Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

MAR 1 1 2014

510(k) SUMMARY

1.	Applicant:	iSYS Medizintechnik GmbH
2.	Address:	Bergwerksweg 21 6370 Kitzbühel / Austria
3.	Contact Person:	Dr. Michael Vogele Tel. +43 (0) 664 2411140
4.	Preparation Date:	January 20, 2014
5.	Device Submitted:	iSYS 1 (U.S.)
6.	Proprietary Name:	iSYS 1 (U.S.)
7.	Common Name:	Robotic Positioning Unit
8.	Classification Name:	System, X-ray, Tomography, computed Product Code JAK, KXX, Reg.No. 892.1750
9.	Substantial Equivalence:	The iSYS 1 is substantially equivalent to the following legally marketed devices: PinPoint manufactured by Philips Medical. The characteristics of this device are similar to those of the predicate devices identified on the comparison chart, which follows. It is our opinion that the iSYS 1 does not have technological characteristics that raise additional types of questions related to terms of safety and effectiveness.
10.	Device Description:	The iSYS 1 is a modular needle guidance platform for interventional radiology and related fields. Core components are a 4 DOF micro positioning unit which allows the submillimetric needle positioning from simple needle angulations up to positioning and angulations with adjustable pivot point and a control unit which is directed by a cable connected control panel. The passive macro positioning unit and different table adapters allow different setups of the system around the patient in the region of interest. The needle-guide-kit (manufactured by ECOLAB) provides disposable components that ensure precise and sterile needle guidance. Planning of the tool position/orientation as well as validation of the correctness of the tool position must be performed with an external planning and measurement system which is not part of the iSYS-1 Interventional Platform. The position of iSYS 1 is visible for most imaging systems due to the used markers. During treatment the tool is controlled by the

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

user.

11. Intended Use: The intended use of the iSYS1 device is to function as a remote-operated positioning and guidance system during interventional procedures. Positioning is done in remote control manner; planning of the position/angulation is done based on 2D/3D patient data (CT, cone-beam CT, fluoroscopy) by external planning software – for example using an external navigation system, or planning software coming with the used imaging device. Also verification of the correct position and orientation of the tool prior to/during/after the intervention is done by means of these external devices. The iSYS1-System is then acting as a guideway during the manual insertion of the interventional tool – usually a needle type device, and the like.

12. Indications for Use The iSYS 1 device is a user-controlled electromechanical arm with a needle guide. It is intended to assist the surgeon in the positioning of a needle or electrode where both computed tomography (CT) and fluoroscopic imaging can be used for target trajectory planning and intraoperative tracking. The needle or electrode is then manually advanced by the surgeon. Trajectory planning is made with software that is not part of the iSYS device

13. Clinical Use The Side Rail Adapter is attached to the side rail for the setup; the Table Top Adapter is attached directly onto the CT table. Both Adapters are equipped with a "starburst" connector, to which the Multifunctional Arm (MFA) can be attached. The MFA is equipped with one "starburst" connector at the bottom and one "spoon" connector at the top. The "spoon" connector has its counterpart on the Robotic Positioning Unit for the setup. The Control Unit is attached directly to the side rail. The Robotic Positioning Unit is connected by a cable to the Control Unit, which has cable connections to both the electric power supply and to a Handheld Control Unit. The Needle Guide Extensions are screw-fixed onto the Robotic Positioning Modules. The Sterile Cover is directly fixed onto the Needle Guide Joints and can be drawn over the robotic parts. The Needle Insert is placed into the appropriate connector of the Needle Guide, to prepare needle usage. The Handheld Control Unit can be clamped onto the side rail and covered with a drape. Planning of the tool position/orientation as well as validation of the correctness of the tool position must be performed with an external planning and measurement system

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

(imaging or navigation software).

14. Biocompatibility: The iSYS 1 is not in contact with patient. At any time when in use a sterile cover sheet is to be placed between the patient and the system. Additionally there are no new materials introduced in the manufacture of the iSYS 1. Therefore, no biocompatibility studies were performed for this device.

15. Performance Data: Operating temperature/humidity range: 15 to 30°C; 30 to 70% relative humidity with no condensation

Storage temperature/humidity range: 10 to 50°C; 30 to 70% relative humidity with no condensation

Power Supply: 50W; 115VAC/230VAC; 50-60Hz; cable: C14 according to IEC/EN 60320-1, US498, CSA C22.2 no. 42;

(b)(4) [redacted]

The accuracy of the intervention depends on the resolution and capabilities of the imaging device or software. The mechanical accuracy of iSYS1 is below 1 mm, but that gives no accuracy value for treatments.

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Device Comparison Summary:

Reference	PinPoint	iSYS 1 (for new submission)	Equivalence ?
510k-Number	K974513	K131433	
Manufacturer	PHILIPS MEDICAL SYSTEMS (CLEVELAND), INC. 595 Miner rd. Cleveland, OH 44143 USA	iSYS Medizintechnik GmbH Bergwerksweg 21 A-6370 Kitzbuehel Austria	
Design			
General device description	Five jointed, position-sensing stereotactic arm, mounted on the CT gantry, and indicated for invasive procedures	Computer controlled electromechanical multi-joined arm indicated for invasive procedures	Yes
Localization means	Robot arm absolute encoders	Fiducial markers on tool holder.	*3)
Image-guided	Yes	Yes	Yes
Planning software	No, not cleared under this 510k (K955268)	No (third party)	Yes
Registration method	During installation	Fiducial markers	*4)
Instrumentation	Cannula Laser needle guide	Marker Tool Holder Sterile Covers (third party)	Yes
Instrument fixation	Cannula attached to the arm (optional: laser needle guidance)	Special tool holders for several applications mounted to the Robot	Yes
Instrument calibration	Factory Calibration Optional: intra operative	Intra operative	*1)
System immobilization between patient and device	Yes	Yes	Yes
Planning and Navigation Software			
N/A.			
System Operation			
Fiducial markers registration with	No	No	Yes

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Reference	PinPoint	iSYS 1 (for new submission)	Equivalence ?
pointer probe			
Optical registration	No	No	Yes
Ultrasound Registration	No	No	Yes
Accuracy verification	Yes, external anatomical verification	Yes, performed by user	Yes
Provide mechanical guidance for tools	Yes	Yes	Yes
Instrument guide position adjustment	Manual	Manual	Yes
Physician carries out final gesture through tool guide	Yes	Yes	Yes
Indications for Use			
Indication for use	The PinPoint is an accessory to a CT system intended to provide the radiologist with a means of simulating and initiating interventional procedures by interactively relating the patient´s CT image volume to the actual target field. This accessory includes mounting the stereotactic arm on a CT-Gantry, a flat panel TV monitor, cabling, biopsy phantom and software. In addition the CT is intended to produce cross-sectional images of the body by computer reconstruction of X-ray transmission data from	The iSYS 1 device is a user-controlled electromechanical arm with a needle guide. It is intended to assist the surgeon in the positioning of a needle or electrode where both computed tomography (CT) and fluoroscopic imaging can be used for target trajectory planning and intraoperative tracking. The needle or electrode is then manually advanced by the surgeon. Trajectory planning is made with software that is not part of the iSYS device.	Yes

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Reference	PinPoint	iSYS 1 (for new submission)	Equivalence ?
	the same axial plane taken at different angels. This device may include signal analysis and display equipment, patient and equipment supports, components and accessories. PinPoint is not limited to any particular region of the body. It is equally viable for planning head and spine interventions as it is in the abdomen. It is expected that its major use will be in the planning of biopsies of abdominal organs and drainage of fluid collections in the abdomen. However, more complicated procedures such as Brachy therapy and bone pinnings will be planned using the PinPoint.		
Intended Use	The PinPoint is an accessory to a CT system intended to provide the radiologist with a means of simulating and initiating interventional procedures by interactively relating the patient´s CT image volume to the actual target field. The system produces cross sectional images by computer reconstruction of x-ray transmission data from the same axial plane taken at different angles. A stereotactic arm on a	The intended use of the iSYS1 device is to function as a remote-operated positioning and guidance system during interventional procedures. Positioning is done in remote control manner; planning of the position/angulation is done based on 2D/3D patient data (CT, cone-beam CT, fluoroscopy) by external planning software – for example using an external navigation system, or planning software coming with the used imaging device. Also	Yes

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Reference	PinPoint	iSYS 1 (for new submission)	Equivalence ?
	CT Gantry, a flat panel TV monitor, and biopsy phantom are used as accessories to produce these images. The primary intend of the system is to provide guidance for biopsies in the abdomen, spine and head.	verification of the correct position and orientation of the tool prior to/during/after the intervention is done by means of these external devices. The iSYS1-System is then acting as a guideway during the manual insertion of the interventional tool – usually a needle type device, and the like.	
Anatomical site	Total Body	Total body	Yes
User	Radiologist	Physician	*2)
Accessory	V-Channel Cannula Cylindrical Cannula	Sterile Covers Table Adapters Cable Sets	Yes
Real-time instrument position	Yes	Yes	Yes
Mechanical Guidance of instruments	Yes	Yes	Yes
Technology			
Powered	Yes	Yes	Yes
CE-Conformity	No	Yes	Yes
Computer-controlled	Yes	Yes	Yes
Materials	Metal, electronics and plastics	Metal, electronics Polyamide Polyethylene Bralen	Yes

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Similarities and Differences:

All three devices are intraoperative instruments used by physician for assisting the spatial positioning and orientation of a surgical tool.

iSYS 1 is equivalent to:

- PinPoint for assisting the spatial positioning and orientation of a surgical tool.
- PinPoint for being localized by the navigation or imaging software.
- PinPoint for being guided by an imaging device
- PinPoint for providing a registration method for the imaging device.
- PinPoint for instrumentation and instrument fixation.
- PinPoint for being immobilized in relation to the patient.
- PinPoint for providing accuracy verification, tool guidance and position adjustment.
- PinPoint for the physician making the final gesture.
- PinPoint for having the same indications for use and region of interest.

Differences:

*1) PinPoint provides a factory instrument calibration of the encoders. During intervention the physician using iSYS1 and PinPoint verifies the position of the needle or needle-type instrument (tool). Verification of the tool position requires greater physical effort but provides for exact (depending on the imaging system) tool localization. The localization of the tool is not required for the iSYS 1 and, thus, this has no effect on safety or effectiveness.

*2) While the PinPoint is indicated to be used by radiologists only, the iSYS 1 is indicated to be used by any trained physician. This has no effects on safety and effectiveness.

*3) PinPoint provides encoders for localization, whereas iSYS uses fudicial markers on the tool. Using fiducial markers provides better localization safety.

*4) While the Pinpoint is registered during installation, the iSYS 1 uses fiducial markers for registration. Again, using fiducial markers provides better localization safety.

Non-Clinical Performance Data:

Non-clinical testing has mainly been performed to prove electrical and mechanical safety of the devices. Similar to the predicate devices, iSYS 1 was tested according to EN ISO 60601-1 2nd edition:

- EN 60601-1:1990 + A1:1993 + A2:1995
- EN 60601-1-8:2004 + A1:2006

The Electromagnetic Compatibility of the iSYS1 System has been tested according to FCC Part15 (Edition 1st October 2010) and ISO 60601-1-2:2007 and meets the acceptance criteria of both.

Performance tests have been performed to prove:

- the accuracy of the needle placement under clinical conditions,
- the compatibility with the imaging modality,
- the tendency to produce artifacts,

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

- the mechanical stability of the system despite external payload under worst conditions
- the mechanical stability of the table adapters despite external payload,
- the accuracy in remote-control mode
- the accuracy of needle guidance
- functionality of hardware modules
- effectiveness of hardware safety measures for the software,
- and the effectiveness of the alarm systems

The results of these performance tests support that the predicate devices and iSYS 1 are substantially equivalent.

Conclusion:

It is our opinion that the iSYS 1 System (U.S.) does not have technological characteristics that raise additional types of safety or effectiveness questions, and we consider them to be an enhancement to the existing devices.

To validate the accuracy of the iSYS 1 an external reference system has to be used. We have used and validated the accuracy of the iSYS 1 System (U.S.) with the Philips Allura Xper Guide FD 20 X-ray system and the Axiom Artis Zeego from Siemens Healthcare, and passed all tests.

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

March 11, 2014

iSYS Medizintechnik GmbH
c/o Mrs. Cornelia Damsky
56 Westcott Road
Stamford, CT 06902

Re: K131433
Trade/Device Name: iSYS 1
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: Class II
Product Code: JAK
Date: February 11, 2014

Dear Mrs. Damsky:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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.

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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Joyce M. Whang -S

for Carlos L. Peña, PhD, MS
Director
Division of Neurological and
Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*
K131433

Device Name
iSYS 1

Indications for Use *(Describe)*
The iSYS 1 device is a user-controlled electromechanical arm with a needle guide. It is intended to assist the surgeon in the positioning of a needle or electrode where both computed tomography (CT) and fluoroscopic imaging can be used for target trajectory planning and intraoperative tracking. The needle or electrode is then manually advanced by the surgeon. Trajectory planning is made with software that is not part of the iSYS device.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Joyce M. Whang -S

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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 number."

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

March 11, 2014

iSYS Medizintechnik GmbH
c/o Mrs. Cornelia Damsky
56 Westcott Road
Stamford, CT 06902

Re: K131433
Trade/Device Name: iSYS 1
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: Class II
Product Code: JAK
Date: February 11, 2014

Dear Mrs. Damsky:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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.

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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Joyce M. Whang -S

for Carlos L. Peña, PhD, MS
Director
Division of Neurological and
Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*
K131433

Device Name
iSYS 1

Indications for Use *(Describe)*
The iSYS 1 device is a user-controlled electromechanical arm with a needle guide. It is intended to assist the surgeon in the positioning of a needle or electrode where both computed tomography (CT) and fluoroscopic imaging can be used for target trajectory planning and intraoperative tracking. The needle or electrode is then manually advanced by the surgeon. Trajectory planning is made with software that is not part of the iSYS device.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Joyce M. Whang -S

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

4

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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 number."

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

5

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

K131433/S2

A1

Section 003	510k Cover Letter 510(k) Number: K131433	iSYS Medizintechnik GmbH

FDA CDRH DMC
JAN 28 2014
Received

Name *Dr. Michael Vogele*

mobil *+43 (0) 664 2411140*
email *michael.vogele@isys.co.at*
web *www.isys.co.at*

iSYS Medizintechnik GmbH

iSYS Medizintechnik GmbH, Bergwerksweg 21, 6370 Kitzbühel, Austria

Food and Drug Administration
Center for Device and Radiological Health
Document Mail Center WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Subject: 510(k) Notification K131433/S002

This is additional information to notify you of the intention of iSYS Medizintechnik GmbH, Bergwerksweg 21, A-6370 Kitzbuehel, Austria to market the following device:

1.	**Proprietary Name:**	iSYS 1 (U.S.)
2.	**Common/Usual Name:**	Robotic Positioning Unit
3.	**Establishment Registration Number:**	pending
4.	**Address of manufacturing and packaging facility:**	Bergwerksweg 21, A-6370 Kitzbuehel, Austria
5.	**Classification Name:**	System, X-ray, Tomography, computed
6.	**Classification:**	Device Class: Class II Classification Panel: Radiology Product Code: JAK, HAW CFR Section: 892.1750
7.	**Reason for Submission:**	New device
8.	**Substantial Equivalence:**	***510(k) Number*** ***Model name*** ***Manufacturer*** K974513 PinPoint Philips Medical
9.	**Performance Standards:**	ÖNORM EN ISO 60601, ÖNORM EN ISO 62304, ANSI/AAMI/ISO 11737, AAMI TIR33, AAMI TIR35, AAMI ST67, ANSI/AAMI/ISO 11607-2, ISO 11137
10.	**Sterile Accessory**	Drapes produced, packaged and sterilized by (b)(4) [redacted] under 510(k) **K863853**. Injection molded components packaged and sterilized by (b)(4) [redacted] (b)(4) Third Party [redacted] under 510(k) **K893814**.

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

36

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

The files coming with this 510k submission file are our response to the Additional Information Request dated 26/08/2013 and contain the required changes. The following addresses the individual items of the request.

Indications for Use

1. **In your submission, you provide an Indications for Use (IFU) statement along with two predicates (Frameless Neuromate and ROSA Surgical Device). However, your IFU diverges significantly from the predicate IFUs. While the predicate IFUs are specific to neurosurgical procedures performed by neurosurgeons, your IFU is expanded to procedures throughout the body done by any physician. Given the predicates that you have provided, we recommend an IFU that similar to the following:**

   The predicate device has been changed to PinPoint (K974513). We have removed all references to the prior predicated devices (ROSA and Neuromate) from the file.

Bench Testing

(b)(4)

[redacted]

3. **The description of your performance testing is incomplete. Please reference Section 18 of the guidance document "Guidance for Industry and FDA Staff: Format for Traditional and Abbreviated 510(k)s," located at: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm084365.htm, and provide the information specified in this guidance document.**

   Section 018 has been revised according to the guidance document.

4. (b)(4)

[redacted]

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

(b)(4)

[redacted]

5. **In some of your provided test reports, which indicate that your device failed your prespecified pass criteria, you state that you provide additional warning to the device operator. For example, in Document PD/B12 (page 2 of 8) you state:**

   "Additional warning in user manual that external force to needle guide must be avoided during needle inserting."

   However, these statements could not be located in your labeling. Therefore, please revise your labeling to include all of these warnings to the operator. Please also provide a listing of all of these warnings in your response, along with the page number that they appear.

   The warnings are in the user manual, pages 55, 57, 85, 91, 93, and 94.

Packaging/Shelf-life for Sterile Device Accessories

(b)(4)

[redacted]

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

7. **We cannot identify the sterile packaging configurations you plan to distribute. Please provide a table in which you identify the sterile components in each packaging configuration you plan to distribute.**

   On pages 4-6 of section 014 the sterile packaging configurations are identified.

(b)(4)

[redacted]

Consensus Standards

9. **We could not locate FDA form 3654 for the consensus standards referenced in your validation of the gamma radiation sterilization process and for establishing packaging integrity and shelf-life for your sterilized device accessories. Please provide FDA form 3654 – Standards Data Report for 510(K)s for each referenced consensus standard.**

   All FDA forms 3654 can be found in Section 002 (Cover Letter), starting from page 8. The forms for the sterile components can be found starting from page 15.

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Cleaning and Disinfecting Instructions for Non-patient Contacting iSYS 1 System Components

10. **Users in the U.S. will not understand terminology such as proofed for compatibility. Please revise the following labeling instructions:**
    From:

    "The system must be cleaned and disinfected prior and after to each use. For cleaning and disinfection use appropriate agents which are proofed for compatibility. iSYS has proofed the following agents as compatible:..."

    To:
    "The system must be cleaned and disinfected prior and after to each use. iSYS System components are validated for cleaning and disinfection using the following agents:..."

    The wording has been changed accordingly. Please refer to page 110 in Section 013.

11. **The reprocessing instructions should only include equipment and products that are legally marketed in the U.S. Please document that the disinfecting products recommended in you**

    The product names have been removed. Please refer to page 117 in Section 013.

Electromagnetic Compatibility (EMC)

12. **Please clarify if wireless technology is incorporated in the device. If wireless technology is part of the device system you should address the safety and effectiveness concerns involving the wireless technology, which are largely outside the scope of the IEC 60601-1-2 standard for EMC. For wireless medical devices please address the following areas with testing and information that describes the device wireless specifications and characteristics, the device functions and associated risks, testing results, and acceptable tolerances for: data integrity, data latency, coexistence with other radiofrequency wireless, EMC of the wireless signals, and data security. The labeling for each device system component incorporating wireless technology should contain a summary of this information as well.**

    No wireless technology is used.

13. **The information in the submission is not clear about what was done to address the EMC of the iSYS-1 device. Please address the following:**
    a. **While the information provided in Electromagnetic Compatibility and Electrical Safety" section of the original submission indicates the device complies with IEC 60601-1-2 standard, EMC testing information to support the claimed compliance appears to be absent in the submissions. Therefore, please provide a summary of all EMC testing (emissions and immunity) of this iSYS-1 device with the test**

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

results and data to support your claims for immunity to electromagnetic interference (EMI). Please note, while the information for compliance to FCC is helpful, the information does not adequately address safety and effectiveness of the iSYS-1 device.

We have added the EMC test report. Please refer to Section 017, pages 8 to 33. Additionally, the device was tested according to FCC 47 CFR Part 15. Please refer to Section 017, pages 34 to 48. For testing against influences of RFID or similar devices please see below issue 13f.

b. **Please provide a statement of the essential performance of the device as called out in the IEC 60601-1-2 standard referenced in the submission.**

The statements on the essential performance characteristics are part of the EMC test report. Please refer to Section 017, page 19.

c. **Please provide a brief explanation of how each EMC test was performed and how the testing for each mode addresses the risks for EMI and demonstrates EMC to the claimed levels. This should include a brief explanation of how the testing addresses connections to the patient, alarms, and the time for the device to perform its function.**

Detailed description of the tests can be found in Section 017, pages 14 to 18 and in the annex of the test report (pages 21 to 33). The main performance characteristics (this includes alarm systems and function) were not influenced during the EMC testing and all actions of the device were still within the given requirements.

d. **Please provide the pass/fail criteria for each of the EMC tests, how these were quantified and measured, and justifications for these criteria.**

The pass/fail criteria for each of the EMC tests are documented in the EMC test report. Please refer to Section 017, pages 11 to 13. For quantification and measurement details please refer to Section 017, page 14 to 18.

e. **If there were any modifications to the device in order to pass any of the EMC tests then you should provide brief summary explanations of the modification and a statement that all modifications will be incorporated into all production units.**

There were no modifications.

f. **Information provided in Proposed Labeling of the previous Supplement 1 submission (page 25) contains a warning against the device exposure to "radiotransmitting devices (such as mobile phones, diathermy units, etc.)" In addition, please specifically address other common RF emitters such as RFID. It is foreseeable that the device**

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

will be exposed to such RF sources. Therefore, you should perform adequate testing to assure safety and effectiveness of your device. In general, the present published consensus standards do not adequately address these potential threats.

We have added a test report addressing the influences of RFID and WLAN devices on the iSYS 1. Please refer to Section 017, pages 49 and following.

14. **Information provided in the Proposed Labeling of the Supplement 1 submission (page 21 through 25) contains EMC related labeling information as called out in the IEC 60601-1-2 standard. However, the EMC testing information to support the claimed compliance level appears to be absent in this and previous submissions. Therefore, please provide EMC testing information to support the claimed compliance level (see point 13c, above). The EMC labeling information should provide clear and consistent summary information about what was done to address the safety and effectiveness of the iSYS-1 device.**

    We have added the required information. Please refer to Section 017, pages 8 to 48 and issue 13 above.

Labeling

15. **In your proposed User's Manual (page 11 of 116), you provide a description of the iSYS 1 system that states,**

    "The iSYS 1 Interventional Platform is a modular needle guidance platform for interventional radiology and related fields"

    Additionally, you state in your included marketing material (beginning on page 113 of 116) that,

    "iSYS 1 is the most advanced needle guidance platform for interventional radiology"

    However, as discussed in Deficiency #1 above, the predicate devices are directed towards neurosurgical uses. Therefore, please remove or revise these documents to be consistent with your Indications for Use statement.

    The predicate device has been changed to PinPoint. Please see issue #1.

16. **In the marketing material (proposed labeling section beginning on page 113 of 116), there are statements that claim or imply superiority over existing devices and are unsubstantiated by the submission. Please remove the following claims from the promotional material or provide data to support them:**
    - **Reduced radiation exposure**
    - **Less risk and stress during interventions**
    - **Higher precision**
    - **Fewer side effects**
    - **Faster recovery**
    - **Better clinical outcomes**

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

- **Higher safety standards**
- **Higher patient throughput**
- **Better cost-benefit ratio**
- **Safer work environment**
- **iSYS 1 is the most advanced needle guidance platform for interventional radiology**
- **Safer for the physician and the patient**
- **Best safety standards**
- **Intuitive and fast use**
- **Maximum mechanical stability/compatibility**

We have added the definition of marketing information including the analysis of marketing phrases to Section 013 of our submission (pages 120 to 126). The analysis contains the required data that supports our statements.

Software

17. **You state that the Level of Concern for the software which controls your device is MINOR. However, your listed predicate devices have software Level of Concern of MODERATE. Further, since prior to the mitigation of hazards, failure of the software could result in injury to the patient we believe the software Level of Concern should be MODERATE. Therefore, please revise your Level of Concern to MODERATE and provide the additional required software documentation for software with a MODERATE Level of Concern. The required documentation may be found in "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices," listed above.**

    As agreed on in the Telko with Dr. Jordan, we have changed the level of concern to "moderate" and added the comment on remaining software anomalies. Please refer to Section 016, pages 2 and 3.
    The development environment can be found on page 5 in Section 016.

Literature

18. **You include a dissertation by Dr. Werner Jaschke in your submission. However, the document is in German and you do not provide an English translation. Therefore, please provide an English translation of the document if you wish for the information to be used to support your claims of substantial equivalence to a legally marketed predicate device. Please also include your summary of the information in the article and a discussion of how that information supports the substantial equivalence of your device to its predicate.**

    The dissertation is not used for proofing substantially equivalency, or to validate any performance criteria.

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

19. **You include various literature articles in your submission. However, you do not provide a discussion of how each article is applicable to support the substantial equivalence of your device to a legally marketed predicate device. Therefore, for each article, please summarize the article and provide a discussion of how the article supports the substantial equivalence of your device to its predicate.**

    The literature articles are not used for proofing substantially equivalency, or to validate any performance criteria.

Administrative

20. **In your proposed 510(k) Summary, you do not provide an IFU statement. Instead, you provide an "Intended Use." Please revise your 510(k) Summary to provide your Indications for Use statement. Please also ensure that your IFU statement is consistent throughout all documents in your submission (e.g., Indications for Use, 510(k) Summary, Labeling and User Manual, etc.)**

    We have added the Indications for Use in Section 005, page 2.

(b)(4)

[redacted]

In case of any questions concerning this application, please contact either Dr. Michael Vogele, CEO at +43 (0) 664 2411140 (michael.vogele@isys.co.at) or Oliver Spitz (Regulatory Consultant) at +49 (0) 173 5904978 (oliver.spitz@isys.co.at).

The eCopy is an exact duplicate of the paper copy.

Sincerely,

Dr. Michael Vogele

CEO

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

iSYS Medizintechnik GmbH

510(k) Premarket Notification

(Basing on "Guidance for Industry and FDA Staff: Format for Traditional and Abbreviated 510(k)s"

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Table of Content

Section	Name	Number of Pages	Appendix/Misc
001	Medical Device User Fee Cover Sheet (Form FDA 3601)	3	No
002	CDRH Premarket Review Submission Cover Sheet	27	Yes
003	510(k) Cover Letter	9	No
004	Indications for Use Statement	1	No
005	510(k) Summary	9	No
006	Premarket Notification Truthful and Accurate Statement	1	No
007	Premarket Notification Class III Certification and Summary	1	No
008	Financial Certification or Disclosure Statement	1	No
009	Declarations of Conformity and Summary Reports (including Risk Management File)	104	No
010	Executive Summary	4	No
011	Device Description	57	No
012	Substantial Equivalence Discussion	7	No
013	Proposed Labeling	135	No
014	Sterilization and Shelf Life	159	No
015	Biocompatibility	1	No
016	Software	38	No
017	Electromagnetic Compatibility and Electrical Safety	66	No
018	Performance Testing – Bench	103	No
019	Performance Testing – Animal	1	No
020	Performance Testing – Clinical	40	Yes

* Highlighted sections are subject to changes due to FDA's Request for additional Information dated 08/26/2013.

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Section 001	Medical Device User Fee Cover Sheet (Form FDA 3601) 510(k) Number: K131433	ISYS Medizintechnik GmbH

Form Approved: OMB No. 0910-511 Expiration Date: February 28, 2013. 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) [redacted]
Write the Payment Identification number on your check.

A completed cover sheet must accompany each original application or supplement subject to fees. If payment is sent by U.S. mail or courier, please include a copy of this completed form with payment. Payment and mailing instructions can be found at: http://www.fda.gov/oc/mdufma/coversheet.html

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

ISYS MEDIZINTECHNIK GMBH
Bergwerksweg 21

KITZBUEHEL
6370
AT

1.1 EMPLOYER IDENTIFICATION NUMBER (EIN)

2. CONTACT NAME
Oliver Spitz
2.1 E-MAIL ADDRESS
oliver.spitz@isys.co.at
2.2 TELEPHONE NUMBER (include Area code)
0049 173 5904978
2.3 FACSIMILE (FAX) NUMBER (Include Area code)

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/oc/mdufma

Select an application type:
[X] Premarket notification(510(k)); except for third party
[ ] 513(g) Request for Information
[ ] Biologics License Application (BLA)
[ ] Premarket Approval Application (PMA)
[ ] Modular PMA
[ ] Product Development Protocol (PDP)
[ ] Premarket Report (PMR)
[ ] Annual Fee for Periodic Reporting (APR)
[ ] 30-Day Notice

3.1 Select a center
[X] CDRH
[ ] CBER
3.2 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)
[X] YES, I meet the small business criteria and have submitted the required qualifying documents to FDA
NO, I am not a small business
4.1 If Yes, please enter your Small Business Decision Number: SBD135332

5. FDA WILL NOT ACCEPT YOUR SUBMISSION IF YOUR COMPANY HAS NOT PAID AN ESTABLISHMENT REGISTRATION FEE THAT IS DUE TO FDA. HAS YOUR COMPANY PAID ALL ESTABLISHMENT REGISTRATION FEES THAT ARE DUE TO FDA?
[X] YES (All of our establishments have registered and paid the fee, or this is our first device, and we will register and pay the fee within 30 days of FDA's approval/clearance of this device.)
[ ] NO (If "NO," FDA will not accept your submission until you have paid all fees due to FDA. This submission will not be processed; see http://www.fda.gov/cdrh/mdufma for additional information)

6. 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
[ ] This biologics application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only
[ ] The sole purpose of the application is to support conditions of use for a pediatric population
[ ] The application is submitted by a state or federal government entity for a device that is not to be distributed commercially

7. 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

PAPERWORK REDUCTION ACT STATEMENT
Public reporting burden for this collection of information is estimated to average 18 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and 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 the address below.

Department of Health and Human Services, Food and Drug Administration, Office of Chief Information Officer, 1350 Piccard Drive, 4th Floor Rockville, MD 20850
[Please do NOT return this form to the above address, except as it pertains to comments on the burden estimate.]

8. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION
(b)(4) [redacted]
03-May-2013

Form FDA 3601 (01/2007)

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Name ***Dr. Michael Vogele***

mobil ***+43 (0) 664 2411140***
email *michael.vogele@isys.co.at*
web *www.isys.co.at*

iSYS Medizintechnik GmbH, Bergwerksweg 21, 6370 Kitzbühel, Austria

Food and Drug Administration
Center for Device and Radiological Health
Document Mail Center WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Subject: 510(k) Notification K131433/S002

This is additional information to notify you of the intention of iSYS Medizintechnik GmbH, Bergwerksweg 21, A-6370 Kitzbuehel, Austria to market the following device:

1.	**Proprietary Name:**	iSYS 1 (U.S.)
2.	**Common/Usual Name:**	Robotic Positioning Unit
3.	**Establishment Registration Number:**	pending
4.	**Address of manufacturing and packaging facility:**	Bergwerksweg 21, A-6370 Kitzbuehel, Austria
5.	**Classification Name:**	System, X-ray, Tomography, computed
6.	**Classification:**	Device Class: Class II Classification Panel: Radiology Product Code: JAK, HAW CFR Section: 892.1750
7.	**Reason for Submission:**	New device
8.	**Substantial Equivalence:**	***510(k) Number*** / ***Model name*** / ***Manufacturer*** K974513 / PinPoint / Philips Medical
9.	**Performance Standards:**	ÖNORM EN ISO 60601, ÖNORM EN ISO 62304, ANSI/AAMI/ISO 11737, AAMI TIR33, AAMI TIR35, AAMI ST67, ANSI/AAMI/ISO 11607-2, ISO 11137
10.	**Sterile Accessory**	Drapes produced, packaged and sterilized by (b)(4) [redacted] under 510(k) **K863853**. Injection molded components packaged and sterilized by (b)(4) [redacted] (b)(4) [redacted] under 510(k) **K893814**.

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

The files coming with this 510k submission file are our response to the Additional Information Request dated 26/08/2013 and contain the required changes. The following addresses the individual items of the request.

Indications for Use

1. **In your submission, you provide an Indications for Use (IFU) statement along with two predicates (Frameless Neuromate and ROSA Surgical Device). However, your IFU diverges significantly from the predicate IFUs. While the predicate IFUs are specific to neurosurgical procedures performed by neurosurgeons, your IFU is expanded to procedures throughout the body done by any physician. Given the predicates that you have provided, we recommend an IFU that similar to the following:**

   The predicate device has been changed to PinPoint (K974513). We have removed all references to the prior predicated devices (ROSA and Neuromate) from the file.

Bench Testing

(b)(4)

[redacted]

3. **The description of your performance testing is incomplete. Please reference Section 18 of the guidance document "Guidance for Industry and FDA Staff: Format for Traditional and Abbreviated 510(k)s," located at: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm084365.htm, and provide the information specified in this guidance document.**

   Section 018 has been revised according to the guidance document.

(b)(4)

[redacted]

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

(b)(4)

[redacted]

5. **In some of your provided test reports, which indicate that your device failed your prespecified pass criteria, you state that you provide additional warning to the device operator. For example, in Document PD/B12 (page 2 of 8) you state:**

   "*Additional warning in user manual that external force to needle guide must be avoided during needle inserting.*"

   However, these statements could not be located in your labeling. Therefore, please revise your labeling to include all of these warnings to the operator. Please also provide a listing of all of these warnings in your response, along with the page number that they appear.

   The warnings are in the user manual, pages 55, 57, 85, 91, 93, and 94.

Packaging/Shelf-life for Sterile Device Accessories

(b)(4)

[redacted]

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

7. **We cannot identify the sterile packaging configurations you plan to distribute. Please provide a table in which you identify the sterile components in each packaging configuration you plan to distribute.**

   On pages 4-6 of section 014 the sterile packaging configurations are identified.

(b)(4)

[redacted]

Consensus Standards

9. **We could not locate FDA form 3654 for the consensus standards referenced in your validation of the gamma radiation sterilization process and for establishing packaging integrity and shelf-life for your sterilized device accessories. Please provide FDA form 3654 – Standards Data Report for 510(K)s for each referenced consensus standard.**

   All FDA forms 3654 can be found in Section 002 (Cover Letter), starting from page 8. The forms for the sterile components can be found starting from page 15.

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Cleaning and Disinfecting Instructions for Non-patient Contacting iSYS 1 System Components

10. **Users in the U.S. will not understand terminology such as proofed for compatibility. Please revise the following labeling instructions:**
    From:

    "The system must be cleaned and disinfected prior and after to each use. For cleaning and disinfection use appropriate agents which are proofed for compatibility. iSYS has proofed the following agents as compatible:…"

    To:
    "The system must be cleaned and disinfected prior and after to each use. iSYS System components are validated for cleaning and disinfection using the following agents:…"

    The wording has been changed accordingly. Please refer to page 110 in Section 013.

11. **The reprocessing instructions should only include equipment and products that are legally marketed in the U.S. Please document that the disinfecting products recommended in you**

    The product names have been removed. Please refer to page 117 in Section 013.

Electromagnetic Compatibility (EMC)

12. **Please clarify if wireless technology is incorporated in the device. If wireless technology is part of the device system you should address the safety and effectiveness concerns involving the wireless technology, which are largely outside the scope of the IEC 60601-1-2 standard for EMC. For wireless medical devices please address the following areas with testing and information that describes the device wireless specifications and characteristics, the device functions and associated risks, testing results, and acceptable tolerances for: data integrity, data latency, coexistence with other radiofrequency wireless, EMC of the wireless signals, and data security. The labeling for each device system component incorporating wireless technology should contain a summary of this information as well.**

    No wireless technology is used.

13. **The information in the submission is not clear about what was done to address the EMC of the iSYS-1 device. Please address the following:**
    a. **While the information provided in Electromagnetic Compatibility and Electrical Safety" section of the original submission indicates the device complies with IEC 60601-1-2 standard, EMC testing information to support the claimed compliance appears to be absent in the submissions. Therefore, please provide a summary of all EMC testing (emissions and immunity) of this iSYS-1 device with the test**

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

results and data to support your claims for immunity to electromagnetic interference (EMI). Please note, while the information for compliance to FCC is helpful, the information does not adequately address safety and effectiveness of the iSYS-1 device.

We have added the EMC test report. Please refer to Section 017, pages 8 to 33. Additionally, the device was tested according to FCC 47 CFR Part 15. Please refer to Section 017, pages 34 to 48. For testing against influences of RFID or similar devices please see below issue 13f.

b. Please provide a statement of the essential performance of the device as called out in the IEC 60601-1-2 standard referenced in the submission.

The statements on the essential performance characteristics are part of the EMC test report. Please refer to Section 017, page 19.

c. Please provide a brief explanation of how each EMC test was performed and how the testing for each mode addresses the risks for EMI and demonstrates EMC to the claimed levels. This should include a brief explanation of how the testing addresses connections to the patient, alarms, and the time for the device to perform its function.

Detailed description of the tests can be found in Section 017, pages 14 to 18 and in the annex of the test report (pages 21 to 33). The main performance characteristics (this includes alarm systems and function) were not influenced during the EMC testing and all actions of the device were still within the given requirements.

d. Please provide the pass/fail criteria for each of the EMC tests, how these were quantified and measured, and justifications for these criteria.

The pass/fail criteria for each of the EMC tests are documented in the EMC test report. Please refer to Section 017, pages 11 to 13. For quantification and measurement details please refer to Section 017, page 14 to 18.

e. If there were any modifications to the device in order to pass any of the EMC tests then you should provide brief summary explanations of the modification and a statement that all modifications will be incorporated into all production units.

There were no modifications.

f. Information provided in Proposed Labeling of the previous Supplement 1 submission (page 25) contains a warning against the device exposure to "radiotransmitting devices (such as mobile phones, diathermy units, etc.)" In addition, please specifically address other common RF emitters such as RFID. It is foreseeable that the device

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

will be exposed to such RF sources. Therefore, you should perform adequate testing to assure safety and effectiveness of your device. In general, the present published consensus standards do not adequately address these potential threats.

We have added a test report addressing the influences of RFID and WLAN devices on the iSYS 1. Please refer to Section 017, pages 49 and following.

14. **Information provided in the Proposed Labeling of the Supplement 1 submission (page 21 through 25) contains EMC related labeling information as called out in the IEC 60601-1-2 standard. However, the EMC testing information to support the claimed compliance level appears to be absent in this and previous submissions. Therefore, please provide EMC testing information to support the claimed compliance level (see point 13c, above). The EMC labeling information should provide clear and consistent summary information about what was done to address the safety and effectiveness of the iSYS-1 device.**

    We have added the required information. Please refer to Section 017, pages 8 to 48 and issue 13 above.

<u>Labeling</u>

15. **In your proposed User's Manual (page 11 of 116), you provide a description of the iSYS 1 system that states,**

    "*The iSYS 1 Interventional Platform is a modular needle guidance platform for interventional radiology and related fields*"

    Additionally, you state in your included marketing material (beginning on page 113 of 116) that,

    "*iSYS 1 is the most advanced needle guidance platform for interventional radiology*"

    However, as discussed in Deficiency #1 above, the predicate devices are directed towards neurosurgical uses. Therefore, please remove or revise these documents to be consistent with your Indications for Use statement.

    The predicate device has been changed to PinPoint. Please see issue #1.

16. **In the marketing material (proposed labeling section beginning on page 113 of 116), there are statements that claim or imply superiority over existing devices and are unsubstantiated by the submission. Please remove the following claims from the promotional material or provide data to support them:**
    - **Reduced radiation exposure**
    - **Less risk and stress during interventions**
    - **Higher precision**
    - **Fewer side effects**
    - **Faster recovery**
    - **Better clinical outcomes**

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

- **Higher safety standards**
- **Higher patient throughput**
- **Better cost-benefit ratio**
- **Safer work environment**
- **iSYS 1 is the most advanced needle guidance platform for interventional radiology**
- **Safer for the physician and the patient**
- **Best safety standards**
- **Intuitive and fast use**
- **Maximum mechanical stability/compatibility**

We have added the definition of marketing information including the analysis of marketing phrases to Section 013 of our submission (pages 120 to 126). The analysis contains the required data that supports our statements.

Software

17. **You state that the Level of Concern for the software which controls your device is MINOR. However, your listed predicate devices have software Level of Concern of MODERATE. Further, since prior to the mitigation of hazards, failure of the software could result in injury to the patient we believe the software Level of Concern should be MODERATE. Therefore, please revise your Level of Concern to MODERATE and provide the additional required software documentation for software with a MODERATE Level of Concern. The required documentation may be found in "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices," listed above.**

    As agreed on in the Telko with Dr. Jordan, we have changed the level of concern to "moderate" and added the comment on remaining software anomalies. Please refer to Section 016, pages 2 and 3.
    The development environment can be found on page 5 in Section 016.

Literature

18. **You include a dissertation by Dr. Werner Jaschke in your submission. However, the document is in German and you do not provide an English translation. Therefore, please provide an English translation of the document if you wish for the information to be used to support your claims of substantial equivalence to a legally marketed predicate device. Please also include your summary of the information in the article and a discussion of how that information supports the substantial equivalence of your device to its predicate.**

    The dissertation is not used for proofing substantially equivalency, or to validate any performance criteria.

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

19. **You include various literature articles in your submission. However, you do not provide a discussion of how each article is applicable to support the substantial equivalence of your device to a legally marketed predicate device. Therefore, for each article, please summarize the article and provide a discussion of how the article supports the substantial equivalence of your device to its predicate.**

    The literature articles are not used for proofing substantially equivalency, or to validate any performance criteria.

Administrative

20. **In your proposed 510(k) Summary, you do not provide an IFU statement. Instead, you provide an "Intended Use." Please revise your 510(k) Summary to provide your Indications for Use statement. Please also ensure that your IFU statement is consistent throughout all documents in your submission (e.g., Indications for Use, 510(k) Summary, Labeling and User Manual, etc.)**

    We have added the Indications for Use in Section 005, page 2.

(b)(4)

[redacted]

In case of any questions concerning this application, please contact either Dr. Michael Vogele, CEO at +43 (0) 664 2411140 (michael.vogele@isys.co.at) or Oliver Spitz (Regulatory Consultant) at +49 (0) 173 5904978 (oliver.spitz@isys.co.at).

The eCopy is an exact duplicate of the paper copy.

Sincerely,

Dr. Michael Vogele

CEO

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Indications for Use Statement

510(k) Number (if known): K131433

Device Name: **iSYS 1 (U.S.)**

Intended Use: The intended use of the iSYS1 device is to function as a remote-operated positioning and guidance system during interventional procedures. Positioning is done in remote control manner; planning of the position/angulation is done based on 2D/3D patient data (CT, cone-beam CT, fluoroscopy) by external planning software – for example using an external navigation system, or planning software coming with the used imaging device. Also verification of the correct position and orientation of the tool prior to/during/after the intervention is done by means of these external devices. The iSYS1-System is then acting as a guideway during the manual insertion of the interventional tool – usually a needle type device, and the like

Indicated User: Physician

Indicated Environment: Operating room

Indicated Surgical Procedures: Applications include, but are not limited to, interventions like biopsy procedures, tumor ablation, nerve blocking, electrode placement, etc.

Indications for Use The iSYS 1 device is a user-controlled electromechanical arm with a needle guide. It is intended to assist the surgeon in the positioning of a needle or electrode where both computed tomography (CT) and fluoroscopic imaging can be used for target trajectory planning and intraoperative tracking. The needle or electrode is then manually advanced by the surgeon. Trajectory planning is made with software that is not part of the iSYS device

Indicated parts of the body: Total body

Prescription Use _YES___ AND/OR Over-The-Counter Use ___NO__
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE 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 2015-10247; Released by CDRH on 07/08/2016

510(k) SUMMARY

1.	Applicant:	iSYS Medizintechnik GmbH
2.	Address:	Bergwerksweg 21 6370 Kitzbühel / Austria
3.	Contact Person:	Dr. Michael Vogele Tel. +43 (0) 664 2411140
4.	Preparation Date:	January 20, 2014
5.	Device Submitted:	iSYS 1 (U.S.)
6.	Proprietary Name:	iSYS 1 (U.S.)
7.	Common Name:	Robotic Positioning Unit
8.	Classification Name:	System, X-ray, Tomography, computed Product Code JAK, HAW, Reg.No. 892.1750
9.	Substantial Equivalence:	The iSYS 1 is substantially equivalent to the following legally marketed devices: PinPoint manufactured by Philips Medical. The characteristics of this device are similar to those of the predicate devices identified on the comparison chart, which follows. It is our opinion that the iSYS 1 does not have technological characteristics that raise additional types of questions related to terms of safety and effectiveness.
10.	Device Description:	The iSYS 1 is a modular needle guidance platform for interventional radiology and related fields. Core components are a 4 DOF micro positioning unit which allows the submillimetric needle positioning from simple needle angulations up to positioning and angulations with adjustable pivot point and a control unit which is directed by a cable connected control panel. The passive macro positioning unit and different table adapters allow different setups of the system around the patient in the region of interest. The needle-guide-kit (b)(4) [redacted] rovides disposable components that ensure precise and sterile needle guidance. Planning of the tool position/orientation as well as validation of the correctness of the tool position must be performed with an external planning and measurement system which is not part of the iSYS-1 Interventional Platform. The position of iSYS 1 is visible for most imaging systems due to the used markers. During treatment the tool is controlled by the

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

user.

11. Intended Use:

The intended use of the iSYS1 device is to function as a remote-operated positioning and guidance system during interventional procedures. Positioning is done in remote control manner; planning of the position/angulation is done based on 2D/3D patient data (CT, cone-beam CT, fluoroscopy) by external planning software – for example using an external navigation system, or planning software coming with the used imaging device. Also verification of the correct position and orientation of the tool prior to/during/after the intervention is done by means of these external devices. The iSYS1-System is then acting as a guideway during the manual insertion of the interventional tool – usually a needle type device, and the like. Applications include, but are not limited to, interventions like biopsy procedures, tumor ablation, nerve blocking, electrode placement, etc.

12. Indications for Use

The iSYS 1 device is a user-controlled electromechanical arm with a needle guide. It is intended to assist the surgeon in the positioning of a needle or electrode where both computed tomography (CT) and fluoroscopic imaging can be used for target trajectory planning and intraoperative tracking. The needle or electrode is then manually advanced by the surgeon. Trajectory planning is made with software that is not part of the iSYS device

13. Clinical Use

The Side Rail Adapter is attached to the side rail for the setup; the Table Top Adapter is attached directly onto the CT table. Both Adapters are equipped with a “starburst” connector, to which the Multifunctional Arm can be attached. The MFA is equipped with one “starburst” connector at the bottom and one “spoon” connector at the top. The “spoon” connector has its counterpart on the Robotic Positioning Unit for the setup. The Control Unit is attached directly to the side rail. The Robotic Positioning Unit is connected by a cable to the Control Unit, which has cable connections to both the electric power supply and to a Handheld Control Unit. The Needle Guide Extensions are screw-fixed onto the Robotic Positioning Modules. The Sterile Cover is directly fixed onto the Needle Guide Joints and can be drawn over the robotic parts. The Needle Insert is placed into the appropriate connector of the Needle Guide, to prepare needle usage. The Handheld Control Unit can be clamped onto the side rail and covered with a drape. Planning of the tool position/orientation as well as validation of the

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

correctness of the tool position must be performed with an external planning and measurement system (imaging or navigation software).

14. Biocompatibility: The iSYS 1 is not in contact with patient. At any time when in use a sterile cover sheet is to be placed between the patient and the system. Additionally there are no new materials introduced in the manufacture of the iSYS 1. Therefore, no biocompatibility studies were performed for this device.

15. Performance Data: Operating temperature/humidity range: 15 to 30°C; 30 to 70% relative humidity with no condensation

Storage temperature/humidity range: 10 to 50°C; 30 to 70% relative humidity with no condensation

Power Supply: 50W; 115VAC/230VAC; 50-60Hz; cable: C14 according to IEC/EN 60320-1, US498, CSA C22.2 no. 42;

Sterilization of the sterile accessories has been validated by (b)(4) [redacted], the companies responsible for packaging and sterilizing the iSYS accessories.

The accuracy of the intervention depends on the resolution and capabilities of the imaging device or software. The mechanical accuracy of iSYS1 is below 1 mm, but that gives no accuracy value for treatments.

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Device Comparison Summary:

Reference	PinPoint	iSYS 1 (for new submission)	Equivalence ?
510k-Number	K974513	K131433	
Manufacturer	PHILIPS MEDICAL SYSTEMS (CLEVELAND), INC. 595 Miner rd. Cleveland, OH 44143 USA	iSYS Medizintechnik GmbH Bergwerksweg 21 A-6370 Kitzbuehel Austria	
Design			
General device description	Five jointed, position-sensing stereotactic arm, mounted on the CT gantry, and indicated for invasive procedures	Computer controlled electromechanical multi-joined arm indicated for invasive procedures	Yes
Localization means	Robot arm absolute encoders	Fiducial markers on tool holder.	*3)
Image-guided	Yes	Yes	Yes
Planning software	No, not cleared under this 510k (K955268)	No (third party)	Yes
Registration method	During installation	Fiducial markers	*4)
Instrumentation	Cannula Laser needle guide	Marker Tool Holder Sterile Covers (third party)	Yes
Instrument fixation	Cannula attached to the arm (optional: laser needle guidance)	Special tool holders for several applications mounted to the Robot	Yes
Instrument calibration	Factory Calibration Optional: intra operative	Intra operative	*1)
System immobilization between patient and device	Yes	Yes	Yes
Planning and Navigation Software			
N/A.			
System Operation			
Fiducial markers registration with	No	No	Yes

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Reference	PinPoint	iSYS 1 (for new submission)	Equivalence ?
pointer probe			
Optical registration	No	No	Yes
Ultrasound Registration	No	No	Yes
Accuracy verification	Yes, external anatomical verification	Yes, performed by user	Yes
Provide mechanical guidance for tools	Yes	Yes	Yes
Instrument guide position adjustment	Manual	Manual	Yes
Physician carries out final gesture through tool guide	Yes	Yes	Yes
Indications for Use			
Indication for use	The PinPoint is an accessory to a CT system intended to provide the radiologist with a means of simulating and initiating interventional procedures by interactively relating the patient´s CT image volume to the actual target field. This accessory includes mounting the stereotactic arm on a CT-Gantry, a flat panel TV monitor, cabling, biopsy phantom and software. In addition the CT is intended to produce cross-sectional images of the body by computer reconstruction of X-ray transmission data from	The iSYS 1 device is a user-controlled electromechanical arm with a needle guide. It is intended to assist the surgeon in the positioning of a needle or electrode where both computed tomography (CT) and fluoroscopic imaging can be used for target trajectory planning and intraoperative tracking. The needle or electrode is then manually advanced by the surgeon. Trajectory planning is made with software that is not part of the iSYS device.	Yes

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Reference	PinPoint	iSYS 1 (for new submission)	Equivalence ?
	the same axial plane taken at different angels. This device may include signal analysis and display equipment, patient and equipment supports, components and accessories. PinPoint is not limited to any particular region of the body. It is equally viable for planning head and spine interventions as it is in the abdomen. It is expected that its major use will be in the planning of biopsies of abdominal organs and drainage of fluid collections in the abdomen. However, more complicated procedures such as Brachy therapy and bone pinnings will be planned using the PinPoint.		
Intended Use	The PinPoint is an accessory to a CT system intended to provide the radiologist with a means of simulating and initiating interventional procedures by interactively relating the patient´s CT image volume to the actual target field. The system produces cross sectional images by computer reconstruction of x-ray transmission data from the same axial plane taken at different angles. A stereotactic arm on a	The intended use of the iSYS1 device is to function as a remote-operated positioning and guidance system during interventional procedures. Positioning is done in remote control manner; planning of the position/angulation is done based on 2D/3D patient data (CT, cone-beam CT, fluoroscopy) by external planning software – for example using an external navigation system, or planning software coming with the used imaging device. Also	Yes

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Reference	PinPoint	iSYS 1 (for new submission)	Equivalence ?
	CT Gantry, a flat panel TV monitor, and biopsy phantom are used as accessories to produce these images. The primary intend of the system is to provide guidance for biopsies in the abdomen, spine and head.	verification of the correct position and orientation of the tool prior to/during/after the intervention is done by means of these external devices. The iSYS1-System is then acting as a guideway during the manual insertion of the interventional tool – usually a needle type device, and the like. Applications include, but are not limited to, interventions like biopsy procedures, tumor ablation, nerve blocking, electrode placement, etc.	
Anatomical site	Total Body	Total body	Yes
User	Radiologist	Physician	*2)
Accessory	V-Channel Cannula Cylindrical Cannula	Sterile Covers Table Adapters Cable Sets	Yes
Real-time instrument position	Yes	Yes	Yes
Mechanical Guidance of instruments	Yes	Yes	Yes
Technology			
Powered	Yes	Yes	Yes
CE-Conformity	No	Yes	Yes
Computer-controlled	Yes	Yes	Yes
Materials	Metal, electronics and plastics	Metal, electronics Polyamide Polyethylene Bralen	Yes

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Similarities and Differences:

All three devices are intraoperative instruments used by physician for assisting the spatial positioning and orientation of a surgical tool.

iSYS 1 is equivalent to:

- PinPoint for assisting the spatial positioning and orientation of a surgical tool.
- PinPoint for being localized by the navigation or imaging software.
- PinPoint for being guided by an imaging device
- PinPoint for providing a registration method for the imaging device.
- PinPoint for instrumentation and instrument fixation.
- PinPoint for being immobilized in relation to the patient.
- PinPoint for providing accuracy verification, tool guidance and position adjustment.
- PinPoint for the physician making the final gesture.
- PinPoint for having the same indications for use and region of interest.

Non-clinical testing has mainly been performed to prove electrical and mechanical safety of the devices. Similar to the predicate devices, iSYS 1 was tested according to EN ISO 60601-1 2nd edition:

- EN 60601-1:1990 + A1:1993 + A2:1995
- EN 60601-1-8:2004 + A1:2006

The Electromagnetic Compatibility of the iSYS1 System has been tested according to FCC Part15 (Edition 1st October 2010) and ISO 60601-1-2:2007 and meets the acceptance criteria of both.

Performance tests have been performed to prove:

- the accuracy of the needle placement under clinical conditions,
- the compatibility with the imaging modality,
- the tendency to produce artifacts,
- the mechanical stability of the system despite external payload under worst conditions
- the mechanical stability of the table adapters despite external payload,
- the accuracy in remote-control mode
- the accuracy of needle guidance
- functionality of hardware modules
- effectiveness of hardware safety measures for the software,
- and the effectiveness of the alarm systems

The results of these performance tests support that the predicate devices and iSYS 1 are substantially equivalent.

Differences:

*1) PinPoint provides a factory instrument calibration of the encoders. During intervention the physician using iSYS1 and PinPoint verifies the position of the needle or needle-type instrument (tool). Verification of the tool position requires greater physical effort but provides for exact (depending on the imaging system) tool localization. The localization of the tool is not required for the iSYS 1 and, thus, this has no effect on safety or effectiveness.

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

*2) While the PinPoint is indicated to be used by radiologists only, the iSYS 1 is indicated to be used by any trained physician. This has no effects on safety and effectiveness.

*3) PinPoint provides encoders for localization, whereas iSYS uses fudicial markers on the tool. Using fiducial markers provides better localization safety.

*4) While the Pinpoint is registered during installation, the iSYS 1 uses fiducial markers for registration. Again, using fiducial markers provides better localization safety.

Statement of safety and effectiveness:

It is our opinion that the iSYS 1 System (U.S.) does not have technological characteristics that raise additional types of safety or effectiveness questions, and we consider them to be an enhancement to the existing devices.

To validate the accuracy of the iSYS 1 an external reference system has to be used. We have used and validated the accuracy of the iSYS 1 System (U.S.) with the Philips Allura Xper Guide FD 20 X-ray system and the Axiom Artis Zeego from Siemens Healthcare, and passed all tests.

