conformity with design controls that includes the following statements:		
A statement that, as required by the risk analysis, all verification and validation activities were performed by the designated individual(s) and the results of the activities demonstrated that the predetermined acceptance criteria were met. This statement is signed by the individual responsible for those particular activities.		
A statement that the manufacturing facility is in conformance with the design control procedure requirements as specified in 21 CFR 820.30 and the records are available for review. This statement is signed by the individual responsible for those particular activities.		

Section 3: Required Elements for an ABBREVIATED 510(k)* submission:

	Present	Inadequate or Missing
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. (If a manufacturer elects to use an alternate approach to address a particular risk, sufficient detail should be provided to justify that approach.)		
For a submission, which relies on a recognized standard, a declaration of conformity [For a listing of the required elements of a declaration of conformity, **SEE Required Elements for a Declaration of Conformity to a Recognized Standard,** which is posted with the 510(k) boilers on the **H drive.**]		

For a submission, which relies on a recognized standard without a declaration of conformity, a statement that the manufacturer intends to conform to a recognized standard and that supporting data will be available before marketing the device.		
For a submission, which relies on a non-recognized standard that has been historically accepted by FDA, a statement that the manufacturer intends to conform to a recognized standard and that supporting data will be available before marketing the device.		
For a submission, which relies on a non-recognized standard that has not been historically accepted by FDA, a statement that the manufacturer intends to conform to a recognized standard and that supporting data will be available before marketing the device and any additional information requested by the reviewer in order to determine substantial equivalence.		
Any additional information, which is not covered by the guidance document, special control, recognized standard and/or non-recognized standard, in order to determine substantial equivalence.		

* - When completing the review of an abbreviated 510(k), please fill out an Abbreviated Standards Data Form (located on the H drive) and list all the guidance documents, special controls, recognized standards and/or non-recognized standards, which were noted by the sponsor.

Section 4: Additional Requirements for ABBREVIATED and TRADITIONAL 510(k) submissions (If Applicable):

	Present	Inadequate or Missing
a) Biocompatibility data for all patient-contacting materials, OR certification of identical material/formulation:	NA	
b) Sterilization and expiration dating information:	NA	
i) sterilization process		
ii) validation method of sterilization process		
iii) SAL		
iv) packaging		
v) specify pyrogen free		
vi) ETO residues		
vii) radiation dose		
viii) Traditional Method or Non-Traditional Method		
c) Software Documentation:	✓	

Items with checks in the "Present or Adequate" column do not require e additional information from the sponsor. Items with checks in the " Missing or Inadequate" column must be submitted before substantive review of the document.

Passed Screening ✓ Yes ____ No
Reviewer: [signature]
Concurrence by Review Branch: _____

Date: _____

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Internal Administrative Form

	YES	NO
1. Did the firm request expedited review?		✓
2. Did we grant expedited review?		✓
3. Have you verified that the Document is labeled Class III for GMP purposes?	NA	
4. If, not, has POS been notified?		
5. Is the product a device?	✓	
6. Is the device exempt from 510(k) by regulation or policy?		✓
7. Is the device subject to review by CDRH?	✓	
8. Are you aware that this device has been the subject of a previous NSE decision?		✓
9. If yes, does this new 510(k) address the NSE issue(s), (e.g., performance data)?		
10. Are you aware of the submitter being the subject of an integrity investigation?		✓
11. If, yes, consult the ODE Integrity Officer.		
12. Has the ODE Integrity Officer given permission to proceed with the review? (Blue Book Memo #I91-2 and Federal Register 90N0332, September 10, 1991.		

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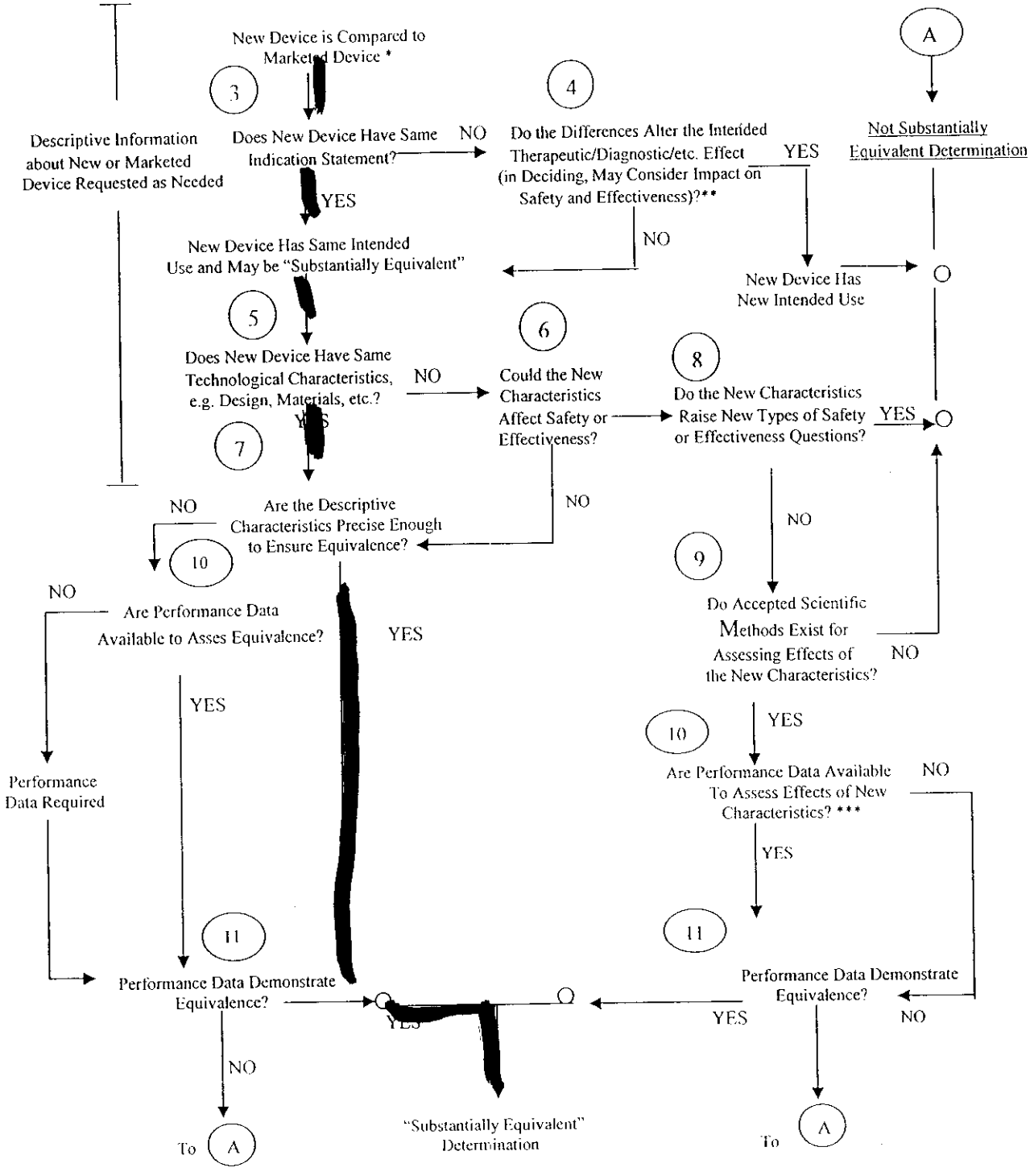
510(k) "SUBSTANTIAL EQUIVALENCE" DECISION-MAKING PROCESS



* 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.

*** Data maybe in the 510(k), other 510(k)s, the Center's classification files, or the literature.

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