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Substantial Equivalence Discussion

Device Comparison Table:

Reference	PinPoint	iSYS 1 (for new submission)	Equivalence?
510k-Number	K974513	K131433	
Manufacturer	PHILIPS MEDICAL SYSTEMS (CLEVELAND), INC. 595 Miner rd. Cleveland, OH 44143 USA	iSYS Medizintechnik GmbH Bergwerksweg 21 A-6370 Kitzbuehel Austria	
Design			
General device description	Five jointed, position-sensing stereotactic arm, mounted on the CT gantry, and indicated for invasive procedures	Computer controlled electromechanical multi-joined arm indicated for invasive procedures	Yes
Localization means	Robot arm absolute encoders	Fiducial markers on tool holder.	*3)
Image-guided	Yes	Yes	Yes
Planning software	No, not cleared under this 510k (K955268)	No (third party)	Yes
Registration method	During installation	Fiducial markers	*4)
Instrumentation	Cannula Laser needle guide	Marker Tool Holder Sterile Covers (third party)	Yes
Instrument fixation	Cannula attached to the arm (optional: laser needle guidance)	Special tool holders for several applications mounted to the Robot	Yes
Instrument calibration	Factory Calibration Optional: intra operative	Intra operative	*1)

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Reference	PinPoint	iSYS 1 (for new submission)	Equivalence?
System immobilization between patient and device	Yes	Yes	Yes
Planning and Navigation Software			
N/A.			
System Operation			
Fiducial markers registration with pointer probe	No	No	Yes
Optical registration	No	No	Yes
Ultrasound Registration	No	No	Yes
Accuracy verification	Yes, external anatomical verification	Yes, performed by user	Yes
Provide mechanical guidance for tools	Yes	Yes	Yes
Instrument guide position adjustment	Manual	Manual	Yes
Physician carries out final gesture through tool guide	Yes	Yes	Yes
Indications for Use			
Indication for use	The PinPoint is an accessory to a CT system intended to provide the radiologist with a means of simulating and initiating interventional procedures by interactively relating the patient´s CT image volume to the actual target field. This accessory includes mounting the	The iSYS 1 device is a user-controlled electromechanical arm with a needle guide. It is intended to assist the surgeon in the positioning of a needle or electrode where both computed tomography (CT) and fluoroscopic imaging can be used for target trajectory planning and	Yes

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Reference	PinPoint	iSYS 1 (for new submission)	Equivalence?
	stereotactic arm on a CT-Gantry, a flat panel TV monitor, cabling, biopsy phantom and software. In addition the CT is intended to produce cross-sectional images of the body by computer reconstruction of X-ray transmission data from the same axial plane taken at different angels. This device may include signal analysis and display equipment, patient and equipment supports, components and accessories. PinPoint is not limited to any particular region of the body. It is equally viable for planning head and spine interventions as it is in the abdomen. It is expected that its major use will be in the planning of biopsies of abdominal organs and drainage of fluid collections in the abdomen. However, more complicated procedures such as Brachy therapy and bone pinnings will be planned using the PinPoint.	intraoperative tracking. The needle or electrode is then manually advanced by the surgeon. Trajectory planning is made with software that is not part of the iSYS device.	
Intended Use	The PinPoint is an accessory to a CT system intended to provide the radiologist with a means of simulating and initiating interventional procedures by interactively relating the patient´s CT image volume to the actual target field. The system produces cross sectional images by computer reconstruction of x-	The intended use of the iSYS1 device is to function as a remote-operated positioning and guidance system during interventional procedures. Positioning is done in remote control manner; planning of the position/angulation is done based on 2D/3D patient data (CT, cone-beam CT, fluoroscopy) by external planning	

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Reference	PinPoint	iSYS 1 (for new submission)	Equivalence?
	ray transmission data from the same axial plane taken at different angles. A stereotactic arm on a CT Gantry, a flat panel TV monitor, and biopsy phantom are used as accessories to produce these images. The primary intend of the system is to provide guidance for biopsies in the abdomen, spine and head.	software – for example using an external navigation system, or planning software coming with the used imaging device. Also verification of the correct position and orientation of the tool prior to/during/after the intervention is done by means of these external devices. The iSYS1-System is then acting as a guideway during the manual insertion of the interventional tool – usually a needle type device, and the like. Applications include, but are not limited to, interventions like biopsy procedures, tumor ablation, nerve blocking, electrode placement, etc.	
Anatomical site	Total Body	Total body	Yes
User	Radiologist	Physician	*2)
Accessory	V-Channel Cannula Cylindrical Cannula	Sterile Covers Table Adapters Cable Sets	Yes
Real-time instrument position	Yes	Yes	Yes
Mechanical Guidance of instruments	Yes	Yes	Yes
Technology			
Powered	Yes	Yes	Yes
CE-Conformity	No	Yes	Yes

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Reference	PinPoint	iSYS 1 (for new submission)	Equivalence?
Computer-controlled	Yes	Yes	Yes
Materials	Metal, electronics and plastics	Metal, electronics Polyamide Polyethylene Bralen	Yes

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Similarities and Differences:

All three devices are intraoperative instruments used by physician for assisting the spatial positioning and orientation of a surgical tool.

iSYS 1 is equivalent to:

- PinPoint for assisting the spatial positioning and orientation of a surgical tool.
- PinPoint for being localized by the navigation or imaging software.
- PinPoint for being guided by an imaging device
- PinPoint for providing a registration method for the imaging device.
- PinPoint for instrumentation and instrument fixation.
- PinPoint for being immobilized in relation to the patient.
- PinPoint for providing accuracy verification, tool guidance and position adjustment.
- PinPoint for the physician making the final gesture.
- PinPoint for having the same indications for use and region of interest.

Non-clinical testing has mainly been performed to prove electrical and mechanical safety of the devices. Similar to the predicate devices, iSYS 1 was tested according to EN ISO 60601-1 2nd edition:

- EN 60601-1:1990 + A1:1993 + A2:1995
- EN 60601-1-8:2004 + A1:2006

The Electromagnetic Compatibility of the iSYS1 System has been tested according to FCC Part15 (Edition 1st October 2010) and ISO 60601-1-2:2007 and meets the acceptance criteria of both.

Performance tests have been performed to prove:

- the accuracy of the needle placement under clinical conditions,
- the compatibility with the imaging modality,
- the tendency to produce artifacts,
- the mechanical stability of the system despite external payload under worst conditions
- the mechanical stability of the table adapters despite external payload,
- the accuracy in remote-control mode
- the accuracy of needle guidance
- functionality of hardware modules
- effectiveness of hardware safety measures for the software,
- and the effectiveness of the alarm systems

The results of these performance tests support that the predicate devices and iSYS 1 are substantially equivalent.

Differences:

*1) PinPoint provides a factory instrument calibration of the encoders. During intervention the physician using iSYS1 and PinPoint verifies the position of the needle or needle-type instrument (tool). Verification of the tool position requires greater physical effort but provides for exact (depending on the imaging system) tool localization. The localization of the tool is not required for the iSYS 1 and, thus, this has no effect on safety or effectiveness.

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

*2) While the PinPoint is indicated to be used by radiologists only, the iSYS 1 is indicated to be used by any trained physician. This has no effects on safety and effectiveness.

*3) PinPoint provides encoders for localization, whereas iSYS uses fudicial markers on the tool. Using fiducial markers provides better localization safety.

*4) While the Pinpoint is registered during installation, the iSYS 1 uses fiducial markers for registration. Again, using fiducial markers provides better localization safety.

Statement of safety and effectiveness:

It is our opinion that the iSYS 1 System (U.S.) does not have technological characteristics that raise additional types of safety or effectiveness questions, and we consider them to be an enhancement to the existing devices.

To validate the accuracy of the iSYS 1 an external reference system has to be used. We have used and validated the accuracy of the iSYS 1 System (U.S.) with the Philips Allura Xper Guide FD 20 X-ray system and the Axiom Artis Zeego from Siemens Healthcare, and passed all tests.

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Proposed Labeling

Content | Page

Product and Packaging Labels	2
User Manual	7
Marketing Material	120
Form FDA 3654	133

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Product and Packaging Labels

Safety Symbols:

STERILE R	Symbol for STERILIZED USING RADIATION
	Symbol for DO NOT USE IF PACKAGE IS DAMAGED
	Symbol for DO NOT REUSE
MR	Symbol for NOT MRI SAFE
	Symbol for ALTERNATING CURRENT
	Symbol for CAUTION, CONSULT ACCOMPANYING DOCUMENTS
	Symbol for TYBE B APPLIED PART
	Symbol for ON/OFF SWITCH (PUSH-PUSH)
	Symbol for PROTECTIVE EARTH
	Symbol for STORAGE TEMPERATURE
	Symbol for DO NOT LITTER IN DOMESTIC WASTE

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Product identification Symbols:

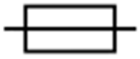
SN	Symbol for SERIAL NUMBER
REF	Symbol for ORDER NUMBER
LOT	Symbol for BATCH NUMBER

Additional Symbols:

CE	Symbol for CE-conformity
+	Symbol for PLUS (increase speed level)
–	Symbol for MINUS (decrease speed level)
	Symbol for POSITIONING
	Symbol for ANGULATION
READY	Label for the ready indicator light
ERROR	Label for the error indicator light
POWER	Label for the power indicator light
USER INTERFACE	Label for the user interface connector
C	Symbol for the confirm push button
Q	Symbol for the quit push button

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

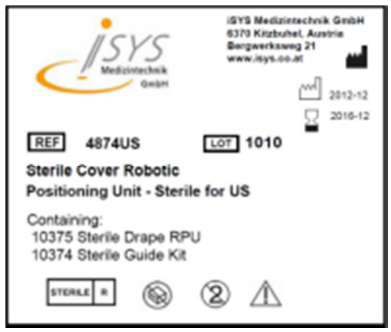
	Symbol for MANUFACTURER
	Symbol for DATE OF MANUFACTURE
	Symbol for USE BY
	Symbol for FUSE
	Symbol for KEEP DRY
	Symbol for THIS SIDE UP
	Label for the Weight
iSYS Medizintechnik GmbH	Company Label

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Examples for Product Labels:

The presented labels are examples for the final product and packaging labels. Lot numbers and dates on these examples are placeholders only. They do not define any format of lot numbers, production or expiry dates.



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

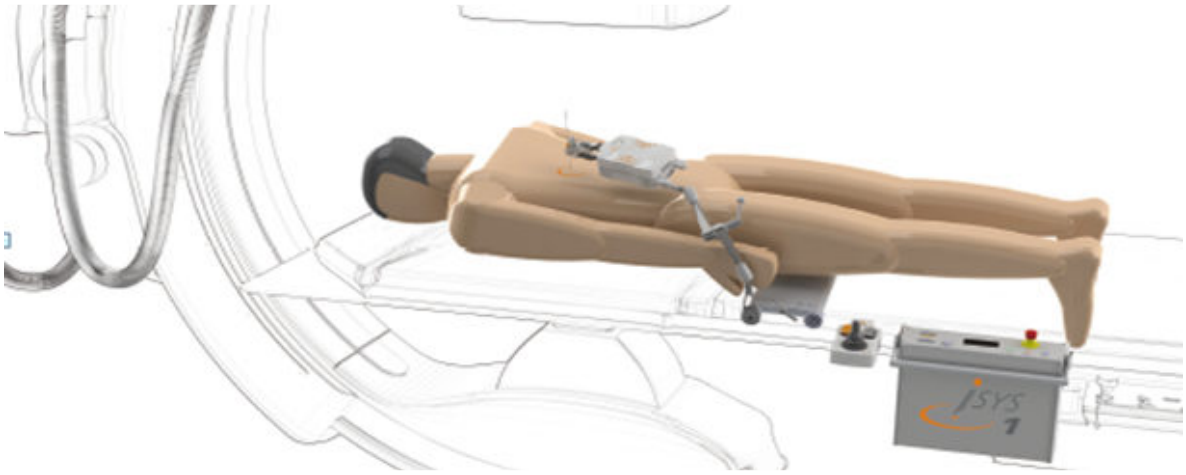
Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

User Manual

USER MANUAL US



iSYS Medizintechnik GmbH
Bergwerksweg 21
6370 Kitzbühel
Austria
www.isys.co.at

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Copyright Statement

© 2011 iSYS Medizintechnik GmbH.

All rights reserved. No part of this document may be reproduced in any form without written permission from the copyright holder.

Use of the information contained herein in any form and/or by any means whatsoever is strictly reserved for iSYS and its licensees.

Trademarks

iSYS, iSYS 1 and iSYS Medizintechnik GmbH or its subsidiaries are subject to filed trademark applications.

All rights reserved.

Acknowledgement of Other Trademarks

Other manufacturer's registered trademarks and trade names that appear in this document are hereby acknowledged.

Referenced Documents

Not all documents referred to in this document are part of the scope of delivery for the equipment.

iSYS reserves the right to determine which documents are delivered with a product.

Contact Information

Manufacturer

iSYS Medizintechnik GmbH

Bergwerksweg 21

6370 Kitzbühel

Österreich

Tel +43 (664) 2411140

www.isys.co.at

Representative USA

Cornelia Damsky

56 Westcott Road
Stamford, CT 06902
USA
Phone: +1 (203) 323- 7535
Email: cdamsky@att.net

CE 0408

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

PD/B16	iSYS 1	iSYS Medizintechnik GmbH
Declaration of Conformity		

Konformitätserklärung / Declaration of Conformity / Declaration de Conformité

Wir,	We,	Nous,
iSYS Medizintechnik GmbH, **Bergwerksweg 21, 6370 Kitzbühel, Austria**		
erklären in alleiniger Verantwortung, dass das Medizinprodukt	declare on our own responsibility that the medical device	déclarons sous notre propre responsabilité que le dispositif médical
iSYS 1 (Art. Nr. 4268) **iSYS 1 (U.S.) (Art. Nr. 6224)** **Seriennummern 003 bis 030 (Revision 1)** **HCU Cable Extension (Art. Nr. 6162)**		
allen Anforderungen der Richtlinie **93/42/EWG** ergänzt durch die Richtlinie **2007/47/EG** entspricht	meets all the provisions of the Directives **93/42/EEC and 2007/47/EC**	remplit toutes les exigences de les directives sur les dispositifs médicaux **93/42/CEE et 2007/47/CE**
Angewandte harmonisierte Normen:	**Applied harmonized standards:**	**Normes harmonisées appliquées:**
OENORM EN 980:2008, EN 1041:2008, OENORM EN 60601-1:2007, OENORM EN 60601-1-2+A1:2006, OENORM EN 60601-1-6:2008, OENORM EN 60601-1-8:2008		
Klassifizierung basiert auf den Anforderungen der **Regel**	**Classification** is based on the requirements of **Rule**	**Classification** La classification est fondée sur les exigences de la **Règle**
12		
des **Anhang IX** der Richtlinie über Medizinprodukte	of **annex IX** of the Medical Device Directive	de **l'annexe IX** de la directive sur les dispositifs médicaux
Medizinprodukt der **Klasse**	Medical device **Class**	les dispositifs médicaux **Classe**
I		
Konformitätsbewertungsverfahren gemäß der Richtlinie 93/42 EWG, **Anhang**	**Conformity assessment procedure** according to Directive 93/42 EEC, **Annex**	**Procédure d'évaluation de la conformité** en application de la directive 93/42/CEE **Appendice**
VII		
Benannte Stelle (falls zutreffend)	**Notified body** (if applicable)	**Organisme notifié** (le cas échéant)
TÜV Austria Services GmbH (CE 0408)		
Diese Konformitätserklärung gilt für obige Serien-/ Lotnummern ab dem Produktionsdatum	**This declaration of conformity is effective for above Serial/ Lot numbers as of the production date**	**Cette déclaration de conformité est valable pour les numéros de série/ du lot dès la date de production**
29. November 2012		
..... Geschäftsführer		Kitzbühel, 29.11.12

Doc No: PD_73_4825	Revision 04 from: 29.11.2012			1/1
Created by:	Approved by:	Invalid since:	Source:	Approval Date:
Oliver Spitz	Thomas Pfeifer		FO_73_2565	07.06.2011

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

PD/B16	iSYS 1	iSYS Medizintechnik GmbH
Declaration of Conformity		

Konformitätserklärung / Declaration of Conformity / Declaration de Conformité

Wir,	We,	Nous,
iSYS Medizintechnik GmbH, **Bergwerksweg 21, 6370 Kitzbühel, Austria**		
erklären in alleiniger Verantwortung, dass das Medizinprodukt	declare on our own responsibility that the medical device	déclarons sous notre propre responsabilité que le dispositif médical
Zubehör iSYS 1 **Side Rail Adapter (Art.Nr. 4095)** **Multi Functional Arm (Art. Nr. 4271)** **Table Top Adapter Version A (Art.Nr. 4117)** **Table Top Adapter Version B (Art.Nr. 4120)**		
allen Anforderungen der Richtlinie **93/42/EWG** ergänzt durch die Richtlinie **2007/47/EG** entspricht	meets all the provisions of the Directives **93/42/EEC and 2007/47/EC**	remplit toutes les exigences de les directives sur les dispositifs médicaux **93/42/CEE et 2007/47/CE**
Angewandte harmonisierte Normen:	**Applied harmonized standards:**	**Normes harmonisées appliquées:**
OENORM EN 980:2008, EN 1041:2008, OENORM EN 60601-1:2007, OENORM EN 60601-1-2+A1:2006, OENORM EN 60601-1-6:2008, OENORM EN 60601-1-8:2008		
Klassifizierung basiert auf den Anforderungen der **Regel**	**Classification** is based on the requirements of **Rule**	**Classification** La classification est fondée sur les exigences de la **Règle**
1		
des **Anhang IX** der Richtlinie über Medizinprodukte	of **annex IX** of the Medical Device Directive	de **l'annexe IX** de la directive sur les dispositifs médicaux
Medizinprodukt der **Klasse**	Medical device **Class**	les dispositifs médicaux **Classe**
I		
Konformitätsbewertungsverfahren gemäß der Richtlinie 93/42 EWG, **Anhang**	**Conformity assessment procedure** according to Directive 93/42 EEC, **Annex**	**Procédure d'évaluation de la conformité** en application de la directive 93/42/CEE **Appendice**
VII		
Benannte Stelle (falls zutreffend)	**Notified body** (if applicable)	**Organisme notifié** (le cas échéant)
TÜV Austria Services GmbH (CE 0408)		
Diese Konformitätserklärung gilt für obige Serien-/ Lotnummern ab dem Produktionsdatum	**This declaration of conformity is effective for above Serial/ Lot numbers as of the production date**	**Cette déclaration de conformité est valable pour les numéros de série/ du lot dès la date de production**
29. November 2012		
Geschäftsführer	Kitzbühel, 29.11.12	

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

PD/B16	Accessory, sterile	iSYS Medizintechnik GmbH
Declaration of Conformity		

Konformitätserklärung / Declaration of Conformity / Declaration de Conformité

Wir,	We,	Nous,
iSYS Medizintechnik GmbH, Bergwerksweg 21, 6370 Kitzbühel, Austria		
erklären in alleiniger Verantwortung, dass die Medizinprodukte	declare on our own responsibility that the medical devices	déclarons sous notre propre responsabilité que les dispositifs médicaux
6289G10US Needle Guide Insert 10G – sterile for US **5990G11US Needle Guide Insert 11G – sterile for US** **5991G12US Needle Guide Insert 12G – sterile for US** **5992G13US Needle Guide Insert 13G – sterile for US** **5993G14US Needle Guide Insert 14G – sterile for US** **4877G15US Needle Guide Insert 15G – sterile for US** **4878G16US Needle Guide Insert 16G – sterile for US** **4879G17US Needle Guide Insert 17G – sterile for US** **4880G18US Needle Guide Insert 18G – sterile for US** **5989G19US Needle Guide Insert 19G – sterile for US** **4881G20US Needle Guide Insert 20G – sterile for US** **4882G21US Needle Guide Insert 21G – sterile for US** **4875US Needle Guide Marker Insert – sterile for US** **4876US Needle Guide Marker Insert centered – sterile for US** **4874US Sterile Cover Robotic Positioning Unit – sterile for US** **4883US Sterile Cover Handheld Control Unit – sterile for US**		
allen Anforderungen der Richtlinie **93/42/EWG** ergänzt durch die Richtlinie **2007/47/EG** entspricht	meets all the provisions of the Directives **93/42/EEC and 2007/47/EC**	remplit toutes les exigences de les directives sur les dispositifs médicaux **93/42/CEE et 2007/47/CE**
Angewandte harmonisierte Normen:	**Applied harmonized standards:**	**Normes harmonisées appliquées:**
OENORM EN 980:2008, DIN EN 1041:2008, ÖNORM EN ISO 11607-1:2007, ÖNORM EN ISO 11607-2:2006		
Klassifizierung basiert auf den Anforderungen der **Regel**	**Classification** is based on the requirements of **Rule**	**Classification** La classification est fondée sur les exigences de la **Règle**
1		
des **Anhang IX** der Richtlinie über Medizinprodukte	of **annex IX** of the Medical Device Directive	de **l'annexe IX** de la directive sur les dispositifs médicaux
Medizinprodukte der **Klasse**	Medical devices **Class**	les dispositifs médicaux **Classe**
Is		
Konformitätsbewertungsverfahren gemäß der Richtlinie 93/42 EWG, **Anhang**	**Conformity assessment procedure** according to Directive 93/42 EEC, **Annex**	**Procédure d'évaluation de la conformité** en application de la directive 93/42/CEE **Appendice**
II		
Benannte Stelle (falls zutreffend)	**Notified body** (if applicable)	**Organisme notifié** (le cas échéant)
TÜV Austria Services GmbH (CE 0408)		
Diese Konformitätserklärung gilt für alle Serien-/ Lotnummern ab dem Produktionsdatum	**This declaration of conformity is effective of all Serial/ Lot numbers as of the production date**	**Cette déclaration de conformité est valable pour toutes les numéros de série/ du lot dès la date de production**
12. Dezember 2012		
Geschäftsführer	Kitzbühel, 29.11.12	

Doc No: PD_73_09597	Revision 01 from: 29.11.2012			1/1
Created by:	Approved by:	Invalid since:	Source:	Approval Date:
Oliver Spitz	Thomas Pfeifer		FO_73_2565	07.06.2011

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

CE-SetDescription	iSYS Medizintechnik GmbH

iSYS Medizintechnik GmbH
Bergwerksweg 21
6370 Kitzbühel
Austria
Tel. +43 (0) 664 / 2411140
Fax. +49 (0) 8232 / 969222
www.isys.co.at

EC Declaration of Conformity

We iSYS Medizintechnik GmbH declare under sole responsibility that the set to which this declaration relates, as an accessory to the **iSYS 1**, meets the essential health and safety requirements and is in conformance with the EC directives 93/42/EC and 2007/47/EC (MDD).

Set description:

iSYS 1 – class I product

Accessory sterile – class Is product

Accessory non-sterile – class I product

The set is classified as Is according to rules 1 and 12.

iSYS Medizintechnik GmbH meets the requirements of EN ISO 13485:2003 as indicated on certificate registration # TÜV-A-MT-1/11/E148.
The registration has been granted by TÜV Austria Services GmbH, Austria (# 0408).

The CE mark is applied with respect to annex II of the MDD. This CE marking has been affixed on the device according to article 17 of the MDD.

This declaration is effective from: see date of sign off

General Manager

Kitzbühel, 29.11.12
Place / date

Dok-Nr: PD_73_6387	Revision 01 vom: 29.11.2012			Seite 1/1
Erstellt von:	Freigabe durch:	Ungültig ab:	Vorlage dazu:	Vom:
Oliver Spitz	Thomas Pfeifer		FO_42_1928	06.06.2011

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Table of Contents:

1. Introduction 16

1.1. About this Manual 16

1.2. Description of iSYS 1 16

1.3. Intended Use 17

1.4. Abbreviations 18

1.5. Glossary 19

1.6. Text Formats 20

2. Safety 21

2.1. Warnings, Cautions and Notes 21

2.2. Manual Handling Procedures 21

2.3. Warning Labels 22

2.3.1. Safety Symbols 22

2.3.2. Product Identification Symbols 23

2.3.3. Additional Symbols 23

2.4. Final Disposal 25

2.5. EMC and Mobile Telephones 26

2.6. Compatibility 31

2.7. Compliance 31

2.7.1. IEC Safety Standards 31

2.7.2. IEC Classification 31

2.8. Training 32

3. Specifications 34

3.1. Environmental Conditions 34

3.1.1. Environmental Conditions for Transport and Storage 34

3.1.2. Environmental Conditions for the Intended Use 34

3.2. Components 35

3.2.1. System iSYS 1 U.S. (Art.No. 6224) 36

3.2.2. Accessory – non sterile 39

3.2.3. Accessory - sterile: 40

3.3. Technical Specifications 41

3.3.1. Robotic Positioning Unit 41

3.3.2. Control Unit 41

3.3.3. RPU Cable Set 1500 41

3.3.4. RPU Cable Set 3000 41

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

3.3.5. Handheld Control Unit 41
3.3.6. HCU Cable Extension 41
3.3.7. Multi Functional Arm 41
3.3.8. Table Top Adapter Version B 42
3.3.9. Table Top Adapter Version A 42
3.3.10. Side Rail Adapter 42

4. Operating iSYS 1 43

4.1. Set-Up and Installation 44

4.1.1. Mounting of the (Radiolucent) Needle Guide Extension to the Robotic Positioning 45
4.1.2. Adaptation of the Table Adapters 47
4.1.3. Mounting of the Multi Functional Arm (MFA) 53
4.1.4. Mounting the Robotic Positioning Unit 55
4.1.5. Mounting the Control Unit to the Side Rail 56
4.1.6. Using the Control Unit without Side Rail 57
4.1.7. Adaptation of the Handheld Control Unit to the Side Rail 59
4.1.8. Connection of the Power and Data Cables 60
4.1.9. Bringing the RPU into the "Parking position" 64
4.1.10. Start-up Procedure of the iSYS 1 Robot 66

4.2. Use of iSYS 1 69

4.2.1. Checking the Mechanical Setup and the Range of iSYS 1 69
4.2.2. Setup and Preparing the Patient 70
4.2.3. Image Acquisition and Treatment Planning 72
4.2.4. Working with the sterile iSYS 1 Disposables 73
4.2.5. Attaching the Sterile Cover over the Robotic Positioning Unit 78
4.2.6. Attaching the Sterile Cover to the HCU 89
4.2.7. Gross-Positioning of the RPU and Insertion of the Sterile Needle Guide Marker Insert into the Needle Guide Adapter 90
4.2.8. Micro-Positioning and Accurate Alignment of the NGA under fluoroscopy 92
4.2.9. Ultra-fine-Positioning and Accurate Alignment of the Needle under fluoroscopy 96
4.2.10. Attachment of the Needle Guide Insert and Needle Placement 97
4.2.11. Removing the NGI and Quick-Release 102

4.3. Emergency Release/ Removing the system in case of emergency 105

4.4. Dismounting 105

4.5. User Interface 107

4.5.1. Alarms 107
4.5.2. Front-Panel of the Control Unit 108

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

4.5.3. Handheld Control Unit 109
4.5.4. Display Messages 111
5. Maintenance 114
5.1. Safety-relevant inspections 115
6. Cleaning and Disinfection 117

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

1. Introduction

1.1. About this Manual

This manual is intended to assist users in the safe and effective operation of the equipment described. The term 'user' is used throughout this manual for both the body that has the authority over the equipment and those persons, who actually handle the equipment.

a) The term clinical user means a qualified person who uses any part of the device and its accessories for the purpose of treating patients, and who has been specifically trained in the safe clinical use of the device. Such treatment is restricted to being therapeutic in nature.

b) The term service user means a qualified service engineer who has been trained in servicing the device, and who operates any part of the device for the purpose of performing tests, adjustments and/or repairs to the equipment without, in any manner, involving the presence or treatment of a patient, and personnel who are involved in site planning and installation of the device.

Before attempting to work with this equipment, you must read, understand, note and, where applicable, strictly observe all danger notices, warnings, cautions and safety markings on the equipment and in this manual paying particular attention to all:

- Warnings
- Cautions
- Notes

Please pay special attention to all the safety information provided, and safety procedures described (see section 2).

The use of this equipment by unauthorized persons is strictly prohibited.

1.2. Description of iSYS 1

The iSYS 1 Interventional Platform is a modular needle guidance platform for interventional radiology and related fields.

Core components are a 4 DOF Robotic Positioning Unit which allows submillimetric needle positioning as well as angulation and a Control Unit which is controlled by a cable connected Handheld Control Unit.

The passive macro positioning unit and different table adapters allow different setups of the system around the patient in the region of interest by still providing maximum rigidity.

The needle-guide-set provides disposable components that ensure precise and sterile needle guidance.

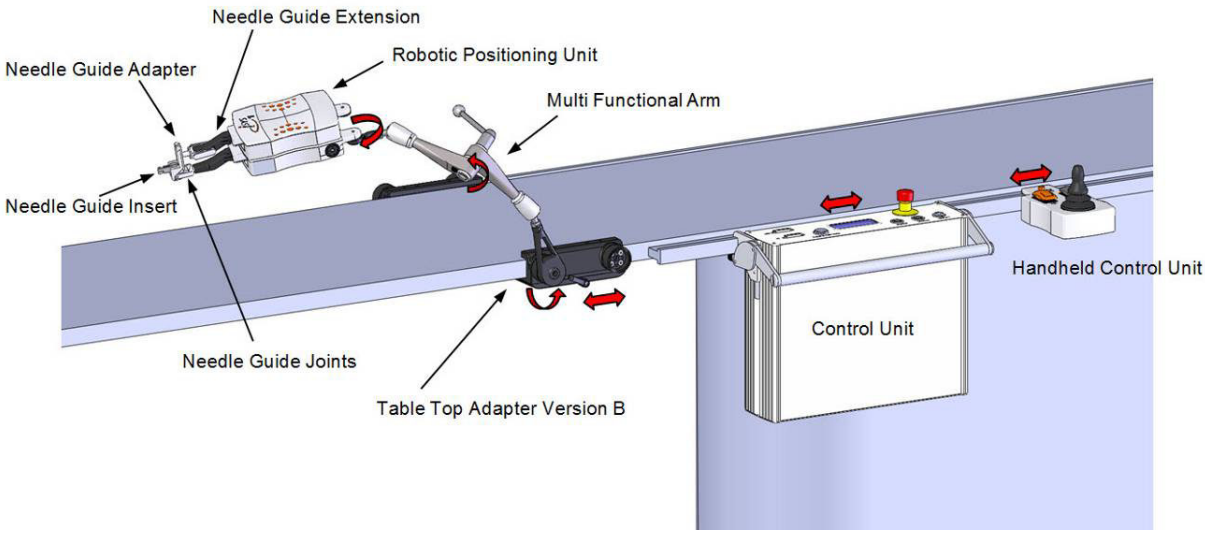
Planning of the intervention is based on digital image data acquired intra-operatively using different kinds of modalities, like CT or fluoroscopy (standard C-arms and/or cone-beam CT systems).

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Planning and verification of both the entry position of the needle-type tool as well as the angulation is performed with the aid of the used imaging device or by an external navigation system.

By using the iSYS 1 Handheld Control Unit the surgeon can remotely move the tool to the desired position and angulation in order to start the clinical procedure.



The system includes the following mechanical parts:

- one Control Unit
- one Table Top Adapter Version B (Bottom Mounted)
- optional: Side Rail Adapter or Table Top Adapter Version A (Top Mounted)
- one Multi Functional Arm
- one Robotic Positioning Unit
- two Needle Guide Extensions

The sterile disposables for each procedure are:

- Sterile Cover Robotic Positioning Unit (not reusable) including Needle Guide Joints and Needle Guide Adapter (not reusable)
- Sterile Cover Handheld Control Unit (not reusable)
- Needle Guide Insert (not reusable)
- Marker Insert (not reusable)

see description in chapter “3.2.4. Accessory – sterile”

1.3. Intended Use

The intended use of the iSYS 1 device is to function as a remote-operated positioning and guidance system during interventional procedures. Positioning is done in remote control manner; planning of the position/angulation is done based on 2D/3D patient data (CT,

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

cone-beam CT, fluoroscopy) by external planning software – for example using an external navigation system, or planning software coming with the used imaging device. Also verification of the correct position and orientation of the tool prior to/during/after the intervention is done by means of these external devices. The iSYS 1 system is then acting as a guideway during the manual insertion of the interventional tool – usually a needle type device, and the like. Applications include, but are not limited to, interventions like biopsy procedures, tumor ablation, nerve blocking, electrode placement, etc.

WARNING
in the USA, Federal law restricts this device to sale by or on the order of a physician.

1.4. Abbreviations

The following are abbreviations and acronyms which are used in this document. Their definition is explained below.

Abbreviation	Definition
AC	Alternating current
ASCII	American Standard Code for Information Interchange
AM	Amplitude modulation
CT	Computed tomography
CU	Control Unit
DOF	Degree of Freedom
EMC	Electromagnetic compatibility
FM	Frequency modulation
HCU	Handheld Control Unit
IEC	International Electrotechnical Commission
iSYS	iSYS Medizintechnik GmbH
LCD	Liquid crystal display
LED	Light emitting diode
MFA	Multi Functional Arm
MRI	Magnet resonance imaging
N/A	Not applicable

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Abbreviation	Definition
NGA	Needle Guide Adapter
NGE	Needle Guide Extension
NGI	Needle Guide Insert
NGMI	Needle Guide Marker Insert centered
OR	Operating room
ÖVE	Österreichischer Verband für Elektrotechnik (*Austrian* Electrotechnical Committee)
RF	Radio frequency
RM	Robotic Module
RPU	Robotic Positioning Unit
SRA	Side Rail Adapter
TTAA	Table Top Adapter Version A - Top Mounted
TTAB	Table Top Adapter Version B - Bottom Mounted
TV	Tele-vision
WxH	Width and height

Table 1-1: Abbreviations and Acronyms

1.5. Glossary

Throughout this manual, the following terms have the specific meaning listed below.

Term	Definition
Imaging device	(Medical) Imaging devices are devices used to create images of the human body (or parts and function thereof) for clinical purposes. Imaging modalities for iSYS 1 include CT or fluoroscopy (standard C-arms and/or cone-beam CT systems).
Gantry	In medical imaging, the Gantry is a circular assembly that allows sensors, and possibly energy sources, to rotate around a patient.
Treatment Table	Also called “Imaging Table” or “Treatment Couch”. Table system of the imaging device. Usually this table has a number of degrees of freedom (DOF) – e.g. for vertical and horizontal movement – in order to preposition the

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Term	Definition
	patient relatively to the imaging arm.
(Carbon fiber) Table Top	Upper part of the Treatment Table. This part of the table usually is made of radiolucent material – in most cases CFRP (carbon-fiber-reinforced plastic).
Side Rail	Most Treatment Tables have a (metal) on the rail left and right side along the table in order to fix components. Depending on the producer of the table these Side Rail setups may differ from each other, for most of the table systems the Side Rail has a rectangular cross section.
Treatment Planning	During Treatment Planning, the surgeon is using pre-operative or intra-operative imaging in order to select the target position for the tool (e.g. the tumor to be treated) as well as the tool trajectory from the skin entry point to the target position. Depending on the used Imaging device such Treatment Planning can be done using 2D or 3D images.

Table 1-2: Glossary

1.6. Text Formats

The following text formats may be found in this document. Their definitions are explained below.

Text Format	Definition
italic	notes
CAPS	symbol names
`courier`	text displayed on screens

Table 1-3: Text Formats

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

2. Safety

2.1. Warnings, Cautions and Notes

The following are examples of how warnings, cautions and notes will appear throughout this document. The text within the examples explains their purpose.

WARNING
Warnings are directions which, if not followed, could constitute a health hazard or cause injury, including fatal or serious injury, or could lead to clinical mistreatment.

CAUTION
Cautions are directions which, if not followed, could cause damage to the equipment described in this manual, and/or any other equipment or goods, and/or could cause environmental damage.

Note: *Notes provide advice and highlight unusual points. A note is not intended as an instruction.*

2.2. Manual Handling Procedures

WARNING
When lifting heavy components, it is important that the correct procedures are adhered to. Local regulations and procedures regarding manual handling must be observed at all times. Failure to do so may lead to fatal or serious personal injury.

WARNING
If any liquids are spilled over components of the iSYS 1, the component needs to be dried in a drying case for at least 24 hours.

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

2.3. Warning Labels

2.3.1. Safety Symbols

STERILE R	Symbol for STERILIZED USING RADIATION
	Symbol for DO NOT USE IF PACKAGE IS DAMAGED
	Symbol for DO NOT REUSE
MR	Symbol for NOT MRI SAFE
	Symbol for ALTERNATING CURRENT
	Symbol for CAUTION, CONSULT ACCOMPANYING DOCUMENTS
	Symbol for TYBE B APPLIED PART
	Symbol for ON/OFF SWITCH (PUSH-PUSH) Power Switch
	Symbol for PROTECTIVE EARTH
	Symbol for STORAGE TEMPERATURE

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

	Symbol for DO NOT LITTER IN DOMESTIC WASTE

2.3.2. Product Identification Symbols

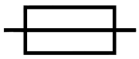
SN	Symbol for SERIAL NUMBER
REF	Symbol for ORDER NUMBER
LOT	Symbol for BATCH NUMBER

2.3.3. Additional Symbols

CE	Symbol for CE-conformity
+	Symbol for PLUS (increase speed level)
–	Symbol for MINUS (decrease speed level)
	Symbol for POSITIONING
	Symbol for ANGULATION
READY	Label for the ready indicator light
ERROR	Label for the error indicator light
POWER	Label for the power indicator light

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

USER INTERFACE	Label for the user interface connector
	Symbol for the confirm push button
	Symbol for the quit push button
	Symbol for MANUFACTURER
	Symbol for DATE OF MANUFACTURE
	Symbol for USE BY
	Symbol for FUSE
	Symbol for KEEP DRY
	Symbol for THIS SIDE UP
	Label for the Weight
iSYS Medizintechnik GmbH	Company Label

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

2.4. Final Disposal

Final disposal means the disposal of the equipment or any part of it in such a way that it can no longer be used for its intended use.

Disposal must always be executed in an environmentally sensitive manner that complies with all local and international regulations and laws. Materials hazardous to human health and the environment must be separately removed and disposed of by competent, licensed facilities. The remaining material may be recycled, where facilities and local regulations permit this.

Never dispose iSYS products in the domestic waste stream.

Prior to disposal, always contact iSYS Medizintechnik GmbH for advice and a list of the substances that require special attention.

WARNING
Incorrect handling or disposal of hazardous material may cause fatal or serious injury and environmental damage. Always disposit iSYS 1 and its components according to the regional regulations.

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

2.5. EMC and Mobile Telephones

The iSYS 1 system is compliant with the requirements according EN 60601-1-2:2007 and FCC: 47 CFR Part 15:

Guidance and manufacturer's declaration – electromagnetic emissions		
iSYS 1 is intended for use in the electromagnetic environment specified below. The customer or the user of iSYS 1 should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions CISPR 11	Group 1	iSYS 1 uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	iSYS 1 is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Not applicable	

Guidance and manufacturer's declaration – electromagnetic immunity			
iSYS 1 is intended for use in the electromagnetic environment specified below. The customer or the user of iSYS 1 should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment –guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines ±2 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV line(s) to line(s)	±1 kV line(s) to line(s)	Mains power quality should be that of a typical commercial or hospital

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

	±2 kV line(s) to earth	±2 kV line(s) to earth	environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % U_T (>95 % dip in U_T) for 0,5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % UT (>95 % dip in U_T) for 5 sec	<5 % U_T (>95 % dip in U_T) for 0,5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % UT (>95 % dip in U_T) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of iSYS 1 requires continued operation during power mains interruptions, it is recommended that the iSYS 1 be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Note U_T is the AC mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration – electromagnetic immunity			
iSYS 1 is intended for use in the electromagnetic environment specified below. The customer or the user of iSYS 1 should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment –guidance**
Conducted RF	3 Vrms 150 kHz to 80	10 Vrms 150 kHz to 80	Portable and mobile RF communications equipment should be used no closer to any part of iSYS 1 including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d = 0{,}35\sqrt{P}$

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

IEC 61000-4-6 Radiated RF IEC 61000-4-3	MHz 3 V/m 80 MHz to 2,5 GHz	MHz 10 V/m 150 kHz to 80 MHz	$d = 0{,}35\sqrt{P}$ MHz 80 MHz to 800 $d = 0{,}70\sqrt{P}$ GHz 800 MHz to 2,5 where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[a], should be less than the compliance level in each frequency range[b]. Interference may occur in the vicinity of equipment marked with the following symbol:
Note 1	At 80 MHz and 800 MHz, the higher frequency range applies.		
Note 2	These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.		

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which iSYS 1 is used exceeds the applicable RF compliance level above, iSYS 1 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating iSYS 1.

[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 10 V/m.

Recommended separation distances between portable and mobile RF

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

communications equipment and iSYS 1

iSYS 1 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of iSYS 1 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and iSYS 1 as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	**Separation distance according to frequency of transmitter** m		
	150 kHz to 80 MHz $d = 0{,}35\sqrt{P}$	**80 MHz to 800 MHz** $d = 0{,}35\sqrt{P}$	**800 MHz to 2,5 GHz** $d = 0{,}70\sqrt{P}$
0,01	0,035	0,035	0,07
0,1	0,11	0,11	0,22
1	0,35	0,35	0,70
10	1,11	1,11	2,21
100	3,50	3,50	7,00

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

Note 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

Note 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

The iSYS 1 system requires special precautions regarding EMC and must be installed and put into service in accordance with the EMC information provided in the accompanying documents.

WARNING
The iSYS 1 system should not be used adjacent to or stacked with other equipment. If the iSYS 1 system is used while positioned adjacent to other equipment, it should be observed to verify normal operation in the configuration in which it will be used.

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

CAUTION
Class A Equipment – iSYS 1 is not suitable for use in domestic establishments and establishments directly connected to a low voltage power supply network which supplies buildings used for domestic purposes.

WARNING
Portable and mobile RF communications equipment can affect medical electrical equipment.

WARNING
Do not allow any radio-transmitting devices (such as mobile phones, diathermy units, etc.) or devices exceeding the limits defined in the applicable EMC standards in the vicinity of the iSYS 1 system.
Such devices could exceed EMC standards and in unusual circumstances could interfere with the correct functioning of the iSYS 1 system. This could lead to fatal or serious injury, clinical mistreatment, or equipment damage.

CAUTION
The use of cables and other components not specified and/or not supplied by iSYS may adversely affect the EMC performance.

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

2.6. Compatibility

Equipment described in this manual shall only be used in combination with other equipment or components, if these are expressly approved by iSYS as compatible. A list of such equipment and components is available from iSYS upon request.

Changes and/or additions to the equipment shall only be carried out by persons expressly authorized by iSYS to do so. Such changes shall comply with best engineering practice and all applicable laws and regulations that have the force of law within the jurisdiction the equipment will be used within.

WARNING
Changes, additions or maintenance to the equipment carried out by persons without appropriate qualifications and training and/or using unapproved spare parts may lead to fatal or serious personal injury and/or damage to the equipment as well as making the warranty void.

2.7. Compliance

Note:	*The iSYS 1 system has been designed and tested for compliance when used in the clinical environment only.*

The iSYS 1 system is designed to comply with internationally recognized standards for safety and performance.

2.7.1. IEC Safety Standards

The iSYS 1 system complies with the following IEC Safety Standards:

- IEC 60601-1 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2 Medical electrical equipment – Part 1-2: General requirements for safety – Collateral standard: Electromagnetic compatibility – Requirements and tests
- IEC 60601-1-6 Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral Standard: Usability
- IEC 60601-1-8 Medical electrical equipment – Part 1-8: General requirements for basic safety and essential performance – Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems

2.7.2. IEC Classification

According to the above listed IEC standards, the iSYS 1 system is classified as set out in

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

the table below:

Type of protection against electric shock	Class I
Degree of protection against electric shock	Type B (the RPU is rated as type B and the needle/tool guided by the system is seen as applied part according IEC 60601-1)
Degree of protection provided by enclosures	IP2X as defined in IEC 60529. (protection against ingress of solid objects with diameter larger than 12,5 mm, no protection against ingress of liquids).
Methods of disinfection recommended by the manufacturer	Disinfected equipment (or elements). See section 6 Cleaning and Disinfection for methods.
Degree of safety of application in the presence of flammable anesthetic mixture with air or with oxygen or with nitrous oxide	Equipment NOT suitable for use in the presence of a flammable anesthetic mixture with air or with oxygen, or nitrous oxide.
Mode of operation	Continuous

Table 2-2: IEC Classification

Explanation of the classification:

A “Class 1 electrical shock classification” means that the iSYS 1 system must be powered via a power cable connected to a protective earth ground.

2.8. Training

Before using the system at the patient, the user must feel confident with the system and therefore adequate training with the system is mandatory.

Training requirements may vary from country to country. Please make sure that you have received enough training without patient and that you are confident with the use of the system (in accordance with local laws or regulations that have the force of law). Information on training is available from the local iSYS representative.

Purpose of the training:

- Learn the safe use of the system.
- Guarantee a safe and fast workflow.
- Learn how to manipulate the NGA with the joystick in 3D. This step is crucial for precise needle alignment.
- The user has to learn the functionality of the joystick and to learn the intuitive use of the joystick.

Important note:

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

- The user needs to understand how she/he wants to integrate the use of iSYS 1 into the overall workflow of the treatment process: Therefore it is mandatory not just to understand how the system works as a standalone, but also how the system interferes with the overall workflow.
- To avoid complications (setup failures for the specific applications, time consuming breaks that lead to inaccuracy and/or additional radiation, etc.) in the overall workflow and overall setup, it is strongly recommended to train the overall workflow as well.

If problems occur or questions remain, please contact iSYS.

WARNING
The iSYS 1 system and its accessories may only be operated by qualified and authorised personnel. 'Qualified' personnel in this case mean personnel which have been approved to operate medical electrical devices by the responsible management of the clinical environment using the iSYS 1 system.

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

3. Specifications

Electrical installations in the room where the iSYS 1 system is used must comply with the following regulations (in other countries the equivalent standards) where applicable:

- ÖVE EN7
- ÖVE EN1
- ÖVE ÖNORM E8007
- ÖVE ÖNORM E8001

3.1. Environmental Conditions

3.1.1. Environmental Conditions for Transport and Storage

CAUTION
Noncompliance with stated transport and storage conditions may result in damage to the iSYS 1 system. In this case it is essential to completely dry the components of the iSYS 1 system for at least 24 hours and check the functionality of the system before using.

The environmental conditions for transport and storage of the iSYS 1 system are specified in table 3-1.

Ambient temperature	+10°C to +50°C (50°F to 122°F)
Relative humidity	30% to 70%, non-condensing (no outdoor storage)
Atmospheric pressure	800 mbar to 1100 mbar

Table 3-1: Environmental conditions for transport and storage

3.1.2. Environmental Conditions for the Intended Use

The environmental conditions for the intended use of the iSYS 1 system are specified in table 3-2.

Ambient temperature	15°C to 30°C (59°F to 96°F)
Relative humidity	30% to 70%, non-condensing
Atmospheric pressure	800 mbar to 1100 mbar
Max. operating altitude	2000m (6560 ft)

Table 3-2: Environmental conditions for the intended use

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

3.2. Components

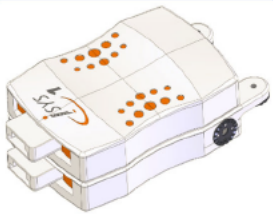
WARNING
iSYS 1 must only be used in combination with accessory described in this manual. Other equipment or components shall only be used, if these are expressly approved by iSYS as compatible. A list of such equipment and components is available from iSYS upon request.

The following tables show the single components of the iSYS 1 system, including optional components for variation of the system according to the user's particular requirements. For further details regarding these optional components please contact iSYS Medizintechnik GmbH.

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

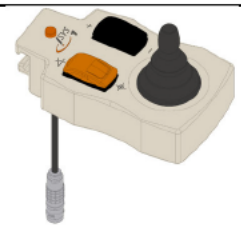
Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

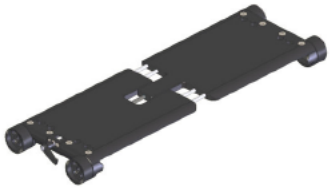
3.2.1. System iSYS 1 U.S. (Art.No. 6224)

Name	Picture	Article-No.:	Standard/Optional/	Description
Robotic Positioning Unit (RPU):		3908	Standard	Robotic Positioning Unit with two 2DOF modules which allows - in combination with the Needle Guide Set - tool angulation (± 30° for both pitch and yaw angle) and needle positioning (± 20 mm for both lateral and longitudinal direction).
Needle Guide Extension 20mm (NGE)		4965	Standard	The Needle Guide Extension comprises two cranked "fingers" which are connected to the Robotic Positioning Unit by screws. This standard version provides an offset of 20mm between the bottom edge of the RPU and the NGE. The "fingers" are made out of radiolucent plastic and thus do not cause imaging artifacts.
Control Unit (CU):		6254	Standard	The iSYS 1 Control Unit aims to control the iSYS 1 Robotic Positioning Unit. The CU is integrated into a metal rack and can be attached to the side rail of the treatment table by a simple locking mechanism. It is designed to interface with a standard OR siderail with the following dimensions: (WxH) 10 mm x 25 mm.
RPU Cable Set:		3926 5905	Standard Standard	Set of two cables to connect the CU and RPU. 3926 - RPU Cable Set 1500 mm 5905 - RPU Cable Set 3000 mm
Handheld Control Unit (HCU):		3901	Standard	The Handheld Control Unit comprises a 2-axis joystick as well as confirmation and control buttons for remote operation of the RPU from "safe" distance. A simple locking mechanism allows the

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

				attachment to the side rail. A sterile cover for the Handheld Control Unit is also available. It is designed to interface with a standard OR siderail with the following dimensions: (WxH) 10 mm x 25 mm.

Name	Picture	Article-No.:	Standard/ Optional/	Description
Multi Functional Arm (MFA):		4271	Standard	Single-lever passive multi-functional arm for flexible pre-positioning of the iSYS 1 Robotic Positioning Unit. There are two different connectors: the "Starburst"-adapter connects the MFA to the different table adapters; the "Spoon"-adapter connects the MFA to the RPU.
Table Top Adapter Version B - Bottom Mounted (TTAB):		4120	Standard	Mechanical adapter for safe and stable connection of the MFA directly to a standard C-Arm Couch Top; It is mounted from the bottom of the Couch Top. This adapter is designed to interface with a carbon fiber table top with the following dimensions: Width between 470 mm and 530 mm Maximal thickness of the table: 6 mm (at the border) and 38mm (in the middle of the table)
Table Top Adapter Version A - Top Mounted (TTAA):		4117	Optional	Mechanical adapter for safe and stable connection of the MFA directly to a standard C-Arm Couch Top; The Table Top Adapter Version A – Top Mounted is mounted from the top and provides maximum stability. This adapter is designed to interface with a carbon fiber table top with the following dimensions: Width between 470 mm and 530 mm Maximal thickness of the table: 6 mm (at the border)
Transport		6098	Standard	Transport box

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

box				
Power Cord:		6163	Standard	Power cord (U.S.) length 2500 mm

Table 3-3: iSYS 1 U.S. System

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

3.2.2. Accessory – non sterile

Name	Picture	Article-No.:	Standard/Optional/	Description
Table Top Adapter Version A - Top Mounted (TTAA):		4117	Optional	Mechanical adapter for safe and stable connection of the MFA directly to a standard C-Arm Couch Top; The Table Top Adapter Version A – Top Mounted is mounted from the top and provides maximum stability. This adapter is designed to interface with a carbon fiber table top with the following dimensions: Width between 470 mm and 530 mm Maximal thickness of the table: 6 mm (at the border)
Side Rail Adapter (SRA):		4095	Optional	Adapter to connect the MFA to a standard side rail. The extension with a metal rod is possible if needed. The rod is inserted and into the adapter and fixed with a screw. The Starburst connector is located at the end of the rod as well as on the adapter itself. This adapter is designed to interface with a standard OR side rail with the following dimensions: (WxH) 10 mm x 25 mm
HCU Cable Extension:		6162	Optional	HCU Cable Extension

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

3.2.3. Accessory - sterile:

Name	Picture	Article No.	Disposable	Description
Sterile Cover RPU - sterile for US:		4874US	Disposable	It is a disposable sterile component to cover the RPU and part of the MFA and RPU Cable Set. This assembly consists of a Sterile Drape (Nr. 10375) and the Needle Guide Kit (Nr. 10374) (including 2 Needle Guide Joints with Fixation Rings). Needle Guide Joints allow a quick and reversible connection of the Needle Guide Adapter to the Needle Guide Extension.
Sterile Cover HCU - sterile for US:		4883US	Disposable	It is a disposable sterile component to cover the HCU during operation.
Needle Guide Marker Insert centered - sterile for US:		4876US	Disposable	The Needle Guide Marker Insert (sterile) allows precise and remote-controlled alignment of the Needle Guide based on real-time imaging data.
Needle Guide Insert xxG - sterile for US:		6289G10US 5990G11US 5991G12US 5992G13US 5993G14US 4877G15US 4878G16US 4879G17US 4880G18US 5989G19US 4881G20US 4882G21US	Disposable	During the intervention the tool is inserted and guided by the sterile Needle Guide Insert. Needle Guide Insert – 10G Needle Guide Insert – 11G Needle Guide Insert – 12G Needle Guide Insert – 13G Needle Guide Insert – 14G Needle Guide Insert – 15G Needle Guide Insert – 16G Needle Guide Insert – 17G Needle Guide Insert – 18G Needle Guide Insert – 19G Needle Guide Insert – 20G Needle Guide Insert – 21G

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

3.3. Technical Specifications

3.3.1. Robotic Positioning Unit

Range of Motion: 40 mm x 40 mm (for each Robotic Module)
Max. Force: 35 N
Dimensions: 266 mm x 139 mm x 68,5 mm
Weight: 1,35 kg

3.3.2. Control Unit

Dimensions: 360 mm x 406 mm x 147 mm
Side rail dimensions: 10 mm x 25 mm
Weight: 5,8 kg
Power rating: 230 V ~
50-60 Hz
50 VA
Fuse rating: 2x T1AL 250 V
Alarm Beeper: approx. 55 dB (A) in a distance of 1 m
Power supply cord: 3x min. 1 mm²; max. length 5 m

3.3.3. RPU Cable Set 1500

Cable length: 1,5 m

3.3.4. RPU Cable Set 3000

Cable length: 3,0 m

3.3.5. Handheld Control Unit

Dimensions: 187 mm x 107 mm x 122 mm
Side rail dimensions: 10 mm x 25 mm
Weight: 0,85 kg
Cable length: 3 m

3.3.6. HCU Cable Extension

Cable length: 10 m

3.3.7. Multi Functional Arm

Dimensions: 500 mm x 105 mm x 145 mm
Weight: 1,36 kg

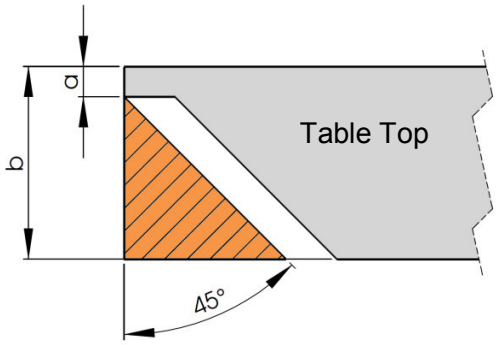
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

3.3.8. Table Top Adapter Version B

Dimensions: 614 mm x 190 mm x 59 mm
Weight: 2,98 kg

Table Top requirements:
Min. table top width: 466 mm
Max. table top width: 535 mm
Min. (a): 3,5 mm
Max. (a): 6 mm
Max. (b): 38 mm



(a) Thickness of the Table Top at the border
(b) Height of the Table Top
Table Top must not reach the orange marked area.

3.3.9. Table Top Adapter Version A

Dimensions: 614 mm x 190 mm x 45 mm
Weight: 2,39 kg

Table Top requirements:
Min. table top width: 466 mm
Max. table top width: 535 mm
Min. (a): 3,5 mm
Max. (a): 6 mm

3.3.10. Side Rail Adapter

Dimensions: 230 mm x 82 mm x 120 mm (without Extension Rod)
610 mm x 45 mm x 25 mm (with Extension Rod)
Side rail dimensions: 10 mm x 25 mm
Weight: 3,29 kg

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

4. Operating iSYS 1

This chapter describes the assembling and operation of the components of the iSYS 1 system. Please be aware that not every type of setup can be described in detail, but with the possibilities described (see below) you should be able to create your desired setup.

WARNING
Never use equipment that is damaged or appears to be working not properly.

WARNING
Never try to touch parts inside of components when operating iSYS 1. Never put your finger in openings. Danger of damage by mains voltage.

WARNING
Always make sure that all components of the hardware setup of iSYS 1 are not causing any collisions with moving parts and/or the gantry of the imaging device.
Therefore, move the gantry and all other moving parts of the imaging device carefully and manually in all desired positions and check for potential collisions before you start the treatment.
Repeat this whenever you have changed the hardware setup of iSYS 1.

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

4.1. Set-Up and Installation

For correct system use and an efficient clinical workflow, please follow the Set-Up and Installation instructions below.

WARNING
Check the power supply cord and plug. Should the power supply cord or plug be damaged, the iSYS 1 system must not be used!

CAUTION
Check the mechanical stability of the setup while setting up the iSYS 1 system!

WARNING
Do not use the iSYS 1 setup in MRI environment.

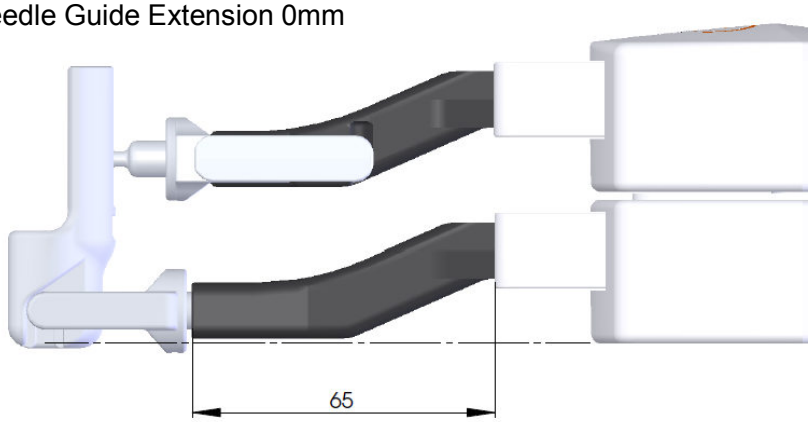
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

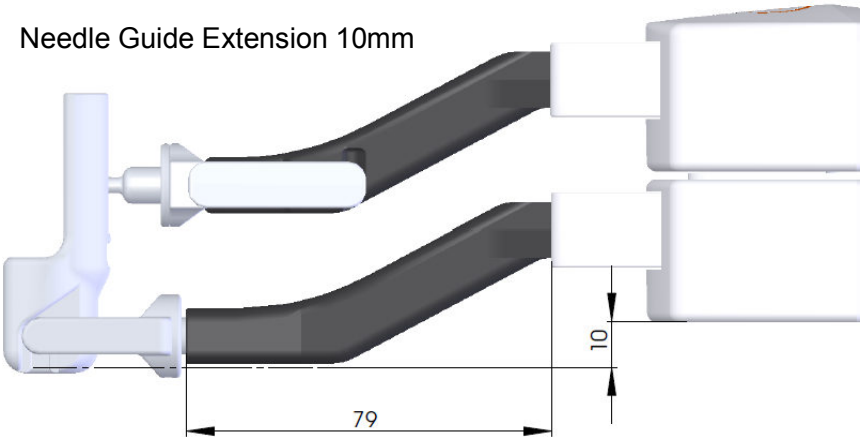
4.1.1. Mounting of the (Radiolucent) Needle Guide Extension to the Robotic Positioning

For the iSYS 1 system different types of Needle Guide Extension are available that differ in offset and length. The system is delivered ready for use with already mounted NGE.

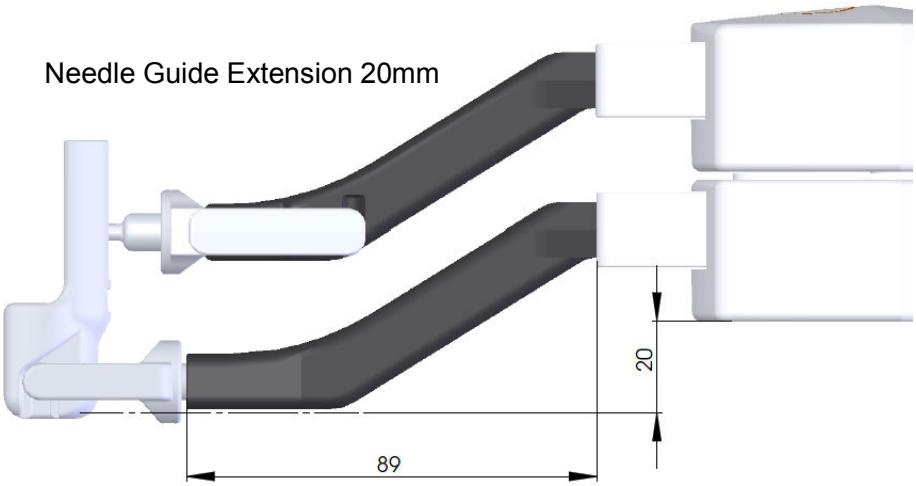
Needle Guide Extension 0mm



Needle Guide Extension 10mm



Needle Guide Extension 20mm



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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Note:	*This setup step is only optional and needs to be done in case the user wants to use a different type of NGE (see descriptions of the NGE above).* *This procedure is performed with the robotic unit only, and can be done outside the treatment room.*

WARNING
The mounting of the (radiolucent) Needle Guide Extension to the Robotic Positioning Unit can only be done by a professional iSYS technician. There has to be done a SW-modification. If you want to change the needle NGE, please contact iSYS Medizintechnik GmbH.

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

4.1.2. Adaptation of the Table Adapters

For attachment of the Robotic Positioning Unit to the imaging table, iSYS is offering three solutions (a, b and c).

Depending on the type of imaging table and the (carbon fiber) table top, one or more of the below described adapter solutions (a, b and c) can be used.

Note:	*Every table adapter offers different features and setup possibilities, depending on the region of interest and the type of intervention.*

CAUTION
Make sure that the treatment couch and/or the table top fulfills the interface requirements for the adapters!
- **Side rail payload: min. 20 kg**
- **Side rail size: 10 mm x 25 mm (WxH)**

In case you are not sure which adapter you can use (or the user manual of the treatment couch and/or the table top manufacturer does not give you the required information), please ask the service technician of the table/couch top manufacturer or contact iSYS for professional advice!

CAUTION
Be aware that the setup does not block intended movements of the table.

WARNING
All table adapters contain metal parts/material and thereof cause imaging artefacts if they are in the field of view of the X-ray beam. Make sure the adapters are outside the field of view of the imaging device!

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

WARNING
For all types of adapters, the following setup rules are essential:

- **Always make sure that the levers are locked properly and that the adapter provides a solid, clearance-free connection to the table!**
  This is not only essential for the accuracy of the final tool placement – any undesired movement of the mechanical setup also is a potential risk for mistreatment or may cause injuriy to the patient!

- **Always perform a manual stability-test (by pushing or pulling the adapter in different directions):**
  The adapter must maintain the position, must not slip and the setup must not wobble!

- **Make sure that the treatment couch and the adapter are permanently fixed to each other. In case you want to move the table with the patient on it, the adapter has to follow this movement!**
  This is not only essential for the accuracy of the tool placement. Failures in the mechanical setup are a potential risk for mistreatment and may cause injuriy to the patient!

- **Be aware that other devices mounted nearby the Table Adapter or the influence of persons may decrease the mechanical stability.**

- **Be aware, that by opening the locking-levers too far, the adapter may not be safely locked and the adapter/setup may drop and this can cause damage to the system or harm the patient!**

WARNING
Make sure that the table is properly fixed before attaching the components of the iSYS 1 system.

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

WARNING
If the Side Rail Adapter is being used please make sure that the side rail is firmly connected to the treatment table before attaching any of the iSYS 1 components.

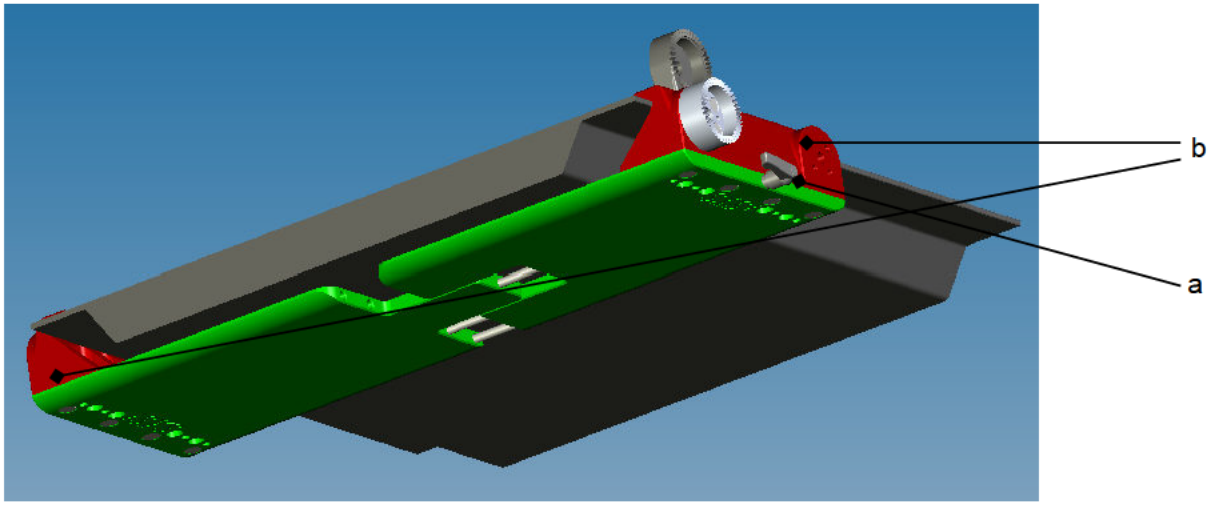
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

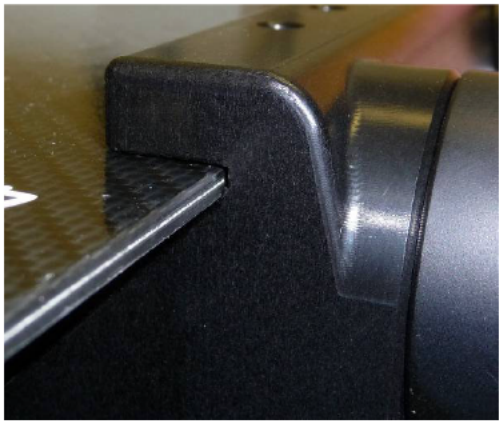
a. Mounting of the Table Top Adapter (Version B - Bottom Mounted)

Open the lever (a) of the Table Top Adapter as far that the clamping jaws (b) can grab the edges of the couch top of the treatment table as shown in the picture below.

By turning the lever clockwise, the clamping jaws (b) of the Table Top Adapter clutch the lateral edges of the table top and thus the adapter is fixed to the table.



The following picture shows the connection between the clamping jaw and the lateral edge of the (carbon) table top.



Once the adapter is locked to the table, it functions as a rigid adapter for the MFA.

If the adapter is not tightened, it can glide and be positioned easily in different positions on the table top.

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

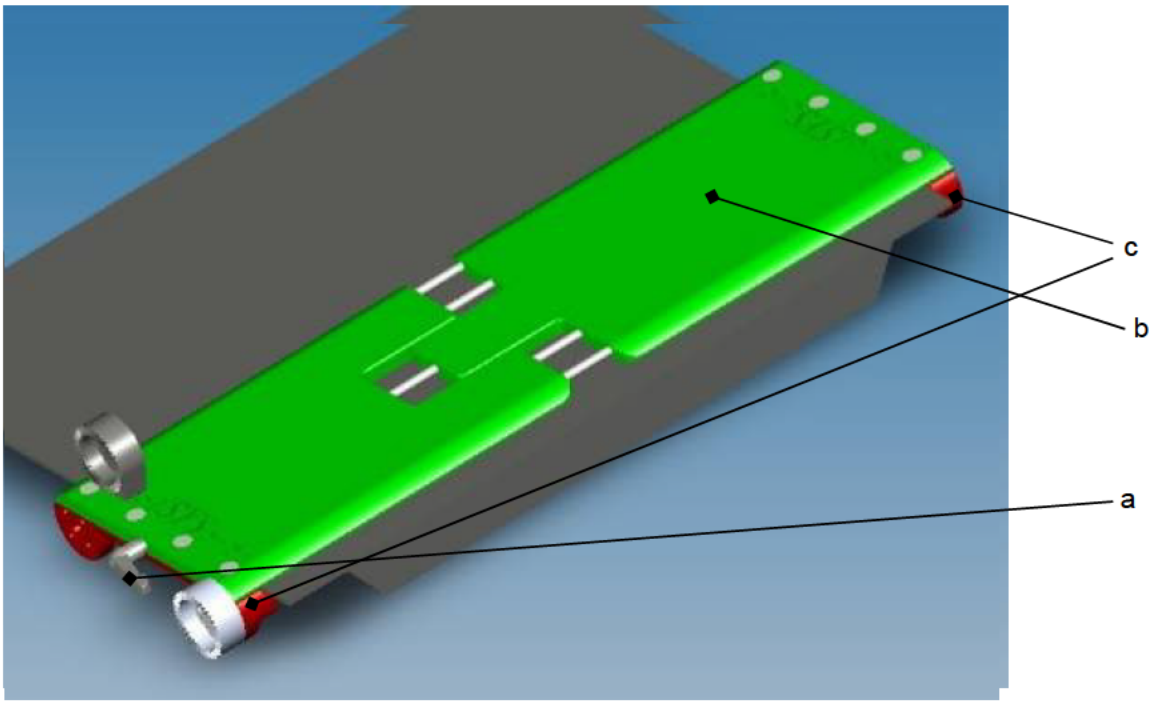
Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

WARNING
Never open the adapter so far that the adapter can fall down.

b. Mounting of the Table Top Adapter (Version A - Top Mounted)

Open the lever (a) of the Table Top Adapter so that the adapter plate (b) can be located on top of the couch top of the treatment table.

By turning the lever (a) clockwise, the clamping jaws (c) of the Table Top Adapter clench the lateral edges of the table top and the adapter is fixed to the table.



Once the adapter is locked to the table, it functions as a rigid adapter for the MFA.

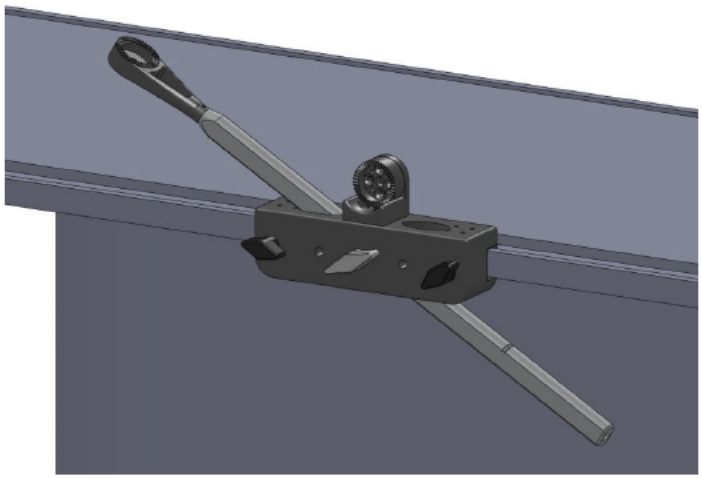
If the adapter is not tightened, it can glide and be positioned easily in different positions on the table

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

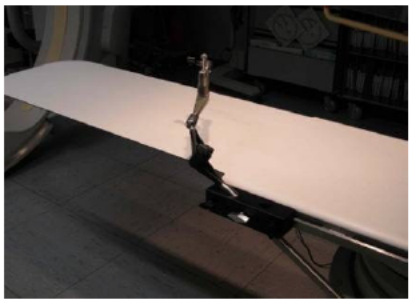
Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

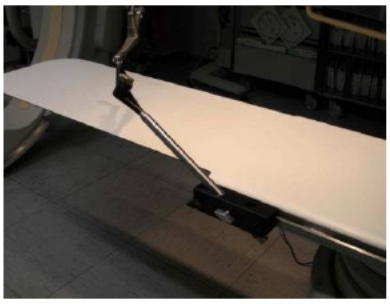
c. Mounting the Side Rail Adapter to the Side Rail of the Imaging Table

Attach the Side Rail Adapter to the side rail of the treatment table as shown below:



By turning the black levers clockwise, the adapter is rigidly attached to the side rail.



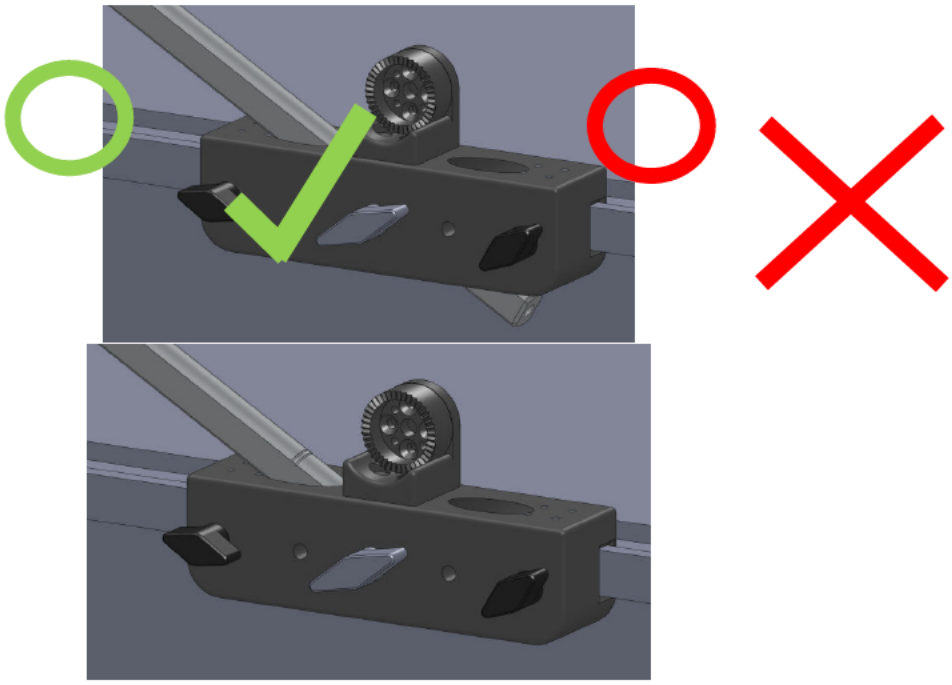


The height of the extension rod can be adjusted by opening and locking the middle lever.

WARNING
Make sure that the markings on the extension rod are not visible!

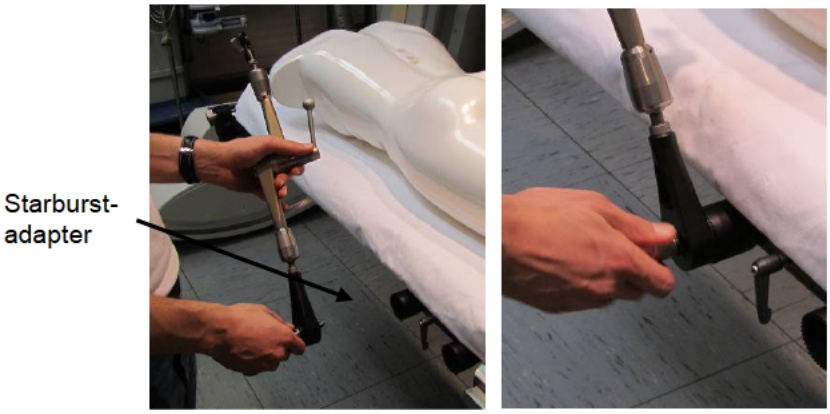
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016



4.1.3. Mounting of the Multi Functional Arm (MFA)

Attach the MFA to one of the Starburst-adapters available on the Table Top Adapter or Side Rail Adapter.



Turn the lever of the Starburst-adapter till the arm is tightly locked to the table adapter.

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

WARNING
Whenever the MFA is mounted or the position of the MFA is being changed (opening and locking) the stability has to be verified with a simple test:
push/pull the Spoon of the MFA or the Robotic Unit gently and check if the MFA and the attached components remain in their position.
Always be aware that the stability of the setup depends on the tightening force of the lever at the MFA.

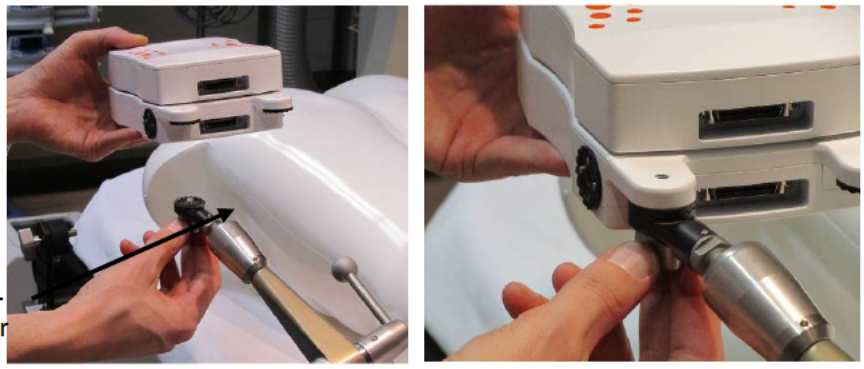
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

4.1.4. Mounting the Robotic Positioning Unit

Attach the Spoon-adapter at the Robot Positioning Unit to the MFA as shown below:

Spoon-adapter



Turn the lever of the Spoon-adapter till the Robot Positioning Unit is tightly locked to the MFA.

WARNING
Always make sure that the levers are locked strong enough and that the mechanical interfaces guarantee a solid, clearance-free connection to each other! This is essential for the treatment, because without high mechanical stability no high accuracies can be achieved with the Robot Positioning Unit!
With a simple manual stability test (by pushing or pulling the RPU carfully in different directions) the rigidity of the mechanical setup can be tested:
The RPU must maintain its position, must not slip and it must not wobble!

WARNING
Whenever the mechanical setup is changed, make sure that the components of iSYS 1 do not cause collisions with the gantry, with the treatment table or with any other part of the imaging device!

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

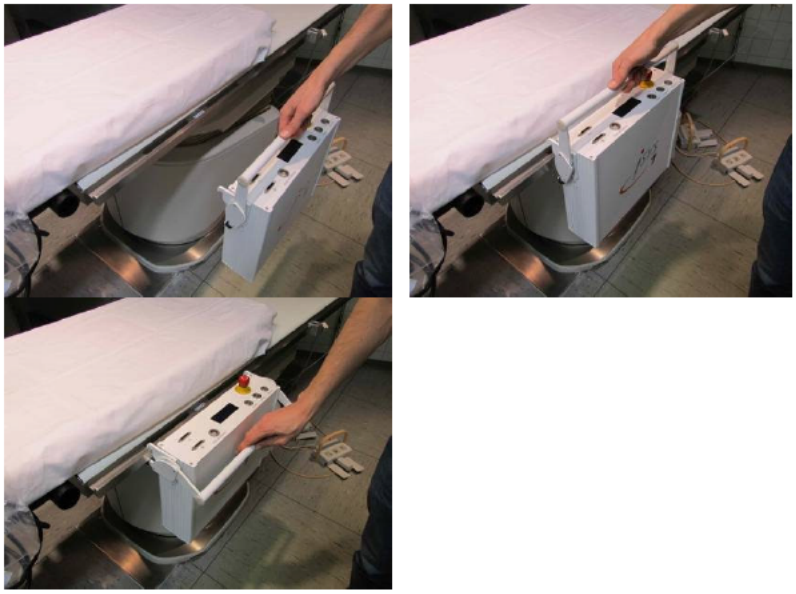
Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

4.1.5. Mounting the Control Unit to the Side Rail

CAUTION
If iSYS 1 or components are attached to the side rail of a table, ensure that the side rail is capable of carrying the weight. Refer to section 3 for technical data.
Please verify also if the connection of the side rail to the table is tight and does not wobble.

WARNING
Do not cover the front panel of the Control Unit or the display to make sure that any safety-relevant information can be recognized.

Move the CU to the side rail of the table with the handle in straight up position. Hang the unit on the side rail and close the locking mechanism by turning down the handle.



WARNING
Make sure the Control Unit is safely locked to the side rail of the treatment couch.

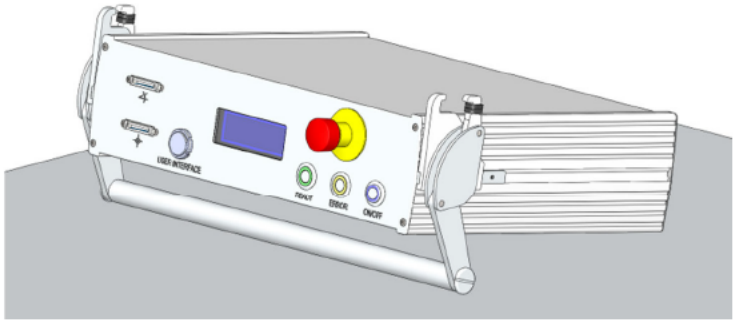
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

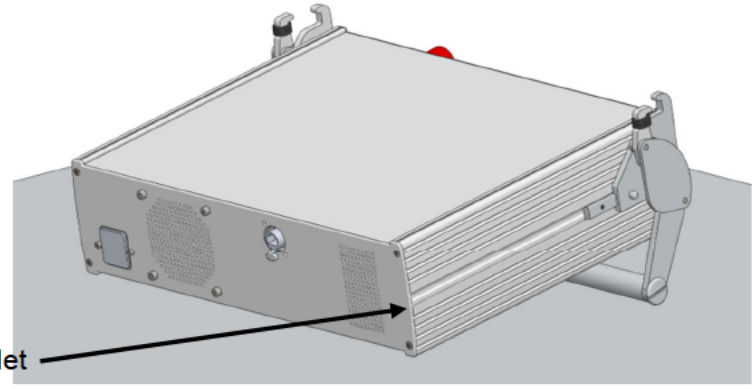
Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

4.1.6. Using the Control Unit without Side Rail

When there is no side rail available make sure the Control Unit is placed on a stable and flat surface which is capable of carrying its weight.

Use the handle as a support as shown in the picture below.





WARNING
Place the Control Unit so that no direct airflow to the patient or sterile areas occur. Otherwise the fan may blow non sterile air to the sterile area.

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

WARNING
You must pay special attention to the stability of the placement of the Control Unit and the cable routing. Carelessness may lead to falling down of components and harm patient or user.

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

4.1.7. Adaptation of the Handheld Control Unit to the Side Rail

CAUTION
If iSYS 1 or components are attached to the side rail of a table, ensure that the side rail is capable of carrying the weight. Refer to section 3 for technical data.
Please verify also if the connection of the side rail to the table is tight and does not wobble.

Hold the upper orange button pressed and attach the HCU to the side rail of the treatment couch as shown below.

After release of the upper orange button, the HCU is locked to the side rail.

Now the mechanical setup is finished.

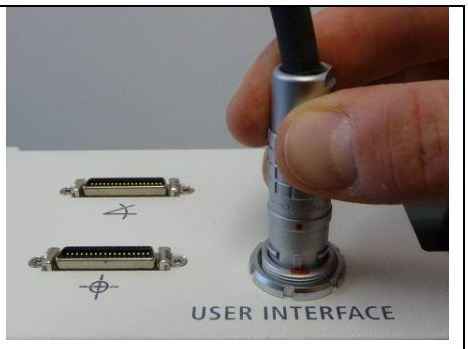
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

4.1.8. Connection of the Power and Data Cables

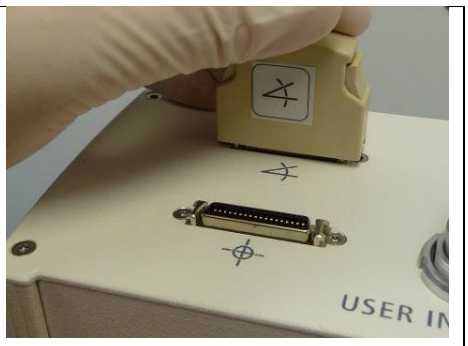
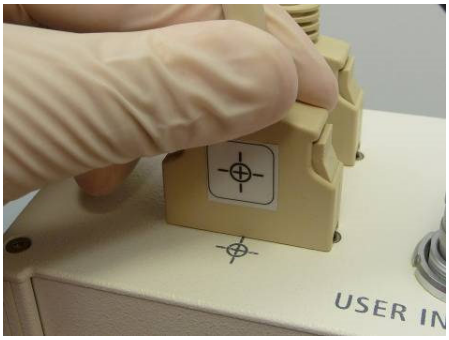
Overview:

Connect the power and data cables like shown in the following table:

Connection between HCU and CU	Connect the circular connector to the socket marked with “USER INTERFACE”. The correct position of the connector is marked with a red dot on both sides, connector and socket	

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

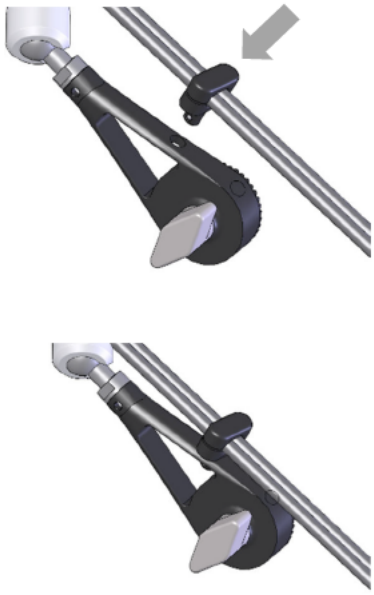
Connection of between RPU and CU	Connect the two flat connectors to the sockets on the CU marked with ⊿ and ⊕. The connectors are marked with the same symbols. Please check for the correct orientation of the connectors before inserting. There should be two “clicks” indicating that the connector is fixed firmly.	 
	Connect the two flat connectors to the sockets on the RPU. The connector marked with ⊕ is for the lower robot module (positioning module), whereas the connector marked with ⊿ is for the upper robot module (angulation module). Please check for the correct orientation of the connectors before inserting. There should be two “clicks” indicating that the connector is fixed firmly.	

In case of wrong connection between CU and RPU an error message will be displayed at the CU (“Check HW(5V,Mod)”, cf. “Error Messages”, chapter 0)

For the cabling between CU and RPU please attach the strain-relief connector to the recess at the MFA accordingly in order to avoid pulling forces to the RPU (see picture below).

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016



WARNING
Make sure that the cables do not cross the routes of the patient or the medical staff.
In case this is not avoidable (e.g. no electrical socket nearby), make sure that the cables are taped to the floor so that the patient/medical staff cannot fall over.

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

WARNING
Attach the strain-relief connector to the recess at the MFA accordingly in order to avoid pulling forces to the RPU. If the strain relief is not connected properly this may cause damage to the RPU or may harm the patient.

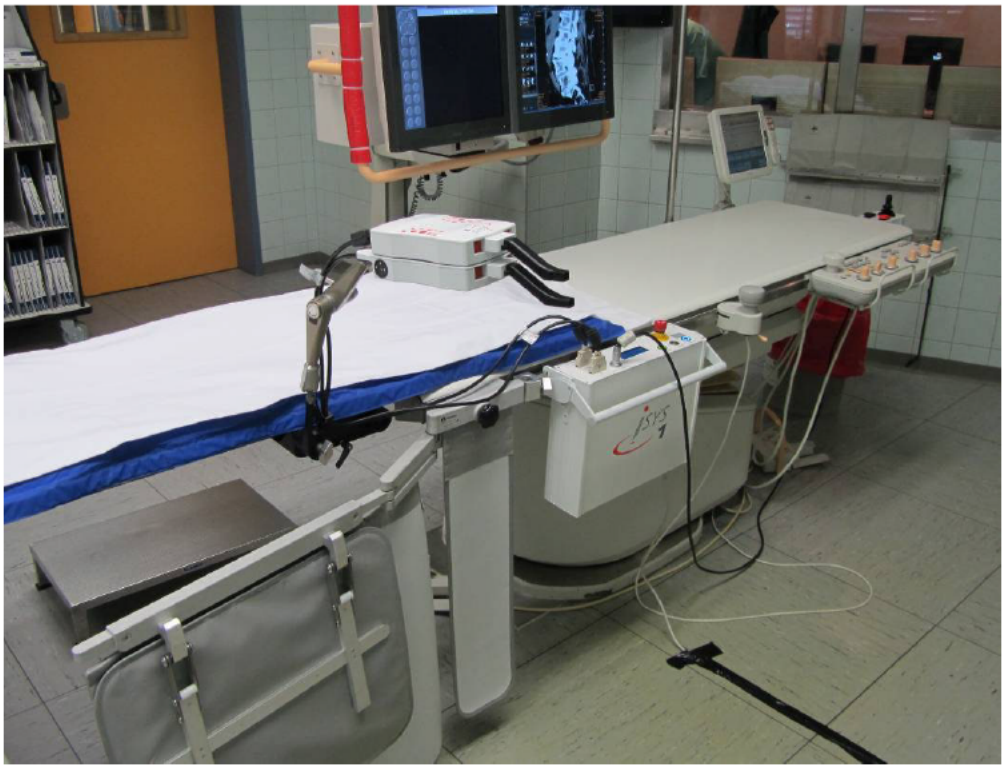
WARNING
Do not pull at the cables, especially when setting up the patient! This may lead to falling down of components, interference with the mechanical setup and potentially harm patient or user.

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

4.1.9. Bringing the RPU into the "Parking position"

After the mechanical system setup, the RPU has to be parked in a safe parking position.



Reasons for the parking position:

- The parking position allows the easy attachment of the sterile cover.
- The parking position makes room for setting up the patient.
- The parking position allows access to the region of interest for preparing the surgical intervention (disinfection of the skin, sterile covering of the patient etc.)

WARNING
The MFA has progressive locking of the joints to allow precise positioning while locking and to avoid sudden movements when opening.
Always be aware that opening the MFA too fast can lead to uncontrolled movements of the arm itself or attached components (i.e. the Robotic Positioning Unit).
Always open the MFA slowly and carefully with one hand and hold the MFA or the attached device (Robotic Positioning Unit) carfully with the other hand!

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

WARNING
Do not misuse iSYS 1 as an armrest or tablet. This can lead to mechanical failures and serious injuries.

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

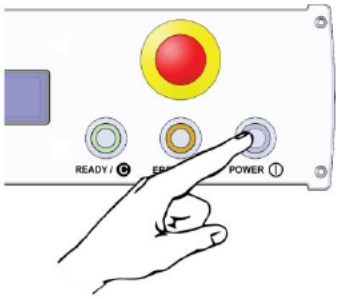
4.1.10. Start-up Procedure of the iSYS 1 Robot

1

Follow the Setup – Procedure (mounting of devices and establishing of cable connections) according to chapter 4.1.

2

Switch-on the system using the POWER switch.



Remark: Ensure that the joystick of the HCU is in its center position.

During boot-up the following message is shown.

```
iSYS1 – Needle
Guidance Platform
--------------------
System Bootup...
```

3

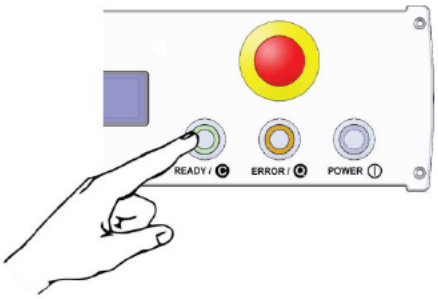
The system is now ready to perform the self-test.

```
### iSYS1 C-ARM  ###
* Running SELFTEST *
Rev1:C1.1/M1.6/W1.5
Press C to start  ->
```

4

Press the **C** (Confirm) button to start the self-test.

CAUTION: All axes of the robot will move approximately 1mm during self-test.



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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

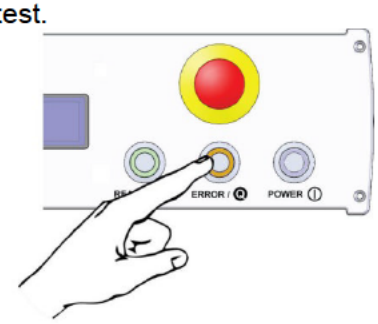
5

After the first step of the self-test you are asked to start the next step.

```
### iSYS1 C-ARM  ###
* Running SELFTEST *
Execute Step 2 of 5
Press Quit-Error  ->
```

6

Press the **Q** (Quit) button to start the next step of the self-test.



Repeat **step 6** until all steps are performed.

7

You will get the following message if the self-test was successfully executed.

```
### iSYS1 C-ARM  ###
Selftest PASSED
```

See instructions at **step 7A + 7B** if the self-test fails.

8

Once the self-test is passed you will get the operation screen.

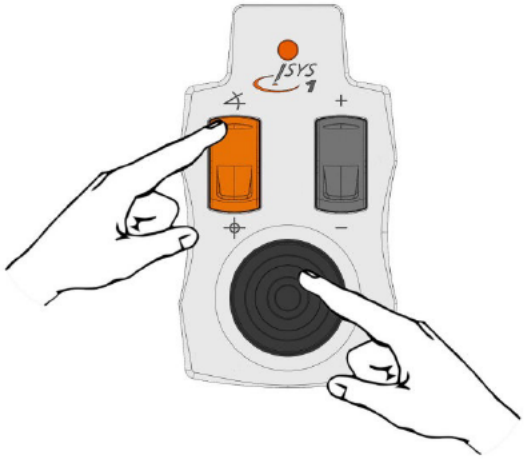
```
### iSYS1 C-ARM  ###

Speedlevel: fast
Joystick Mode  [  ]
```

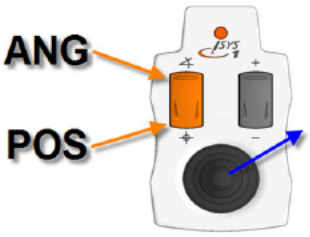

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

9

The system is now ready for operation. Use the Handheld Control Unit (HCU) to activate the desired mode (ANG or POS). During activation you can use the joystick to move the robot. The elongation of the joystick is proportional to the motion speed.
You can change the maximum speed using the +/- rocker-switch on the HCU.





7A

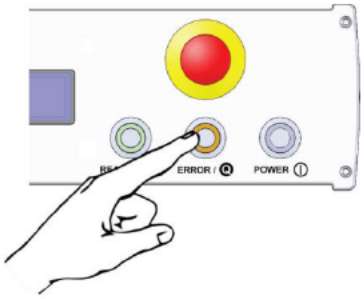
If the self-test fails you will get the following message.

```
### iSYS1 C-ARM  ###
* Running SELFTEST *
Selftest FAILED
Press Q to reset  ->
```

Remark: There are some possible reasons where the self-test fails, even tough no critical failure is present (e.g. a module is very close to its motion limit).

7B

Press the **Q** (Quit) button to restart the self-test and continue the procedure at step **3**.



If the self-test still fails after another trial, please contact the manufacturer.

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

4.2. Use of iSYS 1

The surgical procedure can be divided into several steps. The following workflow, for example, shows the use of the iSYS 1 system for a typical needle procedure under C-arm fluoroscopy.

4.2.1. Checking the Mechanical Setup and the Range of iSYS 1

Position the patient on the treatment table. Before covering the patient and the robot with a sterile cover, make sure that the region of interest is in the field of view of the imaging machine and within the mechanical range of the iSYS 1. Therefore the MFA has to be opened and the RPU roughly positioned manually in the region of interest. During opening of the MFA and checking the range the RPU has to be supported by the physician. The following pictures show different possibilities of potential positions. Please consider the movement of the gantry during imaging to avoid collisions of the iSYS 1 with the gantry.

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

In case the robot cannot reach the region of interest, re-position the patient or re-setup the mechanical parts of the system (e.g. mounting the MFA on a different Starburst-adapter or moving the TTA) so that all (potential) entry-points and target points can be reached.

WARNING
The MFA has progressive locking of the joints to allow precise positioning while locking and to avoid sudden movements when opening.
Always be aware that opening the MFA too fast can lead to uncontrolled movements of the arm itself or attached components (i.e. the Robotic Positioning Unit).
Always open the MFA slowly and carefully with one hand and hold the MFA or the attached device (Robotic Positioning Unit) carfully with the other hand!

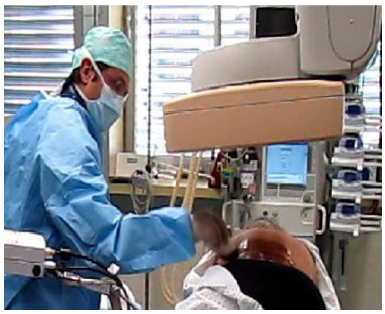
4.2.2. Setup and Preparing the Patient

Setup and prepare the patient for the interventional procedure following the steps below:

Note:	*Let the patient enter the table from the opposite table site of the iSYS 1 setup. Make sure the patient does not collide with any component of iSYS 1.*

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016



Note:	*The following paragraphs describe only the use of the iSYS 1 system. The use of the iSYS 1 system is just a small part of the workflow of an interventional needle procedure.*

This user manual does not take care of all the other important steps (like e.g. preparation of the non-iSYS disposables, cleaning and disinfection of the patient, sterile covering of the patient, use of the imaging machine, use of the planning software etc.). The general workflow for the specific intervention is in the responsibility of the physician.

Depending on the region of interest and of the compliance of the patient, the need of immobilization devices may occur. There are several - commercially available - immobilization devices on the market that can be used for precise patient immobilization.

Depending on the region of interest, respiratory motion may lead to organ movement and therefore to inaccuracy during the targeting process. There are several - commercially available - devices for respiratory motion control available on the market that might be used to overcome this problem.

In some cases - e.g. non cooperative patient - it might even be necessary to sedate/anesthetize the patient.

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

WARNING

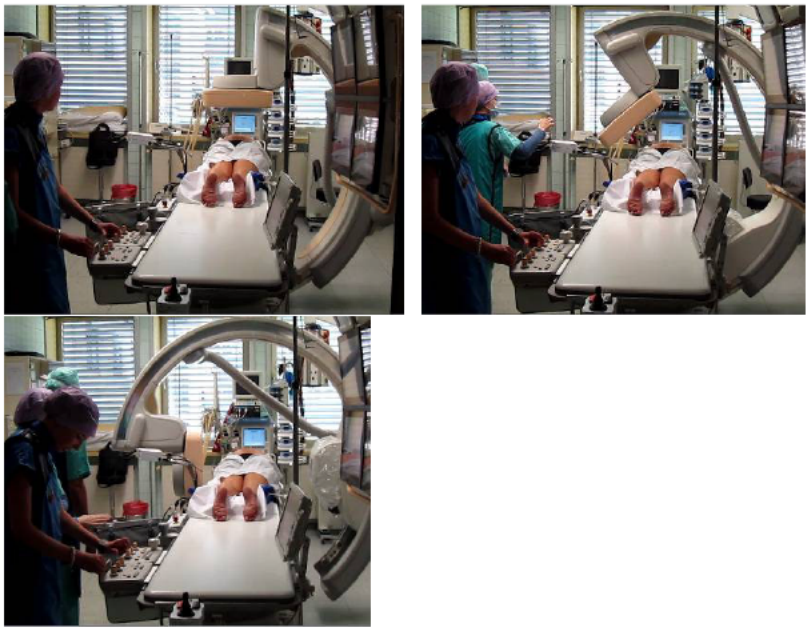
It is in the full responsibility of the physician to use aids e.g. for immobilization, respiratory motion control etc. and/or to sedate the patient.
Criteria for the physician include the physical constitution of the patient, the region of interest, the critical (surrounding) structures/anatomy around the path and the target point and the relation of the region of interest to the lung and other moving organs.

iSYS does not take any responsibility for non-iSYS components and treatment steps e.g. correct patient setup, imaging and planning!

4.2.3. Image Acquisition and Treatment Planning

Before image acquisition, make sure that the gantry does not collide with iSYS 1.

To test this, drive the gantry manually and carefully (slow motion) in all necessary extreme positions and make sure that there are no collisions with the setup.

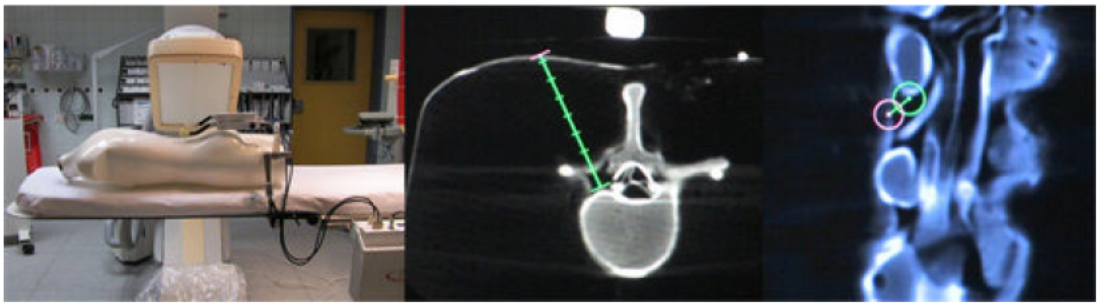


Imaging and planning can be performed with or without the RPU being in the field of view of the imaging device. In case the RPU is placed in the field of view of the imaging device, make sure that only the non-metal parts (plastic NGEs) are in the beam/field of view of the imaging device.

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

WARNING
Only the plastic NGEs ("fingers") do not cause imaging artifacts. If the whole RPU or other parts of the mechanical setup are in the field of view, imaging artifacts may occur!



After imaging of the patient, the planning of the path (entrance and target point) can be done with the planning tool of the imaging machine (not part of the iSYS System!).

Note: *Imaging and planning are not in the responsibility of iSYS.*

Always keep in mind that the iSYS 1 system has only a certain range of movement for gross positioning and micro positioning (see specifications)

In case imaging and planning is not done correctly, it might become necessary at a later point of the workflow to redo these steps (potential consequence: bigger time gap between (re-planning) and treatment and thereof (potentially less accuracy and/or additional radiation cause of the need of re-imaging)

4.2.4. Working with the sterile iSYS 1 Disposables

a. General Information on sterile iSYS 1 Disposables

WARNING
In general, all sterile iSYS 1 disposables are intended for single use for one patient. (Re-) Sterilization of these components is not allowed.

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

WARNING
Do not attempt to clean, sterilize or reuse single use components of the iSYS 1 system. Reuse of single use components might lead to a malfunction of the system and/or an infection of the patient.

WARNING
According to our present state of knowledge, we want to inform you about following known characteristics and technical factors that can lead to hazardous situations in case of reuse of the disposables.

Sterile Covers:
1. **Improper Folding**
2. **Conglutination of the tapes with the foil**
3. **Labels and stickers no longer usable due to opening**

NGE:
1. **Possibility of cross-contamination**
2. **Mechanical damage**

WARNING
Only labeled sterile products are allowed to be used.

WARNING
The single use components are sterile products intended for single use only. Sterility is guaranteed for unopened and intact packaging up to the indicated expiration date. Do not use sterile products if the package is damaged.

Check the Sterilization Indicator Label to make sure the peel pack bag (sterile package) has been processed.

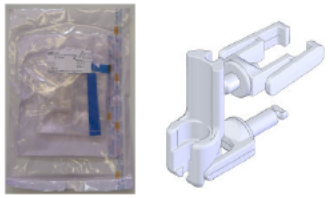
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

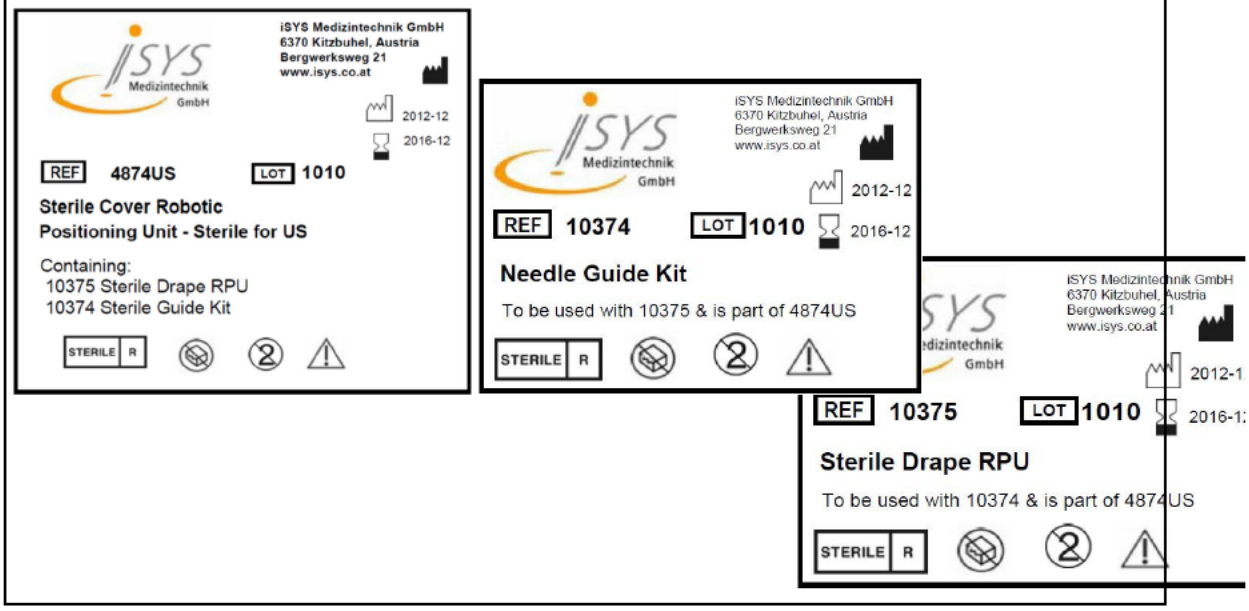
Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

b. Preparation of the Sterile iSYS Disposables

To guarantee a quick and safe workflow, take the iSYS disposables – handed over by a non-sterile assistant – out of the sterile cover and deposit the sterile components on a sterile table/plate.

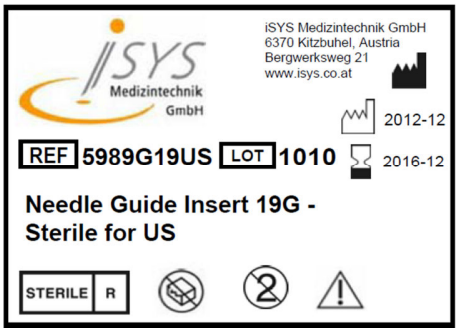
The following disposables are needed for intervention:

Picture	Number of pieces needed	Single Use / Accessories
	1	**Sterile Cover Robotic Positioning Unit** It is a disposable sterile component to cover the RPU and part of the MFA and RPU Cable Set. This assembly consists of a Sterile Drape (Nr. 10375) and the Needle Guide Kit (Nr. 10374) (including 2 Needle Guide Joints with Fixation Rings). Needle Guide Joints allow a quick and reversible connection of the Needle Guide Adapter to the Needle Guide Extension. Order number and name: 4874US Sterile Cover RPU - sterile for US



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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

   	Depending on how many needles are placed	**Sterile Needle Guide Insert**: During the intervention the tool is inserted and guided by the (sterile) Needle Guide Insert. NGIs are available for needle diameters given below. The needle diameter of a NGI is printed on the cover bag as well as embossed to the handle of the NGI. Order number and name: 6289G10US Sterile Needle Guide Insert – 10G 5990G11US Sterile Needle Guide Insert – 11G 5991G12US Sterile Needle Guide Insert – 12G 5992G13US Sterile Needle Guide Insert – 13G 5993G14US Sterile Needle Guide Insert – 14G 4877G15US Sterile Needle Guide Insert – 15G 4878G16US Sterile Needle Guide Insert – 16G 4879G17US Sterile Needle Guide Insert – 17G 4880G18US Sterile Needle Guide Insert – 18G 5989G19US Sterile Needle Guide Insert – 19G 4881G20US Sterile Needle Guide Insert – 20G 4882G21US Sterile Needle Guide Insert – 21G
	1	**Sterile Needle Guide Marker Insert:** The Needle Guide Marker Insert allows precise and remote-controlled alignment of the Needle Guide Insert based on real-time imaging data. Order number and name: 4876US NGMI centered - sterile for US

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

iSYS Medizintechnik GmbH 6370 Kitzbuhel, Austria Bergwerksweg 21 www.isys.co.at 2012-12 REF 4876US LOT 1010 2016-12 **Needle Guide Marker Insert centered - Sterile for US** STERILE R		
 iSYS Medizintechnik GmbH 6370 Kitzbuhel, Austria Bergwerksweg 21 www.isys.co.at 2012-12 REF 4883EU LOT 1010 2016-12 **Sterile Cover Handheld Control Unit - Sterile for US** STERILE R	1	**Sterile Cover Handheld Control Unit:** It is a disposable sterile component to cover the HCU during intervention. Order number and name: 4883US Sterile Cover HCU - sterile for US

Make sure all needed disposables are available. Also ensure that extra disposables are available in case a sterile piece is dropped in the non-sterile area (e.g. floor).

WARNING
Be sure the diameter of your instrument complies with the diameter of the Needle Guide Insert.

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

4.2.5. Attaching the Sterile Cover over the Robotic Positioning Unit

WARNING
Never continue with your procedure if any of the sterile covers is or gets damaged. Continuing the procedure might lead to serious infection of patient.

WARNING
Never touch the sterile area in the operating room after touching non-sterile components of the iSYS 1 without respective treatment (according to the local regulations).

WARNING
The patient must not touch the sterile cover.

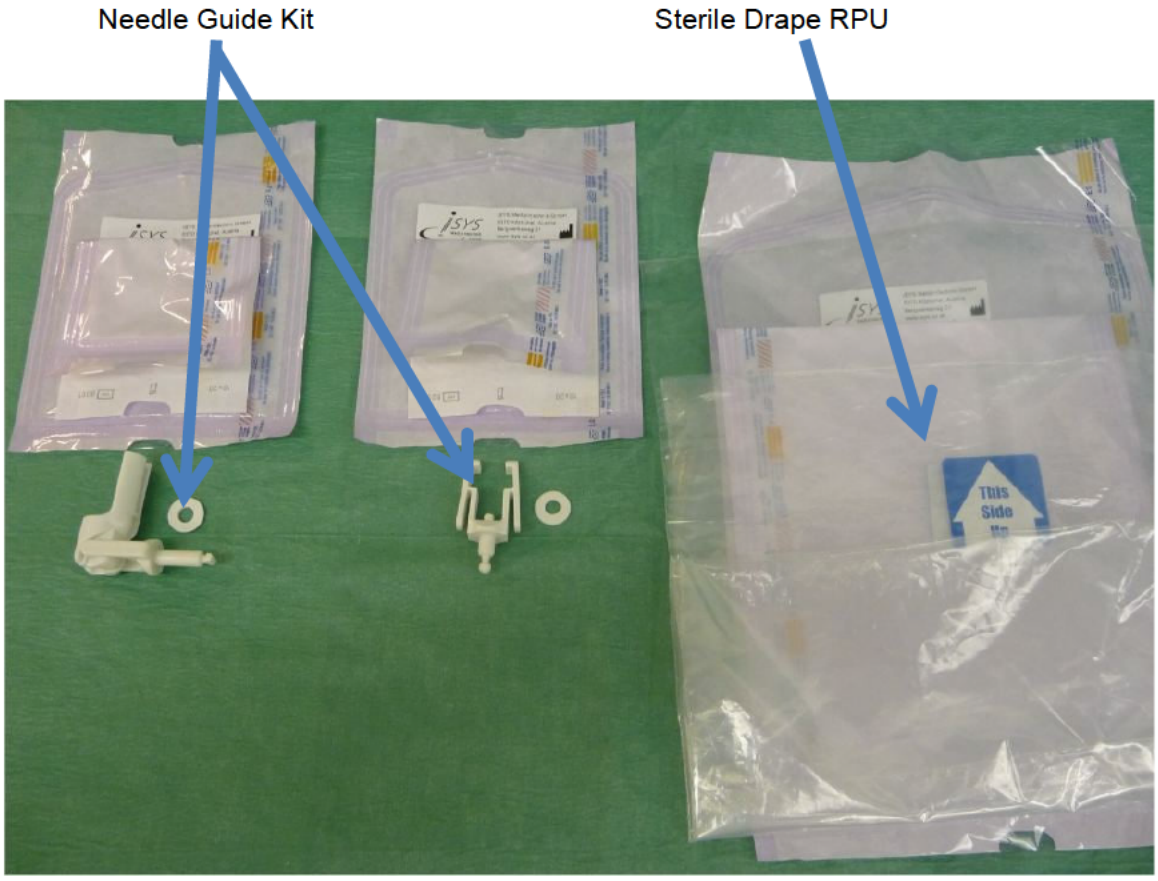
WARNING
Covering the patient's face with the sterile cover can seriously harm the patient.

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

The Robot Positioning Unit and the MFA can be completely covered with a sterile (protective) cover in a simple and safe manner. All non-sterile, reusable parts in the operation area are thereby separated from the sterile parts and the sterile operation area.

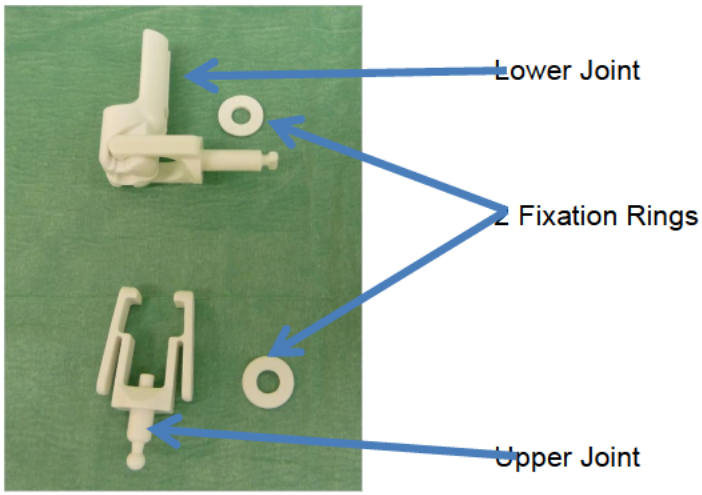
The Sterile Cover RPU consists of 2 parts:



The Needle Guide Kit includes 4 components:

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

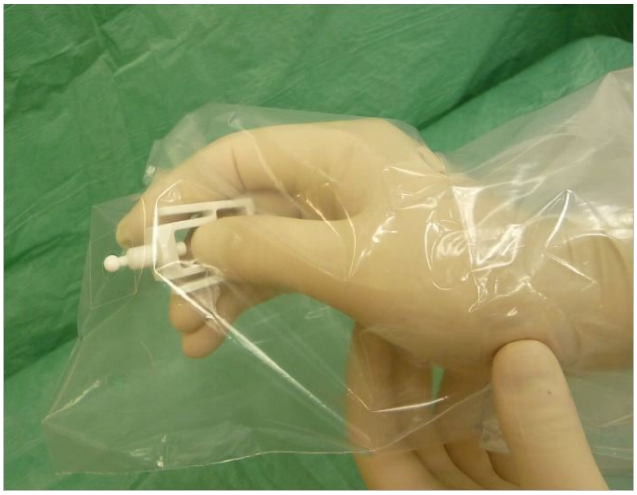


Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Open the sterile packaging and put all components (Sterile Drape, Lower & Upper Joint & 2 Fixation Rings) on the sterile table.

1. Feed the Upper Joint into the sterile drape and stick it through the upper hole.



2. Slip a Fixation Ring onto the Upper Joint

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

3. Feed the Lower Joint from outside the sterile drape into the lower hole.

4. Slip a Fixation Ring onto the Lower Joint from inside the Sterile Drape.

Make sure that both Fixation Rings fixed tight to the Joints!

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

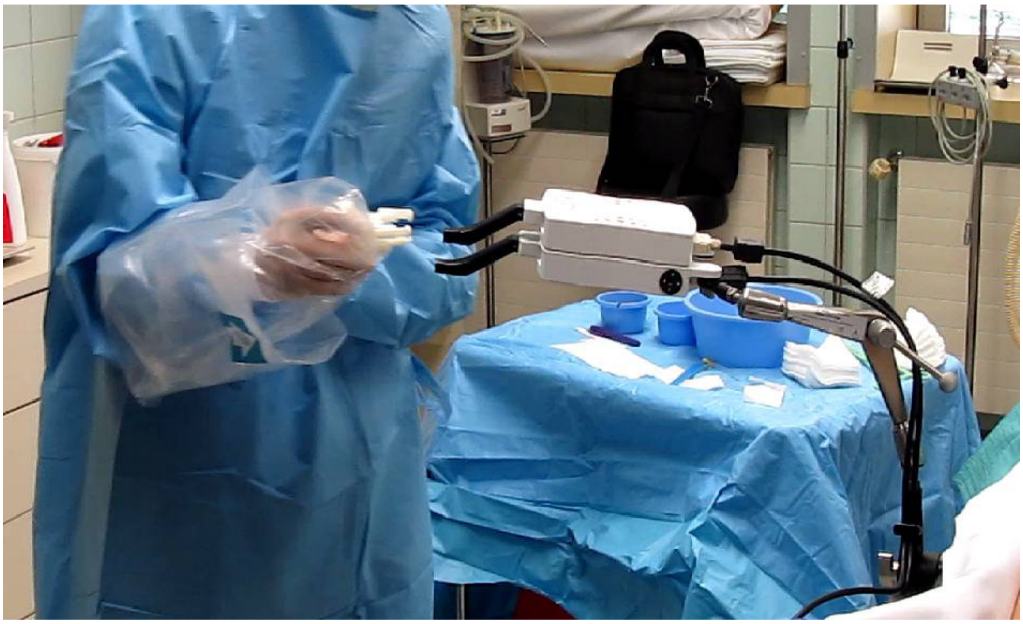
Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

5. Take the Bowl of the Upper Joint and insert it into the guide rail of the Lower Joint.

The final Sterile Cover RPU should look like shown on the pictures.

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

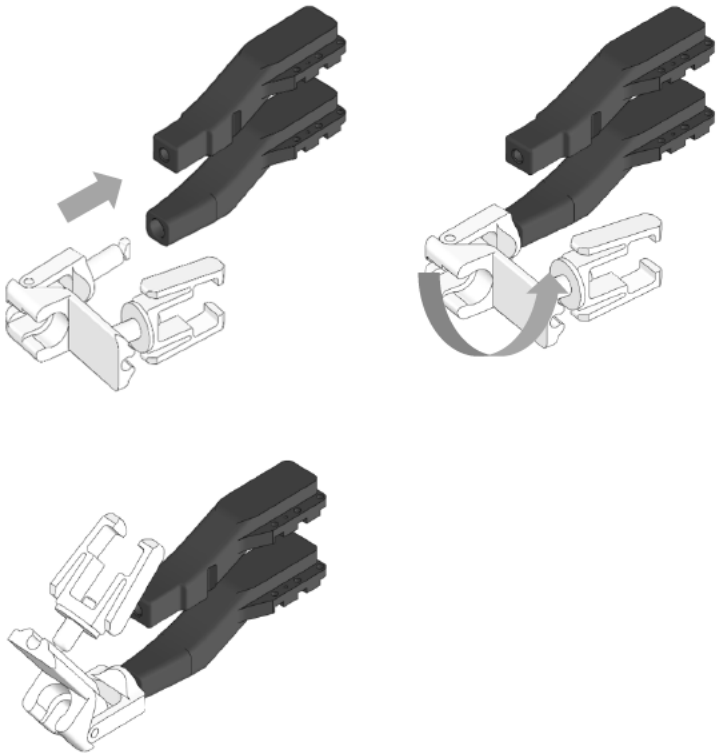


The sterile dressed surgeon grabs the end-effector from inside the plastic tube like shown in the picture above.

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

First the lower joint -is attached to the lower NGE ("finger") by bringing in the pin adapter in a 90 degree angle.

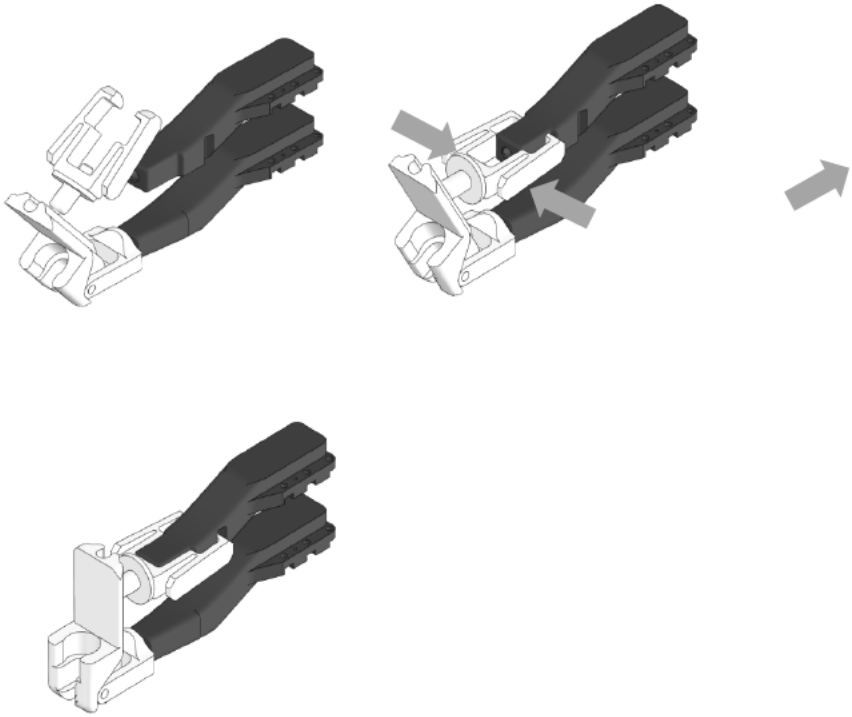


When you have reached the final position, rotate the lower joint 90 degrees up and make sure that the pin is locked safely by gently pulling the lower joint.

Attach the upper joint by attaching the clamp adapter as shown in the picture below:

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016



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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

After attachment of the upper joint, let the (non-sterile) assistant catch the white arrow (see blue marking) and pull the cover over the robotic unit.

After the RPU and MFA is totally covered with the sterile cover, the sterile surgeon can touch the sterile cover and pull the protuberance part of the cover (on the side of the sterile cover) over the handle of the arm and push it back.

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Use the blue tapes to fix the cover in position and to make sure the cover does not slip away.

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

4.2.6. Attaching the Sterile Cover to the HCU

WARNING
The patient or other non-sterile persons must not touch the sterile cover.

WARNING
Covering the patient's face with the sterile cover can seriously harm the patient.

In another simple and safe step, the HCU is completely covered with a sterile protective cover.

The (non-sterile) assistant takes the HCU in his hands. The sterile dressed surgeon takes the Sterile Cover Handheld Control Unit and grabs the HCU from inside the plastic tube.

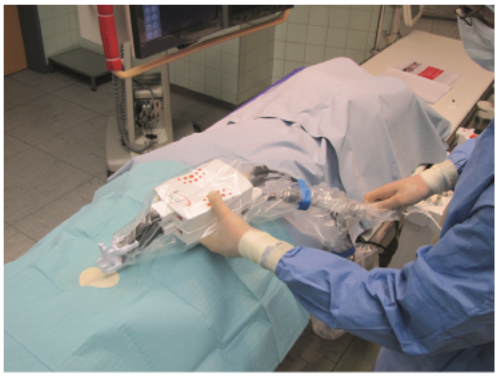
The (non-sterile) assistant catches the end of the plastic tube and pulls the cover over the HCU and its cable.

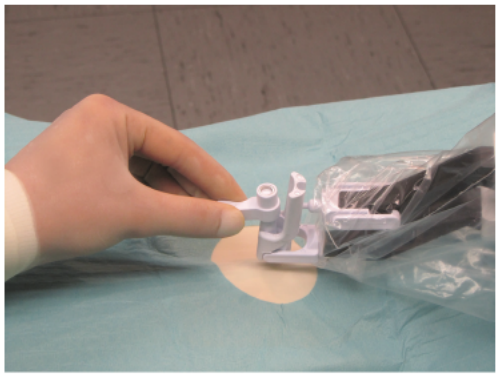
Note:	*This step allows the surgeon to later touch and use the HCU with his sterile hands/gloves. In case a second (assistant) non-sterile surgeon can operate the joystick, a sterile cover for the HCU is not needed and this step can be left out!*

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

4.2.7. Gross-Positioning of the RPU and Insertion of the Sterile Needle Guide Marker Insert into the Needle Guide Adapter





Make sure the entry and target point is in the range of the RU (see specifications above).

Unless it has not already been done before imaging, the RPU needs to be gross-positioned in the region of interest by opening and closing the MFA. To (re-)position the RPU please hold the RPU with one hand and open the MFA handle with the other one.

Please be aware that the MFA offers progressive locking, i.e. the upper link (next to the RPU) opens first, then the middle link and finally the lower link (next to the table/side rail adapter).

WARNING

The MFA has progressive locking of the joints to allow precise positioning while locking and to avoid sudden movements when opening.
Always be aware that opening the MFA too fast can lead to uncontrolled movements of the arm itself or attached components (i.e. the Robotic Positioning Unit).
Always open the MFA slowly and carefully with one hand and hold the MFA or the attached device (Robotic Positioning Unit) carfully with the other hand!

Although the Robotic Positioning Unit has an ergonomic design, always keep in mind that the steril cover may decrease the friction forces: Always hold and handle the MFA and the Robotic Positioning Unit carefully and safely!

Move the robot to the desired position/orientation and lock the MFA after positioning. The MFA handle needs to be tightened firmly so that the MFA can offer its full payload.

Please check the stability of the setup before proceeding with needle insertion.

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

To get a rough estimation about the right gross-positioning, you can use standard (skin) markers, the laser cross-hair (or laser pointer) from the imaging device (that visualizes the path) or fluoroscopy.

In case you use fluoroscopy, be aware to step aside to avoid radiation exposure. Be always aware that this method causes additional radiation to the patient.

WARNING
Make sure that the RPU and the NGE is oriented (approximately) parallel to the patient surface.
Always check if there is a risk of touching or colliding with the patient while remotely driving the robot modules (see chapter 4.2.8).
To double check: Drive the robot with the HCU in all extreme positions under direct visual control.
Collisions of the robot with the patient can cause serious injuries.

After you have reached and checked the desired position, insert the (sterile) Needle Guide Marker Insert into the Needle Guide Adapter.

WARNING
Make sure and double check that the Needle Guide Marker Insert is in the right endposition and is free of play in the NGA.

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

4.2.8. Micro-Positioning and Accurate Alignment of the NGA under fluoroscopy

Use the HCU (as described in chapter 4.5.3) to micro-position the NGA.

WARNING
When using the HCU, be aware not to touch the sterile area with the non-sterile cable of the HCU.

WARNING
Repeat imaging procedure if the Robot Positioning Unit has been accidental pushed or the power supply has been interrupted after imaging. Failing to do so may lead to mistreatment of the patient.

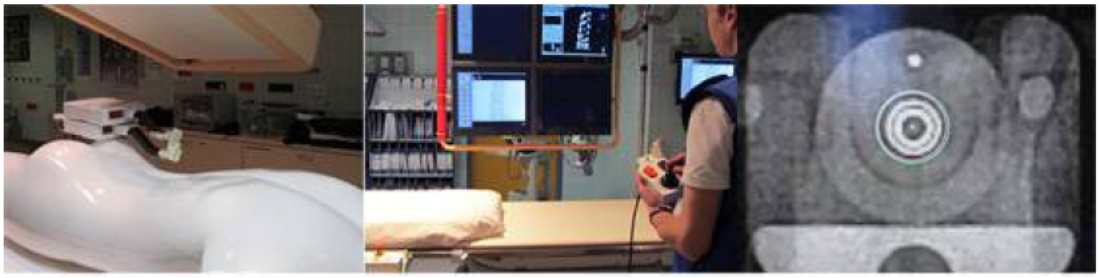
WARNING
Be aware you do not stand on the cables when moving the Robot Positioning Unit. This can lead to wrong positioning of the instrument and mistreatment of the patient.

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

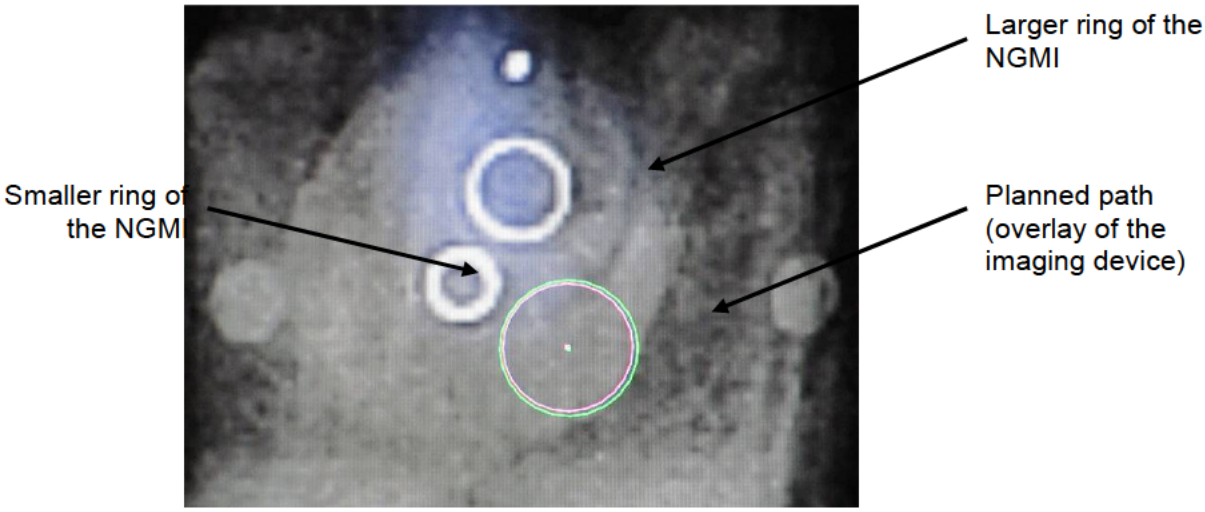
For a first alignment you can use surface markers or the laser cross-hair (or laser pointer) from the imaging device (that visualizes the path). In this case you can stay next to the patient.

If you use real-time-fluoroscopy for the alignment, please stay as far away as possible (minimum 6 feet) from the beam to reduce radiation exposure to a minimum (you just need to have a good view to the monitor that shows the fluoroscopy image).



To avoid unnecessary radiation to the patient, the user can – with the help of the robot – also work "offline" (i.e. without real-time imaging) and use just single Fluoro-Snap-Shots.

For micro-positioning the NG under fluoroscopy the C-Arm has to be orientated perpendicular to the planned path ("entry point view"). To align the Needle Guide with the planned path the user gets the right orientation of the x-, y-, a-, b-axis from the marker Insert:

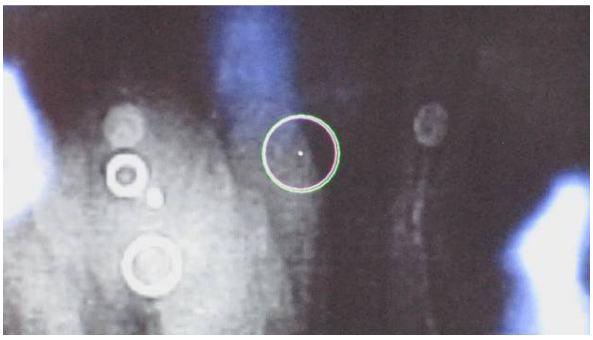


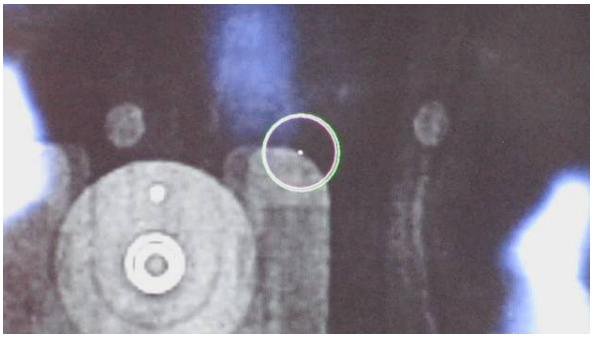
The larger ring of the Needle Guide Marker Insert marks the position of the Needle Guide. The smaller ring indicates the angulation of the Needle Guide.

In a first step the smaller ring has to be aligned roughly with the larger ring by moving the RPU in angulation mode. In this mode only the smaller ring moves as shown in the pictures below.

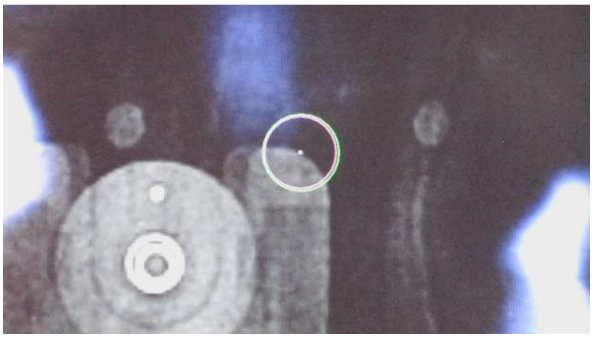
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

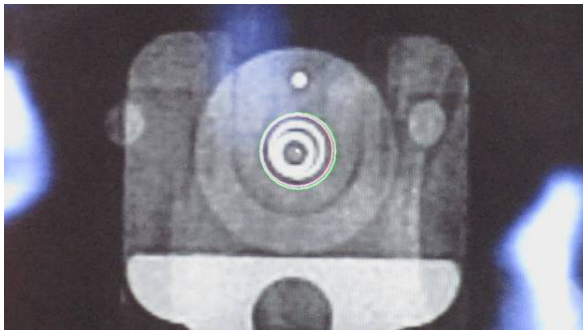
Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016





In the next step, both rings have to be aligned with the planned path (indicated by the two rings overlayed by the imaging device) by moving the RPU in positioning mode. When moving the RPU in positioning mode both rings move:

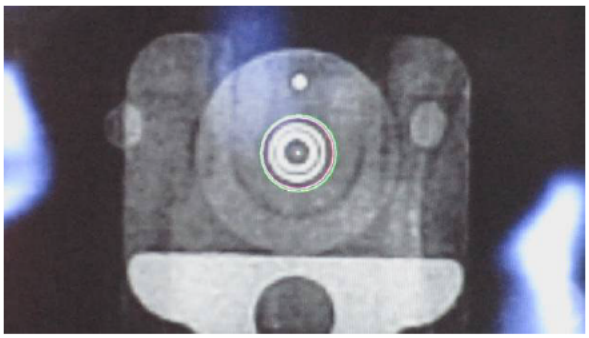


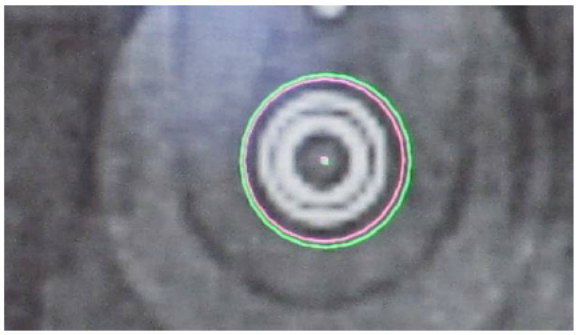


Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Finally the alignment has to be optimized by moving the RPU in positioning and angulation mode as shown below. For easy fine positioning the speed level can be set to slow by pushing the MINUS button on the HCU several times unless you hear a beep signal. The speed level is indicated on the display too.





In case the alignment is done under fluoroscopy, a maximum zoom of the fluoro-image, adjustment of the diameters of the ring (in needle entry view, that represents the preplanned path) to the diameter of the marker and the resolution of the x-ray image (be careful: higher dose!) may increase the accuracy.

As this is not in the responsibility of iSYS, please contact the manufacturer of the imaging device for further information.

After alignment of the NG, remove the NGMI from the NGA.

WARNING
By using only the Marker Insert for Aligment please be aware that you could have an incorrect bearing angle despite the fact that the two rings were positioned correctly. You may have a discrepancy / deviation of the needle tip to the planned target.

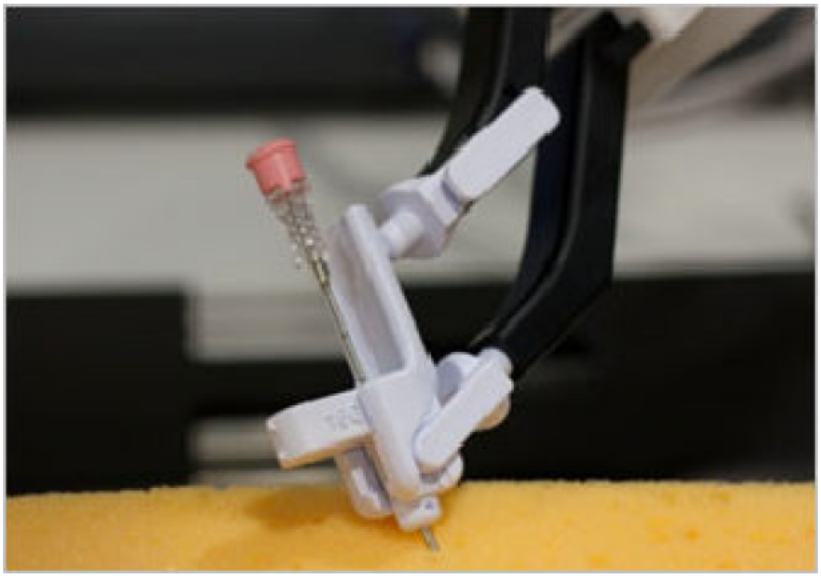
For additional fine alignment please follow next step.

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

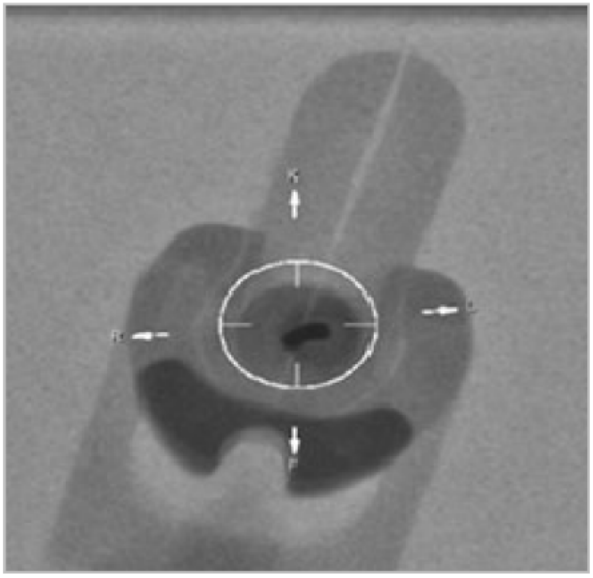
Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

4.2.9. Ultra-fine-Positioning and Accurate Alignment of the Needle under fluoroscopy

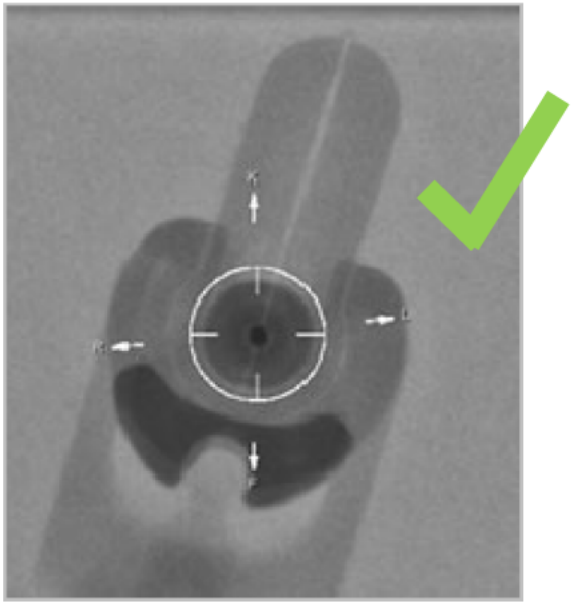
Place the needle into the NGI (see chapter 4.2.9. Attachment of the Needle Guide Insert and Needle Placement). The needle should be 1cm above the surface of the patient.



For micro-positioning the Needle under fluoroscopy the C-Arm has to be orientated perpendicular to the planned path ("entry point view"). To align the Needle with the planned path is done with the HCU as show before.



Before aligment



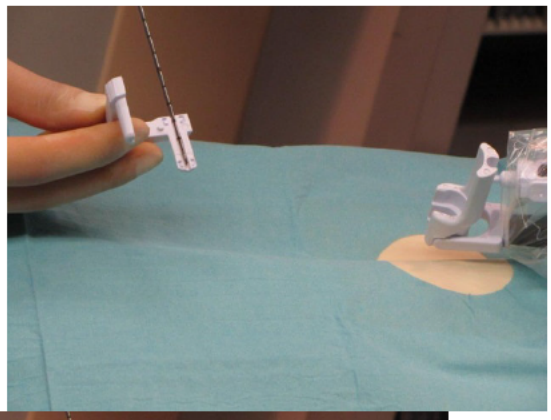
After perfect alignment the needle is shown as a small dot.

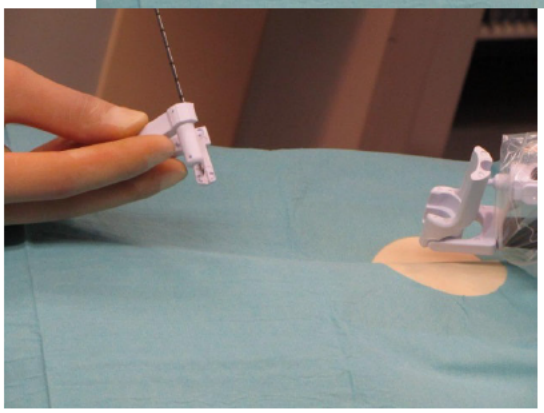
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

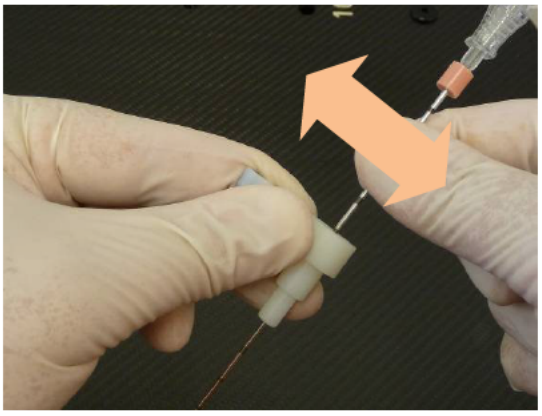
Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

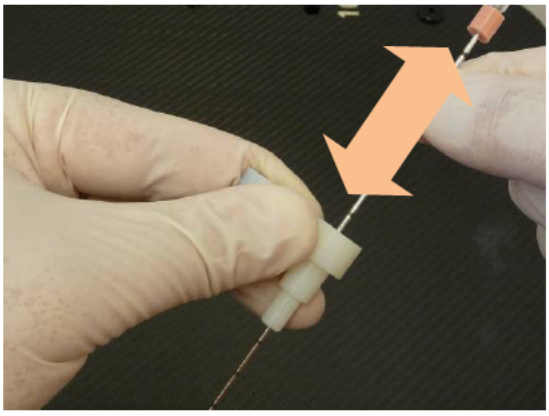
4.2.10. Attachment of the Needle Guide Insert and Needle Placement

The NGI has a very important function for needle guidance and quick release. Before attaching the sterile NGI to the NGA, check if the diameter of the needle fits to the NGI and check with the following manual test if the needle has a play-free and friction free guidance in the needle insert:









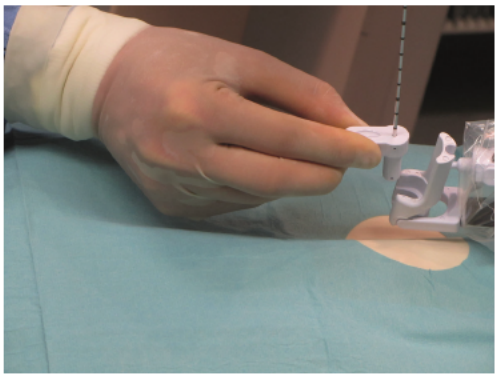
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

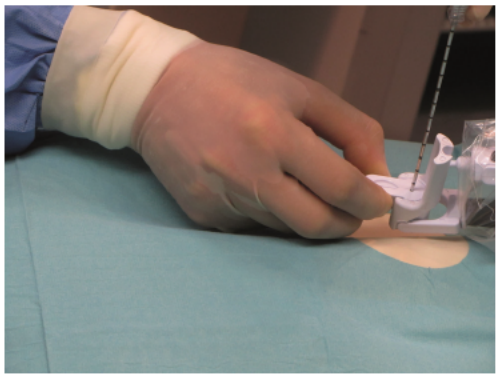
Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

This check takes place in two steps. First insert the needle to the opened NGI, hold the NGI tightly with one hand (pressing the two halves of the NGI together) and try to move the needle in radial direction with the other hand. There should be no detectable play between NGI and needle. For the second step, try to move the needle in axial direction. The needle should move easily – there should be no blocking of the needle during such axial movement.

WARNING
Check the free and easy movement of the needle in the Needle Guide Insert. Be aware that the needle is not clamped.

After you have checked the functionality of the insert, insert the (sterile) Needle Guide Insert into the Needle Guide Adapter.





WARNING
Make sure and double check that the NGI is in the right endposition and that there is no play between NGA and NGI.

WARNING
Precise needle guidance is essential for the accuracy of the needle placement.
Precise needle guidance is only possible, if the needle diameter is in a certain tolerance over the whole length of the needle.
Always check the tolerances of the needle with your needle supplier before using it with the iSYS system!

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

After attachment of the NGI to the NGA, the needle can be introduced manually in z-axis into the patient. This step must be under full control of the surgeon!

Depending on the used imaging device, the depth of the needle placement usually is being calculated by the planning software and is measured between the defined insertion point and the target point. For realization of the correct inserting depth the following procedure is being recommended:

- During planning, define the insertion point exactly on the skin surface of the patient.
- Before insertion of the needle, mark the calculated insertion depth (calculated by the planning system) with a sterile ruler and a sterile pen at the needle.
- Insert the needle until the marked insertion depth is reaching the skin surface
- It is highly recommended to check the needle insertion before reaching the final position by means of an intermediate scan (cf also sub-chapter “Verification and quality assurance” below).

Please note that iSYS is not taking any responsibility for realization of the correct inserting depth!

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

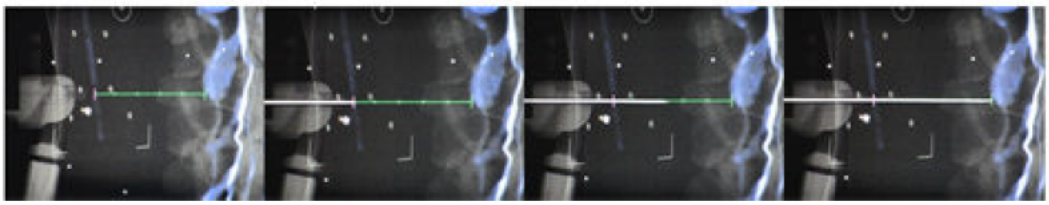
WARNING
Opening the MFA during the needle being inserted and connected to the RPU can lead to serious injuries at the patient.

WARNING
The iSYS 1 system acts as a guidance system. It is not designed to compensate high forces from the needle or the user.

Forces on the mechanical components of iSYS 1 may lead to inaccuracy of the needle placement!

Verification and quality assurance:

As the NGE is radiolucent, the correct needle position can be verified with lateral scans ("needle progress view", "angulated needle guide view", optional: "needle entry view") before, during and after treatment.



It is in the responsibility of the surgeon to decide how often verification scans are necessary (this may depend on the region of interest, planned accuracy, critical/surrounding tissue, etc).

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

WARNING
In case of multiple needle procedures, be aware that the needles do not collide with each other or with iSYS 1 compontents! This can seriously harm the patient.

WARNING
Be aware that the setup of iSYS 1 does not influence the imaging in the area of interest. In case of doubts repeat the imaging procedure to avoid mistreatment of the patient.

WARNING
In case of an error (emergency stop): the error condition has to be resolved and the system has to be in the ready state to go on. The needle position and angulation has to be verified with the imaging device before inserting the needle/tool.

WARNING
The RPU must not be use as a (arm) rest at any time, not even as a support of the surgeons hand while inserting the needle.

WARNING
When inserting the needle avoid forces on the needle except for forces along the needle axis. Otherwise it leads to inaccuracies an may lead to mistreatment or injury of the patient.

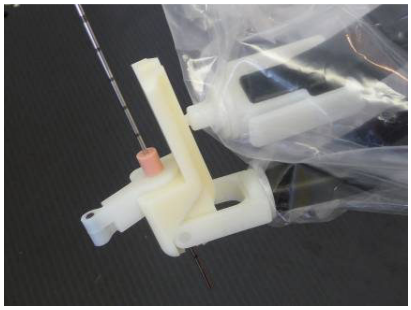
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

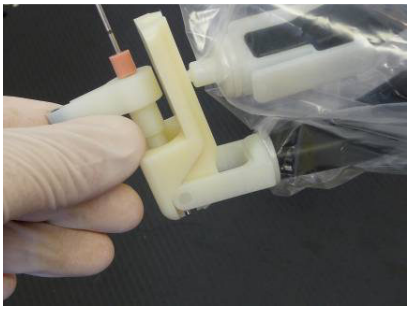
Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

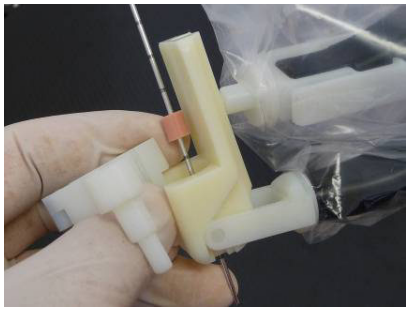
4.2.11. Removing the NGI and Quick-Release

After needle introduction and/or whenever the surgeon steps apart from the patient and/or when the diagnosis/treatment with the needle starts, the NGI has to be removed (i.e. the needle gets decoupled from the robot).

Such decoupling can be easily performed by simply lifting the NGI (along the needle axis) until the NGI is no longer connected to the NGA. In this position the NGI can be opened and the needle is no longer attached to the needle guide.







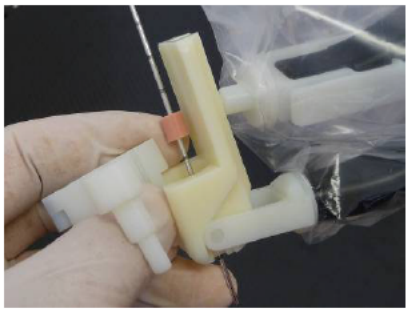
The decoupling also allows free “swinging” of the needle inside the needle guide and a removal of the iSYS 1 system in case of emergency.

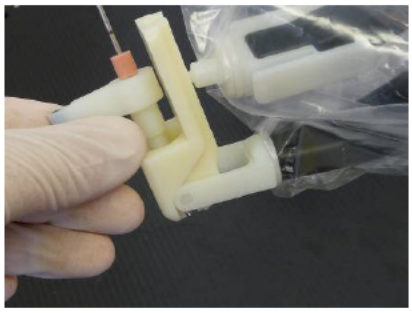
In case of multiple needle placements in larger distance to each other (bigger than the range of the robot), the decoupling also allows the removal of the RPU from the treatment area and a subsequent gross-positioning of the RPU for placement of the next needles.

If decoupling of the needle is only done temporarily (e.g. because the surgeon had to leave the patient for some time), the re-connection between needle and NGA can be done easily in the reverse order. The open NGI is being placed around the needle and being closed afterwards. Then the NGI is moved inside the NGA along the needle axis. Please be sure that the needle is fixed with the other hand during this step in order to avoid unintended needle insertion. For such re-connection the robot must not be moved between decoupling of the needle and re-connection.

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016





WARNING
During manipulation of the NGI for decoupling/coupling the needle from/to the NGA, please be sure that the needle is keeping in place (e.g. fixation with the other hand) in order to avoid unintended needle movement.

WARNING
In case of multiple needle procedures, be aware the needles do not collide with each other or with iSYS 1 compontents! This can seriously harm the patient.

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

WARNING
The MFA has progressive locking of the joints to allow precise positioning while locking and to avoid sudden movements when opening.
Always be aware that opening the MFA too fast can lead to uncontrolled movements of the arm itself or attached components (the robotic positioning unit).
Always open the MFA slowly and carefully with one hand and hold the arm or the attached device (robotic positioning unit) carefully with the other hand!

Although the RPU has an ergonomic design, always keep in mind that the steril cover may decrease the friction forces: Always hold and handle the MFA and the RPU carefully and safely!

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

4.3. Emergency Release/ Removing the system in case of emergency

In case of an emergency (e.g. patient panics), open the MFA, remove the RPU from the patient and bring it into parking position. Before manipulation of the RPU, please make sure to remove the needle from the NGI by either pulling out the needle or de-coupling the needle from the NGI (cf chapter 4.2.11).

WARNING
Before removing the system, always check that the NGI (or the needle) has been removed!
In case the needle insert has not been removed, friction forces can pull and/or push the needle and this can seriously harm the patient.

4.4. Dismounting

Before dismounting the system, bring the RPU into the "parking position" and remove the patient from the treatment table.

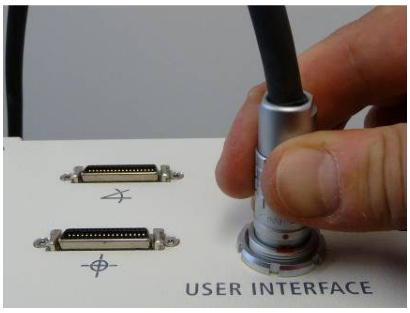
Remove the disposable parts first and dispose them according to the clinic guidelines.

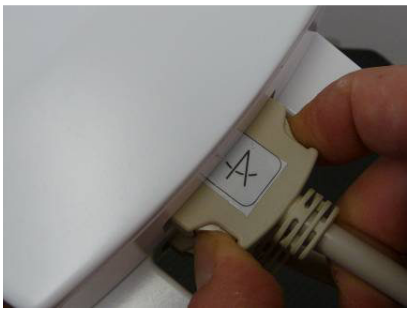
Unplug the system, remove the cables, clean the components and dismount the mechanical parts.

For unplugging of the HCU connection cable please grab the circular connector at the grooved part and simply pull out the plug. For the flat connectors connecting the RPU with the CU please push the two locking rockers of the connector and then pull out the connector.

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016





Store the components carefully in the iSYS storage boxes.

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

4.5. User Interface

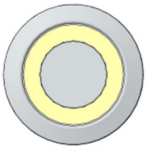
4.5.1. Alarms

This chapter describes the iSYS 1 alarms and what you should do if an alarm occurs.

The device provides only one alarm level, i.e. a technical alarm with low priority. Such a low priority alarm/alert warns you about a condition that prevents the system from operating normally. If, for example, the HCU is not connected to the CU, a runtime error is being detected and reported by triggering a dedicated low priority alarm/alert.

These alarms require your awareness. The alarm signal consists of a yellow LED and a sound that repeats a pattern of two beeps. The display has the message ***EMERGENCY STOP*** and an explanation of the alarm. The tables in Section 4.5.4 explain the alarm conditions and messages in more detail.

LCD Display



Error LED indicator

Alarm beeper

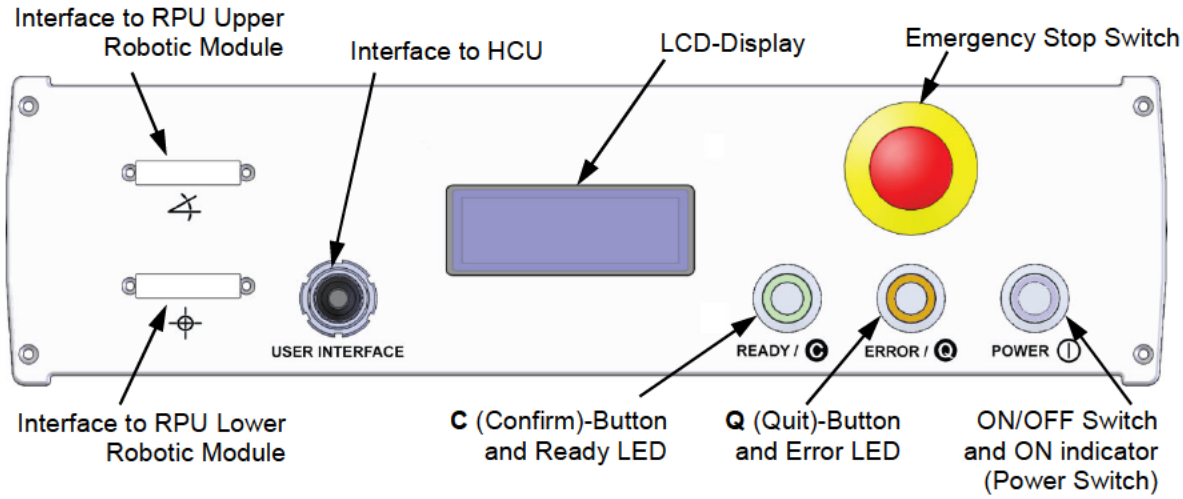
During a low priority alarm/alert:

- Look at the display for text.
- Look up the alarm in the alarm tables in Section 4.5.4 and perform the action specified.
- If the alarm can be cleared: Verify the position and angulation of the tool before you proceed.
- If the alarm persists: Stop the procedure or continue without using iSYS 1. Contact the manufacturer.

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

4.5.2. Front-Panel of the Control Unit



The front panel of the iSYS 1 Control Unit contains the following elements:

Buttons:

- ON/OFF Switch — Used to power the system (not accessible via software)
- **C** (Confirm) Button — Used to confirm triggered actions
- **Q** (Quit) Button — Used for controlled error recovering
- Emergency Stop Switch — Used for user initiated emergency stops

Indicators:

- Ready LED (green) — Indicates the system ready state (lighting) or prompts for confirmation input (flashing)
- Error LED (yellow) — Indicates error situations
- ON Indicator (blue) — Indicates if system is powered (not accessible via software)

LCD Display (4rows x 20 ASCII characters)

The LCD Display shows different states of the system.

Interface socket for Handheld Control Unit

The USER INTERFACE socket provides an electrical interface to control elements on the Handheld Control Unit.

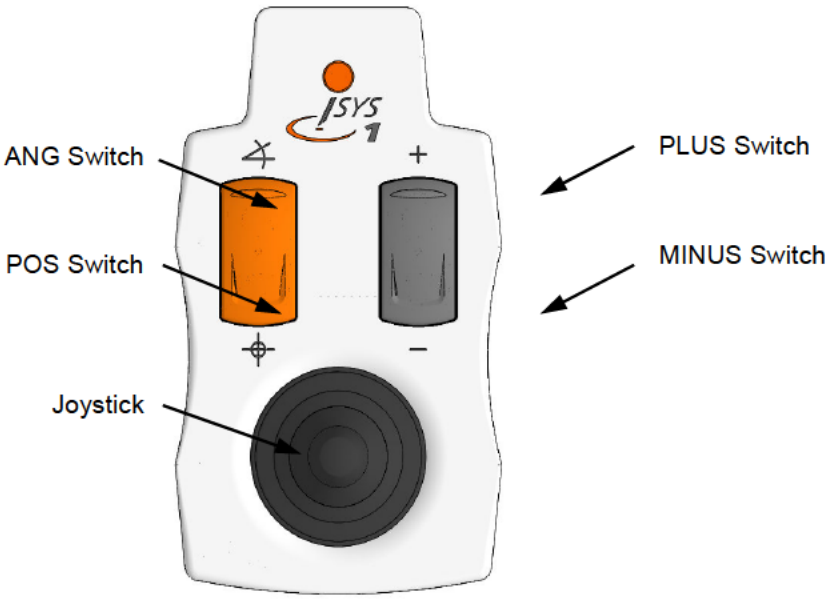
Interface sockets for angulation and positioning module.

..... These sockets provide an electrical interface to the robotic unit.

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

4.5.3. Handheld Control Unit



Left Rocker switch:

- ANG Switch — To activate angulation mode of the RPU
- POS Switch — To activate positioning mode of the RPU

Right Rocker switch:

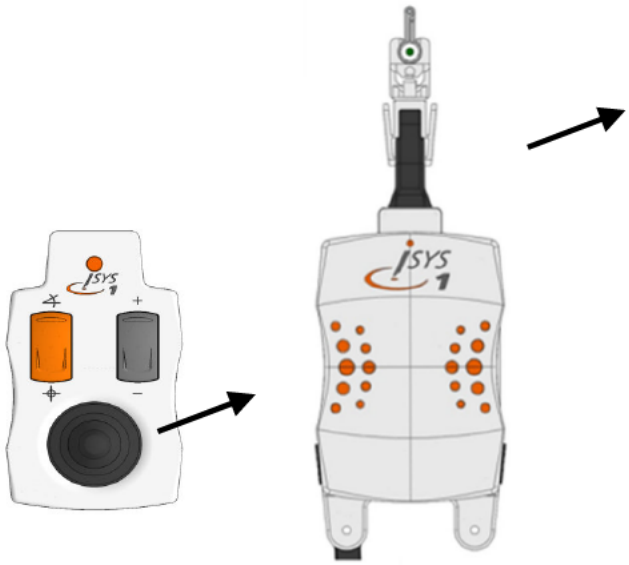
- PLUS Switch (+) — Used to increase the speed limit
- MINUS Switch (-) — Used to decrease the speed limit

Using the PLUS and MINUS button the overall speed level can be switched between 3 levels (100%, 60%, 20%), and thus scales the speed according to the joystick displacement to 100%, 60% or 20%.

Joystick:
The joystick initiates movement of the RPU according to the activated mode (POS or ANG). The shape of the HCU is based on the design of the RPU so that the desired direction of movement can be easily identified.

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016



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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

4.5.4. Display Messages

Boot-up screen

```
iSYS1 - Needle
Guidance Platform
-------------------
System Bootup....
```

Operation Screen

```
### iSYS1 C-ARM  ###

Speedlevel: fast   *
Joystick Mode  [POS]
```

... Header

... Current Actions (Info Messages)

... Speedlevel and MotionInfo

... Joystickinfo

Message text	Description
Joystickinfo	
Joystick Mode [POS]	The positioning mode is active. Any joystick motion leads to an appropriate motion of the positioning module (lower RM).
Joystick Mode [ANG]	The angulation mode is active. Any joystick motion leads to an appropriate motion of the angulation module (upper RM).
Joystick Mode [ ]	The system is not enabled to perform motions. This steady state is supervised by an electronic circuit.
Speed level+Motion Info	
Speedlevel: {slow|medium|fast} [*] Example: Speedlevel: fast *	The currently active speed level is shown (slow| medium| fast). The asterisk "*" appears if the robotic unit is actually moving. It indicates that the elongation of the joystick is big enough to effectively move the robotic unit.
Info Messages	
Enable System...	The system is activated
Init System	The system is initialized
Starting APP	iSYS 1 application is starting
Rev2 C1.1/M1.6/W1.5	Version info
* Running SELFTEST *	The self-test is running now
Selftest PASSED	The self-test has been completed successfully
Selftest FAILED	Error during self-test

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Error Messages / Emergency Stop Screen

```
### iSYS1 C-ARM ###
***Emergency Stop***
Stationary Error
Press Q to reset ->
```

… Header

… ***Emergency Stop***

… Error in Detail (see table below)

… What to do? (e.g. press the Q-button to reset)

Emergency Stop Reasons:

Error Message	Description	Fault correction
Error Init Axis	The axis controller cannot be initialized.	Press Q to recover the system. If the error still arises, please contact the manufacturer.
Error Detect UI	There is no, or a wrong user interface (HCU) connected to the control unit.	Connect the right user interface to the control unit. Check the connection if already connected. Then press Q to recover the system.
Runtime Err Axis	A runtime error in an axis controller was detected.	Press Q to recover the system (if this error arises frequently, please contact the manufacturer).
Runtime Err Ctrl	A runtime error in the master controller was detected.	Press Q to recover the system (if this error arises frequently, please contact the manufacturer).
Prog Abort Axis	The axis controller program was aborted.	Press Q to recover the system (if this error arises frequently, please contact the manufacturer).
Watchdog Error	The watchdog reports a bad response behavior of the master controller.	Press Q to recover the system (if this error arises frequently, please contact the manufacturer).
Wrong App Config	There are wrong or invalid configuration data detected.	Press Q to recover the system (if this error arises frequently, please contact the manufacturer).
Check HW(5V,Mod)	The modules are not connected properly or the cable for angulation and positioning are switched. There is a problem with the internal power supply.	Check the connection of the module - cables. Press Q to recover the system. If the error still arises, please contact the manufacturer.
Emerg-Stop	No special emergency reason was detected by the system.	Check the emergency stop switch (release).

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Error Message	Description	Fault correction
	Probably the Emergency Stop Switch was pressed.	Press Q to recover the system.
Encoder SigError	An encoder signal error occurred.	Press Q to recover the system. If the error still arises, please contact the manufacturer.
Encoder CmpError	An encoder compare error occurred.	Press Q to recover the system. If the error still arises, please contact the manufacturer.
Axis Param Error	The parameters of an axis controller are invalid.	Press Q to recover the system. If the error still arises, please contact the manufacturer.
APP Config Error	The system parameter configuration is invalid.	Press Q to recover the system. If the error still arises, please contact the manufacturer.
Stationary Error	A motion was detected while the enable button (rocker POS/ANG) was not pressed.	Press Q to recover the system. If the error still arises, please contact the manufacturer.
Motor Fault	A motor fault was detected.	Press Q to recover the system. If the error still arises, please contact the manufacturer.
Overload	The applied load on the robotic unit is beyond the defined threshold.	Check the reason for the overload. Press Q to recover the system. If the error still arises, please contact the manufacturer.
Check HCU Center	The joystick of the HCU is not in its center position (is checked during startup). The change of the HCU can also be the reason for this message.	Ensure that the joystick of the HCU is in its center position during startup. Press Q to recover the system. If the error still arises, please contact the manufacturer.

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

5. Maintenance

The product life of the iSYS 1 Unit is **10 years** including a regular service on the device. The service is intended to be performed every year, starting from the 3rd year of use of the device (e.g. device was sold in June 2008; the first service is performed in June 2011). The service includes:

- Detecting wear on the main components
- Detecting failures in the system
- Ensuring the accuracy of the device
- Checking the functionality of the safety relevant components

During the complete lifetime of iSYS 1, all parts and components can be supplied. This means, starting from the end of sale of iSYS 1, the spare parts are available for another ten years.

The lifetime, and thus the end of sales and end of service, might be subject to changes due to growing experience with the product.

For service purposes, iSYS 1 will be sent to iSYS where the service is organized. During that time, the customer will receive a substitute iSYS 1.

WARNING
Changes, additions or maintenance to the equipment carried out by persons without appropriate qualifications and training and/or using unapproved spare parts may lead to fatal or serious personal injury and/or damage to the equipment as well as making the warranty void.

WARNING
Obey the maintenance and service times as given in this section. Disobeying maintanance and service causes loss of warranty and may cause damage of the system and harm of the patient.

WARNING
The housings of the different components may only be opened by an authorized qualified electrician. Before opening a housing, disconnect the iSYS 1 from the main supply.

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

5.1. Safety-relevant inspections

Recurrent testing of safety relevant parameters of the iSYS 1 system as given below has to be done every 24 month. When national laws or regulations prescribe further and/or more frequent inspections or maintenance these rules have to be followed. If the iSYS 1 system fails any step of the inspection/testing the iSYS 1 system must not be used and the manufacturer must be contacted.

WARNING
Measurements are only to be performed by a qualified electrician or under supervision of a qualified electrician.

The mentioned inspections are minimum requirements:

Test/Inspection	Item	Inspection
Functional testing	Emergency stop	When the emergency stop button is activated, no motions of the RPU should be possible
	Drive motors	Smooth operation, abnormal noise development
	Strain relief of RPU Cable Set	Secure hold
	CU and HCU	Side rail: safe locking / secure hold / safe unlocking
	TTAA and TTAB	Table top mounting: safe locking / secure hold / safe unlocking
	CU	Check indicators, beeper and display
Visual inspection	Housing enclosure	Look for damage, cracks etc.
	Contamination	Look for obstruction of moving parts, connector pins etc.
	Cabling	Look for cuts etc.
	Fuse rating	Check correct values after replacement
	Markings and Labeling	Check the integrity of safety markings
	Integrity of mechanical parts	Check for any obstructions

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Protective earth testing	Protective earth connection	According IEC 62353
Insulation resistance test	Insulation between mains parts, accessible parts and earth	According IEC 62353
Leakage measurements	Leakage current	According IEC 62353

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

6. Cleaning and Disinfection

It is important that any part of the equipment which may come into direct contact with patients is cleaned and disinfected on a regular basis. Cleaning is an important requirement for a successful chemical disinfection.

WARNING
Only persons instructed in the use of this medical device are allowed to clean the iSYS 1 system.

WARNING
Always clean and disinfect the reusable components of iSYS 1 according to this manual. Never use equipment that is contaminated or uncleaned as this can lead to serious infections.

WARNING
Do not sterilize the re-usable components of the iSYS 1. Sterilizing of any components of iSYS 1 causes loss of warranty and may cause damage of the system and harm to the patient. If components of iSYS 1 are sterilized by mistake contact the manufacturer.

The system must be cleaned and disinfected prior and after to each use. iSYS system components are validated for cleaning and disinfection using the following substances:

Substances:
• 2-Propanol, 1-Propanol
• 94% Ethanol

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

CAUTION

Before beginning cleaning and disinfection, please note:

- **Unplug the power cable**
- **Make sure all other plugs are properly connected.**
- **None of the (electrical) components must show any visible damage; otherwise water or cleaning/disinfection solution could penetrate. This could lead to malfunction or damage to the electrical components.**
- **Before operating the system again, make sure that there is no residual moisture on the electrical contacts.**
- **All iSYS 1 components must not be cleaned with a water jet, a high pressure cleaner or other similar device! Do not use dipping method for cleaning and disinfection!**
- **Clean/disinfect all iSYS 1 components only with a moist towel!**
- **If you suspect that water or any other form of moisture has penetrated the electrical components, disconnect the power plug immediately. If already disconnected from the power supply, make sure it is not plugged in again. Clearly mark the device as "Defective" and take it immediately out of service. Report this to the operator promptly.**
- **Failure to follow these directions could lead to major damage of the system!**

WARNING

After cleaning and disinfection iSYS 1 has to be dried sufficiently. Follow the specific instructions for use and recommended contact times of the used cleaning and disinfection agents.

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

iSYS Medizintechnik GmbH
Bergwerksweg 21
6370 Kitzbühel
Austria
www.isys.co.at

Order Nr.: 9567

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Marketing Material

Definition and Analysis of Marketing Material:

This document contains the summarized information for the marketing and sales department as it is released by the general management. The information herein can be used to promote the product, e.g. for marketing material, flyers, meetings with customers, exhibitions and key accounts.

Article/Part number:	4268 / 6224
Article/Part name:	iSYS 1 / iSYS 1 U.S.
Clinical Text:	Micro-invasive surgical procedures are gaining increasing importance in medicine due to the high efficiency level (clinical outcome) and low socio-economic costs. Highest quality assurance of medical instrument positioning and mechanical precision is the “sine qua non” for the ever increasing sophistication of interventional radiology and related fields with its concurrent reduction or abolition of safety margins. The iSYS-1 Interventional Platform iSYS Medizintechnik GmbH provides a state-of-the-art solution which is able to fulfill the three main requirements – accurate positioning, easy integration into clinical workflow as well as a simple and fast setup procedure. The iSYS-1 Interventional Platform has clear advantages over alternative methods of instrument placement: - Firstly, the treatment results are markedly improved while the costs of treatment are reduced. - Patient, physician and hospital or practice can all benefit from this situation. - In addition, the radiation exposure for both the patient and the surgical team can be reduced substantially. - In this way, long-term damage to the surgical team carrying out the treatment will be avoided. - Through the use of the iSYS-1 system, it is no longer necessary to work with the "hand in the beam” and / or in the vicinity of the imaging device. Intended Use: The intended use of the iSYS1 device is to function as a remote-operated positioning and guidance system during interventional procedures. Positioning is done in remote control

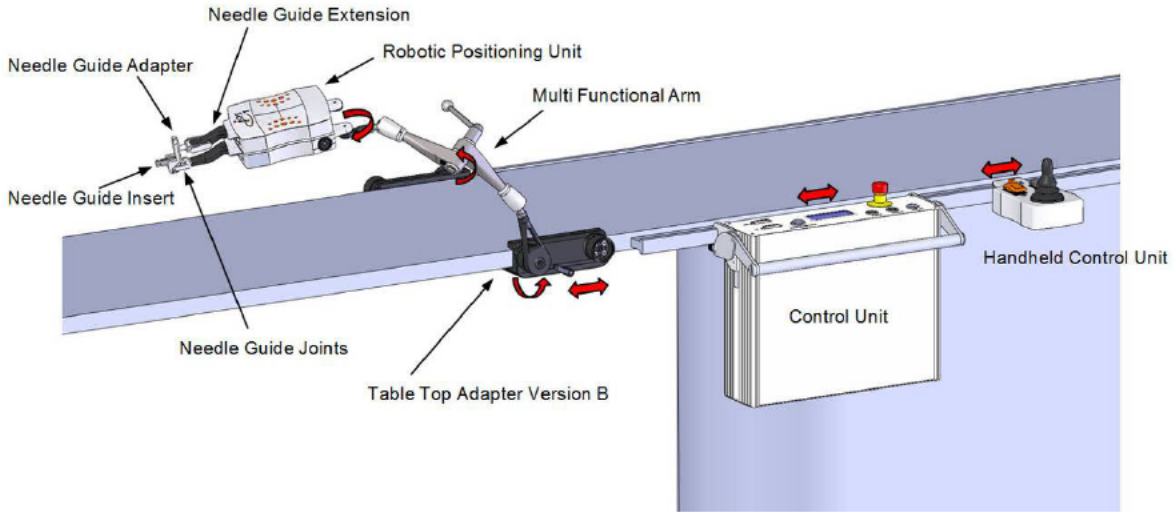
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

	manner; planning of the position/angulation is done based on 2D/3D patient data (CT, cone-beam CT, fluoroscopy) by external planning software – for example using an external navigation system, or planning software coming with the used imaging device. Also verification of the correct position and orientation of the tool prior to/during/after the intervention is done by means of these external devices. The iSYS1-System is then acting as a guideway during the manual insertion of the interventional tool – usually a needle type device, and the like. Applications include, but are not limited to, interventions like biopsy procedures, tumor ablation, nerve blocking, electrode placement, etc.
Technical Text:	The iSYS 1 Interventional Platform is a modular needle guidance platform for interventional radiology and related fields. Core components are a 4 DOF Robotic Positioning Unit which allows submillimetric needle positioning as well as angulation and a Control Unit which is controlled by a cable connected Handheld Control Unit. The passive macro positioning unit and different table adapters allow different setups of the system around the patient in the region of interest by still providing maximum rigidity. The needle-guide-set provides disposable components that ensure precise and sterile needle guidance. Planning of the intervention is based on digital image data acquired intra-operatively using different kinds of modalities, like CT or fluoroscopy (standard C-arms and/or cone-beam CT systems). Planning and verification of both the entry position of the needle-type tool as well as the angulation is performed with the aid of the used imaging device or by an external navigation system. By using the iSYS 1 Handheld Control Unit the surgeon can remotely move the tool to the desired position and angulation in order to start the clinical procedure.

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016



The system includes the following mechanical parts:

- one Control Unit
- one Table Top Adapter Version B (Bottom Mounted)
- optional: Side Rail Adapter or Table Top Adapter Version A (Top Mounted)
- one Multi-Functional Arm
- one Robotic Positioning Unit
- two Needle Guide Extensions

The sterile disposables for each procedure are:

- Sterile Cover Robotic Positioning Unit (not reusable) including Needle Guide Joints and Needle Guide Adapter (not reusable)
- Sterile Cover Handheld Control Unit (not reusable)
- Needle Guide Insert (not reusable)
- Marker Insert (not reusable)

Compatibility:

Equipment described in this manual shall only be used in combination with other equipment or components, if these are expressly approved by iSYS as compatible. A list of such equipment and

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

	components is available from iSYS upon request. Changes and/or additions to the equipment shall only be carried out by persons expressly authorized by iSYS to do so. Such changes shall comply with best engineering practice and all applicable laws and regulations that have the force of law within the jurisdiction the equipment will be used within. The following components are compatible with the system but are optional: • Table Adapters • Needles • CT-Systems • System Carts
Technical Data/Information (including photos, drawings if available etc.):	The interface and mounting of the Side-Rail-Adapters of the Control Unit, the Handheld Control Unit as well as the MFA is adjustable along the whole side rail as needed by the user. Additionally the MFA can be rotated in a half circle of 450mm, with the center of rotation being the interface MFA to Side-Rail-Adapter. All starburst or spoon interfaces can be set up in the angle needed, between at least 0-180°. The maximum reachable straight length is 300mm Side Rail Adapter Extension Rod, MFA 450mm, Robotic Positioning Unit 170mm plus 20mm adjustability, Needle Guide Extension and Holder 120mm, leading to an overall length of 940mm. When using any of the Table Top Adapters, the 300mm extension rod is not available, therefore maximum reachable straight length lies at about 640mm. The Robotic Positioning Unit is a robotic unit consisting of two 2DOF modules which allows tool angulation (± 30° for both pitch and yaw angle) and needle positioning (± 20 mm for both lateral and longitudinal direction) with a weight of max. 1,5kg, size is 170x120x70mm. Additional weight is strongly depending on the setup used. The MFA weights 1,3kg with 450x140x60mm, the Control Unit, 700x350x105mm, being the heaviest component with 6 kg. All components can be set up separately. Operating temperature/humidity range: 15 to 30°C; 30 to 70% relative humidity with no condensation Storage temperature/humidity range: 10 to 50°C; 30 to 70% relative humidity with no condensation Power Supply: 50W; 115VAC/230VAC; 50-60Hz; cable: C14 according to IEC/EN 60320-1, US498, CSA C22.2 no. 42
Remarks:	Claimed benefit of the medical product - Firstly, the treatment results are markedly improved while the costs of treatment are reduced. - Patient, physician and hospital or practice can all benefit from this situation. - In addition, the radiation exposure for both the patient and the surgical team is being reduced substantially.

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

- In this way, long-term damage to the surgical team carrying out the treatment will be avoided.
- Through the use of the iSYS-1 system, it is no longer necessary to work with the "hand in the beam" and / or in the vicinity of the imaging device.

Clinical studies/ Pre-clinical investigations for reference

From the given literature, we conclude that video-assisted and computer-assisted robotic techniques are safe and may be the pathway to improve minimal invasive operations. The damage to healthy tissue can be significantly reduced which results in shorter operating times and hospital length of stay. The data proves that robotic systems in general are capable to achieve the performances intended by the manufacturer. The iSYS 1 is designed, manufactured and packaged in a way that it is suitable for the functions referred to in the intended use, and thus fulfills Annex I.3 of MDD.

CAS (computer assisted surgery) allows for increased three-dimensional accuracy, improved precision and the reproducibility of procedures. The ability to transmit to the other side of the operating room or to a remote site via high-speed communications links is an additional advantage. Furthermore, the surgeon will be able to share his expertise and skill through teleconsultation and telemanipulation, bringing the patient closer to the expert surgical team.

Surgical robotics is the study and application of advanced robotic technology to diverse surgical procedures, particularly to minimally invasive surgery. The advanced robotic technology in minimally invasive surgery leads to momentous change in and generates a tremendous impact on surgery, resulting in less pain and scarring, reduced blood loss and transfusions, lower risk of complication, shorter hospital stays and faster recovery periods. Systems such as the da VinciTM surgical system of Intuitive Surgical Inc., which facilitates minimally invasive surgery with increased dexterity, are commercially available. Preoperative simulation and planning of surgical robot setups should accompany advanced robotic surgery if their advantages are to be further pursued. Feedback from the planning system will play an essential role in computer-aided robotic surgery in addition to preoperative detailed geometric information from patient CT/MRI images.

While other authors find no statistical differences between experienced surgeons and non-surgeons in the number of errors (block drooping) as well as the completion time and the tool tip path length at different time delays, the CEDIT considers robots to meet the requirements of accuracy, innocuity and minimal invasion characterizing neurosurgical practice. No other technique of neuronavigation currently provides this degree of accuracy. The CEDIT recommends the NeuroMate (R) stereotactic robot for centres handling a large number of patients with stereotactic neurosurgery indications, but also recommends a harnessing of expertise (neurology, neuroradiology, neurosurgery, and neurophysiology) with recognized experience in the field. The neurosurgery department of the Henri-Mondor hospital

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

	corresponds to these requirements. Limitations: Robotic surgical systems, such as the da Vinci Surgical System (Intuitive Surgical, Inc., Sunnyvale, California), have revolutionized laparoscopic surgery but are limited by large size, increased costs, and limitations in imaging. Miniature in vivo robots are being developed that are inserted entirely into the peritoneal cavity for laparoscopic and natural orifice transluminal endoscopic surgical procedures. In the future, miniature camera robots and microrobots should be able to provide a mobile viewing platform. CAS is a more expensive technology on a per case basis due to more expensive robot specific instrumentation and physician labour reflected by increased OR time reported in the clinical literature. There is insufficient evidence to conclude that any of the three surgical approaches is superior with regard to functional and oncological outcomes. Despite implicit or explicit claims that this technology is superior, for most indications its distinct advantages are currently unproven and highly dependent on surgical skills and professional experience.
Marketing material requested?	☒ yes What kind of: Flyers and Marketing Material for ECR 2011 (see PDM "Marketing"). ☐ no
Analysis of Marketing Information:	**Costs and effectiveness:** EX_66_2396_wi_FIC-2008: "*The use of the robotic assistant did not slow down the procedure, which must be considered as a very positive result for a pilot clinical trial.*" EX_73_09750_wi_SCH-2012: "*Results All phantom interventions (n040) could be performed successfully. Mean target access path within the phantom was 8.5 cm (min 4.2 cm, max 13.5 cm). Average needle tip deviation was 1.1 mm (min 0 mm, max 4.5 mm), time duration was 3:59 min (min 2:07 min, max 10:37 min). Conclusion When using the proposed robot device in a CBCT intervention suite, highly accurate needle-based interventional punctures are possible in a reasonable timely manner in single as well as in double oblique trajectories.*" → Higher patient throughput EX_66_2706_wi_KRO-2003: "*Reduced treatment costs due to lower morbidity*"…"*Shortening of the interventional procedure*".

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

→ Better cost-benefit ratio

EX_66_2396_wi_FIC-2008: "*The system provided needle placement accuracy superior to that of conventional templates while offering much greater flexibility, owing to its biaxial needle angulation and continuum Cartesian needle spacing. These features were achieved without causing interference with established clinical hardware, workflow, or calibration standards.*"

EX_66_2706_wi_KRO-2003: "*Improved accuracy and consistent results of biopsy samples*".

EX_73_09750_wi_SCH-2012: "*Results: All phantom interventions (n040) could be performed successfully. Mean target access path within the phantom was 8.5 cm (min 4.2 cm, max 13.5 cm). Average needle tip deviation was 1.1 mm (min 0 mm, max 4.5 mm), time duration was 3:59 min (min 2:07 min, max 10:37 min). Conclusion When using the proposed robot device in a CBCT intervention suite, highly accurate needle-based interventional punctures are possible in a reasonable timely manner in single as well as in double oblique trajectories.*"

→ Higher precision

EX_66_2396_wi_FIC-2008: "*Robotic needle positioning offers potential for more conformal treatment planning due to the capability for finer adjustments in needle positioning, as well as the potential for reduced number of needles required for a given volume. "*

EX_66_2706_wi_KRO-2003: "*Planning of complex access routes*".

EX_66_6855_wi_BAL-2012: "*The drawbacks of conventional computed tomography/ ultrasound/magnetic resonance imaging (CT/US/MRI) guided radiofrequency ablation (RFA) are the absence of planning software, imprecise probe placement, imprecise control of probe placement and the ablation zone as well as the lack of reliability and reproducibility.*

Methodological innovations: Stereotactic and robot-assisted systems allow planning of multiple probe positions based on CT/MRI and positron emission tomography (PET) planning data. The probes can be precisely placed according to the coordinates of the image datasets.

Performance: The 1 and 3 year survival rates after stereotactic RFA (SRFA) of cholangiocellular carcinoma were 91% and 70% respectively and the median overall survival was 60 months. After SRFA of 189 colorectal liver metastases in 63 patients there was no significant difference in local recurrence rates between tumors < 3 cm (17.7%), 3–5 cm (11.1%) and > 5 cm (17.4%). The median overall survival was 33.2 months and the 1, 3, and 5 year overall survival rates after SRFA in patients with resectable colorectal cancer were 92%, 66% and 48%, respectively.

Achievements: In our opinion the excellent and, to a large extent user-independent results justify the

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

increased efforts in time and costs especially for the treatment of patients with large and irregular tumors."

→ Better clinical outcomes

Patient benefits:

EX_66_2706_wi_KRO-2003: "*Reduced radiation dose for the radiologist and patient during intervention*". See also Kato et al.: "Radiation dosimetry at CT fluoroscopy".

EX_66_5705_wi_BRA-2011: "*Total mean effective doses with cone-beam CT guidance were 7.6 mSv in the upper thorax, 12.3 mSv in the lower thorax, 16.1 mSv in the upper abdomen, and 13.4 mSV in the lower abdomen. Effective doses with uncollimated cone-beam CT alone were 2.0, 2.9, 4.2 and 3.5 mSv in the respective regions. Effective doses with CT-guided interventions were 13.0, 15.1, 20.4 and 15.4 mSv in the respective regions. Cone-beam CT guidance results in reduction of 13% - 42% of total effective dose compared with conventional CT guidance.*"

EX_66_09749_wi_SCH-2012: "*The high accuracy finally might save the patient from a dose of radiation because the intervention time can be kept at a low level.*"

→ Reduced radiation exposure; Fewer side effects due to less radiation dose and higher accuracy; Faster recovery due to fewer side effects.

Ergonomics:

Test Reports: Test 1/3, Test 1/4, Test 2/4, Test 4

→ Intuitive and fast use

Test Reports: Test 1/3, Test 1/4

→ iSYS 1 is the most advanced needle guidance platform for interventional radiology

Safety:

Use of watchdog, dead man switch, reduced translation speed, and visual and acoustic alarm system, interrupting the current flow immediately, cannot be found in predicate devices or concurrent systems. For validation of safety systems and integration see PD_73_3872 (safety structure of iSYS 1).

EX_66_2706_wi_KRO-2003: "*Reduced radiation dose for the radiologist and patient during intervention*". See also Kato et al.: "Radiation dosimetry at CT fluoroscopy".

EX_66_2400_wi_WAG-2009: "*By using the technology [fluoroscopy], they're [physician] achieving better*

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

accuracy than before – and leaving themselves open to various forms of cancer and other conditions known to develop after years of radiation exposure….The first line of protection is to keep yourself out of the beam. The second line of protection is to keep yourself 6 feet away from the beam."

Test Reports: Test 2/5, Test 2/6, Test 3/2, Test 5, Test 6

→ Safer work environment

EX_66_2706_wi_KRO-2003: "*Reduced radiation dose for the radiologist and patient during intervention*". See also Kato et al.: "Radiation dosimetry at CT fluoroscopy".

EX_66_09749_wi_SCH-2012: "*Measurements showed the highest radiation dose at the eye and thyroid level. In comparison to 2D-DSA (3.9 Sv eye-exposure), the 3D procedures caused an increased radiation exposure both in standard FOV (8 s/rotation: 28.0 Sv, 20 s/rotation: 79.3 Sv, 5 s/2 rotations: 32.5 Sv) and large FOV (37.6 Sv). Proportional distributions were measured for the residual heights. With the use of lead glass, irradiation of the eye lens was reduced to 0.2 Sv (2D DSA) and 10.6 Sv (3D technique with 20 s/rotation). Conclusion: Rotational flat-panel angiography and C-arm cone beam applications significantly increase radiation exposure to the attending operator in comparison to 2D angiography. Our study indicates that the physician should wear protective devices and leave the examination room when performing 3D examinations.*"

EX_66_09749_wi_SCH-2012: "*Apart from the improved accuracy, an advantage of using a mechanical device for needle guidance could be the reduced x-ray exposure to the attending staff because the robot can be aligned to the correct bearing from a safe distance. Both before and during the needle insertion, neither a direct exposure of the interventionalist's hands to the radiation beam will occur, nor are inaccurate holding devices such as forceps necessary. The high accuracy finally might save the patient from a dose of radiation because the intervention time can be kept at a low level.*"

Test Reports: Test 6

→ Safer for the physician

Safer work environment and higher safety for the physician

Operator controls the robot from the control room → no radiation exposure for the user

The „Joystick"-extension cable allows an extension of the standard „Joystick"-cable from 3 meters to 11 meters.

The higher the radiation dose for the user, the more health risk for the user (see publication EX_66_2400_wi_WAG-2009)

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

The greater the distance to the beam results in less radiation exposure (see publication EX_66_2400_wi_WAG-2009)

The user knows that radiation harms him, so he stresses himself to be very fast. At the same point of time he should not make a mistake when placing the needle, this causes additional stress

With the iSYS 1 he can easily make the needle alignment under fluoroscopy outside the 6 foot line. Being inside the 6 foot line is seen as critical, even with radiation protection.

→ Less risk and stress during interventions

EX_66_2396_wi_FIC-2008: "*A Phase-I clinical feasibility and safety trial has been successfully completed with the system. We encountered needle tip positioning errors of a magnitude greater than 4 mm in only 2 of 179 robotically guided needles, in contrast to manual template guidance where errors of this magnitude are much more common. Further clinical trials are necessary to determine whether the apparent benefits of the robotic assistant will lead to improvements in clinical efficacy and outcomes.*"…" *The robot allowed for fine adjustments in needle/seed positioning, which we used at times to achieve insertion points between the standard template positions. In addition, the ability to easily shift the frame of reference of the robotic needle guide avoids a difficult situation encountered in standard procedures where systematic errors in needle placement are often observed despite careful pre-clinical calibration. In such cases, we could easily compensate for the apparent bias…*"

EX_66_2706_wi_KRO-2003: "*Reduced radiation dose for the radiologist and patient during intervention*". See also Kato et al.: "Radiation dosimetry at CT fluoroscopy".

Test reports: Test 1/1

→ Safer for the patient; higher accuracy than manual procedures

Use of watchdog, dead man switch, reduced translation speed, and visual and acoustic alarm system, interrupting the current flow immediately, cannot be found in predicate devices or concurrent systems. For validation of safety systems and integration see PD_73_3872 (safety structure of iSYS 1).

Test reports: Test 2/1, Test 2/2, Test 2/3, Test 3/1, Test 5, Test 8 – 10

→ Higher safety standards; Best safety standards

EX_66_2396_wi_FIC-2008: "*In contrast to actual needle tip positions, the Polaris measurements consistently showed the robotic positioning of the needle guide to be accurate generally to within 1mm. Given that the Polaris measurements were of the robot arm position instead of needle position at depth,*

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

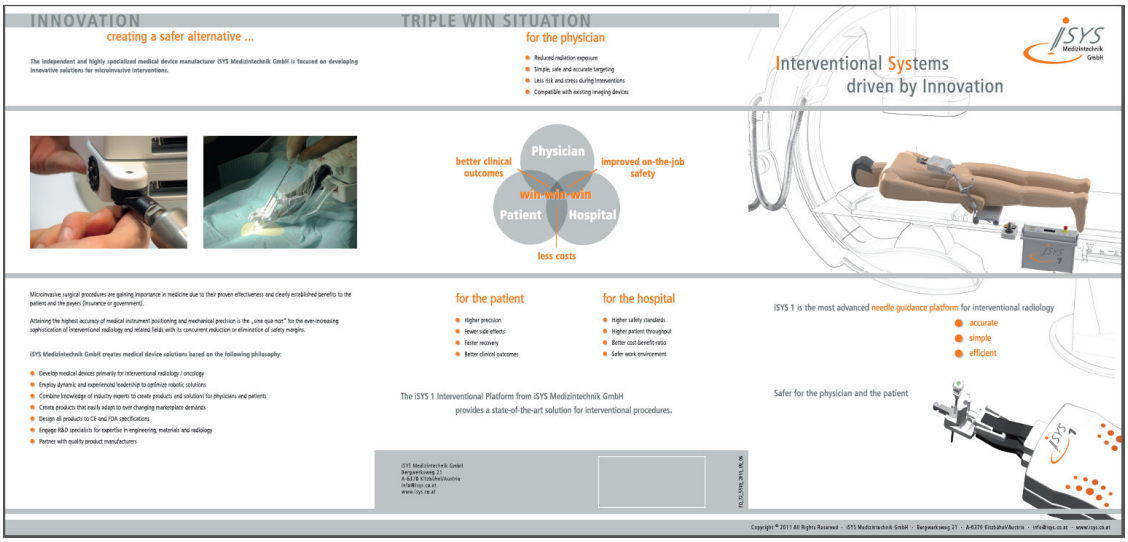
	they are not affected by tissue deflection of the needle upon insertion and thus are a more relevant indication of robotic positioning accuracy versus the template." Test reports: Test 2/1, Test 2/2, Test 2/3, Test 2/4, Test 3/1 → Maximum mechanical stability/compatibility **Multicenter study:** (covering several phrases) EX_66_11430_wi_KRO-2013: "*The outlined work-flow has been evaluated in a series of ex vivo trials in 5 different institutions and with different imaging systems. Tests have been performed with different protocols, e.g. for usability evaluation, evaluation of radiation dose, accuracy, and others. The following group of results should serve as an example for these multi-centric tests (n=35 needle placements):* • *avg. alignment time: 21.23 sec (min. 11 s, max. 35s)* • *avg. additional dose: 2.076 mGy (min. 1.389 mGy, max. 3.243 mGy)* • *mean deviation 0.4 mm (RMS) from planned path with a mean insertion length of 6.73 cm* *DISCUSSION* *A work-flow has been developed in order to allow a seamless integration of a novel robot system for percutaneous needle placement with CBCT imaging. Evaluation has been performed in a series of ex vivo tests and multi-centric patient trials for different applications and target regions. All (in vivo) procedures were successfully conducted without any technical problems.* ***By using the developed work-flow the procedures have been rated as simpler, more comfortable, safer for patient and physician, and faster."***

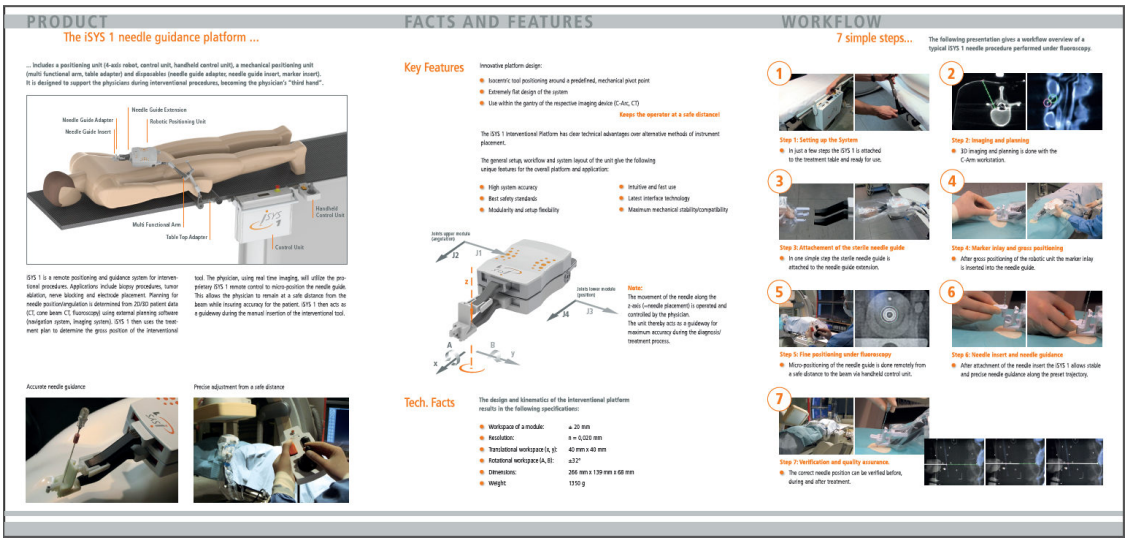
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Section 013	Proposed Labeling 510(k) Number: K131433	iSYS Medizintechnik GmbH

Flyer (6 pages):





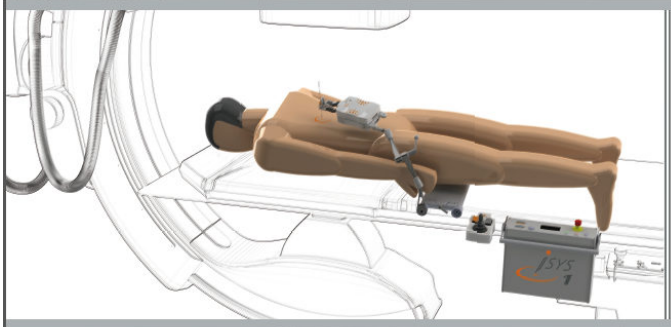
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

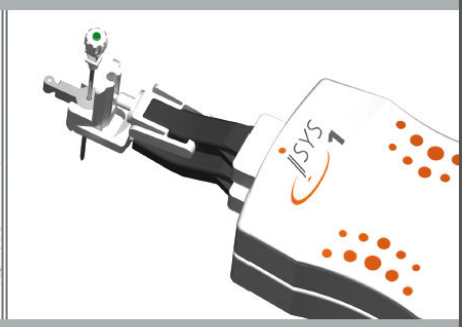
Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Product Flyer (2 pages):

Interventional Systems driven by Innovation

iSYS Medizintechnik GmbH





iSYS 1 is the most advanced needle guidance platform for interventional radiology

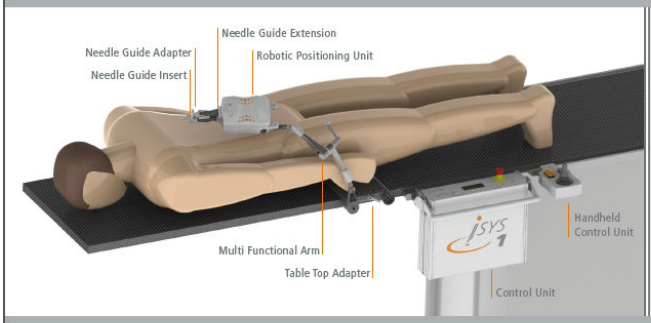
- accurate
- simple
- efficient

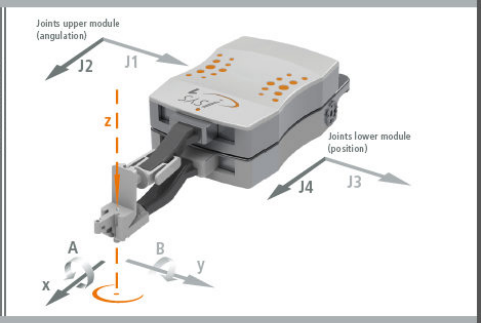
Safer for the physician and the patient

Copyright © 2011 All Rights Reserved · iSYS Medizintechnik GmbH · Bergwerksweg 21 · A-6370 Kitzbühel/Austria · info@isys.co.at · www.isys.co.at

On target from a safe distance.

iSYS Medizintechnik GmbH





System description:

The intended use of the iSYS 1 device is to function as a remote-operated positioning and guidance system during interventional procedures.

Core component is a robotic-positioning unit with 4 degrees of freedom which allows submillimetric needle positioning in x, y (range +/- 20mm) and angulation in A, B (range +/- 35°) around a fixed pivot point.

The passive gross positioning unit and variety of table adaptors allow for different system configurations of the system around the patient in the region of interest while providing maximum rigidity.
Planning of the desired position/angulation is done based on 2D/3D patient data (CT, cone-beam CT, fluoroscopy).

Fine positioning/angulation is done remotely from a safe distance.

After adjustment of the needle guide, the iSYS 1 acts as a guideway during the manual insertion of the interventional tool.

System benefits:

- High system accuracy — better clinical outcomes
- Small and lightweight robot — high safety standards
- Modularity and compatibility — maximum setup flexibility
- Intuitive use — easy and fast handling
- Latest technology — good cost-benefit ratio
- Extremely flat design — use inside the gantry

Keeps the operator at a safe distance!

FO_72_395 from 16.03.2011

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Form FDA 3654

Form Approved: OMB No. 0910-0120; Expiration Date: 12/31/13

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

ISO 15223-1 Second Edition 2012-07-01, Medical devices - Symbols to be used with medical device labels, labelling, and informati

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	#5-73	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☐	☒
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☒
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☒	☐
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☒	☐
If yes, was the guidance document followed in preparation of this 510k?	☒	☐

Title of guidance: Guidance for the Content of Premarket Submissions, Guidance for Off-the-Shelf Software, et. al.

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

[5] The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[6] The online search for CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html

FORM FDA 3654 (12/10) Page 1

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE
ISO 15223-1 Second Edition 2012-07-01, Medical devices - Symbols to be used with medical device labels, labelling, and informati

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
5	Symbols	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *
Symbol 5.2.8. is used although not recognized (see SIS)

DESCRIPTION

JUSTIFICATION
Symbol is common and used in the U.S. Use of it does not bear any risk. The meaning is described in the User Manual.

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

* Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

Paperwork Reduction Act Statement

Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and 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:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
1350 Piccard Drive, Room 400
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 number.

FORM FDA 3654 (12/10) Page 2

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Sterilization and Shelf Life

Table of Content

	Page
In General	2
Proposed Labeling	7
Validation Report (Packaging)	11
Summary Repor (b)(4) [redacted]	28
Sterilization Validation (b)(4) [redacted]	34
Summary Report (b)(4) [redacted]	59
Sterilization Validation (b)(4) [redacted]	61
Bioburden Routine Report	75
Validation of Bioburden Determination	89
Data Sheets	100
Certificates	135

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Section 014	Sterilization and Shelf Life 510(k) Number: K131433	iSYS Medizintechnik GmbH

In General

With the iSYS 1 system several single use sterile devices are supplied. They are not meant to be reused or user sterilized, but are for single use only.

Cleaning and disinfection procedures according to regular clinical standards are recommended in the user manual and should be applied to the hardware modules only, as they are reusable.

1. Sterile Equipment Covers (Drapes)

The sterile equipment covers for the US market are obtained from (b)(4) [redacted] (b)(4) [redacted] and are part of the PM product family covered by their 510(k) K863853. They are delivered ready packaged, la[redacted] (b) [redacted]. Thereafter, they are added to the final iSYS products at (b)(4) [redacted] (b)(4) [redacted].

For a comparison of the iSYS equipment covers with the existing products from Preferred Medical see below chapter “Summary Reports Preferred Medicals” (product adoption).

2. Needle Guide Adapter, Needle Guide Inserts, and Needle Guide Marker Inserts:

The Needle Guide Adapters, Inserts, and Marker Inserts are part of the robotic system manufactured by iSYS (b)(4) [redacted] performs packaging and sterilization under 510(k) K893814.

For the “Sterile Cover RPU” the Needle Guide Adapter is packed in a kit together with the drape.

Kit Certification:

We certify that the following components of our kit have been found to be substantially equivalent through the premarket notification process for the use for which the kit is intended (i.e., I am not claiming or causing a new use for the components). We further certify that these components are not purchased in bulk, but are purchased in finished form, i.e., they are packaged, labeled, etc., and consistent with their premarket notification criteria and status.

Sterilization method:

(b)(4) [redacted]

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

(b)(4)

[redacted]

For details see also Appendix/Misc. Files “008_(b)(4) [redacted] VDMax Final Report” and below.

Description of packaging:

All components are double packed and sealed with peel packs in different sizes (Tool 3.2 or 2.1) and “Internal Pouch 4x5 w”. For details on the packaging or the packaging material see below (Data Sheets) and the following table:

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Section 014	Sterilization and Shelf Life 510(k) Number: K131433	

(b)(4)

[redacted]

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Section 014	Sterilization and Shelf Life 510(k) Number: K131433	

(b)(4)

[redacted]

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

(b)(4)

[redacted]

The packaging is performed with the (b)(4) [redacted] and at (b)(4) [redacted] (b)(4) [redacted] For validations please see reports below starting from page 11.

Device Description

Details see Section 011, pages 26 – 36 and 56 – 57, for technical data sheets see below.

Flammability:

See TDS below: according to UL 94, IEC 60695-2-12 and FMVSS 302.

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Proposed Labeling

Safety Symbols:

STERILE EO	Symbol for STERILIZED USING ETHYLENE OXIDE
STERILE R	Symbol for STERILIZED USING RADIATION
	Symbol for DO NOT USE IF PACKAGE IS DAMAGED
	Symbol for DO NOT REUSE
MR	Symbol for NOT MRI SAFE
	Symbol for CAUTION, CONSULT ACCOMPANYING DOCUMENTS
	Symbol for STORAGE TEMPERATURE
	Symbol for DO NOT LITTER IN DOMESTIC WASTE

Product Identification:

SN	Symbol for SERIAL NUMBER
REF	Symbol for ORDER NUMBER
LOT	Symbol for BATCH NUMBER

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Additional Information

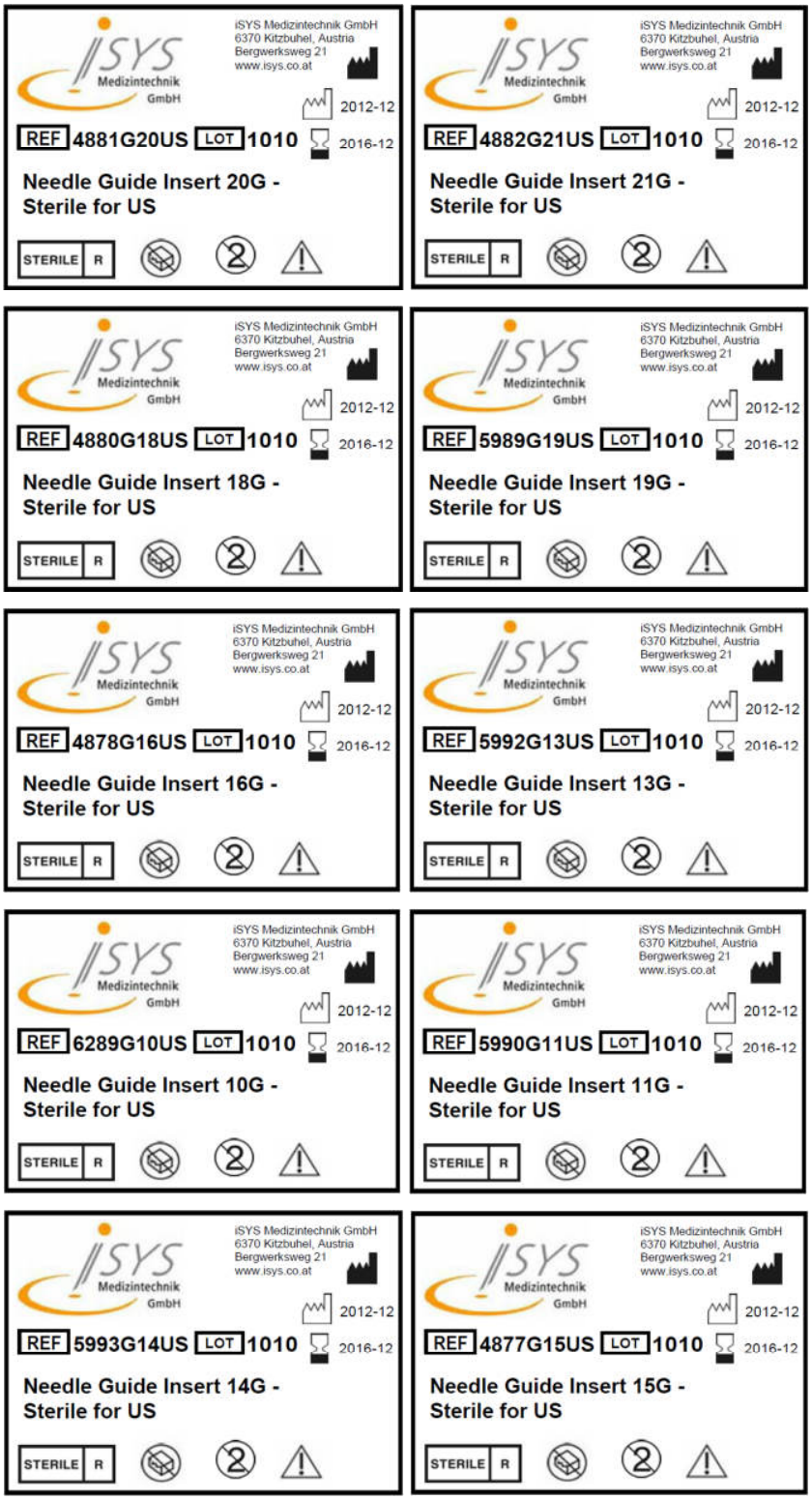
CE	Symbol for CE-conformity
	Symbol for MANUFACTURER
	Symbol for DATE OF MANUFACTURE
	Symbol for USE BY

Samples of Labels:

The presented labels are examples for the final product and packaging labels. Lot numbers and dates on these examples are placeholders only. They do not define any format of lot numbers, production or expiry dates.

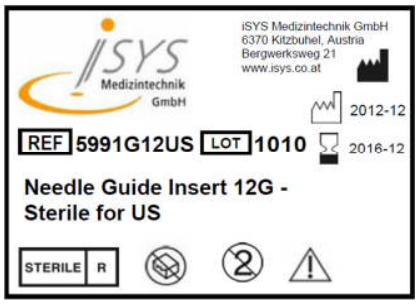
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

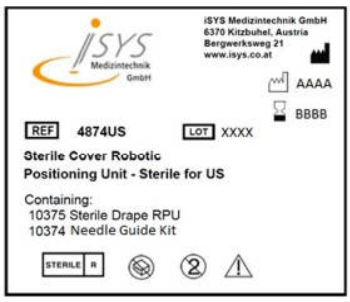
Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

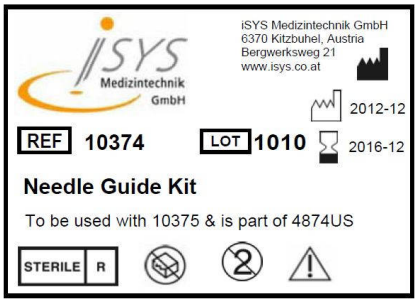


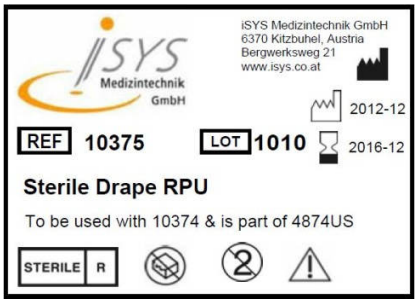
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016









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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Validation Report (Packaging)

(b)(4)

[redacted]

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

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4)

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

(b)(4) Third Party Test Data

[redacted]

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

(b)(4) Third Party Test Data

[redacted]

Qu

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

(b)(4) Third Party Test Data

[redacted]

Que

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

MICROMED LABORATORIES
TODAY'S CHALLENGES • TOMORROW'S SOLUTIONS

L08752
Bill Runion
Bioseal
167 Orangethorpe Ave.
Placentia, CA 92870

Lab Number: L08752				
Sample ID	Bacterial Count	Fungal Count	Total	Estimated
C1	1	0	1	*12.3*
C2*	1	0	1	*12.3*
C3	2	0	2	*24.6*
C4	1	0	1	*12.3*
C5	1	0	1	*12.3*
C6	2	1	3	*36.9*
C7	2	2	4	*49.2*
C8	2	0	2	*24.6*
C9	1	1	2	*24.6*
C10	2	0	2	*24.6*
Note: The Estimated value is calculated using the SIP of 10 and a correction factor of 1.23 for the Esmark Family. Note all plates had spreading colonies.			*Average*	*23.37*

Correction Factor: 1.23 for Esmark, SIP of 10.
Overall Average=25.83 CFU/product.
SIP 1/10th of normal product.
Verification dose = 8.1 kGy + (log 0.1 x 3.37) = 4.73 kGy. See Table 1 TIR 27.

NOTE: CFU's greater than 300 are considered estimates.

1129 McDowell Blvd Petaluma, CA 94954 tel. 707.782.0792 fax. 707.782.0705
info@micromedlabs.com ; www.micromedlabs.com

Created on October 10, 2006

PDM SN 14234

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

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Section 014	Sterilization and Shelf Life 510(k) Number: K131433	

(b)(4) Third Party Test Data

[redacted]

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

(b)(4) Third Party Test Data

[redacted]

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Section 014	Sterilization and Shelf Life 510(k) Number: K131433	

(b)(4) Third Party Test Data

[redacted]

Q

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4)Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Software

Table of Content

	Page
In General	2
Software Description	4
Software Risk List	30
Verification and Validation	35
Standards Data Reports	37

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

In General

The iSYS 1 (U.S.) is controlled by software, used with the help of a Handheld Control Unit (HCU) and user relevant information is displayed on the Control Unit.

The *Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices*, published on May 11, 2005 by *Center for Devices and Radiological Health (CDRH) – Office of Device Evaluation* complements the *guidance documents General Principals of Software Validation and Guidance for Off-the-Shelf Software Use in Medical Devices. ISYS shall utilize these guidance documents* for the purpose of validating the software associated with the ISYS 1.

The standard report forms can be found at the end of the document (pages 39 and 40). The documentation of the design process for usability is part of the risk management and can be found in section “009 Declarations of Conformity and Summary Reports”.

Level of concern:

According to the figure below the determination of the Level of Concern for the iSYS1 software results in a “**Moderate level of concern**”.

According to Chapter 3 of the *Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices* and the *Level of Concern* of this product, the following documentation will provide the following content:

SOFTWARE DOCUMENTATION	MINOR CONCERN	MODERATE CONCERN	MAJOR CONCERN
Level of Concern	A statement indicating the Level of Concern and a description of the rationale for that level.		
Software Description	A summary overview of the features and software operating environment.		
Device Hazard Analysis	Tabular description of identified hardware and software hazards, including severity assessment and mitigations.		
Software Requirements Specification (SRS)	Summary of functional requirements from SRS.	**The complete SRS document.**	
Architecture Design Chart	No documentation is necessary in the submission.	**Detailed depiction of functional units and software modules. May include state diagrams as well as flow charts.**	
Software Design Specification (SDS)	No documentation is necessary in the submission.	**Software design specification document.**	
Traceability Analysis	Traceability among requirements, specifications, identified hazards and mitigations, and Verification and Validation testing.		
Software Development Environment Description	No documentation is necessary in the submission.	**Summary of software life cycle development plan, including a summary of the configuration**	Summary of software life cycle development plan. Annotated list of control documents generated during

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

		management and maintenance activities.	**development process. Include the configuration management and maintenance plan documents.**
Verification and Validation Documentation	Software functional test plan, pass / fail criteria, and results.	**Description of V&V activities at the unit, integration, and system level. System level test protocol, including pass/fail criteria, and tests results.**	**Description of V&V activities at the unit, integration, and system level. Unit, integration and system level test protocols, including pass/fail criteria, test report, summary, and tests results.**
Revision Level History	Revision history log, including release version number and date.		
Unresolved Anomalies (Bugs or Defects)	**No documentation is necessary in the submission.**	**List of remaining software anomalies, annotated with an explanation of the impact on safety or effectiveness, including operator usage and human factors.**	

No software anomalies were remaining.

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Software Description

(b)(4)

[redacted]

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

(b)(4)

(b)(4)

(b)(4) Software Document

(b)(4) Software Document

(b)(4) Software Document

(b)(4) Software Document

(b)(4) Software Document

(b)(4) Software Document

(b)(4) Software Document

(b)(4) Software Document

(b)(4) Software Document

(b)(4) Software Document

(b)(4) Software Document

(b)(4) Software Document

(b)(4) Software Document

(b)(4) Software Document

(b)(4) Software Document

(b)(4) Software Document

(b)(4) Software Document

(b)(4) Software Document

(b)(4) Software Document

(b)(4) Software Document

(b)(4) Software Document

(b)(4) Software Document

(b)(4) Software Document

(b)(4) Software Document

(b)(4) Software Document

(b)(4) Software Document

(b)(4) Software Document

(b)(4) Software Document

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Verification and Validation

(b)(4)

[redacted]

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

(b)(4) Software Document

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Standards Data Reports

Form Approved: OMB No. 0910-0120; Expiration Date: 12/31/13

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

IEC 62366, Medical devices - Application of usability engineering to medical devices

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	#5-50	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☐	☒
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☒
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☒	☐
If yes, was the guidance document followed in preparation of this 510k?	☒	☐

Title of guidance: Medical Device Use-Safety: Incorporating Human Factors into Risk Management

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

[5] The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[6] The online search for CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html

FORM FDA 3654 (12/10) Page 1

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Form Approved: OMB No. 0910-0120; Expiration Date: 12/31/13

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

IEC 62304 First edition 2006-05, Medical device software - Software life cycle processes

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	#13-8	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☐	☒
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☒
Were there any deviations or adaptations made in the use of the standard? If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐ ☐	☒ ☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard? If yes, was the guidance document followed in preparation of this 510k?	☒ ☒	☐ ☐

Title of guidance: Guidance for the Content of Premarket Submissions, Guidance for Off-the-Shelf Software, et. al.

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

[5] The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[6] The online search for CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html

FORM FDA 3654 (12/10) Page 1

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Electromagnetic Compatibility and Electrical Safety

Table of Content

General	2
Forms FDA 3654	3
Test Report “Electrical Safety”	6
Test Report “Electromagnetic Compatibility”	8
Test Report “FCC 47 CFR Part 15”	34
Test Report “RFID and WLAN”	49
Certificates	65

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Electromagnetic Compatibility:

Tests according to ÖNORM EN ISO 60601-1-2 and FCC requirements performed at seibersdorf laboratories. Additional test performed for influences of RFID devices and WLAN. For test report and certificates see below.

Electrical Safety:

At the **present and until April 2013** (EN ISO 60601-1 2nd edition becoming invalid) testing of each individual system at the Notified Body 0408 (TUV Austria) according to:

- EN 60601-1:1990 + A1:1993 + A2:1995
- EN 60601-1-8:2004 + A1:2006

Example of test report and certificates can be found in below.

Starting from **QIII/2013** type testing including CB-test report and UL-listing at the Notified Body 0408 (TUV Austria) according to:

- IEC 60601-1 3rd Edition
- IEC 60601-1-8

Test strategy is prepared and a risk analysis is already running.

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Forms FDA 3654

Form Approved: OMB No. 0910-0120; Expiration Date: 12/31/13

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

IEC 60601-1, Medical Electrical Equipment - Part 1: General Requirements for Safety, 1988; Amendment 1, 1991-11, Amendment

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	#5-4	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☒
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: _____

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

[5] The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[6] The online search for CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html

FORM FDA 3654 (12/10) Page 1

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Form Approved: OMB No. 0910-0120; Expiration Date: 12/31/13

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

IEC 60601-1-2, Medical Electrical Equipment - Part 1-2: General Requirements for Safety - Collateral standard: Electromagnetic C

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3] #5-34		
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☒
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☒	☐
If yes, was the guidance document followed in preparation of this 510k?	☐	☒

Title of guidance: _____

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

[5] The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[6] The online search for CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html

FORM FDA 3654 (12/10) Page 1

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Form Approved: OMB No. 0910-0120; Expiration Date: 12/31/13

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

IEC 60601-1-8 Ed. 1, Medical electrical equipment - Part 1-8: General requirements for safety - Collateral Standard: Alarm System

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3] #5-49		
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☒
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510k?	☐	☐
Title of guidance:		

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

[5] The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[6] The online search for CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html

FORM FDA 3654 (12/10) Page 1

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Test Report "Electrical Safety" (Example)

(b)(4) Third Party Test Data

[redacted]

Qu

(b)(4) Third Party Test Data

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Section 017	Electromagnetic Compatibility and Electrical Safety 510(k) Number: K131433	

Test Report "Electromagnetic Compatibility"

(b)(4) Third Party Test Data

[redacted]

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

K131433

PD/B18	510k Cover Letter 510(k) Number:	iSYS Medizintechnik GmbH

Name Dr. Michael Vogele

mobil +43 (0) 664 2411140
email michael.vogele@isys.co.at
web www.isys.co.at

iSYS Medizintechnik GmbH, Bergwerksweg 21, 6370 Kitzbühel, Austria

iSYS Medizintechnik GmbH

FDA CDRH DMC
MAY 16 2013
Received

Food and Drug Administration
Center for Device and Radiological Health
Document Mail Center WO66-G609
10903 New Hampshire Avenue
Silver Spring MD 20993-0002

Subject: 510(k) Notification

This is to notify you of the intention of iSYS Medizintechnik GmbH, Bergwerksweg 21, A-6370 Kitzbuehel, Austria to market the iSYS1.

1. **Proprietary Name:** iSYS 1 (U.S.)
2. **Common/Usual Name:** Robotic Positioning Unit
3. **Establishment Registration Number:** pending
4. **Address of manufacturing and packaging facility:** Bergwerksweg 21, A-6370 Kitzbuehel, Austria
5. **Classification Name:** Neurological stereotaxic instrument
6. **Classification:**
   Device Class: Class II
   Classification Panel: RA (90) Radiology Devices
   Product Code: HAW
   CFR Section: 882.4560
7. **Reason for Submission:** New device
8. **Substantial Equivalence:**

510(k) Number	*Model name*	*Manufacturer*
K101791	ROSA	Medtech
K091081	Neuromate	Integrated Surgical Systems

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

12

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

9. Performance Standards: ÖNORM EN ISO 60601, ÖNORM EN ISO 62304, ANSI/AAMI/ISO 11737, AAMI TIR33, AAMI TIR35, AAMI ST67, ANSI/AAMI/ISO 11607-2, ISO 11137

10. Sterile Accessory Drapes supplied by (b)(4) [redacted] (Reg. No. 1038913) under 510(k) **K863853** and packaged and sterilized by (b)(4) [redacted] Reg. No. 2027062) under 510(k) **K893814**.

The iSYS Needle Guide Adapters, which are part of the robotic system, are packaged and (b)(4) [redacted] The drapes, which are manufactured by (b)(4) [redacted], and [redacted] are not part of this submission. The drapes for iSYS 1 are no longer part of this submission but will be supplied and manufactured by (b)(4) Test Report [redacted] (b)(4) Third Party Test Data [redacted] and packaged and sterilized by (b)(4) [redacted] under their own responsibility.

In case of any questions concerning this application, please contact either Dr. Michael Vogele, CEO at +43 (0) 664 2411140 (michael.vogele@isys.co.at) or Oliver Spitz (Regulatory Consultant) at +49 (0) 173 5904978 (oliver.spitz@isys.co.at).

The eCopy is an exact duplicate of the paper copy.

Sincerely,

Dr. Michael Vogele
CEO

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

iSYS Medizintechnik GmbH

510(k) Premarket Notification

(Basing on “Guidance for Industry and FDA Staff: Format for Traditional and Abbreviated 510(k)s“

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Table of Content

Section	Name	Number of Pages	Appendix/Misc
001	Medical Device User Fee Cover Sheet (Form FDA 3601)	4	No
002	CDRH Premarket Review Submission Cover Sheet	7	No
003	510(k) Cover Letter	2	No
004	Indications for Use Statement	1	No
005	510(k) Summary	6	No
006	Premarket Notification Truthful and Accurate Statement	1	No
007	Premarket Notification Class III Certification and Summary	1	No
008	Financial Certification or Disclosure Statement	1	No
009	Declarations of Conformity and Summary Reports (including Risk Management File)	92	No
010	Executive Summary	4	No
011	Device Description	57	No
012	Substantial Equivalence Discussion	4	No
013	Proposed Labeling	116	No
014	Sterilization and Shelf Life	89	Yes
015	Biocompatibility	1	No
016	Software	14	No
017	Electromagnetic Compatibility and Electrical Safety	24	No
018	Performance Testing – Bench	22	No
019	Performance Testing – Animal	1	No
020	Performance Testing – Clinical	40	Yes

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Following files are on the Appendix CD for the paper version of this submission respectively in the Miscellaneous Files for the eCopy:

Filename	Document	Applies to Section
001_HamlynSymposium_iSYS Workflow_final	Workflow presented on the Hamlyn Symposium	20
002_Clinical cases	Summary of Clinical Cases	20
003_Dissertation-Schamberger	Dissertation Dr. Schamberger	20
004_ECR2013_C-2559	Presentation of Clinical Case	20
005_iSys robot iGuide	Phantom Study on Accuracy	20
006_Multi Center Study	Multi-Center Study	20
007_Zeego Schulz Zangos	Report Radiation Exposure	20
008_(b)(4) VDMax Final Report.zip	(b)(4) Sterilization Report (b)(4)	14
009_PM_Hygiene Monitoring plan_RDP 0500_2011	(b)(4) Hygiene Monitoring Plan 2011	14
010_PM_Clean room Monitoring_Results2012	(b)(4) Clean room Monitoring Results2012	14
011_PM_Gamma validation Prüfplan_PRD0400_2010	Gamma validation test plan	14
012_PM_Bioburden_SC-80_report904377_2012	(b)(4) Report 2012	14

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Form Approved: OMB No. 0910-511 Expiration Date: February 28, 2013. 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)
Write the Payment Identification number on your check.

A completed cover sheet must accompany each original application or supplement subject to fees. If payment is sent by U.S. mail or courier, please include a copy of this completed form with payment. Payment and mailing instructions can be found at: http://www.fda.gov/oc/mdufma/coversheet.html

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

ISYS MEDIZINTECHNIK GMBH
Bergwerksweg 21

KITZBUEHEL
6370
AT

1.1 EMPLOYER IDENTIFICATION NUMBER (EIN)

2. CONTACT NAME
Oliver Spitz
2.1 E-MAIL ADDRESS
oliver.spitz@isys.co.at
2.2 TELEPHONE NUMBER (include Area code)
0049 173 5904978
2.3 FACSIMILE (FAX) NUMBER (Include Area code)

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/oc/mdufma

Select an application type:
[X] Premarket notification(510(k)); except for third party
[ ] 513(g) Request for Information
[ ] Biologics License Application (BLA)
[ ] Premarket Approval Application (PMA)
[ ] Modular PMA
[ ] Product Development Protocol (PDP)
[ ] Premarket Report (PMR)
[ ] Annual Fee for Periodic Reporting (APR)
[ ] 30-Day Notice

3.1 Select a center
[X] CDRH
[ ] CBER
3.2 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)
[X] YES, I meet the small business criteria and have submitted the required qualifying documents to FDA
NO, I am not a small business
4.1 If Yes, please enter your Small Business Decision Number: SBD135332

5. FDA WILL NOT ACCEPT YOUR SUBMISSION IF YOUR COMPANY HAS NOT PAID AN ESTABLISHMENT REGISTRATION FEE THAT IS DUE TO FDA. HAS YOUR COMPANY PAID ALL ESTABLISHMENT REGISTRATION FEES THAT ARE DUE TO FDA?
[X] YES (All of our establishments have registered and paid the fee, or this is our first device, and we will register and pay the fee within 30 days of FDA's approval/clearance of this device.)
[ ] NO (If "NO," FDA will not accept your submission until you have paid all fees due to FDA. This submission will not be processed; see http://www.fda.gov/cdrh/mdufma for additional information)

6. 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
[ ] This biologics application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only
[ ] The sole purpose of the application is to support conditions of use for a pediatric population
[ ] The application is submitted by a state or federal government entity for a device that is not to be distributed commercially

7. 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

PAPERWORK REDUCTION ACT STATEMENT
Public reporting burden for this collection of information is estimated to average 18 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and 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 the address below.

Department of Health and Human Services, Food and Drug Administration, Office of Chief Information Officer, 1350 Piccard Drive, 4th Floor Rockville, MD 20850
[Please do NOT return this form to the above address, except as it pertains to comments on the burden estimate.]

8. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION
(b)(4) 03-May-2013

Form FDA 3601 (01/2007)

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

PD/B18	CDRH Premarket Review Submission Cover Sheet 510(k) Number:	ISYS Medizintechnik GmbH

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

CDRH PREMARKET REVIEW SUBMISSION COVER SHEET

Form Approval
OMB No. 0910-0120
Expiration Date: December 31, 2013
See PRA Statement on page 5.

Date of Submission	User Fee Payment ID Number	FDA Submission Document Number *(if known)*
08.05.2013	MD6068500-956733	

SECTION A — TYPE OF SUBMISSION

PMA	PMA & HDE Supplement	PDP	510(k)	Request for Feedback
☐ Original Submission	☐ Regular (180 day)	☐ Original PDP	☒ Original Submission:	☐ Pre-Submission
☐ Premarket Report	☐ Special	☐ Notice of Completion	☒ Traditional	☐ Informational Meeting
☐ Modular Submission	☐ Panel Track (PMA Only)	☐ Amendment to PDP	☐ Special	☐ Submision Issue Meeting
☐ Amendment	☐ 30-day Supplement		☐ Abbreviated (Complete section I, Page 5)	☐ Day 100 Meeting
☐ Report	☐ 30-day Notice		☐ Additional Information	☐ Agreement Meeting
☐ Report Amendment	☐ 135-day Supplement		☐ Third Party	☐ Determination Meeting
☐ Licensing Agreement	☐ Real-time Review			☐ Study Risk Determination
	☐ 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 ISYS MEDIZINTECHNIK GMBH	Establishment Registration Number *(if known)*		
Division Name *(if applicable)*	Phone Number *(including area code)* +43 (0) 664 2411140		
Street Address BERGWERKSWEG 21	FAX Number *(including area code)*		
City KITZBUEHEL	State / Province TIROL	ZIP/Postal Code 6370	Country AUSTRIA
Contact Name OLIVER SPITZ			
Contact Title MANAGER REGULATORY AFFAIRS	Contact E-mail Address OLIVER.SPITZ@ISYS.CO.AT		

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

(b)(4)

[redacted]

FORM FDA 3514 (1/13)

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

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

- ☐ New Device
- ☐ 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
- ☐ Process change:
  - ☐ Manufacturing ☐ Packaging
  - ☐ Sterilization
  - ☐ Other *(specify below)*
- ☐ Response to FDA correspondence:
- ☐ Change in design, component, or specification:
  - ☐ Software / Hardware
  - ☐ Color Additive
  - ☐ Material
  - ☐ Specifications
  - ☐ Other *(specify below)*
- ☐ Labeling change:
  - ☐ Indications
  - ☐ Instructions
  - ☐ Performance Characteristics
  - ☐ Shelf Life
  - ☐ Trade Name
  - ☐ Other *(specify below)*
- ☐ Location change:
  - ☐ Manufacturer
  - ☐ Sterilizer
  - ☐ Packager
- ☐ Report Submission:
  - ☐ Annual or Periodic
  - ☐ Post-approval Study
  - ☐ Adverse Reaction
  - ☐ Device Defect
  - ☐ Amendment
- ☐ 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
- ☐ Response 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)*:

FORM FDA 3514 (1/13) Page 2 of 5 Pages

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

SECTION E — ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS

Product codes of devices to which substantial equivalence is claimed

1	HAW	2		3		4	
5		6		7		8	

Summary of, or statement concerning, safety and effectiveness information

- [x] 510 (k) summary attached
- [ ] 510 (k) statement

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

	510(k) Number		*Trade or Proprietary or Model Name*		*Manufacturer*
1	K101791	1	ROSA SURGICAL DEVICE	1	MEDTECH SAS
2	K091081	2	FRAMELESS NEUROMATE	2	INTEGRATED SURGICAL SYSTEMS, INC.
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 name

iSYS 1 (U.S.)

	Trade or Proprietary or Model Name for This Device		Model Number
1	iSYS 1 (U.S.)	1	6224
2	Accessory, non-sterile	2	div
3	Accessory, sterile	3	div
4		4	
5		5	

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

1 K113495	2	3	4	5	6
7	8	9	10	11	12

Data Included in Submission

- [x] Laboratory Testing
- [ ] Animal Trials
- [ ] Human Trials

SECTION G — PRODUCT CLASSIFICATION - APPLICATION TO ALL APPLICATIONS

Product Code: HAW

C.F.R. Section *(if applicable)*:

Device Class

- [ ] Class I
- [x] Class II
- [ ] Class III
- [ ] Unclassified

Classification Panel

90 Radiology

Indications *(from labeling)*

The intended use of the iSYS1 device is to function as a remote-operated positioning and guidance system during interventional procedures. Positioning is done in remote control manner; planning of the position/angulation is done based on 2D/3D patient data (CT, cone-beam CT, fluoroscopy) by external planning software – for example using an external navigation system, or planning software coming with the used imaging device. Also verification of the correct position and orientation of the tool prior to/during/after the intervention is done by means of these external devices. The iSYS1-System is then acting as a guideway during the manual insertion of the interventional tool – usually a needle type device, and the like. Applications include, but are not limited to, interventions like biopsy procedures, tumor ablation, nerve blocking, electrode placement, etc.

FORM FDA 3514 (1/13)

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Note: Submission of the information entered in Section H does not affect the need to submit device establishment registration.	FDA Document Number *(if known)*

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

☐ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number: isy83218	☒ Manufacturer ☐ Contract Manufacturer	☐ Contract Sterilizer ☐ Repackager / Relabeler
Company / Institution Name: ISYS MEDIZINTECHNIK GMBH		Establishment Registration Number: PENDING	
Division Name *(if applicable)*		Phone Number *(including area code)*: +43 (0) 664 2411140	
Street Address: BERGWERKSWEG 21		FAX Number *(including area code)*	
City: KITZBUEHEL		State / Province: TIROL	ZIP Code: 6370 / Country: AUSTRIA
Contact Name: OLIVER SPITZ	Contact Title: MANAGER REGULATORY AFFAIRS	Contact E-mail Address: OLIVER.SPITZ@ISYS.CO.AT	

(b)(4)

[redacted]

☐ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) 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 Code / Country
Contact Name	Contact Title	Contact E-mail Address	

[redacted]

FORM FDA 3514 (1/13) Add Continuation Page Page 4 of 5 Pages

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

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	60601-1	IEC	Medical Electrical Equipment - Part 1: General Requirements for Safety	Amendment 1 Amendment 2	10/01/2005
2	60601-1-2	IEC	Medical Electrical Equipment - Part 1-2: General Requirements for Safety - Collateral standard: Electromagnetic Compatibility - Requirements and Tests	Edition 2.1 consolidated with Amendment 1	3/3/2008
3	60601-1-8	IEC	Medical electrical equipment - Part 1-8: General requirements for safety - Collateral Standard: Alarm Systems - Requirements, tests and guidances - General requirements and guidelines for alarm systems in medical equipment	Edition 1	08/08/2006
4	62366	IEC	Medical devices - Application of usability engineering to medical devices	First Edition	08/08/2009
5	62304	IEC	Medical device software - Software life cycle processes.	First Edition	08/20/2008
6	15223-1	ISO	Medical devices - Symbols to be used with medical device labels, labelling, and information to be supplied - Part 1: General requirements	Second Edition	07/01/2012
7					

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

This section applies only to requirements of the Paperwork Reduction Act of 1995.

"DO NOT SEND YOUR COMPLETED FORM TO THE FDA STAFF ADDRESS BELOW."

The burden time for this collection of information is estimated to average 0.5 hour per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
1350 Piccard Drive, Room 400
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 number.

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

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	11137-1	AAMI / ANSI / ISO	Sterilization of health care products - Radiation - Part 1: Requirements for development, validation, and routine control of a sterilization process for medical devices		03/16/2012
2	11137-2	AAMI / ANSI / ISO	Sterilization of health care products - Radiation - Part 2: Establishing the sterilization dose		01/15/2013
3	11137-3	AAMI / ANSI / ISO	Sterilization of health care products - Radiation - Part 3: Guidance on dosimetric aspects		03/16/2012
4	11607-1	AAMI / ANSI / ISO	Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems		03/16/2012
5	11607-2	AAMI / ANSI / ISO	Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes		03/16/2012
6	11737-1	AAMI / ANSI / ISO	Sterilization of medical devices - Microbiological methods Part 1: Determination of the population of microorganisms on product, 2ed	Second Edition	08/20/2012
7	D4169-09	ASTM	Standard Practice for Performance Testing of Shipping Containers and Systems		01/15/2013

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

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF ADDRESS BELOW.

The burden time for this collection of information is estimated to average 0.5 hour per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
1350 Piccard Drive, Room 400
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 number.

FORM FDA 3514 (1/13) Page 5 of 5 Pages

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

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	D-4332-01	ASTM	Standard practice for conditioning containers, packages, or packaging components for testing		05/05/2010
2	F88/F88M-09	ASTM	Standard Test Method for Seal Strength of Flexible Barrier Materials		01/15/2013
3	F1886/F1886M-09	ASTM	Standard Test Method for Determining Integrity of Seals for Flexible Packaging by Visual Inspection		01/15/2013
4	F1929-98	ASTM	Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration		01/15/2013
5	F1980-07	ASTM	Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices		01/15/2013
6	F2096-11	ASTM	Standard Test Method for Detecting Gross Leaks in Packaging by Internal Pressurization (Bubble Test		01/15/2013
7					

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

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF ADDRESS BELOW.

The burden time for this collection of information is estimated to average 0.5 hour per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
1350 Piccard Drive, Room 400
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 number.

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Name ***Dr. Michael Vogele***

mobil ***+43 (0) 664 2411140***
email *michael.vogele@isys.co.at*
web *www.isys.co.at*

iSYS Medizintechnik GmbH, Bergwerksweg 21, 6370 Kitzbühel, Austria

Food and Drug Administration
Center for Device and Radiological Health
Document Mail Center WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Subject: 510(k) Notification

This is to notify you of the intention of iSYS Medizintechnik GmbH, Bergwerksweg 21, A-6370 Kitzbuehel, Austria to market the iSYS1.

1.	**Proprietary Name:**	iSYS 1 (U.S.)
2.	**Common/Usual Name:**	Robotic Positioning Unit
3.	**Establishment Registration Number:**	pending
4.	**Address of manufacturing and packaging facility:**	Bergwerksweg 21, A-6370 Kitzbuehel, Austria
5.	**Classification Name:**	Neurological stereotaxic instrument
6.	**Classification:**	Device Class: Class II Classification Panel: RA (90) Radiology Devices Product Code: HAW CFR Section: 882.4560
7.	**Reason for Submission:**	New device
8.	**Substantial Equivalence:**	

510(k) Number	***Model name***	***Manufacturer***
K101791	ROSA	Medtech
K091081	Neuromate	Integrated Surgical Systems

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

9.	**Performance Standards:**	ÖNORM EN ISO 60601, ÖNORM EN ISO 62304, ANSI/AAMI/ISO 11737, AAMI TIR33, AAMI TIR35, AAMI ST67, ANSI/AAMI/ISO 11607-2, ISO 11137
10.	**Sterile Accessory**	Drapes supplied by (b)(4) [redacted] (Reg. No. 1038913) under 510(k) **K863853** and packaged and sterilized by (b)(4) [redacted] (b)(4) [redacted] under 510(k) **K893814**.

The iSYS Needle Guide Adapters, which are part of the robotic system, are packaged and (b)(4) [redacted] The drapes, which are manufactured by (b)(4) [redacted] and [redacted] are not part of this submission. The drapes for iSYS 1 are no longer part of this submission but will be supplied and manufactured by (b)(4) [redacted] (b)(4) Test Report [redacted] and packaged and sterilized by Bioseal under their own responsibility.

In case of any questions concerning this application, please contact either Dr. Michael Vogele, CEO at +43 (0) 664 2411140 (michael.vogele@isys.co.at) or Oliver Spitz (Regulatory Consultant) at +49 (0) 173 5904978 (oliver.spitz@isys.co.at).

The eCopy is an exact duplicate of the paper copy.

Sincerely,

Dr. Michael Vogele

CEO

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Indications for Use Statement

510(k) Number (if known): -

Device Name: **iSYS 1 (U.S.)**

Indications for Use:

Intended Use: The intended use of the iSYS1 device is to function as a remote-operated positioning and guidance system during interventional procedures. Positioning is done in remote control manner; planning of the position/angulation is done based on 2D/3D patient data (CT, cone-beam CT, fluoroscopy) by external planning software – for example using an external navigation system, or planning software coming with the used imaging device. Also verification of the correct position and orientation of the tool prior to/during/after the intervention is done by means of these external devices. The iSYS1-System is then acting as a guideway during the manual insertion of the interventional tool – usually a needle type device, and the like

Indicated User: Physician

Indicated Environment: Operating room

Indicated Surgical Procedures: Applications include, but are not limited to, interventions like biopsy procedures, tumor ablation, nerve blocking, electrode placement, etc.

The iSYS 1 System is indicated for any medical condition in which the use of a stable and precise needle/tool guidance system may be appropriate, and where external navigation technology and/or imaging technology (e.g. CB-CT, CT, X-Ray) can be used for exact planning and tracking of the needle/tool.

Indicated parts of the body: Total body

Prescription Use _YES___ AND/OR Over-The-Counter Use ___NO__
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE 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 2015-10247; Released by CDRH on 07/08/2016

510(k) SUMMARY

1.	Applicant:	iSYS Medizintechnik GmbH
2.	Address:	Bergwerksweg 21 6370 Kitzbühel / Austria
3.	Contact Person:	Dr. Michael Vogele Tel. +43 (0) 664 2411140
4.	Preparation Date:	April 30, 2013
5.	Device Submitted:	iSYS 1 (U.S.)
6.	Proprietary Name:	iSYS 1 (U.S.)
7.	Common Name:	iSYS 1 (U.S.)
8.	Classification Name:	Neurological Stereotaxic Instrument Product Code HAW, Reg.No. 882.4560
9.	Substantial Equivalence:	The iSYS 1 is substantially equivalent to the following legally marketed devices: Medtech's Rosa and Neuromate by Integrated Surgical Systems: The characteristics of this device are similar to those of the predicate devices identified on the comparison chart, which is provided with the premarket notification submission. It is our opinion that the iSYS 1 does not have technological characteristics that raise additional types of questions related to terms of safety and effectiveness.
10.	Device Description:	The iSYS 1 is a modular needle guidance platform for interventional radiology and related fields. Core components are a 4 DOF micro positioning unit which allows the submillimetric needle positioning from simple needle angulations up to positioning and angulations with adjustable pivot point and a control unit which is directed by a cable connected control panel. The passive macro positioning unit and different table adapters allow different setups of the system around the patient in the region of interest. The needle-guide-kit (manufactured by ECOLAB) provides disposable components that ensure precise and sterile needle guidance. Planning of the tool position/orientation as well as validation of the correctness of the tool position must be performed with an external planning and measurement system which is not part of the iSYS-1 Interventional Platform. The position of iSYS 1 is

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

visible for most imaging systems due to the used markers. During treatment the tool is controlled by the user.

11. Intended Use:

The intended use of the iSYS1 device is to function as a remote-operated positioning and guidance system during interventional procedures. Positioning is done in remote control manner; planning of the position/angulation is done based on 2D/3D patient data (CT, cone-beam CT, fluoroscopy) by external planning software – for example using an external navigation system, or planning software coming with the used imaging device. Also verification of the correct position and orientation of the tool prior to/during/after the intervention is done by means of these external devices. The iSYS1-System is then acting as a guideway during the manual insertion of the interventional tool – usually a needle type device, and the like. Applications include, but are not limited to, interventions like biopsy procedures, tumor ablation, nerve blocking, electrode placement, etc.

The iSYS 1 System is indicated for any medical condition in which the use of a stable and precise needle/tool guidance system may be appropriate, and where external navigation technology and/or imaging technology (e.g. CB-CT, CT, X-Ray) can be used for exact planning and tracking of the needle/tool.

12. Clinical Use

The Side Rail Adapter is attached to the side rail for the setup; the Table Top Adapter is attached directly onto the CT table. Both Adapters are equipped with a “starburst” connector, to which the Multifunctional Arm can be attached. The MFA is equipped with one “starburst” connector at the bottom and one “spoon” connector at the top. The “spoon” connector has its counterpart on the Robotic Positioning Unit for the setup. The Control Unit is attached directly to the side rail. The Robotic Positioning Unit is connected by a cable to the Control Unit, which has cable connections to both the electric power supply and to a Handheld Control Unit. The Needle Guide Extensions are screw-fixed onto the Robotic Positioning Modules. The Sterile Cover is directly fixed onto the Needle Guide Joints and can be drawn over the robotic parts. The Needle Insert is placed into the appropriate connector of the Needle Guide, to prepare needle usage. The Handheld Control Unit can be clamped onto the side rail and covered with a drape. Planning of the tool position/orientation as well as validation of the correctness of the tool position must be performed with

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

an external planning and measurement system (imaging or navigation software).

13. Biocompatibility: The iSYS 1 is not in contact with patient. At any time when in use a sterile cover sheet is to be placed between the patient and the system. Additionally there are no new materials introduced in the manufacture of the iSYS 1. Therefore, no biocompatibility studies were performed for this device.

14. Performance Data: Operating temperature/humidity range: 15 to 30°C; 30 to 70% relative humidity with no condensation

Storage temperature/humidity range: 10 to 50°C; 30 to 70% relative humidity with no condensation

Power Supply: 50W; 115VAC/230VAC; 50-60Hz; cable: C14 according to IEC/EN 60320-1, US498, CSA C22.2 no. 42;

Sterilization of the sterile accessories has been validated by Bioseal, the company responsible for packaging and sterilizing the iSYS accessories.

The accuracy of the intervention depends on the resolution and capabilities of the imaging device or software. The mechanical accuracy of iSYS1 is below 1 mm, but that gives no accuracy value for treatments.

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Device Comparison Summary:

Reference	Frameless Neuromate	ROSA Surgical Device	iSYS 1 (for new submission)
510k-Number	K091081	K101791	-
Manufacturer	INTEGRATED SURGICAL SYSTEMS, INC. 1850 Research Park Dr. Davis, CA 95616 USA	Medtech Surgical Inc. 211 Warren Street Suite 306 Newark, NJ 07103 USA	Submitter
Design			
General device description	Computer controlled electromechanical multi-joined arm indicated for use as a stereotactic instrument	Computer controlled electromechanical multi-joined arm indicated for use as a stereotactic instrument	Computer controlled electromechanical multi-joined arm indicated for invasive procedures
Localization means	Robot arm absolute encoders	Robot arm absolute encoders	Fiducial markers on tool holder.
Image-guided	Yes	Yes	Yes
Planning software	No (third party)	Yes	No (third party)
Instrumentation	Laser pointer Tool Holder	Navigation probe Laser pointer Tool Holder	Marker Tool Holder Sterile Covers
Instrument fixation	Instruments are mounted onto robot arm	Instruments are mounted onto robot arm	Special tool holders for several applications mounted to the Robot
Instrument calibration	Factory Calibration	Factory Calibration	By navigation/imaging software during intervention
System immobilization between patient and device	Yes	Yes	Yes
Indications for Use			
Indication for use	Stereotactic spatial positioning and orientation of an instrument holder or tool guide to be used by a surgeon to manually guide standard neurosurgical instruments (biopsy needle, stimulation or recording electrode, endoscope).	Intended to be used in the operating room for the spatial positioning and orientation of an instrument holder or tool guide, The system is intended to be used by neurosurgeons to guide standard neurosurgical instruments (biopsy needle, stimulation or recording electrode,	The intended use of the iSYS1 device is to function as a remote-operated positioning and guidance system during interventional procedures. Positioning is done in remote control manner; planning of the position/angulation is done based on 2D/3D patient data

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Reference	Frameless Neuromate	ROSA Surgical Device	iSYS 1 (for new submission)
		endoscope). Indicated for any neurosurgical condition in which the use of stereotactic surgery may be appropriate.	(CT, cone-beam CT, fluoroscopy) by external planning software – for example using an external navigation system, or planning software coming with the used imaging device. Also verification of the correct position and orientation of the tool prior to/ during/after the intervention is done by means of these external devices. The iSYS1-System is then acting as a guideway during the manual insertion of the interventional tool – usually a needle type device, and the like. Applications include, but are not limited to, interventions like biopsy procedures, tumor ablation, nerve blocking, electrode placement, etc.
Anatomical site	Head	Head	no restrictions
User	Neurosurgeon	Neurosurgeon	Surgeon
Accessory	Sterile drapes	Sterile drapes Fiducial markers Head Holder Light source	Sterile Covers Table Adapters Cable Sets
Registration	Ultrasound	Marker Optical	Marker
Real-time instrument position	Yes	Yes	Yes
Mechanical Guidance of instruments	Yes	Yes	Yes
Instrument Guide	Manual	Manual	Manual
Technology			
Powered	Yes	Yes	Yes

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Reference	Frameless Neuromate	ROSA Surgical Device	iSYS 1 (for new submission)
CE-Conformity	Yes	Yes	Yes
Computer-controlled	Yes	Yes	Yes

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Premarket Notification Truthful And Accurate Statement

[As Required by 21 CFR 807.87(k)]

I certify that, in my capacity as the president of iSYS Medizintechnik GmbH, I believe to the best of my knowledge, that all data and information submitted in the premarket notification are truthful and accurate and that no material fact has been omitted.

_____

(Signature)

Dr. Michael Vogele

CEO

May 6th 2013

(Date)

-

_____

*(Premarket Notification [510(k)] Number)

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Premarket Notification Class III Certification and Summary

Not applicable

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Financial Certification or Disclosure Statement

Not applicable

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Declarations of Conformity and Summary Reports

Table of Content: Page

Declarations of Conformity (iSYS)	2
Declaration of Conformity (Bioseal)	6
Summary Report Sterility	8
Summary Report Software	10
Summary Report Electricity	13
Risk Management File	15

Remark to Risk Management File:

The risk management file was established before iSYS Medizintechnik GmbH decided to apply for the US-American market. Thus, (b)(4) [redacted] the supplier for sterile components for the US-American market, does not appear in the file, but the European supplier (websinger) does.

The abbreviations “NAK” and “AK” in the risk management file are standard in Austria and stand for “not acceptable” and “acceptable”. The abbreviation “DIMDI” refers to the medical vigilance system in Germany.

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Declarations of Conformity iSYS

PD/B16	iSYS 1	iSYS Medizintechnik GmbH
Declaration of Conformity		

Konformitätserklärung / Declaration of Conformity / Declaration de Conformité

Wir,	We,	Nous,
iSYS Medizintechnik GmbH, **Bergwerksweg 21, 6370 Kitzbühel, Austria**		
erklären in alleiniger Verantwortung, dass das Medizinprodukt	declare on our own responsibility that the medical device	déclarons sous notre propre responsabilité que le dispositif médical
iSYS 1 (Art. Nr. 4268) **iSYS 1 (U.S.) (Art. Nr. 6224)** **Seriennummern 003 bis 030 (Revision 1)** **HCU Cable Extension (Art. Nr. 6162)**		
allen Anforderungen der Richtlinie 93/42/EWG ergänzt durch die Richtlinie 2007/47/EG entspricht	meets all the provisions of the Directives **93/42/EEC and 2007/47/EC**	remplit toutes les exigences de les directives sur les dispositifs médicaux **93/42/CEE et 2007/47/CE**
Angewandte harmonisierte Normen:	**Applied harmonized standards:**	**Normes harmonisées appliquées:**
OENORM EN 980:2008, EN 1041:2008, OENORM EN 60601-1:2007, OENORM EN 60601-1-2+A1:2006, OENORM EN 60601-1-6:2008, OENORM EN 60601-1-8:2008		
Klassifizierung basiert auf den Anforderungen der **Regel**	**Classification** is based on the requirements of **Rule**	**Classification** La classification est fondée sur les exigences de la **Règle**
12		
des **Anhang IX** der Richtlinie über Medizinprodukte	of **annex IX** of the Medical Device Directive	de **l'annexe IX** de la directive sur les dispositifs médicaux
Medizinprodukt der **Klasse**	Medical device **Class**	les dispositifs médicaux **Classe**
I		
Konformitätsbewertungsverfahren gemäß der Richtlinie 93/42 EWG, **Anhang**	**Conformity assessment procedure** according to Directive 93/42 EEC, **Annex**	**Procédure d'évaluation de la conformité** en application de la directive 93/42/CEE **Appendice**
VII		
Benannte Stelle (falls zutreffend)	**Notified body** (if applicable)	**Organisme notifié** (le cas échéant)
TÜV Austria Services GmbH (CE 0408)		
Diese Konformitätserklärung gilt für obige Serien-/ Lotnummern ab dem Produktionsdatum	**This declaration of conformity is effective for above Serial/ Lot numbers as of the production date**	**Cette déclaration de conformité est valable pour les numéros de série/ du lot dès la date de production**
29. November 2012		
Geschäftsführer		Kitzbühel, 29.11.12

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

CE-SetDescription	iSYS Medizintechnik GmbH

iSYS Medizintechnik GmbH
Bergwerksweg 21
6370 Kitzbühel
Austria
Tel. +43 (0) 664 / 2411140
Fax. +49 (0) 8232 / 969222
www.isys.co.at

EC Declaration of Conformity

We iSYS Medizintechnik GmbH declare under sole responsibility that the set to which this declaration relates, as an accessory to the **iSYS 1**, meets the essential health and safety requirements and is in conformance with the EC directives 93/42/EC and 2007/47/EC (MDD).

Set description:

iSYS 1 – class I product

Accessory sterile – class Is product

Accessory non-sterile – class I product

The set is classified as Is according to rules 1 and 12.

iSYS Medizintechnik GmbH meets the requirements of EN ISO 13485:2003 as indicated on certificate registration # TÜV-A-MT-1/11/E148.
The registration has been granted by TÜV Austria Services GmbH, Austria (# 0408).

The CE mark is applied with respect to annex II of the MDD. This CE marking has been affixed on the device according to article 17 of the MDD.

This declaration is effective from: see date of sign off

General Manager

Kitzbühel, 29.11.12
Place / date

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

PD/B16	iSYS 1
Declaration of Conformity	

Konformitätserklärung / Declaration of Conformity / Declaration de Conformité

Wir,	We,	Nous,
iSYS Medizintechnik GmbH, **Bergwerksweg 21, 6370 Kitzbühel, Austria**		
erklären in alleiniger Verantwortung, dass das Medizinprodukt	declare on our own responsibility that the medical device	déclarons sous notre propre responsabilité que le dispositif médical
Zubehör iSYS 1 **Side Rail Adapter (Art.Nr. 4095)** **Multi Functional Arm (Art. Nr. 4271)** **Table Top Adapter Version A (Art.Nr. 4117)** **Table Top Adapter Version B (Art.Nr. 4120)**		
allen Anforderungen der Richtlinie 93/42/EWG ergänzt durch die Richtlinie 2007/47/EG entspricht	meets all the provisions of the Directives **93/42/EEC and 2007/47/EC**	remplit toutes les exigences de les directives sur les dispositifs médicaux **93/42/CEE et 2007/47/CE**
Angewandte harmonisierte Normen:	**Applied harmonized standards:**	**Normes harmonisées appliquées:**
OENORM EN 980:2008, EN 1041:2008, OENORM EN 60601-1:2007, OENORM EN 60601-1-2+A1:2006, OENORM EN 60601-1-6:2008, OENORM EN 60601-1-8:2008		
Klassifizierung basiert auf den Anforderungen der **Regel**	**Classification** is based on the requirements of **Rule**	**Classification** La classification est fondée sur les exigences de la **Règle**
1		
des **Anhang IX** der Richtlinie über Medizinprodukte	of **annex IX** of the Medical Device Directive	de **l'annexe IX** de la directive sur les dispositifs médicaux
Medizinprodukt der **Klasse**	Medical device **Class**	les dispositifs médicaux **Classe**
I		
Konformitätsbewertungsverfahren gemäß der Richtlinie 93/42 EWG, **Anhang**	**Conformity assessment procedure** according to Directive 93/42 EEC, **Annex**	**Procédure d'évaluation de la conformité** en application de la directive 93/42/CEE **Appendice**
VII		
Benannte Stelle (falls zutreffend)	**Notified body** (if applicable)	**Organisme notifié** (le cas échéant)
TÜV Austria Services GmbH (CE 0408)		
Diese Konformitätserklärung gilt für obige Serien-/ Lotnummern ab dem Produktionsdatum	**This declaration of conformity is effective for above Serial/ Lot numbers as of the production date**	**Cette déclaration de conformité est valable pour les numéros de série/ du lot dès la date de production**
29. November 2012		
..... Geschäftsführer		Kitzbühel, 29.11.12

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

PD/B16	Accessory, sterile
Declaration of Conformity	

Konformitätserklärung / Declaration of Conformity / Declaration de Conformité

Wir,	We,	Nous,
iSYS Medizintechnik GmbH, Bergwerksweg 21, 6370 Kitzbühel, Austria		
erklären in alleiniger Verantwortung, dass die Medizinprodukte	declare on our own responsibility that the medical devices	déclarons sous notre propre responsabilité que les dispositifs médicaux
6289G10US Needle Guide Insert 10G – sterile for US **5990G11US Needle Guide Insert 11G – sterile for US** **5991G12US Needle Guide Insert 12G – sterile for US** **5992G13US Needle Guide Insert 13G – sterile for US** **5993G14US Needle Guide Insert 14G – sterile for US** **4877G15US Needle Guide Insert 15G – sterile for US** **4878G16US Needle Guide Insert 16G – sterile for US** **4874US Sterile Cover Robotic Positioning Unit – sterile for US** **4883US Sterile Cover Handheld Control Unit – sterile for US**	**4879G17US Needle Guide Insert 17G – sterile for US** **4880G18US Needle Guide Insert 18G – sterile for US** **5989G19US Needle Guide Insert 19G – sterile for US** **4881G20US Needle Guide Insert 20G – sterile for US** **4882G21US Needle Guide Insert 21G – sterile for US** **4875US Needle Guide Marker Insert – sterile for US** **4876US Needle Guide Marker Insert centered – sterile for US**	
allen Anforderungen der Richtlinie 93/42/EWG ergänzt durch die Richtlinie 2007/47/EG entspricht	meets all the provisions of the Directives **93/42/EEC and 2007/47/EC**	remplit toutes les exigences de les directives sur les dispositifs médicaux **93/42/CEE et 2007/47/CE**
Angewandte harmonisierte Normen:	**Applied harmonized standards:**	**Normes harmonisées appliquées:**
OENORM EN 980:2008, DIN EN 1041:2008, ÖNORM EN ISO 11607-1:2007, ÖNORM EN ISO 11607-2:2006		
Klassifizierung basiert auf den Anforderungen der **Regel**	**Classification** is based on the requirements of **Rule**	**Classification** La classification est fondée sur les exigences de la **Règle**
1		
des **Anhang IX** der Richtlinie über Medizinprodukte	of **annex IX** of the Medical Device Directive	de **l'annexe IX** de la directive sur les dispositifs médicaux
Medizinprodukte der **Klasse**	Medical devices **Class**	les dispositifs médicaux **Classe**
IIa		
Konformitätsbewertungsverfahren gemäß der Richtlinie 93/42 EWG, **Anhang**	**Conformity assessment procedure** according to Directive 93/42 EEC, **Annex**	**Procédure d'évaluation de la conformité** en application de la directive 93/42/CEE **Appendice**
II		
Benannte Stelle (falls zutreffend)	**Notified body** (if applicable)	**Organisme notifié** (le cas échéant)
TÜV Austria Services GmbH (CE 0408)		
Diese Konformitätserklärung gilt für alle Serien-/ Lotnummern ab dem Produktionsdatum	**This declaration of conformity is effective of all Serial/ Lot numbers as of the production date**	**Cette déclaration de conformité est valable pour toutes les numéros de série/ du lot dès la date de production**
12. Dezember 2012		
Geschäftsführer	Kitzbühel, 29.11.12	

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

PD/B18	Declarations of Conformity and Summary Reports 510(k) Number:	iSYS Medizintechnik GmbH

(b)(4) Third Party Test Data

[redacted]

Q

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

PD/B18	Declarations of Conformity and Summary Reports 510(k) Number:	iSYS Medizintechnik GmbH

(b)(4) Third Party Test Data

[redacted]

Qu

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

PD/B18	Declarations of Conformity and Summary Reports 510(k) Number:	

Summary Report Sterility

(b)(4) Third Party Test Data

[redacted]

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

PD/B18	Declarations of Conformity and Summary Reports 510(k) Number:	iSYS Medizintechnik GmbH

(b)(4) Third Party Test Data

[redacted]

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

PD/B18	Declarations of Conformity and Summary Reports 510(k) Number:	iSYS Medizintechnik GmbH

Summary Report Software

(b)(4)

[redacted]

(b)(4)

(b)(4)

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

PD/B18	Declarations of Conformity and Summary Reports 510(k) Number:	iSYS Medizintechnik GmbH

Summary Report Electricity

(b)(4)

[redacted]

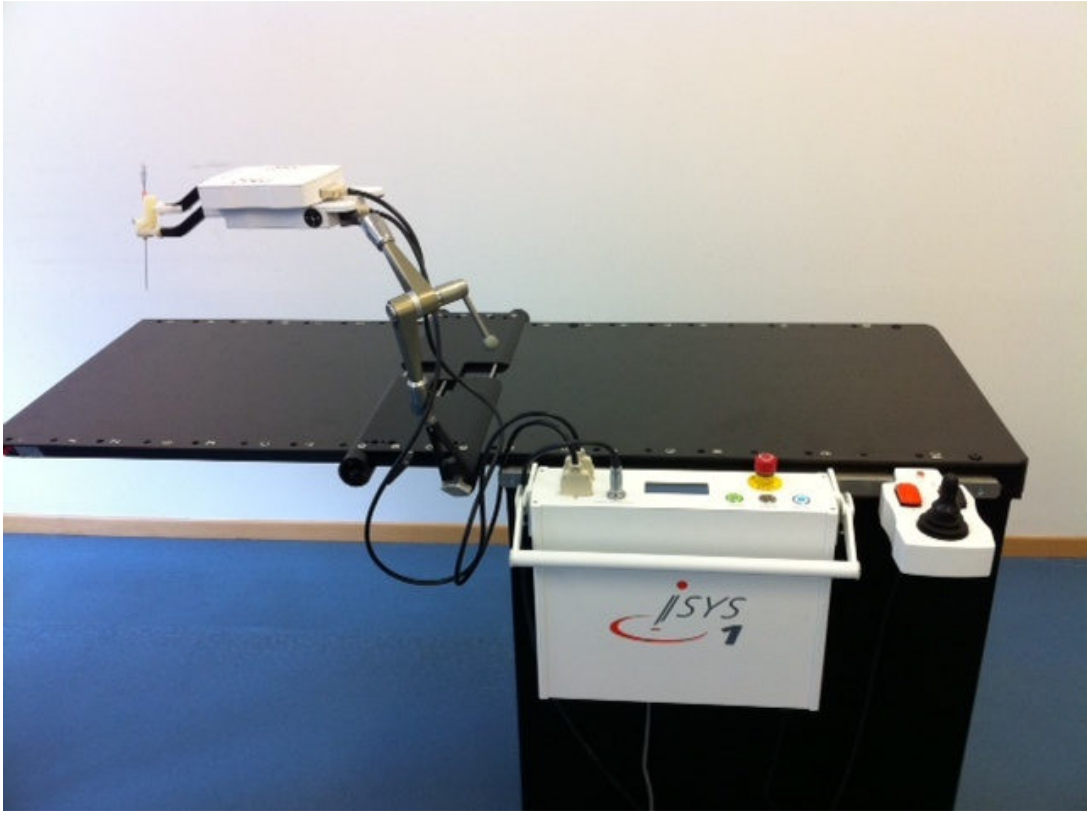
(b)(4)

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Risk Management File

Risk Management

for iSYS 1



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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Revision-History:

Reference	Effective Date	Description of changes
Rev 01	2010-12-13	Start of Risk Analysis Process: Chapter 1, 2, 3, 4 Risk Management Plan
Rev 02	2011-04-08	Risk Analysis
Rev 03	2011-05-12	Risk Evaluation
Rev 04	2011-05-13	Summary
Rev05	2012-08-21	Product Lifetime

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

TABLE OF CONTENTS

1 Scope / Description of iSYS 1 18

1.1 Lifecycle of iSYS 1 20

2 Related Documentation 22

2.1 Specification / Design Documents 22

2.2 Guidance Documents 22

2.3 Abbreviations and Acronyms 22

3 The Risk Analysis Team 23

4 Identification of Applicable Hazards 24

4.1 Fault Assumptions 24

4.2 Method 24

4.3 Usability 25

4.4 Classification of the Severity of each Risk 25

4.5 Estimation of Probability of Occurrence of each Cause 26

4.6 Determination of the Potential Causes of each Hazard 26

4.7 Definition of Risk Mitigation Measures 27

5 Summary 28

6 Identification of the Qualitative and Quantitative Characteristics 30

7 Checklist for Identification of Possible Hazards 40

8 Risk Management Table 46

9 Summary of Mitigations 86

10 Overview Risk Management Plan 92

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

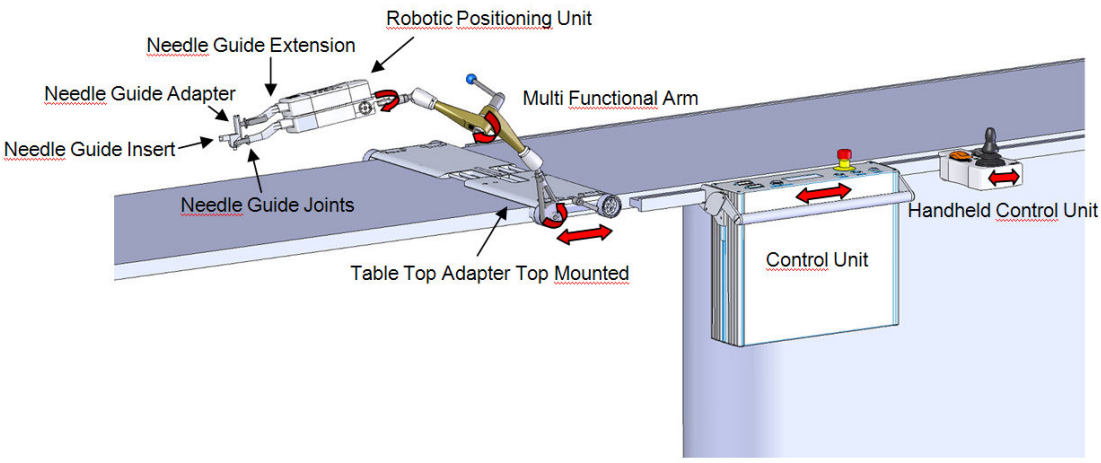
1 Scope / Description of iSYS 1

iSYS 1 is a modular equipment for the following intended use:

The intended use of iSYS 1 device is to function as a remote-operated positioning and guidance system during interventional procedures. Positioning is done in remote control manner; planning of the position/angulation is done based on 2D/3D patient data (CT, cone-beam CT, fluoroscopy) by external planning software – for example using an external navigation system, or planning software coming with the used imaging device. Also verification of the correct position and orientation of the tool prior to/during/after the intervention is done by means of these external devices. The iSYS1-System is then acting as a guideway during the manual insertion of the interventional tool – usually a needle type device, and the like. Applications include, but are not limited to, interventions like biopsy procedures, tumor ablation, nerve blocking, electrode placement, etc.

It is typically configured by the physician or the nurse to a system which includes components from various manufacturers. The iSYS 1 risk analysis cannot cover all of these components because not all are under control of the manufacturer of iSYS 1. This section defines which components are covered by this risk analysis and which are not.

The Basic Hardware Elements of iSYS 1 are elucidated in the following schematic picture:



iSYS 1 will be shipped in a basic configuration which consists of the following:

- one Control Unit
- one Handheld Control Unit with a Sterile Cover (not reusable) if required
- one Table Top or Side Rail Adapter

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

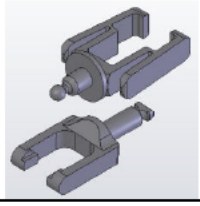
- one Multi Functional Arm
- one Robotic Positioning Device consisting of two Robot Modules
- two Needle Guide Extensions
- two Needle Guide Joints coupled with the Sterile Cover (not reusable)
- one Needle Guide Adapter (not reusable)
- one Needle Guide Insert (not reusable)
- one Needle Guide Marker Inlay for the setup (not reusable)

See "QA_73_2200_PD-B01_CoreProdDef" for further information.

The following components are integrated into the system but are optional:

On purchasing accessories, the user might expand the standard setup to achieve different variations. These accessories include: a Side Rail Adapter, a Table Top Adapter – Version B - Bottom Mounted, and a Cable Set 3m (from Robotic Positioning Unit to Control Unit) as well as a User Interface Cable Extension 5m (from Control Unit to HCU).

The following third party components are attachable to the system via interfaces provided by iSYS 1. This risk analysis does also cover the hazards created or mitigated by these components, except risks deriving from the sterility of the components:

	iSYS 1	**Needle Guide Set (disposable parts)**
	Component	**Needle Guide Joints and Sterile Cover (sterile)**
	Description	The Needle Guide Joints allow a quick and reversible connection of the Needle Guide Adapter to the Needle Guide Extension. The sterile cover is fixed onto the joints to one unit building the sterile bridge for the iSYS1.
	Component	**Needle Guide Adapter (sterile)**
	Description	The Needle Guide connects both Needle Guide Joints and allows accurate and safe needle guidance with 4 degrees of freedom.

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

	Component	Needle Guide Inserts (sterile)
	Description	During the intervention the tool is inserted and guided by the (sterile) Needle Guide Insert. It is available for needle diameters in the range between 9 and 22 gauge (= from 3.7mm to 0.7mm needle diameter); for the iSYS1.
	Component	**Needle Guide Marker Inlay (sterile)**
	Description	The Needle Guide Marker Inlay allows precise and remote-controlled alignment of the Needle Guide based on real-time imaging data;

1.1 Lifecycle of iSYS 1

The product life of the iSYS 1 Unit is **10 years*** including a regular service on the device. The service is intended to be performed every year, starting from the 3rd year of use of the device (e.g. device was sold in June 2008; the first service is performed in June 2011). The service includes:

- Detecting wear on the main components
- Detecting failures in the system
- Ensuring the accuracy of the device
- Checking the functionality of the safety relevant components

During the complete lifetime of iSYS 1, all parts and components must be supplied. This means, starting from the last sale of iSYS 1, the spare parts must be available for another five years.

The lifetime, and thus the end of sales and end of service, might be subject to changes due to growing experience with the product.

For service purposes, iSYS 1 will be sent to iSYS where the service is organized. During that time, the customer will receive a spare iSYS 1 to continue the interventions.

Upgrades to iSYS 1 are planned already and will be performed during 2011. The Needle Guide Extensions will receive markers to reduce the time for the intervention. This will lead to iSYS 1.1. In the coming years, the iSYS 2 will be presented, which allows an automatic positioning of the needle. Both upgrades will be offered to the customers of iSYS 1. Thus, the upgrade must be compatible in hard- and software.

Additionally, further inserts for needles with different diameters and other instruments will be developed. They are covered by this risk analysis.

The lifecycle of iSYS 1 covers the following phases:

- Development
- Production
- Sales
- Use
- Disposal

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

* The lifetime has been changed from 5 years to 10 years. In the beginning, the lifetime was defined basing on the use of the device by the physician 16 hours per day and 365 days per year. Then, an analysis of the lifetime of the single components has led to a lifetime of 5 years.

After two years of clinical experience with the iSYS 1 we can now say, that a use of the device 10 hours a day at 280 days are year is much more reasonable.

Therefore, the lifetime of the iSYS 1 is changed to 10 years.

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

2 Related Documentation

2.1 Specification / Design Documents

Core Product Definition	V 1.0 of 2010-09-16
Accessories	V 1.0 of 2010-09-17
Variations of the Product	V 2.0 of 2011-02-15

2.2 Guidance Documents

The methodology used in sections 6 and 7 was influenced by the following guidelines: ÖNORM EN ISO 14971: 2009 Medical Devices – Application of risk management to medical devices.

No	Standard	Title
1	ISO 62304	Medizingeräte-Software – Software-Lebenszyklus-Prozesse
2	ISO 60601-1	Medizinische elektrische Geräte
3	ISO 60601-1-6	Gebrauchstauglichkeit
4		
5		

2.3 Abbreviations and Acronyms

AC	Alternating Current
ALARP	As Low as Reasonably Practicable
CEO	Chief Executive Officer
CT	Computer Tomography
DIN	German Institute of Standards (Deutsches Institut für Normung)
EN	Europäische Norm
FDA	Food and Drug Administration
FMEA	Failure Mode and Effect Analysis
ISO	International Organization for Standardization
MOF	Main Operating Function (dt.: Hauptbedienfunktion)
ÖNORM	Österreichische Norm
PD	Product Documentation

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

3 The Risk Analysis Team

The iSYS 1 Risk Analysis Team evaluated the risks associated with the iSYS 1 system. The members of this team are:

Name	Position in the company	Function within the risk analysis
Dr. Gernot Kronreif	ACMIT	expert for the operation and functions of the device
(b)(6) [redacted]	ACMIT	expert for the manufacturing of the mechanical parts
(b)(6) [redacted]	-	expert for the manufacturing of the electronics
Dr. Michael Vogele	CEO	expert for the use of the device
(b)(6 [redacted]	Manager Regulatory Affairs	expert for the risk analysis process
(b)(6) [redacted]	ACMIT	expert for the electrical hardware design
	ACMIT	expert for the software design
	ACMIT	project manager
Dr. Michael Vogele	CEO	expert for evaluation of hazard severity
(b)(6) [redacted]	ACMIT	documentation
Dr. Michael Vogele	CEO	product manager
Dr. Michael Vogele	CEO	clinical expert

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

4 Identification of Applicable Hazards

4.1 Fault Assumptions

The "single fault philosophy" of the IEC 60601 series was used in this risk analysis. It means that within a limited period of time only single points of failure are considered. This first failure shall not lead to a hazard. If it is not a hazard and not detected (a 'passive failure'), an additional failure has to be assumed after a certain time (device specific) has elapsed. Also this second failure shall not lead to a hazard. Three independent failures are usually not assumed during the life time of a medical device. The time after which an independent second failure has to be assumed depends on the type of device and is usually defined by a standard. The currently applicable standards for a medical robotic system do not include this definition. Therefore this time is defined as 'one treatment'. This means that all passive failures have to be detected before the next use of the device.
Operator errors have been assumed as far as foreseeable, given the trained and instructed physician as the only operator.

4.2 Method

A list of potential hazards was established, at first separately for patient, operators, bystanders, and technical devices which could be affected. This includes hazards deriving from the usability of the product.

Note: A hazardous situation is always the result of a causal chain which starts from subtle, often barely noticeable technical or psychological causes and results in damage to the human body. In this risk analysis a "hazard" is understood as that link of the causal chain where the human body is affected for the first time.

Where necessary, the generic hazards have been divided in more specific hazards. Hazards are identified in the risk management table with an identifier of the form "H_…".

Sources of Information:
For finding the applicable hazards the following sources have been used:

- experience of the design engineers with similar products
- brainstorming in the team
- analysis of FDA Medical Device Reports and the DIMDI

List of the Applicable Potential Hazards
This is the list of applicable potential hazards found by the iSYS 1 risk analysis team:

Hazards to the patient:
- H_P1 Electrical Shock
- H_P2 Infection
- H_P3 Burning
- H_P4 Mechanical Injury
- H_P5 Mistreatment

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Hazards to the operator and other persons, e.g. service technician
- H_O1 Electrical shock
- H_O2 Infection
- H_O3 Burning
- H_O4 Mechanical Injury
- H_O5 Ergonomics

Generic hazards
- H_X1 Interference with other medical devices
- H_X2 Malfunction of other devices
- H_X3 Environmental hazards

The list of potential hazards and contributing factors given in ISO 14971 annex A was used for a check of completeness of the device hazard list. The result of this check is documented in the checklist in annex A of this hazard analysis.

4.3 Usability

The usability of the medical device is examined during the risk analysis. The basic for the evaluation are the main operating functions and, according to the type of the device, either ISO 62304 or ISO 60601-1-6. Parts of the usability are also evaluated in the Essential Requirements (see PD-B08).

Main Operating Functions (MOF):

- MOF1: Usage of the HCU in combination with the sterile cover (foil)
- MOF2: Applying the Needle Insert to the Robot Unit
- MOF3: Using the table adapters, cables and the MFA for the set-up
- MOF4: Cleaning and disinfecting the devices
- MOF5: Receiving status information at the display of the control unit

4.4 Classification of the Severity of each Risk

For each applicable hazard the severity was estimated under responsibility of a medical expert. The severity was assigned in a semi-quantitative way by means of categories. As given by the risk management plan, the following four severity levels were defined:

Severity	Value	Effect on Patient	Examples
Negligible	1	little or no potential of injury	1. black marks 2. minor infections
Marginal	2	potential of injury	1. mechanical injury by sharp edge 2. minor electrical shock 3. infection 4. elongation of treatment
Critical	3	potential of death or serious injury	1. serious infection 2. harming of healthy tissue

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

			3. electrical shock with mains voltage
Catastrophic	4	potential of multiple deaths or serious injuries	1. repeated death of several patients due to systematic malfunction

4.5 Estimation of Probability of Occurrence of each Cause

For each of the causes of the applicable hazards (see section 4.2 of this report) the probability of occurrence was estimated. The following sources of information were used:

- experience with similar products
- agreed rules of technology
- life tests
- if nothing else was available, the best engineering guess of the team

Note: if an individual probability cannot be estimated, it must be set to probability level 5 (100%) and, thus must be mitigated.

The result of the probability estimation was assigned as semi-quantitative categories as given by the risk management plan. Six categories were defined:

Category	Value	Frequency	Examples
Incredible	1	Very unlikely to occur during lifetime of all instruments of this type	simultaneous random hardware failures in two independent microcontroller systems within the same treatment
Improbable	2	May occur once in the life time of a device	random hardware failure of a component on a microcontroller system (e.g. failure of RAM, EPROM, crystal oscillator, etc.)
Remote	3	May occur once in 100 treatments	mains power failure
Occasional	4	May occur once in 10 treatments	operator error
Probable	5	May occur once in a treatment	systematic failure while positioning of the device
Frequent	6	May occur several times in a treatment	unintended movements (bounce) of the iSYS 1 (loose mechanical connection)

4.6 Determination of the Potential Causes of each Hazard

For each of the hazards given in sections 4.2 of this report the potential causes were determined. The search was done first intuitively according to the expertise of each of the team members. Additional hazards were found later by an FMEA of the preliminary design.

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

The applicable causes for each hazard are documented in the risk management file in column "Causes and sub causes". They are identified with an identifier of the form

Cxx_IN	Integration cause
Cxx_HU	Human cause
Cxx_HW	Hardware cause
Cxx_SW	Software cause

4.7 Definition of Risk Mitigation Measures

If the risk region was not already "broadly acceptable", risk mitigation measures were defined for each hazard/cause pair. Where more than one measure was defined, the combined effect of all countermeasures was considered to be necessary.
The risk mitigation measures are documented in column "Mitigation Measures" in the risk management table. They are identified with an identifier of the form "M…".

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

5 Summary

As shown in the risk management table, the residual risk of each individual hazard/cause pair is either reduced to the broadly acceptable level or it is in the ALARP region, and for each ALARP case a rationale is provided why a further reduction is not practicable.
The following tables provide an overview for the status pre and post mitigation. They show how many of the applicable hazard/cause pairs are assigned to each of the fields of the tables. As can be seen, pre mitigation **62** cases were not acceptable and **5** cases were ALARP. Post mitigation there aren't any more cases which are not acceptable and the remaining **48** ALARP cases are in the lower ALARP area.

pre mitigation

		Severity			
		1	2	3	4
Proba-bility	6				
	5				1
	4	19	3	27	
	3		2	9	
	2	7	8	23	
	1	2	3	3	

post mitigation

	Severity			
	1	2	3	4
6				
5				
4				
3				
2	6	3		
1	32	18	48	

Following hazards have been mitigated to an acceptable risk level:

- H_P3 Burning
- H_P4 Mechanical Injury
- H_O2 Infection
- H_O3 Burning
- H_O4 Mechanical Injury
- H_O5 Ergonomics
- H_X1 Interference with other medical devices
- H_X2 Malfunction of other devices
- H_X3 Environmental hazards

The following hazards have been mitigated to the ALARP region:

- H_P1 Electrical Shock
- H_P2 Infection
- H_P5 Mistreatment
- H_O1 Electrical shock

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

The remaining hazards concerning the **electrical shock** derive from the general danger of electrical components. Any measure that is reasonable has been taken and the system is tested according to the IEC 60601-1 for electrical safety. Nevertheless, an electric system in an operation theatre bears a remaining risk.
The danger of **infecting a patient** derives from the foreseeable misuse of reusing the single use (sterilized) components, which can especially for poor countries never been excluded. All measures including a summary of risks in case of misuse in the user manual are taken and the components are labeled accordingly. Further measures are not applicable.
The remaining hazard of **mistreatment** derives from the invention itself. Independent from using a robotic unit or performing the treatment freehand, any shifting of the target after imaging and before treatment has the probability of a mistreatment. Although the use of a robot unit reduces the risk of a mistreatment, a certain amount of risk remains.

Therefore also the overall risk can be considered as acceptable.
Since robotic units are used in operation theatres since many years, the medical benefit of such a machine is beyond any doubt. Therefore the risk benefit ratio can be considered as positive.
The additional information from the Post Marketing Surveillance must be added to this risk file according to the VA_73_2544 (Post Marketing).

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

6 Identification of the Qualitative and Quantitative Characteristics

This section describes the risk-related characteristics of iSYS 1. In the early phase of the project, when the preliminary risk analysis was performed, not yet all of these characteristics have been finally decided. For the unknown data preliminary estimations have been used, and during the further development final data have been added when available.
The following list contained in ISO 14971 annex C was used as a tool for determination of the risk-related characteristics of the product. In the following the questions are given and the answers to each question.
The list cannot be complete for each product. Thus, any relevant information (risk-related characteristic) that could affect the risk management process must be added at the end of this list. Questions that are not applicable, should be marked with a “N/A”.

a) What is the intended use and how is the medical device to be used?

Factors that should be considered include:

- what is the medical device's role relative to
  - diagnosis, prevention, monitoring, treatment or alleviation of disease,
  - compensation for injury or handicap or
  - replacement or modification of anatomy, or control of conception?
- what are the indications for use (e.g. patient population)?
- does the medical device sustain or support life?
- is special intervention necessary in the case of failure of the medical device?

The intended use of the iSYS1 device is to function as a remote-operated positioning and guidance system during interventional procedures. Positioning is done in remote control manner; planning of the position/angulation is done based on 2D/3D patient data (CT, cone-beam CT, fluoroscopy) by external planning software – for example using an external navigation system, or planning software coming with the used imaging device. Also verification of the correct position and orientation of the tool prior to/during/after the intervention is done by means of these external devices. The iSYS1-System is then acting as a guideway during the manual insertion of the interventional tool – usually a needle type device, and the like. Applications include, but are not limited to, interventions like biopsy procedures, tumor ablation, nerve blocking, electrode placement, etc.

- **diagnosis (tissue harvesting), treatment, alleviation**
- **no compensation**
- **no replacement or modification, control of conception**
- **no restrictions of patient population (in case of uncontrolled movements of the patient)**
- **no life support**
- **the system provides an emergency-stop system**

b) Is the medical device intended to be implanted?

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Factors that should be considered include the location of implantation, the characteristics of the patient population, age, weight, physical activity, the effect of ageing on implant performance, the expected lifetime of the implant, the reversibility of the implantation.

N/A

c) Is the device intended to contact the patient or other persons?

Factors that should be considered include intended contact, surface contact, invasive contact, implantation and, respectively, period and frequency of contact.

- **no intended direct contact**
- **but connection to the patient via the needle**
- **unintended contact is possible, but only short-time**

d) What materials and/or components are incorporated in the device or are used with, or are in contact with, the medical device?

Factors that should be considered include:
- compatibility with relevant substances;
- compatibility with tissues or body fluids;
- whether characteristics relevant to safety are known;
- is the device manufactured utilizing materials of animal origin?

- **materials: electronic components, PA6 , PA6 GF30, stainless steel, paint, aluminum, copper, cabling, rubber, (see data sheets for details) → Compatibility to cleaning and disinfection will be tested**
- **for the hardware components of iSYS 1 no biocompatibility is necessary as no intended contact to patient**
- **material is selected due to the mechanical stability of the system**
- **the sterile cover has contact to the patient, but this is not a medical product produced by iSYS, but by Websinger, and is not covered with this risk analysis**
- **No materials of animal origin**
- **REACH, RoHS and WEEE compatible**

e) Is energy delivered to and/or extracted from the patient?

Factors that should be considered include:
- the type of energy transferred;
- its control, quality, quantity, intensity and duration;
- whether energy levels are higher than those currently used for similar devices.

N/A

f) Are substances delivered to and/or extracted from the patient?

Factors that should be considered include:
- whether the substance is delivered or extracted;
- whether it is a single substance or range of substances;

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

– the maximum and minimum transfer rates and control thereof.

N/A

g) Are biological materials processed by the device for subsequent re-use, transfusion or transplantation?

Factors that should be considered include the type of process and substance(s) processed (e.g. autotransfusion, dialysis, blood component or cell therapy processing).

N/A

h) Is the device supplied sterile or intended to be sterilized by the user, or are other microbiological controls applicable?

Factors that should be considered include
- whether the medical device is intended for single use or re-use packaging;
- shelf-life issues;
- limitation on the number of re-use cycles
- method of product sterilization;
- the impact of other sterilization methods not intended by the manufacturer.

N/A. Websinger (see above)

i) Is the medical device intended to be routinely cleaned and disinfected by the user?

Factors that should be considered include the types of cleaning or disinfecting agents to be used and any limitations on the number of cleaning cycles. The design of the medical device can influence the effectiveness of routine cleaning and disinfection. In addition, consideration should be given to the effect of cleaning and disinfecting agents on the safety or performance of the device.

Yes, cleaning and disinfection must be performed prior to each use. Compatibility to the agents will be tested.

j) Is the medical device intended to modify the patient environment?

Factors that should be considered include:
- temperature;
- humidity;
- atmospheric gas composition;
- pressure;
- light

N/A

k) Are measurements taken?

Factors that should be considered include the variables measured and the accuracy and the precision of the measurement results.

N/A

l) Is the medical device interpretative?

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Factors that should be considered include whether conclusions are presented by the medical device from input or acquired data, the algorithms used, and confidence limits. Special attention should be given to unintended applications of the data or algorithm.

Yes, the marker inlay is visible in the imaging device and is used for the positioning of the needle.

Additionally, information is displayed on the control unit (display, status LEDs).

m) Is the medical device intended for use in conjunction with other medical devices, medicines or other medical technologies?

Factors that should be considered include identifying any other medical devices, medicines or other medical technologies that can be involved and the potential problems associated with such interactions, as well as patient compliance with the therapy.

Yes, the iSYS1 is used with the interventional device (needle, etc.), the tabletop of the treatment couch, the siderail of the treatment couch, the imaging device (C-Arm, etc.) and the planning software.

To be considered are also the use and installation of the iSYS1 with clinical gloves and the use of defibrillator, life-support measures and syringe pumps or similar (infusion, etc.).

n) Are there unwanted outputs of energy or substances?

Energy-related factors that should be considered include noise and vibration, heat, radiation (including ionizing, non-ionizing, and ultraviolet/visible/infrared radiation), contact temperatures, leakage currents, and electric or magnetic fields.
Substance-related factors that should be considered include substances used in manufacturing, cleaning or testing having unwanted physiological effects if they remain in the product.
Other substance-related factors that should be considered include discharge of chemicals, waste products, and body fluids.

Yes, these are noise and vibration, heat, radiation (non-ionizing), contact temperatures, leakage currents, and electric or magnetic fields.

o) Is the medical device susceptible to environmental influences?

Factors that should be considered include the operational, transport and storage environments. These include light, temperature, humidity, vibrations, spillage, and susceptibility to variations in power and cooling supplies, and electromagnetic interference.

Yes, the environmental conditions must be defined according to the data sheets (use, transport and storage). The visibility of the display depends on the surrounding light. The device depends on the power supply and the electromagnetic fields.

p) Does the medical device influence the environment?

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Factors that should be considered include:
- the effects on power and cooling supplies;
- emission of toxic materials;
- the generation of electromagnetic disturbance.

The iSYS1 is connected to the power supply and can produce electromagnetic fields.

q) Are there essential consumables or accessories associated with the medical device?

Factors that should be considered include specifications for such consumables or accessories and any restrictions placed upon users in their selection of these.

Yes, the needle guide kits are for single use. Only consumables supplied by iSYS are allowed.

r) Is maintenance or calibration necessary?

Factors that should be considered include:
- whether maintenance or calibration are to be carried out by the operator or user or by a specialist;
- are special substances or equipment necessary for proper maintenance or calibration?

Yes, the iSYS1 will receive regular maintenance after three years of use and any two years (see lifecycle in chapter 1.1).

s) Does the medical device contain software?

Factors that should be considered include whether software is intended to be installed, verified, modified or exchanged by the operator or user or by a specialist.

Yes, in case (upgrade) new software will be installed on the iSYS1 by a specialist.

t) Does the medical device have a restricted shelf-life?

Factors that should be considered include labeling or indicators and the disposal of such medical devices when the expiration date is reached.

Yes, the shelf-life of the iSYS1 is restricted to five years. Experiences with former prototypes show no problems within 7.5 years.

u) Are there any delayed or long-term use effects?

Factors that should be considered include ergonomic and cumulative effects. Examples could include pumps for saline that corrode over time, mechanical fatigue, loosening of straps and attachments, vibration effects, labels that wear or fall off, long term material degradation.

Yes, see r)

v) To what mechanical forces will the medical device be subjected?

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Factors that should be considered include whether the forces to which the medical device will be subjected are under the control of the user or controlled by interaction with other persons.

Yes, the mechanical arm and the table adapters are tightened by the user and might be overtightened.

Misuse: the cables could be hauled by the user.

w) What determines the lifetime of the medical device?

Factors that should be considered include ageing and battery depletion.

The data sheets of the single components give the lifetime of these components. Aging of single components (plastics, electronic components) might occur.

x) Is the medical device intended for single use?

Factors that should be considered include: does the medical device self-destruct after use? Is it obvious that the device has been used?

Yes, the needle guide kits are for single use. Only consumables supplied by iSYS are allowed.

y) Is safe decommissioning or disposal of the medical device necessary?

Factors that should be considered include the waste products that are generated during the disposal of the medical device itself. For example, does it contain toxic or hazardous material, or is the material recyclable?

Yes, RoHS and WEEE are complied with. National regulations must be followed.

z) Does installation or use of the medical device require special training or special skills?

Factors that should be considered include the novelty of the medical device and the likely skill and training of the person installing the device.

Yes, installation and use require special training.

aa) How will information for safe use be provided?

Factors that should be considered include:

- whether information will be provided directly to the end user by the manufacturer or will it involve the participation of third parties such as installers, care providers, health care professionals or pharmacists and whether this will have implications for training;
- commissioning and handing over to the end user and whether it is likely/possible that installation can be carried out by people without the necessary skills;
- based on the expected life of the device, whether re-training or re-certification of operators or service personnel would be required.

User Manual and User Trainings are provided by iSYS.

ab) Will new manufacturing processes need to be established or introduced?

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Factors that should be considered include new technology or a new scale of production.

No, iSYS will not produce the iSYS1, but specialized companies.

ac) Is successful application of the medical device critically dependent on human factors such as the user interface?

ac.1) Can the user interface design features contribute to use error?

Factors that should be considered are user interface design features that can contribute to use error. Examples of interface design features include: control and indicators, symbols used, ergonomic features, physical design and layout, hierarchy of operation, menus for software driven devices, visibility of warnings, audibility of alarms, standardization of colour coding. See IEC 60601-1-6[25] for additional guidance on usability and IEC 60601-1-8[26] for guidance on alarms.

The use of the marker inlay is critical for the correct positioning of the invasive device. The information on the display, acoustic alarms and status LEDs have influence on a safe use as they have to be considered (needle placement).

ac.2) Is the medical device used in an environment where distractions can cause use error?

Factors that should be considered include:

- the consequence of use error;
- whether the distractions are commonplace;
- whether the user can be disturbed by an infrequent distraction.

The visual alarms can be overlooked and lead to mistreatment.

Under normal circumstances the user cannot be distracted during the use of iSYS1.

The patient is partly visually covered by iSYS1. The robot unit is visible in the imaging device and might partly overlap the patient's image. The image might contain a marker-like structure which can be mistaken in the positioning process.

ac.3) Does the medical device have connecting parts or accessories?

Factors that should be considered include the possibility of wrong connections, similarity to other products' connections, connection force, feedback on connection integrity, and over- and under-tightening.

Table top adapter: the table adapter is connected to the treatment couch and might be over- or undertightened. Overtightening might lead to damage of the components. Undertightening cannot be detected easily.

Mechanical Arm: the mechanical arm is connected to the table top adapter and might be over- or undertightened. Overtightening might lead to damage of the components. Undertightening cannot be detected easily.

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Robot unit: the robot unit is connected to the mechanical arm and might be over- or undertightened. Overtightening might lead to damage of the components. Undertightening cannot be detected easily.

Needle Guide Kit: the needle guide kit is connected to the robot unit by the means of a twist lock and a snap fit. Improper connection is possible and might lead to mistreatment.

Needle: the needle inserted in the needle insert. Use of an insert with a too big size leads to an improper guidance of the needle, use of a too small insert might lead to a sticking needle.

Cabling: the cables are connected to the several components. The cables can be mixed and connected to the wrong devices.

ac.4) Does the medical device have a control interface?

Factors that should be considered include spacing, coding, grouping, mapping, modes of feedback, blunders, slips, control differentiation, visibility, direction of activation or change, whether the controls are continuous or discrete, and the reversibility of settings or actions.

Handheld Control Unit: the HCU offers a joystick for movement control, a rocker switch for selection of angulation or positioning and a rocker switch for speed level. All setting and actions are fully reversible.

ac.5) Does the medical device display information?

Factors that should be considered include visibility in various environments, orientation, the visual capabilities of the user, populations and perspectives, clarity of the presented information, units, colour coding, and the accessibility of critical information.

The control unit has a display for information regarding speed level, alarms, mode of movement, and status of the iSYS1.

At the control unit are three light indicators for status information (green, red, and blue), green for “ready for use”, red for “error” and blue for “power”.

Color coding is performed according to 60601-1, chapter 7.8.1.

The display is back-lighted and, thus, also visible in the dark.

ac.6) Is the medical device controlled by a menu?

Factors that should be considered include complexity and number of layers, awareness of state, location of settings, navigation method, number of steps per action, sequence clarity and memorization problems, and importance of control function relative to its accessibility and the impact of deviating from specified operating procedures.

The display contains no menu, but the HCU offers the possibility to change the speed and the mode of movement.

ac.7) Will the medical device be used by persons with special needs?

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Factors that should be considered include the user, their mental and physical abilities, skill and training, ergonomic aspects, the use environment, installation requirements, and the patient's capability to control or influence the use of the medical device. Special attention should be paid to users with special needs, such as handicapped persons, the elderly and children. Their special needs might include assistance by another person to enable the use of a medical device. Is the medical device intended to be used by individuals with various skill levels and cultural backgrounds?

The iSYS1 is only operated and installed by trained clinical personnel. The personnel might be of different cultural and linguistic background.

ac.8) Can the user interface be used to initiate user actions?

Factors that should be considered include the possibility of initiating a deliberate action for the user to enter a controlled operation mode, which enlarges the risks for the patient and which creates awareness for the user for this condition.

N/A

ad) Does the medical device use an alarm system?

Factors that should be considered are the risk of false alarms, missing alarms, disconnected alarm systems, unreliable remote alarm systems, and the medical staff's possibility of understanding how the alarm system works. Guidance for alarm systems is given in IEC 60601-1-8.

Yes, the iSYS1 uses acoustic and optical alarms to inform the user about errors. The acoustic alarms are designed according to the respective standards. <u>The optical alarms are subject to review.</u>

ae) In what way(s) might the medical device be deliberately misused?

Factors that should be considered are incorrect use of connectors, disabling safety features or alarms, neglect of manufacturer's recommended maintenance.

Incorrect use of connectors, neglect cleaning and disinfection procedures, re-use of single use components, neglect of manufacturer's recommended maintenance, use of not released accessories, neglect disposal recommendations, mounting siderail adapter on loose siderail, positioning robot unit on patient's skin, using the iSYS1 as a rest or placement area, use the iSYS1 in combination with unsuitable imaging devices, use outside the intended use (other interventions), neglect the recommendation for the sterile cover, neglect the specified lifetime, neglect specified workflow.

af) Does the medical device hold data critical to patient care?

Factors that should be considered include the consequence of the data being modified or corrupted.

N/A

ag) Is the medical device intended to be mobile or portable?

Factors that should be considered are the necessary grips, handles, wheels, brakes, mechanical stability and durability.

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Yes, but only for setup.

ah) Does the use of the medical device depend on essential performance?

Factors that should be considered are, for example, the characteristics of the output of life-supporting devices or the operation of an alarm.

N/A

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

7 Checklist for Identification of Possible Hazards

The following lists contained in ISO14971 annex E were used as a tool for identification of possible hazards. Since some of the items of this list are hazards in the sense of this risk analysis, and some are causes of hazards, they have been considered either in the hazard or in the causes determination.
For each point it is explained if it is relevant for iSYS 1 and - if relevant - which hazard or which cause reflects it.
Be aware, that the following lists are only an example, and the hazards and causes for the product might differ. Add additional points to the list, where applicable and set “N/A”, if a hazard is not relevant for the product.

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Energy hazards

Item from ISO 14971	applicability to iSYS 1	Ref.
Electromagnetic energy		
Line voltage	Yes, electrical safety acc. to EN 60601-1 has to be tested.	
Leakage current (enclosure, earth or patient)	Yes, electrical safety acc. to EN 60601-1 has to be tested.	
Electric fields	Yes, tested at Seibersdorf Laboratory GmbH acc. to EN 60601-1-2.	
Magnetic fields (e.g., MRI)	n/a.	
Radiation energy		
Ionizing radiation	n/a.	
Non-ionizing radiation	see above, electric fields.	
Thermal energy		
High temperature	Yes, iSYS1 can overheat. Test at ACMIT will be performed.	
Low temperature	n/a.	
Mechanical energy		
Gravity (falling, suspended masses)	Yes, the device can be badly fixed and fall on the user or patient. Ergonomics will be tested.	
Vibration	Yes, if components (e.g. fan) break. In case of vibrations, the device must not be used.	UM
Stored energy	Only at the HCU, but not hazardous.	
Moving parts	Yes, but the movements are so slow and limited in force that no hazardous situation can occur.	
Torsion, shear and tensile force	In case of bad fixation of the device, it can fall down and harm user or patient.	
Moving and positioning of patient	n/a.	
Acoustic energy (ultrasonic, infrasound, sound)	The acoustic alarms are acc. to EN 60601-1-8 and thus not hazardous. Movements in the robot units can lead to unintended noise (e.g. wrong control settings). In this case, the device must not be used.	UM Goods Inspections Service Manual

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Item from ISO 14971	applicability to iSYS 1	Ref.
High pressure fluid injection	n/a.	

Biological and chemical hazards

Item from ISO 14971	applicability to iSYS 1	Ref.
Biological		
Bacteria	Yes, if cleaning and disinfection procedures are neglected or the sterile cover is not used.	UM
Viruses	Yes, if cleaning and disinfection procedures are neglected or the sterile cover is not used.	UM
Other agents (e.g. prions)	Yes, if cleaning and disinfection procedures are neglected or the sterile cover is not used.	UM
Re- or cross-infection	Yes, if cleaning and disinfection procedures are neglected or the sterile cover is not used.	UM
Chemical (exposure of airway, tissues, environment or property to:)		
Acids or alkalis	n/a.	
Residues	Yes, if the cleaning agents remain on the iSYS1 and the cleaning and disinfection procedure is shortened.	UM
Contaminates	Yes, if cleaning and disinfection procedures are neglected or the sterile cover is not used.	
Additives or processing aids	Yes, if the grease from the drive chain gets in contact with patient or user. Yes, if glue or other liquids from the manufacturing process remain on the iSYS1.	Goods Inspections
Cleaning, disinfection or testing agents	Yes, if the cleaning agents remain on the iSYS1 and the cleaning and disinfection procedure is shortened.	UM
Degradation products	n/a.	
Medical gasses	n/a.	

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Item from ISO 14971	applicability to iSYS 1	Ref.
Anaesthetic products	n/a.	
Biocompatibility		
Allergenicity	n/a, no intended contact to patient.	
Mutagenicity	n/a, no intended contact to patient.	
Oncogenicity	n/a, no intended contact to patient.	
Teratogenicity	n/a, no intended contact to patient.	
Carcinogenicity	n/a, no intended contact to patient.	
Pyrogenicity	n/a, no intended contact to patient.	

Operational hazards

Item from ISO 14971	applicability to iSYS 1	Ref.
Function		
Incorrect or inappropriate output or functionality	Yes, each individual device will be tested before delivered to the user.	Goods Inspections
Incorrect measurement	n/a.	
Erroneous data transfer	Yes, each individual device will be tested before delivered to the user.	Goods Inspections
Loss or deterioration of function	Not within the specified lifetime. Use after the lifetime is covered by intended misuse.	UM
Use error		
Attentional failure	Yes, but only when placing the instrument, not during the use of the iSYS1.	UM
Memory failure	Yes, but only when placing the instrument, not during the use of the iSYS1.	UM
Rule-based failure	Yes, e.g. shortening or neglecting the cleaning and disinfection procedures. Yes, shortening or neglecting the workflow.	UM

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Item from ISO 14971	applicability to iSYS 1	Ref.
Knowledge-based failure	Yes, but training on the iSYS1 will be provided.	
Routine violation	see above (rule-based failure).	UM

Environmental hazards (deriving from the former version of the standard)

Item from ISO 14971	applicability to iSYS 1	Ref.
Electromagnetic fields	Yes, see above.	
Susceptibility to electromagnetic interference	Yes, see above.	
Emissions of electromagnetic interference	Yes, see above.	
Inadequate supply of power	Yes, but the iSYS1 will have a power-supply unit with universal input. Different fuses required for different voltages (e.g. US market).	
Inadequate supply of coolant	n/a.	
Storage or operation outside prescribed environmental conditions	Yes, storage and transport is possible. Operation is in clinical environment.	
Incompatibility with other devices with which it is intended to be used	Yes, collision with imaging device is possible. It also might happen that imaging quality is being influenced by the iSYS system, especially if the robot is placed in the imaging beam.	UM
Accidental mechanical damage	Yes, collision with imaging device is possible. Damage due to falling down of a component leading to malfunction.	UM
Contamination due to waste products and /or medical device disposal	Yes, national regulations must be applied.	UM

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Information hazards

Item from ISO 14971	applicability to iSYS 1	Ref.
Labeling		
Incomplete instructions for use	Yes, a validation of the UM will be performed.	
Inadequate description of performance characteristics	Yes, a validation of the performance data will be performed (accuracy, compatibility to agents, power supply, movement ranges, compatibility to imaging devices, fixing devices like MFA etc., environmental conditions, weight and dimensions)	
Inadequate specification of intended use	Yes, the intended use has to be validated. Any information in the intended use has to be tested.	
Inadequate disclosure of limitations	Yes, the limitations have to be defined by the risk analysis team and clinical experts.	
Operating instructions		
Inadequate specification of accessories	No, the accessories are limited and defined in the UM. The use of any other accessory is restricted or forbidden.	
Inadequate specification of pre-use checks	Yes, the pre-use checks have to be defined and validated.	
Overcomplicated operating instructions	Yes, a validation of the UM will be performed.	
Warnings		
Insufficient warning of side effects	n/a.	
Inadequate warning of hazards likely with re-use of single use medical devices	Yes, the warnings have to be in the UM.	
Specification of service and maintenance	Yes, the service and maintenance procedures have to be defined acc. to specifications of the single components.	

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

8 Risk Management Table

Severity (Se)

1 = Negligible
2 = Marginal
3 = Critical
4 = Catastrophic

Probability (Pr)

1 = Incredible
2 = Improbable
3 = Remote
4 = Occasional
5 = Probable
6 = Frequent

Risk

P\S	1	2	3	4
6		NAK	NAK	NAK
5		NAK	NAK	NAK
4	AK	NAK	NAK	NAK
3	AK		NAK	NAK
2	AK	AK	NAK	NAK
1	AK	AK		NAK

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Hazards to the patient

H_P1 Harm due to Electrical Shock

	Pre Mitigation				Post Mitigation		
Potential causes and sub causes	**Se**	**Pr**	**Risk**	**Mitigation Measures**	**Se**	**Pr**	**Risk**
C1 Due to cabling							
C1.1 due to EMC problems (FMEA line 70)	2	4	NAK	M1 Test according to IEC 60601-1-2 M2 construction: defined length of cables	2	1	AK
C1.2 due to missing grounding (FMEA line 71)	3	2	NAK	M3 periodically inspection in the clinic (user / service manual) M4 safe connection to housing M5 contact surfaces on each component	3	1	ALARP
C1.3 due to damages caused by mechanical or chemical influences (power supply)	3	2	NAK	M6 Reinforced and/or double insulation and/or class I housing (see technical drawings for details) M7 Warning in UM	3	1	ALARP
C1.4 due to damages caused by mechanical or chemical influences (data cable, HCU cable)	1	3	AK	M6 Reinforced and/or double insulation and/or class I housing (see technical drawings for details) M7 Warning in UM	1	1	AK
C1.5 due to damages by X-Ray radiation of the imaging device (power supply)	3	1	AK	M8 Literature / Data Sheets	3	1	ALARP
C1.6 due to damages by X-Ray radiation of the imaging device (data cable, HCU cable)	1	1	AK	M8 Literature / Data Sheets	1	1	AK
C2 Due to wrong power supply of components (FMEA lines 91-94, 96-98), (MOF3)	3	4	NAK	M9 Test according to IEC 60601-1 M10 Usage of wide range power supply unit M11 Fuses for high current M12 Alarm due to voltage watchdog	2	1	AK

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

	Pre Mitigation				Post Mitigation		
Potential causes and sub causes	**Se**	**Pr**	**Risk**	**Mitigation Measures**	**Se**	**Pr**	**Risk**
				M13 LED “ready-to-use” ceases			
C3 Failure in the power supply unit	3	4	NAK	M11 Fuses for high current M6 class 1 housing for the control unit M14 Overvoltage protection in the power supply (schematics should be provided to TÜV by Traco)	2	1	AK
C4 Housing of control unit not sufficiently grounded and voltage on touchable parts (230V)	3	4	NAK	M15 Grounding pins on every part M5 contact surfaces on each component	3	1	ALARP
C5 Power supply cable of the control unit gets damaged and touches the secondary circuit							
C5.1 on the 24V cabling	3	1	NAK	M16 usage of varistor and Schottky Zener diode (30V)	2	1	AK
C5.2 on the Power Led cable	3	2	NAK	M17 direct connection of the Power LED to the output of the Power Supply M16 usage of varistor and Schottky Zener diode (30V)	2	1	AK
C5.3 on the PEC	3	2	NAK	M18 Construction with dividing plate M2 defined length of cabling preventing M6 class 1 housing for the control unit M11 Fuses for high current	3	1	ALARP
C6 Due to condensed water in the devices	3	2	NAK	M19 Definition of operating, storage and transport conditions M6 Class1 housing of control unit M9 air clearance and creepage distance acc. to IEC 60601-1 M20 User Manual: if transported outside the	2	1	AK

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

	Pre Mitigation				Post Mitigation		
Potential causes and sub causes	**Se**	**Pr**	**Risk**	**Mitigation Measures**	**Se**	**Pr**	**Risk**
				specification, time for drying defined.			
C7 Due to spilling on the device	3	3	NAK	M9 Test acc. to IEC 60601-1 M6 Class1 housing of control unit M21 Construction: openings on the bottom side M22 UM/Workflow: covering by sterile cover	2	1	AK
C8 Due to rests of disinfection liquids (MOF4)	3	4	NAK	M23 UM/Workflow: drying after disinfection and cleaning M6 Class1 housing of control unit M9 Test acc. to IEC 60601-1 M21 Construction: openings on the bottom side	2	1	AK
C9 Due to fluids getting into the housing (MOF4)							
C9.1 of the control unit	3	4	NAK	M9 Test acc. to IEC 60601-1 M6 Class1 housing of control unit M21 Construction: openings on the bottom side	2	1	AK
C9.2 of the robot unit	1	3	AK	M9 Test acc. to IEC 60601-1 M24 Low voltage power supply (6,5V) M22 UM/Workflow: covering by sterile cover	1	1	AK
C9.3 of the HCU	1	3	AK	M9 Test acc. to IEC 60601-1 M25 Low voltage power supply (24V)	1	1	AK
C10 Due to overheating of components and, thus, malfunction of components	1	2	AK	M9 Test for overheating (IEC 60601-1)	2	1	AK
C11 Due to overvoltage in the mains supply	3	2	NAK	M1 Test according to IEC 60601-1-2 M14 Overvoltage protection in the power supply (schematics should be provided to TÜV by Traco)	1	1	AK

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

	Pre Mitigation				Post Mitigation		
Potential causes and sub causes	**Se**	**Pr**	**Risk**	**Mitigation Measures**	**Se**	**Pr**	**Risk**
C12 loose cabling in the Robot Unit	1	3	AK	M26 insulated housing	1	1	AK
C13 breaking of the housing	3	1	ALARP	M9 Test according to IEC 60601-1	1	1	AK
C14 loose connector of Cable (MOF3)							
C14.1 between Control Unit and Robot Unit	1	3	NAK	M27 construction of plugs, pins not reachable M28 Warning in the UM: check connections between components M29 Workflow/UM: first all components connected to each other, then main power supply	1	1	AK
C14.2 between Control Unit and HCU	1	3	NAK	M27 construction of plugs, pins not reachable M28 Warning in the UM: check connections between components M29 Workflow/UM: first all components connected to each other, then main power supply	1	1	AK
C14.3 Mains cable	3	2	NAK	M27 construction of plugs, pins not reachable M28 Warning in the UM: check connections between components M29 Workflow/UM: first all components connected to each other, then main power supply	3	1	AK
C15 Due to electrostatic discharge of the operator	1	2	NAK	M30 insulation of the patient connection	1	1	AK
C16 touching the circuits in the Robot Unit, due to loose/broken covering band	1	2	NAK	M9 distance to circuits acc. IEC 60601-1 M31 User Manual: never touch inside components	1	1	AK
C17 touching a metallic part inside the Robot Unit, due to loose/broken covering band and single fault condition in the insulation of the circuits of the Robot Unit	1	2	NAK	M31 User Manual: never touch inside components M32 construction: covering (warning color) the front side of the robot unit	1	1	AK

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

	Pre Mitigation				Post Mitigation		
Potential causes and sub causes	**Se**	**Pr**	**Risk**	**Mitigation Measures**	**Se**	**Pr**	**Risk**
C18 due to wrong re-assembling after service (MOF3)	1	2	NAK	M33 Service Manual: provide checklist after service (Technical Safety Check)	1	1	AK
C19 due to aging of components	3	2	NAK	M149 User Manual: define times for service and maintenance acc. to chapter 1	3	1	AK

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

H_P2 Harm due to Infection

	Pre Mitigation				Post Mitigation		
Potential causes and sub causes	**Se**	**Pr**	**Risk**	**Mitigation Measures**	**Se**	**Pr**	**Risk**
C1 by re-use of single use, sterile parts (FMEA line 6), (MOF2)	4	5	NAK	M34 Combining the sterile cover with the Needle Guide Adapter M35 Labelling: single use, sterile M36 Warning in the UM: single use, sterile, misuse	3	1	ALARP
C2 by loosening of the sterile cover (connection to needle guide joints)							
C2.1 due to application of patient disinfection and/or mechanical forces (MOF2)	3	2	NAK	M37 Chemical and mechanical Tests (websinger) M38 Redundant fixation of the sterile cover to the joints (glue and mechanical shim)	3	1	ALARP
C2.2 due to bad manufacturing (FMEA line 26)	3	2	NAK	M39 Qualified supplier for manufacturing M40 Special assembling tool + Sampling inspection of components	3	1	ALARP
C3 by touching the non-sterile robot components and then touching the sterile area (FMEA line 28), (MOF2)	3	4	NAK	M41 Using a sterile cover for the robot unit M42 Warning in the UM: never touch non-sterile components and the sterile area M43 Disinfection of the robot unit prior to its use	3	1	ALARP
C4 by touching the not sterile MFA and then touching the sterile area (MOF2)	3	4	NAK	M44 Using a sterile cover for the MFA M42 Warning in the UM M45 Disinfection of the MFA prior to its use	3	1	ALARP
C5 by touching the not sterile HCU and then touching the sterile area (MOF2)	3	4	NAK	M46 Disinfection of the HCU prior to its use M 42Warning in the UM M47 Using a sterile cover for the HCC	3	1	ALARP
C6 Damaging the sterile covers							
C6.1 by using the lever at the MFA	3	4	NA	M48 Test for opening of the MFA with attached	3	1	ALA

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

	Pre Mitigation				Post Mitigation		
Potential causes and sub causes	**Se**	**Pr**	**Risk**	**Mitigation Measures**	**Se**	**Pr**	**Risk**
			K	sterile cover M49 Warning in the UM: Do not continue procedure if cover is damaged M50 Use of robust material for the sterile cover			RP
C6.2 by sharp edges	3	4	NAK	M51 Avoid sharp edges in the design of outside surfaces M49 Warning in the UM: Do not continue procedure if cover is damaged M50 Use of robust material for the sterile cover	3	1	ALARP
C6.3 by opening the packaging of the sterile cover (MOF2)	3	4	NAK	M52 Design of packaging (easy opening) M49 Warning in the UM: Do not continue procedure if cover is damaged M50 Use of robust material for the sterile cover	3	1	ALARP
C6.4 by using the tape at the sterile cover (MOF2)	3	4	NAK	M53 Selection of compatible of tapes at the sterile cover M54 Test of tapes at the sterile cover M49 Warning in the UM: Do not continue procedure if cover is damaged M50 Use of robust material for the sterile cover	3	1	ALARP
C6.5 with the needle/instrument (FMEA line 27), (MOF2)	3	4	NAK	M55 Components inside the cover are disinfected M49 Warning in the UM: Do not continue procedure if cover is damaged M50 Use of robust material for the sterile cover	3	1	ALARP
C6.6 by tearing open the sterile cover due to movements of the robot unit	3	4	NAK	M56 Design of the cover (wide enough) M57 Test for moving the robot unit with sterile cover M49 Warning in the UM: Do not continue procedure	3	1	ALARP

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

	Pre Mitigation				Post Mitigation		
Potential causes and sub causes	**Se**	**Pr**	**Risk**	**Mitigation Measures**	**Se**	**Pr**	**Risk**
				if cover is damaged M50 Use of robust material for the sterile cover			
C6.7 while mounting the needle guide joints (MOF2)	3	4	NAK	M58 Appropriate packing of the cover M59 Test for mounting the needle guide joints M49 Warning in the UM: Do not continue procedure if cover is damaged M50 Use of robust material for the sterile cover	3	1	ALARP
C6.8 by movements of the patient	3	4	NAK	M50 Use of robust material for the sterile cover	3	1	ALARP
C7 Incorrect usage of the sterile cover and, thus, not separating the sterile area from the non-sterile area	3	4	NAK	M60 UM: Description of the right use and the workflow of the sterile cover	3	1	ALARP
C8 Use of inappropriate accessories (sterile, single-use parts)	3	4	NAK	M61 UM: Defining of allowed accessories M62 Warning in the UM: The use of any other accessory is restricted or forbidden.	3	1	ALARP
C9 Touching sterile area with non-sterile components (MOF2)			NAK				
C9.1 robot unit cabling	3	4	NAK	M2 Appropriate length and running of cables	3	1	ALARP
C9.1 HCU cabling	3	4	NAK	M2 Appropriate running of cables M63 Warning in the UM: Do not touch sterile cover with the HCU cabling.	3	1	ALARP
C9.1 patient touches sterile components	3	4	NAK	M64 Warning in the UM: The patient must not touch sterile cover.	3	1	ALARP
C10 Touching non-sterile components and then touching the sterile area (user and patient), (MOF2)	3	4	NAK	C10.1 to C10.10: M65 Workflow/UM (sterile / non-sterile area)	3	1	ALARP

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

	Pre Mitigation				Post Mitigation		
Potential causes and sub causes	**Se**	**Pr**	**Risk**	**Mitigation Measures**	**Se**	**Pr**	**Risk**
				M42 Warning in the UM			
C10.1 control unit							
C10.2 HCU including cabling							
C10.3 robot unit including cabling							
C10.4 cabling (power supply)							
C10.5 MFA							
C10.6 Table/Side Rail Adapter							
C10.7 Needle Guide Extensions							
C11 Putting sterile components in the non-sterile area	3	4	NAK	M65 Workflow/UM M42 Warning in the UM	3	1	ALARP
C12 Infecting the patient by fluids and additives flowing out of the device (MOF4)	3	2	NAK	M19 Definition of operating, storage and transport conditions M20 User Manual: if transported outside the specification, time for drying defined. M9 Test for overheating M66 Construction: Minimal use/disuse of fluids and additives M22 UM/Workflow: covering by sterile cover M23 UM/Workflow: drying after disinfection and cleaning	3	1	ALARP
C13 Infecting the patient during the set-up of the iSYS1 while the patient is on the treatment couch (MOF2)	3	2	NAK	M23 Workflow/UM M67 User Manual: Disinfection and cleaning of components prior to use	3	1	ALARP
C14 Fan blowing non sterile air to the sterile area	3	2	NAK	M68 Mounting of control unit thus no direct airflow to the patient occurs	3	1	ALARP

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

	Pre Mitigation				Post Mitigation		
Potential causes and sub causes	**Se**	**Pr**	**Risk**	**Mitigation Measures**	**Se**	**Pr**	**Risk**
				M21 Construction: openings on the bottom side M69 Small fan			
C15 Improper cleaning and disinfection of the device (MOF4)	2	1	AK	M70 Use of standardized disinfection and cleaning procedures M23 Description in the UM	1	1	AK
C16 Improper dismantling of the system (MOF2, 3)	3	2	NAK	M71 Description in the UM: setup and demounting	3	1	ALARP
C17 Mechanical injury of the user leading to infections	2	1	AK	M51 Construction: no sharp edges	1	1	AK
C18 Device is strongly contaminated during manufacturing and, thus, cannot be disinfected properly	2	1	AK	M72 Incoming inspection of supplied parts M73 Clean manufacturing rooms	1	1	AK

- Since the use of the iSYS1 requires installation by the operator, and since human errors cannot be excluded completely, some residual risks remain in case of human error. However, this reflects the current state of the art and further mitigation is not practicable.

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

H_P3 Harm due to Burning

	Pre Mitigation				Post Mitigation		
Potential causes and sub causes	**Se**	**Pr**	**Risk**	**Mitigation Measures**	**Se**	**Pr**	**Risk**
C1 by touching the hot surface of the:	2	2	AK	C1.1 to C1.4: M11 Fuses for high current M9 Test according to IEC 60601-1	1	1	AK
C1.1 Robot Unit							
C1.2 Control Unit							
C1.3 HCU							
C1.4 Cables							
C2 by burning of the device (flames)	2	2	AK	C2.1 to C2.5: M11 Fuses for high current	1	1	AK
C2.1 Robot Unit due to electrical overheating							
C2.2 Control Unit due to electrical overheating							
C2.3 Control Unit, when standing on the bottom surface and thus blocking the air convention				M74 Mounting the CU if there is no siderail available			
C2.4 HCU due to electrical overheating							
C2.5 Cables due to electrical overheating							
C3 by hot liquids running out of the robot unit	2	2	AK	M11 Fuses for high current M9 Test according to IEC 60601-1	1	1	AK
C4 by residuals of disinfection and cleaning agents inflamed by a spark	2	2	AK	M23 UM/Workflow: drying after disinfection and cleaning	1	1	AK

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

H_P4 Harm due to Mechanical injury

	Pre Mitigation				Post Mitigation		
Potential causes and sub causes	**Se**	**Pr**	**Risk**	**Mitigation Measures**	**Se**	**Pr**	**Risk**
C1 Falling of the device on the patient due to lose mechanical connection							
C1.1 Robot Unit	1	3	AK	M75 Lightweight design M76 UM/Workflow: correct setup and checks	1	2	AK
C1.2 MFA	1	3	AK	M75 Lightweight design M76 UM/Workflow: correct setup and checks	1	2	AK
C1.3 Control Unit if siderail is not used	1	3	AK	M77 Warning in the UM	1	1	AK
C2 Falling of the device (robot unit) on the patient due to pulling at the cable	1	3	AK	M2 Appropriate length of cables M78 Test for mechanical stability of MFA M79 Strain relief for cables M80 Warning in the UM	1	1	AK
C3 Falling of the device (robot unit + MFA) on the patient due to pushing of the device with the moving imaging device	2	4	NAK	M76 UM/Workflow: correct setup and checks M81 Warning in the UM: be aware the imaging device does not hit the iSYS 1	2	2	AK
C4 Unintended movement of the inserted needle due to:							
C4.1 unintended movement of the Robot Unit	3	4	NAK		3	1	ALARP
C4.1.1 by using the HCU while the needle is being inserted				M82 Enable switch M83 Warning in the UM: do not move the robot, when needle is inserted			
C4.1.2 by malfunction of control components/electronic components				M84 Stationary check M85 Encoder check			

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

	Pre Mitigation				Post Mitigation		
Potential causes and sub causes	**Se**	**Pr**	**Risk**	**Mitigation Measures**	**Se**	**Pr**	**Risk**
				M86 Emergency stop			
C4.1.3 by software error				M84 Stationary check M87 Error handling within software M88 Watchdog M86 Emergency stop			
C4.1.4 by breaking of mechanical components (FMEA line 19)				M9 Design according EN 60601-1 M78 Test of mechanical stability			
C4.1.5 by electromagnetic interference of other devices				M1 Test according EN 60601-1-2			
C4.1.6 environmental conditions (short circuit due to humidity)				M9 Test according EN 60601-1 M19 Definition of operating, storage and transport conditions M20 User Manual: if transported outside the specification, time for drying defined. M84 Stationary check M86 Emergency stop			
C4.1.6 by bad fixation at the table (FMEA line 43), (MOF3)				M76 UM/Workflow: Test of fixation during setup			
C4.1.7 due to unintended loosing of the fixation at the table (FMEA line 44), (MOF3)				M87 Design: self-locking lead screw M76 UM/Workflow: Test of fixation at the table			
C4.1.8 due to malfunction of electronic components due to X-Ray radiation of the imaging device				M88 Literature and datasheet analysis			
C4.1.9 due to bad fixation/loose mechanical fixation during setup (MOF3)				M76 UM/Workflow: Test of fixation at the table			
C4.2 unintended movement of the table	3	4	NA	M89 Mechanical Design: Robot + Adapter + Table is	3	1	ALA

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

	Pre Mitigation				Post Mitigation		
Potential causes and sub causes	**Se**	**Pr**	**Risk**	**Mitigation Measures**	**Se**	**Pr**	**Risk**
			K	one Unit M90 Warning User Manual: table must be fixed and not move			RP
C4.3 movement of the patient	3	4	NAK	M91 Warning in the UM (“Adequate compliance and immobilization of the patient is necessary and in the responsibility of the physician”)	3	1	ALARP
C4.4 movement of the mechanical setup cause of interference with the user (“Physician uses the setup as an arm rest”, misuse)	3	4	NAK	M78 Test of mechanical stability M92 Warning in the UM: do not misuse the iSYS 1 as an armrest or tablet	1	1	AK
C4.5 accidental pushing of the device	3	2	NAK	M78 Test of mechanical stability M93 Warning in the UM: do not accidental push the device, in case repeat imaging	1	1	AK
C4.6 falling of the control unit and thus pulling on the cables (FMEA lines 36-40)	3	2	NAK	M94 Secure locking mechanism of control unit M78 Test of mechanical stability M79 Strain relief for cables	3	1	ALARP
C4.7 loose or to tight mechanical connection (MOF3)	3	3	NAK	M76 UM/Workflow: correct setup and checks M94 Design of the needle insert (User can check the needle guidance over the whole needle length by testing the needle insert) M95 Warning in Manual: check the needle guidance over the whole needle length by testing the needle insert	3	1	ALARP
C4.7.1 due to inaccuracies in the diameter of the needle/instrument (FMEA line 5)				M96 Warning in the Manual: use correct diameter of needle guide insert			
C4.7.2 inaccurate production of the needle guide insert (FMEA line 3)				M72 incoming good inspections			
C4.7.3 usage of wrong needle guide insert				M97 inscription of diameter on the needle guide			

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

	Pre Mitigation				Post Mitigation		
Potential causes and sub causes	**Se**	**Pr**	**Risk**	**Mitigation Measures**	**Se**	**Pr**	**Risk**
(FMEA line 4)				insert M95 Warning in Manual: check the needle guidance over the whole needle length by testing the needle insert			
C4.8 wear of the components (neglect maintenance)	3	2	NAK	M98 Warning in the UM: obey maintenance and lifecycle times	3	1	ALARP
C4.9 falling of the HCU on the Joystick	3	3	NAK	M82 Enable switch M86 Emergency Stop	2	1	AK
C4.10 collision of the device with the imaging device (FMEA line 42)	3	3	NAK	M83 Warning in the UM: do not move the robot, when needle is inserted	2	1	AK
C4.11 breaking of the needle guide extensions	1	3	AK	M78 Test of mechanical stability	1	1	AK
C4.12 moving the needle with the insert when releasing it (FMEA line 15)	1	3	AK	M99 Warning in the UM: do not move the inserted needle when releasing the needle	1	2	AK
C4.13 Unintended opening of the MFA	3	2	NAK	M100 Warning in the UM: unintended opening of the MFA can lead to serious injuries.	3	1	ALARP
C5 Misuse of the device	3	3	NAK		3	1	ALARP
C5.1 use in MRI environment				M101 Warning in the UM: do not use in MRI environment M102 Labelling: not MRI-compatible			
C5.2 incorrect use of connectors				M103 Module detection M104 Labeling the connectors			
C5.3 mounting to loosened siderail				M76 UM/Workflow: correct setup and checks			
C5.4 touching the patients skin with the Robot							

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

	Pre Mitigation				Post Mitigation		
Potential causes and sub causes	**Se**	**Pr**	**Risk**	**Mitigation Measures**	**Se**	**Pr**	**Risk**
Unit							
C5.4.1 during setup				M75 Lightweight design M51 No sharp edges			
C5.4.2 while moving the Robot Unit				M105 Limited range of motion and forces M51 No sharp edges			
C5.5 neglect specified lifetime or maintenance				M98 Warning in the UM: obey maintenance and lifecycle times			
C5.6 applying a sterilization procedure				M106 Warning in the UM: do not sterilize the components of the iSYS 1			
C6 Sharp edges	2	3	ALARP	M75 Design: no sharp edges	2	1	AK
C7 Overhanging parts	1	3	AK	M75 Design: no sharp edges	1	2	AK
C8 Pinching of the patient while moving of the Robot Unit	1	3	AK	M105 Limited range of motion and forces	1	1	AK
C9 Covering the head with the sterile cover (MOF3)	1	2	AK		1	1	AK
C9.1 during setup				M107 Warning in the UM: do not cover the patient's face with the sterile cover			
C9.2 while moving the Robot Unit				M105 Limited range of motion of the robot unit			
C10 Strangulation with the cables (MOF3)	1	2	AK		1	1	AK
C10.1 standing on the cable				M108 Warning in the UM: do not stand on the cables M79 Streng relief			
C10.2 while moving the Robot Unit				M105 Limited range of motion and forces			
C11 Improper dismantling of the system (MOF3)	1	3	AK		1	1	AK

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

	Pre Mitigation				Post Mitigation		
Potential causes and sub causes	**Se**	**Pr**	**Risk**	**Mitigation Measures**	**Se**	**Pr**	**Risk**
C11.1 patient is standing up while Robot Unit is not completely dismantled				M76 UM/Workflow: correct setup and checks			
C11.2 Robot Unit or MFA is falling on the patient while dismantling				M75 Lightweight Design M76 UM/Workflow: correct setup and checks			
C12 Harming the patient with the moving Table Top Adapter	1	3	AK	M109 Design of the table adapters	1	1	AK
C13 Small plastic parts fall in the open wound of the patient	2	2	AK	M110 incoming goods inspection: needle insert free of burrs M111 Design of the needle insert	2	1	AK
C14 Due to collision of needles in case of multiple planning (pre-inserted needles)	2	4	NAK	M112 Warning in the UM: in case of multiple needle procedures, be aware the needles to not collide with another	2	2	AK
C15 Due to needle getting stuck in the quick release (FMEA line 34, 35)	2	2	AK	M113 Design: Possibility of either removing the needle or the needle guide insert M114 User Manual: check the free and easy movement of the needle in the insert	2	1	AK
C16 due to aging of components	3	2	NAK	M149 User Manual: define times for service and maintenance acc. to chapter 1	3	1	AK

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

H_P5 Harm due to Mistreatment

	Pre Mitigation				Post Mitigation		
Potential causes and sub causes	**Se**	**Pr**	**Risk**	**Mitigation Measures**	**Se**	**Pr**	**Risk**
Harming of healthy tissue due to wrong position of the needle leading to damaging healthy tissue or wrong diagnosis	3	3	NAK		3	1	ALARP
C1 Needle Guidance Insert gets loose							
C1.1 due to mechanical failure (breaking of components, FMEA line 19)				M115 Safety relevant components are tested and traced in the device history			
C2 Needle Guide Adapter gets loose due to mechanical failure							
C2.1 due to mechanical failure (breaking of components, FMEA line 19, 68, 69)				M115 Safety relevant components are tested traced in the device history			
C2.2 due to bad adoption by the user (FMEA 64-66) (MOF3)				M76 UM/Workflow: correct setup and checks			
C3 Needle Guide Extension gets loose due to mechanical failure (FMEA line 59-63)				M116 Design: use of multiple screws			
C4 Parts in the robot unit are instable (FMEA line 46 – 50)				M115 Safety relevant components are tested traced in the device history			
C5 Due to movements of the patient (FMEA line 33)				M91 Warning in the UM (“Adequate compliance and immobilization of the patient is necessary and in the responsibility of the physician”)			
C6 Due to movements of the target				M91 Warning in the UM (“Planning, targeting and intervention in the same breathing phase, it is in the responsibility of the physician”)			
C7 Due to wrong movements of the robot unit (FMEA line 51)							
C7.1 mixing the cables				M103 Module detection M104 Labeling the connectors			

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

	Pre Mitigation				Post Mitigation		
Potential causes and sub causes	**Se**	**Pr**	**Risk**	**Mitigation Measures**	**Se**	**Pr**	**Risk**
C7.2 due to mechanical failure (breaking of components) in the robot unit				M85 Encoder comparison			
C7.3 due to failure in the electronic or software (FMEA line 107)				M82 Enable switch M84 Stationary check M85 Encoder check M87 Error handling within software M88 Watchdog			
C7.4 due to bad fixation at the table (FMEA line 43), (MOF3)				M76 UM/Workflow: correct setup and checks			
C7.5 due to unintended loosing of the fixation at the table (FMEA line 44)				M117 Design: self-locking lead screw M76 UM/Workflow: correct setup and checks			
C7.6 due to unintended movements by the user (FMEA line 105)							
C7.7 due to damage of the Control Unit by shortening the Outputs to the Robot Unit				M118 Test of shortening the Outputs to the Robot Unit			
C7.8 due to unintended movement of one Robotic Module while moving (intended) the other Robotic Module				M119 Design: Both - position and angulation - can be seen with the imaging device when verifying the correct targeting.			
C8 Due to artifacts of the robot unit (FMEA line 16, 29, 32)				M120 Test for artefacts			
C9 Due to electromagnetic interference				M1 Test according EN 60601-1-2			
C10 Due to badly manufactured parts (FMEA lines 20-23)				M115 Safety relevant components are tested and traced in the device history M121 Assembling instructions			
C10.1 due to inaccuracies at the markers on the marker inlay (FMEA line 17, 18)							
C10.2 due to inaccuracies in the clearance of the							

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

	Pre Mitigation				Post Mitigation		
Potential causes and sub causes	**Se**	**Pr**	**Risk**	**Mitigation Measures**	**Se**	**Pr**	**Risk**
parts (FMEA line 3)							
C10.3 due to inaccuracies in the diameter of the needle/instrument (FMEA line 5)							
C10.4 other parts							
C11 Due to bad inserting of the marker inlay or the needle guide insert in the needle guide adapter (FMEA lines 10, 18, 109), (MOF2)				M76 UM/Workflow: correct setup and checks			
C12 Due to bad connecting of the needle guide joints to the needle guide extensions and needle guide adapter (FMEA line 24), (MOF2)				M76 UM/Workflow: correct setup and checks			
C13 Due to wrong inserting of the needle guide marker inlay in the needle guide adapter				M122 Usability Test M123 User Training M76 UM/Workflow: correct setup and checks			
C14 Due to wrong alignment of the imaging device (entry point view)				M122 Usability Test M123 User Training M76 UM/Workflow: correct setup and checks			
C15 Due to bad/inaccurate planning of the trajectory				M123 User Training M76 UM/Workflow: correct setup and checks			
C16 Due to bad fine positioning of the marker when using the imaging device				M122 Usability Test M123 User Training M76 UM/Workflow: correct setup and checks			
C16.1 due to instabilities of the complete setup (FMEA line 41)				M122 Usability Test M123 User Training M76 UM/Workflow: correct setup and checks			
C17 Due to movements of the robot unit after fine positioning with the marker or while inserting the							

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

	Pre Mitigation				Post Mitigation		
Potential causes and sub causes	**Se**	**Pr**	**Risk**	**Mitigation Measures**	**Se**	**Pr**	**Risk**
needle							
C17.1 due to intended moving the robot unit after fine positioning				M83 Warning in the UM: do not move the robot, when needle is inserted			
C17.2 due to unintended moving the robot unit after fine positioning (FMEA line 53) with the HCU				M82 Enable switch M83 Warning in the UM: do not move the robot, when needle is inserted			
C17.3 due to bad/loose mechanical connections (FMEA lines 20-25, 55-58), (MOF2, 3)				M78 Test of mechanical stability M122 Usability Test M76 UM/Workflow: correct setup and checks			
C17.4 due to bad electrical signals (FMEA lines 102-104)				M85 Encoder check M124 Use of line drivers M84 Stationary check			
C17.5 due to bad software signals				M84 Stationary check M87 Error handling within software M88 Watchdog			
C18 Due to a stick-slip-effect on components				M125 Selection of appropriate materials / Data Sheets M126 Test of stick-slip effect			
C19 Due to bad communication in the intervention team (e.g. moving the robot unit while inserting the needle)				M122 Usability Test M123 User Training M76 UM/Workflow: correct setup and checks			
C20 Due to partially covering areas of interest on the patient with the robot unit (e.g. catheter)				M127 Warning in the UM: setup must not cover area of interest			
C21 Due to wrong/bad use of the needle while inserting in the patient (MOF2)				M122 Usability Test M123 User Training			

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

	Pre Mitigation				Post Mitigation		
Potential causes and sub causes	**Se**	**Pr**	**Risk**	**Mitigation Measures**	**Se**	**Pr**	**Risk**
				M76 UM/Workflow: correct setup and checks			
C21.1 due to radial forces on the needle when penetrating the skin							
C21.2 due to collision with harder tissue/substances (artificial or natural) inside the patient							
C21.3 due to sticking of the needle in the insert (FMEA line 13)							
C21.4 touching the needle with the insert when releasing it (FMEA line 15)							
C22 Due to positioning the robot unit in a way, that the needle does not reach the point of interest (MOF1)				M122 Usability Test M123 User Training M76 UM/Workflow: correct setup and checks			
C22.1 due to positioning the robot to far from the patient's skin							
C22.2 due to misinterpretation of the inserting depth of the needle							
C23 Due to covering the signal LEDs on the control unit and thus not realizing the alarm (MOF5)				M128 Acoustic alarm M129 Activation of emergency stop state in case of a serious error M130 Warning in the UM: do not cover the display or the front panel of the control unit			
C24 Due to misinterpretation of the signal LEDs on the control unit and thus not realizing the alarm (MOF5)				M131 Colors according EN 60601-1-8 M128 Acoustic alarm M129 Activation of emergency stop state in case of a serious error			
C25 Unintended movement after fine positioning and							

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

	Pre Mitigation				Post Mitigation		
Potential causes and sub causes	**Se**	**Pr**	**Risk**	**Mitigation Measures**	**Se**	**Pr**	**Risk**
before inserting the needle							
C25.1 unintended movement of the Robot Unit							
C25.1.1 by using the HCU (FMEA line 101), (MOF1)				M82 Enable switch M132 Warning in the UM: do not move the robot after positioning			
C25.1.2 by malfunction of control components/electronic components				M133 All safety relevant systems are redundant systems			
C25.1.3 by software error				M84 Stationary check M87 Error handling within software M88 Watchdog			
C25.1.4 by breaking of mechanical components (FMEA line 19)				M78 Test of mechanical stability			
C25.1.5 by electromagnetic interference of other devices (FMEA line 103)				M1 the device is designed to comply with the relevant standards (IEC 60601-1-2)			
C25.1.6 environmental conditions (short circuit due to humidity)				M1 the device is designed to comply with the relevant standards (IEC 60601-1-2)			
C25.1.7 due to malfunction of electronic components due to X-Ray radiation of the imaging device				M85 safety circuit “encoder comparison” M84 safety circuit “stationary check” M134 software positioning check M8 Literature			
C25.2 unintended movement of the table				M89 Mechanical Design: Robot + Adapter + Table is one Unit M90 Warning User Manual: table must be fixed and not move			
C25.3 movement of the patient (e.g. breathing)				M91 Warning in the UM (“Adequate compliance and immobilization of the patient is necessary and			

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

	Pre Mitigation				Post Mitigation		
Potential causes and sub causes	**Se**	**Pr**	**Risk**	**Mitigation Measures**	**Se**	**Pr**	**Risk**
				in the responsibility of the physician”)			
C25.4 using the device as an arm rest				M78 Test of mechanical stability M92 Warning in the UM: do not misuse the iSYS 1 as an armrest or tablet			
C25.5 accidental pushing of the device				M78 Test of mechanical stability M93 Warning in the UM: do not accidental push the device, in case repeat imaging			
C25.6 falling of the control unit and thus pulling on the cables				M94 Secure locking mechanism of control unit M78 Test of mechanical stability M79 Strain relief for cables			
C25.7 loose mechanical connection (FMEA lines 20-25, 30, 31), (MOF3)				M76 UM/Workflow: correct setup and checks M94 Design of the needle insert (User can check the needle guidance over the whole needle length by testing the needle insert) M95 Warning in Manual: check the needle guidance over the whole needle length by testing the needle insert			
C25.8 wear of the components (neglect maintenance)				M98 Warning in the UM: obey maintenance and lifecycle times			
C25.9 falling of the HCU on the Joystick (MOF1)				M82 Enable switch M86 Emergency Stop			
C25.10 collision of the device with the imaging device (FMEA line 42)				M81 Do not move the imaging device while the needle is inserted			
C25.11 breaking of the needle guide extensions (FMEA line 19)				M78 Test of mechanical stability			
C26 Using a needle/instrument not appropriate to the				M97 inscription of diameter on the needle guide			

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

	Pre Mitigation				Post Mitigation		
Potential causes and sub causes	**Se**	**Pr**	**Risk**	**Mitigation Measures**	**Se**	**Pr**	**Risk**
needle guide insert (FMEA line 4)				insert M96 Warning in the Manual: use correct diameter of needle guide insert			
Harm due to additional imaging procedures (additional radiation)	2	3	ALARP	M122 Usability Test M123 User Training M76 UM/Workflow: correct setup and checks	2	2	AK
C27 Fine positioning or imaging takes too long/longer or must be repeated							
C27.1 due to untrained personnel							
C27.2 due to wrong speed level (FMEA line 72-74)							
C27.3 due to wrong mode of movement							
C27.4 due to misinterpretation of the direction of movement (MOF5)							
C27.5 due to wrong pre-positioning of the robot unit and thus not reaching the point of interest (MOF3)							
C27.6 due to technical failure (FMEA lines 75, 99, 100)							
C27.7 due to emergency stop or reboot of the iSYS1 (FMEA lines 83-91)							
C27.7.1 due to misinterpretation of an alarm (MOF5)							
C27.7.2 due to unintended switching off (FMEA lines 76-78)							
C27.7.3 due to unintended plugging off (FMEA lines 95, 108)							
C27.8 due to not reaching the region of interest							

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

	Pre Mitigation				Post Mitigation		
Potential causes and sub causes	**Se**	**Pr**	**Risk**	**Mitigation Measures**	**Se**	**Pr**	**Risk**
with the robot (gross positioning)							
C27.9 due to patient movement and thus restarting the procedure							
C27.10 due to overcomplicated workflow or wrong workflow (e.g. sterilization during planning)							
C27.11 due to missing of the right accessories (e.g. wrong needle guide insert)							
C27.12 due to short power cord/cable and additional setup							
C27.13 due to failures in the display (FMEA lines 79-82), (MOF5)							
C28 due to aging of components	3	2	NAK	M149 User Manual: define times for service and maintenance acc. to chapter 1	3	1	AK

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Hazards to the operator

H_O1 Harm due to Electrical Shock

	Pre Mitigation				Post Mitigation		
Potential causes and sub causes	**Se**	**Pr**	**Risk**	**Mitigation Measures**	**Se**	**Pr**	**Risk**
C1 Due to cabling							
C1.1 due to EMC problems (FMEA line 70)	2	4	NAK	M1 Test according to IEC 60601-1-2 M2 construction: defined length of cables	2	1	AK
C1.2 due to missing grounding (FMEA line 71)	3	2	NAK	M3 periodically inspection in the clinic (user / service manual) M4 safe connection to housing M5 contact surfaces on each component	3	1	ALARP
C1.3 due to damages caused by mechanical or chemical influences (power supply)	3	2	NAK	M6 Reinforced and/or double insulation and/or class I housing (see technical drawings for details) M7 Warning in UM	3	1	ALARP
C1.4 due to damages caused by mechanical or chemical influences (data cable, HCU cable)	1	3	AK	M6 Reinforced and/or double insulation and/or class I housing (see technical drawings for details) M7 Warning in UM	1	1	AK
C1.5 due to damages by X-Ray radiation of the imaging device (power supply)	3	1	AK	M8 Literature / Data Sheets	3	1	ALARP
C1.6 due to damages by X-Ray radiation of the imaging device (data cable, HCU cable)	1	1	AK	M8 Literature / Data Sheets	1	1	AK
C2 Due to wrong power supply of components (FMEA lines 91-94, 96-98)	3	4	NAK	M9 Test according to IEC 60601-1 M10 Usage of wide range power supply unit M11 Fuses for high current M12 Alarm due to voltage watchdog	2	1	NAK

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

	Pre Mitigation				Post Mitigation		
Potential causes and sub causes	**Se**	**Pr**	**Risk**	**Mitigation Measures**	**Se**	**Pr**	**Risk**
				M13 LED “ready-to-use” ceases			
C3 Failure in the power supply unit	3	4	NAK	M11 Fuses for high current M6 class 1 housing for the control unit M14 Overvoltage protection in the power supply (schematics should be provided to TÜV by Traco)	2	1	NAK
C4 Housing of control unit not sufficiently grounded and voltage on touchable parts (230V)	3	4	NAK	M15 Grounding pins on every part M5 contact surfaces on each component	3	1	ALARP
C5 Power supply cable of the control unit gets damaged and touches the secondary circuit							
C5.1 on the 24V cabling	3	1	NAK	M16 usage of varistor and Schottky Zener diode (30V)	2	1	AK
C5.2 on the Power Led cable	3	2	NAK	M17 direct connection of the Power LED to the output of the Power Supply M16 usage of varistor and Schottky Zener diode (30V)	2	1	AK
C5.3 on the PEC	3	2	NAK	M18 Construction with dividing plate M2 defined length of cabling preventing M6 class 1 housing for the control unit M11 Fuses for high current	3	1	ALARP
C6 Due to condensed water in the devices	3	2	NAK	M19 Definition of operating, storage and transport conditions M6 Class1 housing of control unit M9 air clearance and creepage distance acc. to IEC 60601-1 M20 User Manual: if transported outside the	2	1	ALARP

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

	Pre Mitigation				Post Mitigation		
Potential causes and sub causes	**Se**	**Pr**	**Risk**	**Mitigation Measures**	**Se**	**Pr**	**Risk**
				specification, time for drying defined.			
C7 Due to spilling on the device	3	3	NAK	M9 Test acc. to IEC 60601-1 M6 Class1 housing of control unit M21 Construction: openings on the bottom side M22 UM/Workflow: covering by sterile cover	2	1	AK
C8 Due to rests of disinfection liquids (MOF4)	3	4	NAK	M23 UM/Workflow: drying after disinfection and cleaning M6 Class1 housing of control unit M9 Test acc. to IEC 60601-1 M21 Construction: openings on the bottom side	2	1	AK
C9 Due to fluids getting into the housing							
C9.1 of the control unit	3	4	NAK	M9 Test acc. to IEC 60601-1 M6 Class1 housing of control unit M21 Construction: openings on the bottom side	2	1	AK
C9.2 of the robot unit	1	3	AK	M9 Test acc. to IEC 60601-1 M24 Low voltage power supply (6,5V) M22 UM/Workflow: covering by sterile cover	1	1	AK
C9.3 of the HCU	1	3	AK	M9 Test acc. to IEC 60601-1 M25 Low voltage power supply (24V)	1	1	AK
C10 Due to overheating of components and, thus, malfunction of components	1	2	AK	M9 Test for overheating (IEC 60601-1)	2	1	AK
C11 Due to overvoltage in the mains supply	3	2	NAK	M1 Test according to IEC 60601-1-2 M14 Overvoltage protection in the power supply (schematics should be provided to TÜV by Traco)	1	1	AK

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

	Pre Mitigation				Post Mitigation		
Potential causes and sub causes	**Se**	**Pr**	**Risk**	**Mitigation Measures**	**Se**	**Pr**	**Risk**
C12 loose cabling in the Robot Unit	1	3	AK	M26 insulated housing	1	1	AK
C13 breaking of the housing	3	1	ALARP	M9 Test according to IEC 60601-1	1	1	AK
C14 loose connector of Cable (MOF3)							
C14.1 between Control Unit and Robot Unit	1	3	NAK	M27 construction of plugs, pins not reachable M28 Warning in the UM: check connections between components M29 Workflow/UM: first all components connected to each other, then main power supply	1	1	AK
C14.2 between Control Unit and HCU	1	3	NAK	M27 construction of plugs, pins not reachable M28 Warning in the UM: check connections between components M29 Workflow/UM: first all components connected to each other, then main power supply	1	1	AK
C14.3 Mains cable	3	2	NAK	M27 construction of plugs, pins not reachable M28 Warning in the UM: check connections between components M29 Workflow/UM: first all components connected to each other, then main power supply	3	1	AK
C16 touching the circuits in the Robot Unit, due to loose/broken covering band	1	2	NAK	M9 distance to circuits acc. IEC 60601-1 M31 User Manual: never touch inside components	1	1	AK
C17 touching a metallic part inside the Robot Unit, due to loose/broken covering band and single fault condition in the insulation of the circuits of the Robot Unit	1	2	NAK	M31 User Manual: never touch inside components M32 construction: covering (warning color) the front side of the robot unit	1	1	AK
C18 use of wrong power supply cable				M135 Warning in User Manual: only use provided components, never use accessories that are			

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

	Pre Mitigation				Post Mitigation		
Potential causes and sub causes	**Se**	**Pr**	**Risk**	**Mitigation Measures**	**Se**	**Pr**	**Risk**
				not cleared by iSYS			
C20 use of damaged components				M136 User Manual: Warning, never operate damaged components			
C21 due to wrong re-assembling after service	1	2	NAK	M33 Service Manual: provide checklist after service (Technical Safety Check)	1	1	AK
C22 due to aging of components	3	2	NAK	M149 User Manual: define times for service and maintenance acc. to chapter 1	3	1	AK

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

H_O2 Harm due to Infection

Statement: **There is no increased risk due to infection by the use of iSYS 1 for the operator compared with not using this system.**	**Pre Mitigation**				**Post Mitigation**		
Potential causes and sub causes	**Se**	**Pr**	**Risk**	**Mitigation Measures**	**Se**	**Pr**	**Risk**
C1 by re-use of single use, sterile parts (FMEA line 6)			n.a.				
C2 Use of inappropriate accessories (sterile, single-use parts)			n.a.				
C3 Improper cleaning and disinfection of the device			n.a.				
C4 Improper dismantling of the system			n.a.				
C5 Mechanical injury of the user leading to infections			n.a.				
C6 Device is strongly contaminated during manufacturing and, thus, cannot be disinfected properly			n.a.				

- Since the use of the iSYS1 requires installation by the operator, and since human errors cannot be excluded completely, some residual risks remain in case of human error. However, this reflects the current state of the art and further mitigation is not practicable.

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

H_O3 Harm due to Burning

	Pre Mitigation				Post Mitigation		
Potential causes and sub causes	**Se**	**Pr**	**Risk**	**Mitigation Measures**	**Se**	**Pr**	**Risk**
C1 by touching the hot surface of the:	2	2	AK	C1.1 to C1.4: M11 Fuses for high current M9 Test according to IEC 60601-1	1	1	AK
C1.1 Robot Unit							
C1.2 Control Unit							
C1.3 HCU							
C1.4 Cables							
C2 by burning of the device (flames)	2	2	AK	C2.1 to C2.5: M11 Fuses for high current	1	1	AK
C2.1 Robot Unit due to electrical overheating							
C2.2 Control Unit due to electrical overheating							
C2.3 Control Unit, when standing on the bottom surface and thus blocking the air convention				M74 Mounting the CU if there is no siderail available			
C2.4 HCU due to electrical overheating							
C2.5 Cables due to electrical overheating							
C3 by hot liquids running out of the robot unit	2	2	AK	M11 Fuses for high current M9 Test according to IEC 60601-1	1	1	AK
C4 by residuals of disinfection and cleaning agents inflamed by a spark	2	2	AK	M23 UM/Workflow: drying after disinfection and cleaning	1	1	AK

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

H_O4 Harm due to Mechanical Injury

	Pre Mitigation				Post Mitigation		
Potential causes and sub causes	**Se**	**Pr**	**Risk**	**Mitigation Measures**	**Se**	**Pr**	**Risk**
C1 falling of the control unit (MOF3)							
C1.1 due to bad fixing at the siderail (FMEA line 36)	2	3	ALARP	M94 Secure locking mechanism of control unit M78 Test of mechanical stability M79 Strain relief for cables	2	2	AK
C1.2 due to unintended loosing (FMEA line 37)	2	3	ALARP	M94 Secure locking mechanism of control unit M78 Test of mechanical stability M79 Strain relief for cables	2	2	AK
C1.3 due to instable siderail (FMEA line 39, 40)	2	2	AK	M140 User Manual: siderail must be safe and rigid	2	2	AK
C1.4 due to persons tripping over power cable/ HCC cable	2	3	ALARP	M78 Test of mechanical stability	2	2	AK
C2 Falling of the robot unit on the user due to pulling at the cable	1	3	AK	M78 Test of mechanical stability M79 Strain relief for cables	1	1	AK
C3 Falling of the device on the user due to pushing of the device with the moving imaging device	2	3	ALARP	M81 Warning in the UM: be aware the imaging device does not hit the iSYS 1	2	2	AK
C4 Misuse of the device							
C4.1 neglect specified lifetime or maintenance	1	2	AK	M98 Warning in the UM: obey maintenance and lifecycle times	1	1	AK
C4.2 applying a sterilization procedure	1	2	AK	M106 Warning in the UM: do not sterilize the components of the iSYS 1	1	1	AK
C5 Sharp edges	2	3	ALARP	M75 Design: no sharp edges	2	1	AK
C6 Overhanging parts	1	3	AK	M75 Design: no sharp edges	1	2	AK
C7 Improper dismantling of the system, components	1	3	AK	M122 Usability Test	1	2	AK

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

	Pre Mitigation				Post Mitigation		
Potential causes and sub causes	**Se**	**Pr**	**Risk**	**Mitigation Measures**	**Se**	**Pr**	**Risk**
are falling on the user (MOF3)				M123 User Training M76 UM/Workflow: correct setup and checks			
C8 Harming the operator with the moving Table Top Adapter	1	3	AK	M122 Usability Test M123 User Training M76 UM/Workflow: correct setup and checks	1	2	AK
C9 Harm to user due to getting exposed to radiation	2	3	ALARP	M122 Usability Test M123 User Training M76 UM/Workflow: correct setup and checks	2	1	AK
C10 due to aging of components	3	2	NAK	M149 User Manual: define times for service and maintenance acc. to chapter 1	3	1	AK

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

H_O5 Harm due to Ergonomics

	Pre Mitigation				Post Mitigation		
Potential causes and sub causes	**Se**	**Pr**	**Risk**	**Mitigation Measures**	**Se**	**Pr**	**Risk**
C1 falling of the control unit (MOF3)	2	2	AK		2	1	AK
C1.1 due to bad fixing at the siderail (FMEA line 36)				M94 Secure locking mechanism of control unit M78 Test of mechanical stability M79 Strain relief for cables			
C1.2 due to unintended loosing (FMEA line 37)				M94 Secure locking mechanism of control unit M78 Test of mechanical stability M79 Strain relief for cables			
C1.3 due to instable siderail (FMEA line 39, 40)				M140 User Manual: siderail must be safe and rigid			
C2 due to weight of the complete system including packaging (transport case)	2	2	AK	M141 Warning in the UM (“Do not lift alone”) M142 Label of weight on packaging	2	1	AK

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Hazards to other persons, e.g. service technician

H_O1 Harm due to Electrical Shock

Additional risks for other persons

	Pre Mitigation				Post Mitigation		
Potential causes and sub causes	**Se**	**Pr**	**Risk**	**Mitigation Measures**	**Se**	**Pr**	**Risk**
C1 due to opening the housings when still connected to the main supply	3	3	NAK	M137 Warning in Service Manual: first step, disconnect from main supply M138 Labeling: label on the components: disconnect from main supply before opening	3	1	ALARP
C2 due to service measures that are done while the components are connected to the main supply	3	3	NAK	M139 Service Manual: measures are only to be performed by an electrically qualified person	3	1	ALARP

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Generic hazards

H_X1 Interference with other medical devices

	Pre Mitigation				Post Mitigation		
Potential causes and sub causes	**Se**	**Pr**	**Risk**	**Mitigation Measures**	**Se**	**Pr**	**Risk**
C1 Unpredictable malfunction of the device due to electromagnetic irradiation or disturbances on power line	3	3	NAK	M1 the device is designed to comply with the relevant standards (IEC 60601-1-2)	2	1	ALARP
C2 due to aging of components	3	2	NAK	M149 User Manual: define times for service and maintenance acc. to chapter 1	3	1	AK

H_X2 Malfunction of other devices

	Pre Mitigation				Post Mitigation		
Potential causes and sub causes	**Se**	**Pr**	**Risk**	**Mitigation Measures**	**Se**	**Pr**	**Risk**
C1 markings on the needle get rubbed off when guided through the needle insert	1	1	AK	n.a.	1	1	AK
C2 Blocking the movement of the patient table	1	3	AK	M143 User Manual: be aware that the setup does not block intended movements of the table	1	2	AK
C3 Collision of the system with the imaging device	1	3	AK	M91	1	2	AK
C4 Blunting of the needle tip while inserting into the NG Insert	1	3	AK	M144 Design: use appropriate material that does not cause wear on the needle	1	1	AK

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

H_X3 Environmental hazards

	Pre Mitigation				Post Mitigation		
Potential causes and sub causes	**Se**	**Pr**	**Risk**	**Mitigation Measures**	**Se**	**Pr**	**Risk**
C1 Toxic materials used in construction could be hazardous waste when disposed	*	*	*	M145 Avoidance of highly toxic materials M146 User Manual: do not litter in domestic waste M147 User Manual: apply to local and national regulations according to disposal of electronic waste M148 Labeling: use label for “do not litter in domestic waste”	*	*	*

* For environmental hazards the quantification in terms of hazard severity and probability is not practicable.

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

9 Summary of Mitigations

The Summary of Mitigations summarizes all mitigations of the risk analysis and evaluation including the dates when they have been added. This summary is forwarded to “FO_73_2553_PD-B06_RiskContr” where the mitigations are traced to hazards and causes mapped or applicable product specification/requirements.

Mitigation Measure in RA	Added (Date)
M1 Test according to IEC 60601-1-2	2011-05-12
M2 construction: defined length of cables	2011-05-12
M3 periodically inspection in the clinic (user / service manual)	2011-05-12
M4 safe connection to housing	2011-05-12
M5 contact surfaces on each component	2011-05-12
M6 Reinforced and/or double insulation and/or class I housing	2011-05-12
M7 Warning in UM	2011-05-12
M8 Literature / Data Sheets	2011-05-12
M9 Test according to IEC 60601-1	2011-05-12
M10 Usage of wide range power supply unit	2011-05-12
M11 Fuses for high current	2011-05-12
M12 Alarm due to voltage watchdog	2011-05-12
M13 LED “ready-to-use” ceases	2011-05-12
M14 Overvoltage protection in the power supply	2011-05-12
M15 Grounding pins on every part	2011-05-12
M16 usage of varistor and Schottky Zener diode (30V)	2011-05-12
M17 direct connection of the Power LED to the output of the Power Supply	2011-05-12
M18 Construction with dividing plate	2011-05-12
M19 Definition of operating, storage and transport conditions	2011-05-12
M20 User Manual: if transported outside the specification, time for drying defined.	2011-05-12
M21 Construction: openings on the bottom side	2011-05-12
M22 UM/Workflow: covering by sterile cover	2011-05-12
M23 UM/Workflow: drying after disinfection and cleaning	2011-05-12
M24 Low voltage power supply (6,5V)	2011-05-12
M25 Low voltage power supply (24V)	2011-05-12

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

M26 insulated housing	2011-05-12
M27 construction of plugs, pins not reachable	2011-05-12
M28 Warning in the UM: check connections between components	2011-05-12
M29 Workflow/UM: first all components connected to each other, then main power supply	2011-05-12
M30 insulation of the patient connection	2011-05-12
M31 User Manual: never touch inside components	2011-05-12
M32 construction: covering (warning color) the front side of the robot unit	2011-05-12
M33 Service Manual: provide checklist after service (Technical Safety Check)	2011-05-12
M34 Combining the sterile cover with the Needle Guide Adapter	2011-05-12
M35 Labelling: single use, sterile	2011-05-12
M36 Warning in the UM: single use, sterile, misuse	2011-05-12
M37 Chemical and mechanical Tests (websinger)	2011-05-12
M38 Redundant fixation of the sterile cover to the joints (glue and mechanical shim)	2011-05-12
M39 Qualified supplier for manufacturing	2011-05-12
M40 Special assembling tool + Sampling inspection of components	2011-05-12
M41 Using a sterile cover for the robot unit	2011-05-12
M42 Warning in the UM: never touch non-sterile components and the sterile area	2011-05-12
M43 Disinfection of the robot unit prior to its use	2011-05-12
M44 Using a sterile cover for the MFA	2011-05-12
M45 Disinfection of the MFA prior to its use	2011-05-12
M46 Disinfection of the HCU prior to its use	2011-05-12
M47 Using a sterile cover for the HCC	2011-05-12
M48 Test for opening of the MFA with attached sterile cover	2011-05-12
M49 Warning in the UM: Do not continue procedure if cover is damaged	2011-05-12
M50 Use of robust material for the sterile cover	2011-05-12
M51 Avoid sharp edges in the design of outside surfaces	2011-05-12
M52 Design of packaging (easy opening)	2011-05-12

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

M53 Selection of compatible of tapes at the sterile cover	2011-05-12
M54 Test of tapes at the sterile cover	2011-05-12
M55 Components inside the cover are disinfected	2011-05-12
M56 Design of the cover (wide enough)	2011-05-12
M57 Test for moving the robot unit with sterile cover	2011-05-12
M58 Appropriate packing of the cover	2011-05-12
M59 Test for mounting the needle guide joints	2011-05-12
M60 UM: Description of the right use and the workflow of the sterile cover	2011-05-12
M61 UM: Defining of allowed accessories	2011-05-12
M62 Warning in the UM: The use of any other accessory is restricted or forbidden	2011-05-12
M63 Warning in the UM: Do not touch sterile cover with the HCU cabling.	2011-05-12
M64 Warning in the UM: The patient must not touch sterile cover	2011-05-12
M65 Workflow/UM (sterile / non-sterile area)	2011-05-12
M66 Construction: Minimal use/disuse of fluids and additives	2011-05-12
M67 User Manual: Disinfection and cleaning of components prior to use	2011-05-12
M68 Mounting of control unit thus no direct airflow to the patient occurs	2011-05-12
M69 Small fan	2011-05-12
M70 Use of standardized disinfection and cleaning procedures	2011-05-12
M71 Description in the UM: setup and demounting	2011-05-12
M72 Incoming inspection of supplied parts	2011-05-12
M73 Clean manufacturing rooms	2011-05-12
M74 Mounting the CU if there is no siderail available	2011-05-12
M75 Lightweight design	2011-05-12
M76 UM/Workflow: correct setup and checks	2011-05-12
M76 UM/Workflow: Test of fixation during setup	
M76 UM/Workflow: Test of fixation at the table	
M77 Warning in the UM	2011-05-12
M78 Test for mechanical stability of MFA	2011-05-12
M79 Strain relief for cables	2011-05-12

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

M80 Warning in the UM	2011-05-12
M81 Warning in the UM: be aware the imaging device does not hit the iSYS 1	2011-05-12
M82 Enable switch	2011-05-12
M83 Warning in the UM: do not move the robot, when needle is inserted	2011-05-12
M84 Stationary check	2011-05-12
M85 Encoder check	2011-05-12
M86 Emergency stop	2011-05-12
M87 Error handling within software	2011-05-12
M88 Watchdog	2011-05-12
M89 Mechanical Design: Robot + Adapter + Table is one Unit	2011-05-12
M90 Warning User Manual: table must be fixed and not move	2011-05-12
M91 Warning in the UM (“Adequate compliance and immobilization of the patient is necessary and in the responsibility of the physician”)	2011-05-12
M92 Warning in the UM: do not misuse the iSYS 1 as an armrest or tablet	2011-05-12
M93 Warning in the UM: do not accidental push the device, in case repeat imaging	2011-05-12
M94 Secure locking mechanism of control unit	2011-05-12
M95 Warning in Manual: check the needle guidance over the whole needle length by testing the needle insert	2011-05-12
M96 Warning in the Manual: use correct diameter of needle guide insert	2011-05-12
M97 inscription of diameter on the needle guide insert	2011-05-12
M98 Warning in the UM: obey maintenance and lifecycle times	2011-05-12
M99 Warning in the UM: do not move the inserted needle when releasing the needle	2011-05-12
M100 Warning in the UM: unintended opening of the MFA can lead to serious injuries.	2011-05-12
M101 Warning in the UM: do not use in MRI environment	2011-05-12
M102 Labelling: not MRI-compatible	2011-05-12
M103 Module detection	2011-05-12
M104 Labeling the connectors	2011-05-12
M105 Limited range of motion and forces	2011-05-12

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

M106 Warning in the UM: do not sterilize the components of the iSYS 1	2011-05-12
M107 Warning in the UM: do not cover the patient's face with the sterile cover	2011-05-12
M108 Warning in the UM: do not stand on the cables	2011-05-12
M109 Design of the table adapters	2011-05-12
M110 incoming goods inspection: needle insert free of burrs	2011-05-12
M111 Design of the needle insert	2011-05-12
M112 Warning in the UM: in case of multiple needle procedures, be aware the needles to not collide with another	2011-05-12
M113 Design: Possibility of either removing the needle or the needle guide insert	2011-05-12
M114 User Manual: check the free and easy movement of the needle in the insert	2011-05-12
M115 Safety relevant components are tested and traced in the device history	2011-05-12
M116 Design: use of multiple screws	2011-05-12
M117 Design: self-locking lead screw	2011-05-12
M118 Test of shortening the Outputs to the Robot Unit	2011-05-12
M119 Design: Both - position and angulation - can be seen with the imaging device when verifying the correct targeting	2011-05-12
M120 Test for artefacts	2011-05-12
M121 Assembling instructions	2011-05-12
M122 Usability Test	2011-05-12
M123 User Training	2011-05-12
M124 Use of line drivers	2011-05-12
M125 Selection of appropriate materials / Data Sheets	2011-05-12
M126 Test of stick-slip effect	2011-05-12
M127 Warning in the UM: setup must not cover area of interest	2011-05-12
M128 Acoustic alarm	2011-05-12
M129 Activation of emergency stop state in case of a serious error	2011-05-12
M130 Warning in the UM: do not cover the display or the front panel of the control unit	2011-05-12
M131 Colors according EN 60601-1-8	2011-05-12
M132 Warning in the UM: do not move the robot after positioning	2011-05-12

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

M133 All safety relevant systems are redundant systems	2011-05-12
M134 software positioning check	2011-05-12
M135 Warning in User Manual: only use provided components, never use accessories that are not cleared by iSYS	2011-05-12
M136 User Manual: Warning, never operate damaged components	2011-05-12
M137 Warning in Service Manual: first step, disconnect from main supply	2011-05-12
M138 Labeling: label on the components: disconnect from main supply before opening	2011-05-12
M139 Service Manual: measures are only to be performed by an electrically qualified person	2011-05-12
M140 User Manual: siderail must be safe and rigid	2011-05-12
M141 Warning in the UM (“Do not lift alone”)	2011-05-12
M142 Label of weight on packaging	2011-05-12
M143 User Manual: be aware that the setup does not block intended movements of the table	2011-05-12
M144 Design: use appropriate material that does not cause wear on the needle	2011-05-12
M145 Avoidance of highly toxic materials	2011-05-12
M146 User Manual: do not litter in domestic waste	2011-05-12
M147 User Manual: apply to local and national regulations according to disposal of electronic waste	2011-05-12
M148 Labeling: use label for “do not litter in domestic waste”	2011-05-12
M149 User Manual: define times for service and maintenance acc. to chapter 1	2012-08-21

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

10 Overview Risk Management Plan

The following paragraph illustrates, where the several parts of the risk management plan as they are required by the standard ISO 14971:2009, can be found:

Lifecycle of the product	see chapter 1.1
Responsibilities	see chapter 3
Controls	see VA_73_2191 and VA_73_2538
Criteria for acceptance	see chapters 4.4, 4.5 and 5.
Verification	see chapter 8 and FO_73_2553
Post marketing	see VA_73_2544

END of DOCUMENT

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Executive Summary

Device Description:

The iSYS 1 is a modular needle guidance platform for interventional radiology and related fields. The core components are a 4 DOF micro positioning unit and the control unit. The micropositioning unit provides submillimetric needle positioning from simple needle angulations up to positioning and angulations with an adjustable pivot point. The control unit is directed by a cable connected to the control panel. The passive macro positioning unit and different table adapters allow different setups of the system around the patient in the region of interest. The needle-guide-kits provide disposable components that ensure precise and sterile needle guidance.
The iSYS 1 System is indicated for any medical condition in which the use of a stable and precise needle/tool guidance system may be appropriate, and where external navigation technology and/or imaging technology (e.g. CB-CT, CT, X-Ray) can be used for exact planning and tracking of the needle/tool.

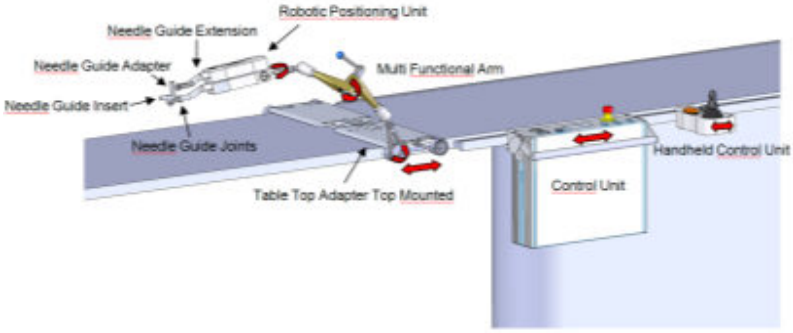


Fig. 1 iSYS 1

Intended Use:

The intended use of the iSYS1 device is to function as a remote-operated positioning and guidance system during interventional procedures. Positioning is done in remote control manner; planning of the position/angulation is done based on 2D/3D patient data (CT, cone-beam CT, fluoroscopy) by external planning software – for example using an external navigation system, or planning software coming with the used imaging device. Also verification of the correct position and orientation of the tool prior to/during/after the intervention is done by means of these external devices. The iSYS1-System is then acting as a guideway during the manual insertion of the interventional tool – usually a needle type device, and the like. Applications include, but are not limited to, interventions like biopsy procedures, tumor ablation, nerve blocking, electrode placement, etc.

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Device Comparison Table:

Reference	Frameless Neuromate	ROSA Surgical Device	iSYS 1 (for new submission)
510k-Number	K091081	K101791	-
Manufacturer	INTEGRATED SURGICAL SYSTEMS, INC. 1850 Research Park Dr. Davis, CA 95616 USA	Medtech Surgical Inc. 211 Warren Street Suite 306 Newark, NJ 07103 USA	Submitter
Design			
General device description	Computer controlled electromechanical multi-joined arm indicated for use as a stereotactic instrument	Computer controlled electromechanical multi-joined arm indicated for use as a stereotactic instrument	Computer controlled electromechanical multi-joined arm indicated for invasive procedures
Localization means	Robot arm absolute encoders	Robot arm absolute encoders	Fiducial markers on tool holder.
Image-guided	Yes	Yes	Yes
Planning software	No (third party)	Yes	No (third party)
Registration method	Bone-mounted ultrasound device	Fiducial markers Optical registration device	Fiducial markers
Instrumentation	Laser pointer Tool Holder	Navigation probe Laser pointer Tool Holder	Marker Tool Holder Sterile Covers (third party)
Instrument fixation	Instruments are mounted onto robot arm	Instruments are mounted onto robot arm	Special tool holders for several applications mounted to the Robot
Instrument calibration	Factory Calibration	Factory Calibration	Intra operative
System immobilization between patient and device	Yes	Yes	Yes
Planning and Navigation Software			
N/A.			
System Operation			
Fiducial markers registration with pointer probe	No.	Yes.	No.
Optical registration	No.	Yes.	No.
Registration with US	Yes.	No.	No.

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Reference	Frameless Neuromate	ROSA Surgical Device	iSYS 1 (for new submission)
Accuracy verification	Yes, laser pointer.	Yes, navigation probe, laser beam.	Yes, performed by user
Provide mechanical guidance for tools	Yes.	Yes.	Yes.
Instrument guide position adjustment	Automatic.	Automatic.	Manual.
Surgeon carries out final gesture through tool guide	Yes.	Yes.	Yes.
Indications for Use			
Indication for use	Stereotactic spatial positioning and orientation of an instrument holder or tool guide to be used by a surgeon to manually guide standard neurosurgical instruments (biopsy needle, stimulation or recording electrode, endoscope).	Intended to be used in the operating room for the spatial positioning and orientation of an instrument holder or tool guide, The system is intended to be used by neurosurgeons to guide standard neurosurgical instruments (biopsy needle, stimulation or recording electrode, endoscope). Indicated for any neurosurgical condition in which the use of stereotactic surgery may be appropriate.	The intended use of the iSYS1 device is to function as a remote-operated positioning and guidance system during interventional procedures. Positioning is done in remote control manner; planning of the position/angulation is done based on 2D/3D patient data (CT, cone-beam CT, fluoroscopy) by external planning software – for example using an external navigation system, or planning software coming with the used imaging device. Also verification of the correct position and orientation of the tool prior to/during/after the intervention is done by means of these external devices. The iSYS1-System is then acting as a guideway during the manual insertion of the interventional tool – usually a needle type device,

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Reference	Frameless Neuromate	ROSA Surgical Device	iSYS 1 (for new submission)
			and the like. Applications include, but are not limited to, interventions like biopsy procedures, tumor ablation, nerve blocking, electrode placement, etc.
Anatomical site	Head	Head	Total body
User	Neurosurgeon	Neurosurgeon	Surgeon
Accessory	Sterile drapes	Sterile drapes Fiducial markers Head Holder Light source	Sterile Covers Table Adapters Cable Sets
Real-time instrument position	Yes	Yes	Yes
Mechanical Guidance of instruments	Yes	Yes	Yes
Technology			
Powered	Yes	Yes	Yes
CE-Conformity	Yes	Yes	Yes
Computer-controlled	Yes	Yes	Yes

Performance Testing:

Standard	Topic	Performed at	Remarks
OENORM EN 60601-1	Electrical Safety	Notified Body	at present acc. to 2nd Edition, Tests for IEC 60601-1 3rd Edition and UL-listing are pending
OENORM EN 60601-1-2	Electromagnetic comp.	seibersdorf laboratory	acc. to FCC
OENORM EN 60601-1-6	Usability	internal validation at reference sites	Results lead to present version
OENORM EN 60601-1-8	Alarm Systems	internal	included in pending tests for 3rd Edition

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Device Description

Device Description:

Micro-invasive surgical procedures are gaining increasing importance in medicine due to the high efficiency level (clinical outcome) and low socio-economic costs. Highest quality assurance of medical instrument positioning and mechanical precision is the “sine qua non” for the ever increasing sophistication of interventional radiology and related fields with its concurrent reduction or abolition of safety margins.

The iSYS 1 System by iSYS Medizintechnik GmbH provides a state-of-the-art solution, which is able to fulfill the three main requirements – accurate positioning, easy integration into clinical workflow as well as a simple and fast setup procedure. The iSYS-1 Interventional Platform has clear advantages over alternative methods of instrument placement:

- the treatment results are markedly improved while the costs of treatment are reduced
- the radiation exposure for both the patient and the surgical team is being reduced
- long-term damage to the surgical team carrying out the treatment will be avoided
- Through the use of the iSYS-1 system, it is no longer necessary to work with the "hand in the beam” and / or in the vicinity of the imaging device.

The iSYS 1 is a modular needle guidance platform for interventional radiology and related fields. The core components are a 4 DOF micro positioning unit and the control unit. The micro positioning unit provides submillimetric needle positioning from simple needle angulations up to positioning and angulations with an adjustable pivot point. The control unit is directed by a cable connected to the control panel. The passive macro positioning unit and different table adapters allow different setups of the system around the patient in the region of interest by still providing maximum rigidity. Planning of the intervention is based on digital image data acquired intra-operatively using different kinds of modalities, like CT or fluoroscopy (standard C-arms and/or cone-beam CT systems). Planning of the entry position of the needle-type tool as well as angulation and validation of the correctness of the tool position must be performed with an external planning and measurement system, which is not part of the iSYS-1 Interventional Platform. The position of iSYS 1 is visible for most imaging systems due to the used markers. During treatment the tool is controlled by the user and the iSYS1 is without any other function than providing rigid tool guidance.

The iSYS 1 System is indicated for any medical condition in which the use of a stable and precise needle/tool guidance system may be appropriate, and where external navigation technology and/or imaging technology (e.g. CB-CT, CT, X-Ray) can be used for exact planning and tracking of the needle/tool.

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

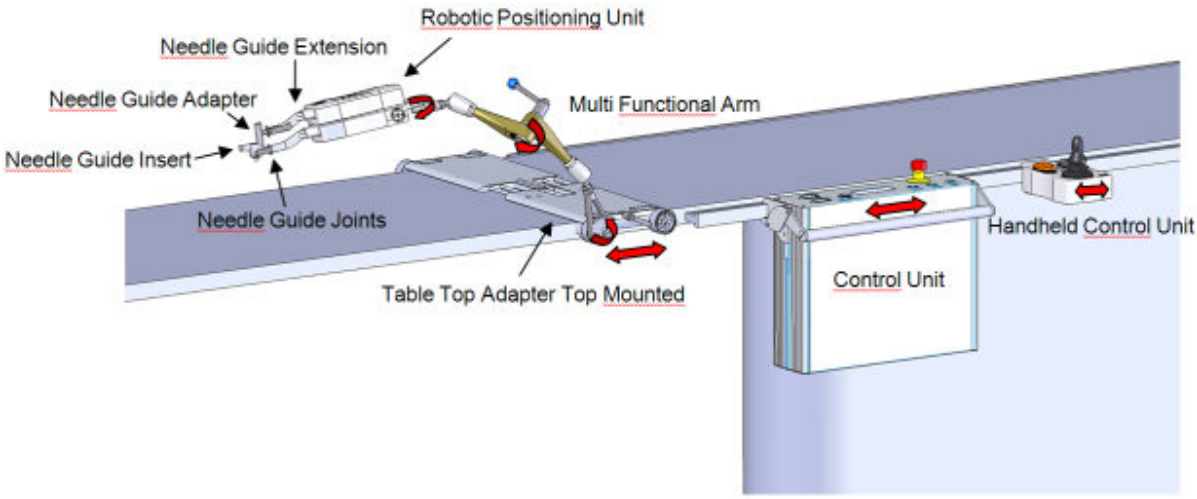


Figure 2: General iSYS system setup (no sterile covers)

Performance Data:

The interface and mounting of the adapters, the Control Unit and the Handheld Control Unit (HCU) is adjustable along the entire length of the side rail as needed by the user. Additionally the Multi Functional Arm (MFA) can be rotated in a half circle of 450 mm, with the center of rotation being the interface MFA to Side-Rail-Adapter. All starburst or spoon interfaces can be set up in the angle needed, between 0° and at least 180°. The maximum straight length is 300 mm for Side Rail Adapter with Extension Rod, 450 mm for MFA, 170 mm for Robotic Positioning Unit plus 20mm adjustability, 120 mm for Needle Guide Extension and Holder, leading to an overall length of 940 mm. When using any of the Table Top Adapters, the 300 mm extension rod is not available; therefore the maximum reachable straight length lies at 640 mm. The Robotic Positioning Unit is a robotic unit consisting of two 2 DOF modules which allows tool angulation (± 30° for both pitch and yaw angle) and needle positioning (± 20 mm for both lateral and longitudinal direction). Each RPU measures 170 x 120 x 70 mm and weighs max. 1.5 kg. Additional weight is strongly dependent on the setup used. The MFA weights 1.3 kg with 450 x 140 x 60 mm. The Control Unit measures 700 x 350 x 105 mm and, being the heaviest component, weighs 6 kg. All components can be set up separately.

The drapes are manufactured by (b)(4) [redacted] and sterilized by (b)(4) [redacted].

The Needle Guide Adapter is manufactured by iSYS and packaged and sterilized by Bioseal. Following sterilization the components have an SAL 10^{-6} and a Lifetime/Shelf-life of 3 years.

Sterilization Method (b)(4) [redacted]

Validation Method: ASTM F 1980

The accuracy depends on the resolution and capabilities of the imaging device or software. The mechanical accuracy is precise to be within 1mm, but that gives no accuracy value for treatments.

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Environmental Conditions:

Operating temperature/humidity range: 15° to 30°C; 30 to 70% relative humidity with no condensation

Storage temperature/humidity range: 10° to 50°C; 30 to 70% relative humidity with no condensation.

Power Supply: 50W; 115VAC/230VAC; 50-60Hz; cable: C14 according to IEC/EN 60320-1, US498, CSA C22.2 no. 42.

Clinical Use:

For attachment of the Robotic Positioning Unit to the imaging table, iSYS is offering three solutions (a, b and c).

Depending on the type of imaging table and the (carbon fiber) table top, one or more of the below described adapter solutions (a, b and c) can be used.

Note:	*Every table adapter offers different features and setup possibilities, depending on the region of interest and the type of intervention.*

CAUTION
Make sure that the treatment couch and/or the table top fulfills the interface requirements for the adapters!
- **Side rail payload: min. 20 kg**
- **Side rail size: 10 mm x 25 mm (W x H)**

In case you are not sure which adapter you can use (or the user manual of the treatment couch and/or the table top manufacturer does not give you the required information), please ask the service technician of the table/couch top manufacturer or contact iSYS for professional advice!

CAUTION
Be aware that the setup does not block intended movements of the table.

WARNING
All table adapters contain metal parts/material and thereof cause imaging artifacts if they are in the field of view of the X-ray beam. Make sure the adapters are outside the field of view of the imaging device!

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

WARNING
For all types of adapters, the following setup rules are essential:

- **Always make sure that the levers are locked properly and that the adapter provides a solid, clearance-free connection to the table!**
  This is essential for the accuracy of the final tool placement – any undesired movement of the mechanical setup is a potential risk for mistreatment or may cause injuriy to the patient!

- **Always perform a manual stability-test (by pushing or pulling the adapter in different directions):**
  The adapter must maintain the position, must not slip and the setup must not wobble!

- **Make sure that the treatment couch and the adapter are permanently fixed to each other. In case you want to move the table with the patient on it, the adapter has to follow this movement!**
  This is essential for the accuracy of the tool placement. Failures in the mechanical setup are a potential risk for mistreatment and may cause injury to the patient!

- **Be aware that other devices mounted nearby the Table Adapter or the influence of persons may decrease the mechanical stability.**

- **Be aware, that by opening the locking-levers too far, the adapter may not be safely locked and the adapter/setup may drop and this can cause damage to the system or harm the patient!**

WARNING
Make sure that the table is properly fixed before attaching the components of the iSYS 1 system.

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

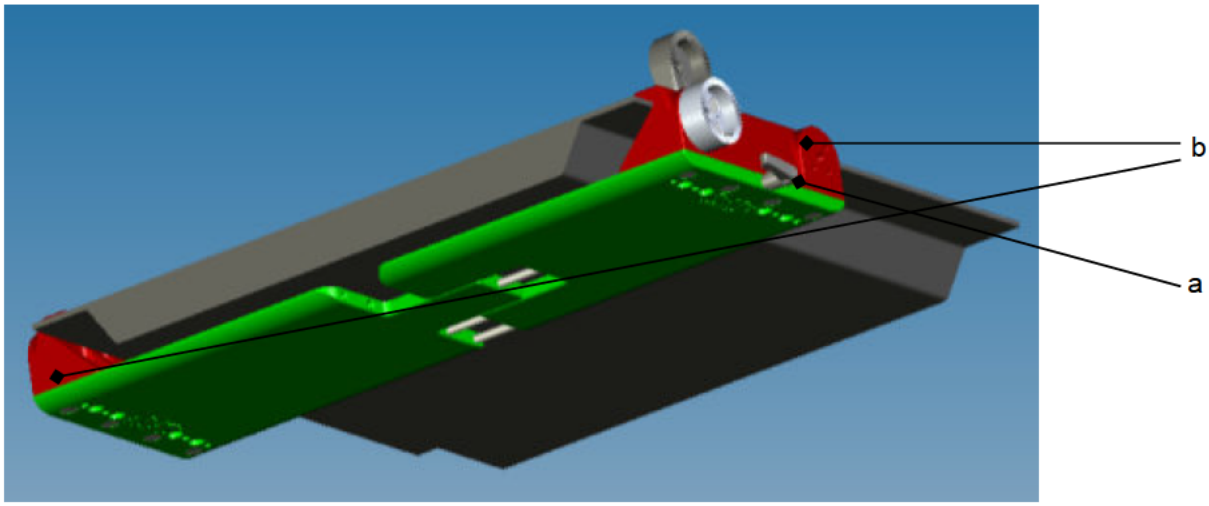
Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

WARNING
If the Side Rail Adapter is being used, please make sure that the side rail is firmly connected to the treatment table before attaching any of the iSYS 1 components.

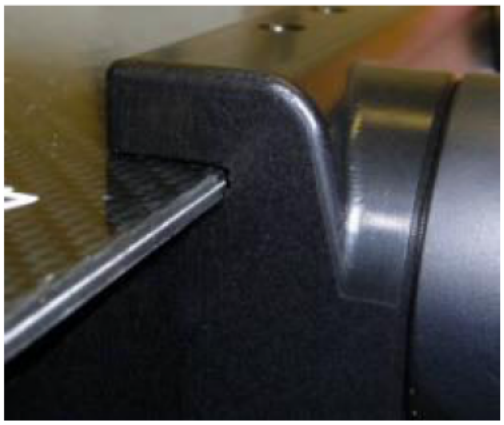
Mounting of the Table Top Adapter (Version B - Bottom Mounted)

Open the lever (a) of the Table Top Adapter to allow the clamping jaws (b) to grab the edges of the couch top of the treatment table as shown in the picture below.

By turning the lever clockwise, the clamping jaws (b) of the Table Top Adapter clutch the lateral edges of the table top and thus the adapter is fixed to the table.



The following picture shows the connection between the clamping jaw and the lateral edge of the (carbon) table top.



Once the adapter is locked to the table, it functions as a rigid adapter for the MFA.

If the adapter is not tightened, it can glide and be easily moved in different positions.

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

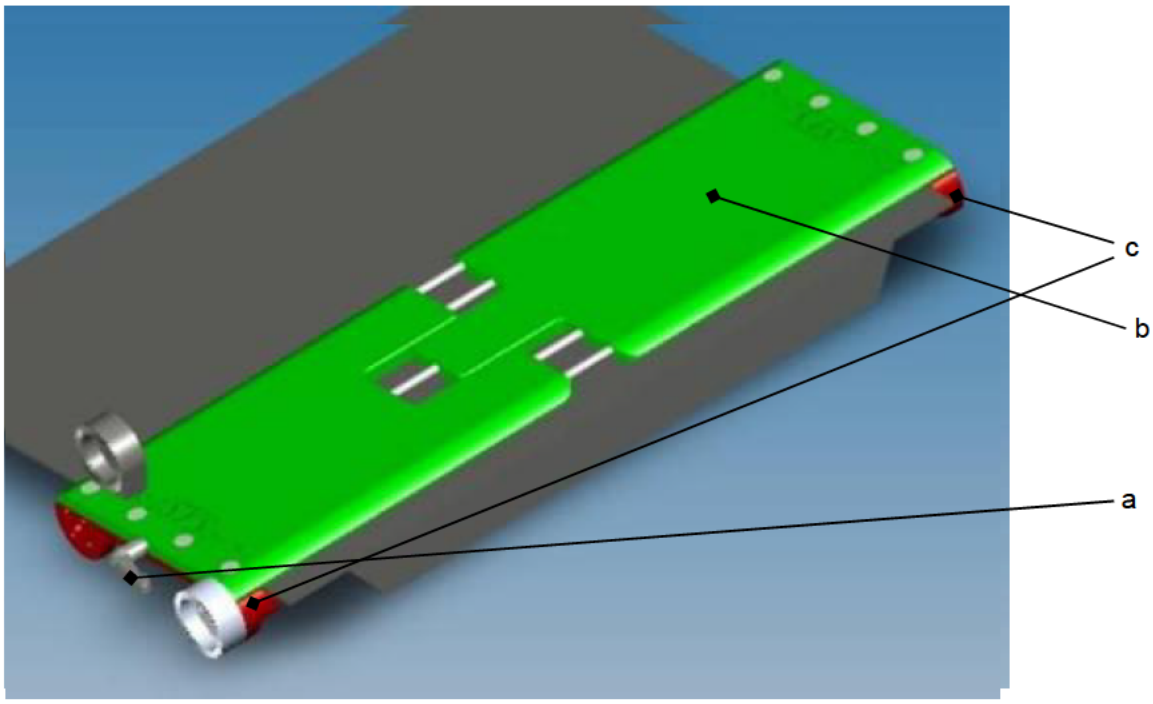
Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

WARNING
Never open the adapter so far that the adapter can fall.

Mounting of the Table Top Adapter (Version A - Top Mounted)

Open the lever (a) of the Table Top Adapter so that the adapter plate (b) can be placed on top of the couch top of the treatment table.

By turning the lever (a) clockwise, the clamping jaws (c) of the Table Top Adapter grab the lateral edges of the table top and the adapter is securely attached to the table.



Once the adapter is locked to the table, it functions as a rigid adapter for the MFA.

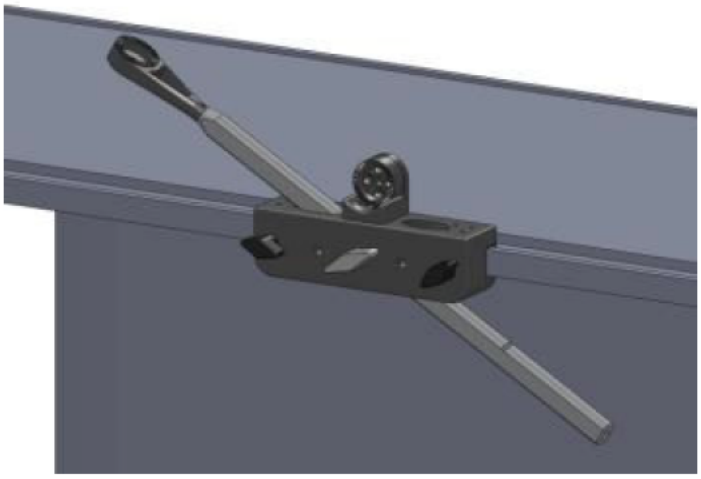
If the adapter is not tightened, it can glide and be easily moved in different positions.

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Mounting the Side Rail Adapter to the Side Rail of the Imaging Table

Attach the Side Rail Adapter to the side rail of the treatment table as shown below:



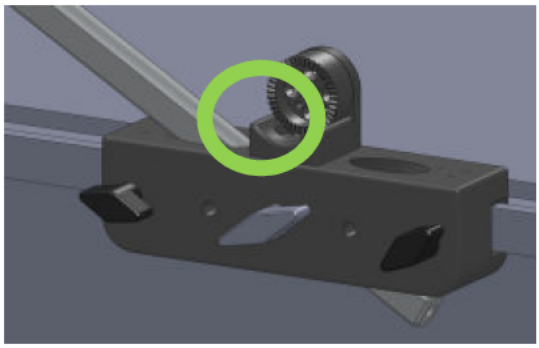
By turning the black levers clockwise, the adapter is rigidly attached to the side rail.

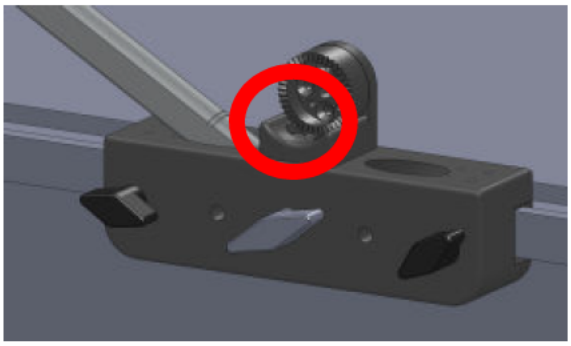
The height of the extension rod can be adjusted by opening and locking the middle lever.

WARNING
Make sure that the markings on the extension rod are not visible!

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016





Mounting of the Multi Functional Arm (MFA)

Attach the MFA to one of the Starburst-adapters available on the Table Top Adapter or Side Rail Adapter.

Starburst -adapter

Turn the lever of the Starburst-adapter till the arm is tightly locked to the table adapter.

WARNING
Whenever the MFA is mounted or the position of the MFA is being changed (opened and locked) the stability has to be verified with a simple test:
push/pull the Spoon of the MFA or the Robotic Unit gently and check if the MFA and the attached components remain in their position.
Always be aware that the stability of the setup depends on the tightening force of the MFA lever.

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Mounting the Robotic Positioning Unit

Attach the Spoon-adapter at the Robot Positioning Unit to the MFA as shown below:

Spoon-adapter

Turn the lever of the Spoon-adapter untill the Robot Positioning Unit is tightly locked to the MFA.

WARNING
Always make sure that the levers are securely locked and that the mechanical interfaces guarantee a solid, clearance-free connection to each other! This is essential, because without mechanical stability the high degree of accuracy of the Robotic Positioning Unit cannot be assured!
With a simple manual stability test (by pushing or pulling the RPU carfully in different directions) the rigidity of the mechanical setup can be tested:
The RPU must maintain its position, must not slip and it must not wobble!

WARNING
Whenever the mechanical setup is changed, make sure that the components of iSYS 1 do not cause collisions with the gantry, with the treatment table or with any other part of the imaging device!

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Mounting the Control Unit to the Side Rail

CAUTION
If iSYS 1 or components are attached to the side rail of a table, ensure that the side rail is capable of carrying the weight. Refer to section 3 for technical data.
Verify that the side rail connection to the table is tight and does not wobble.

WARNING
Do not cover the front panel of the Control Unit or the display.
Make sure that any safety-relevant information can be recognized.

Move the CU to the side rail of the table with the handle in the straight up position. Hang the unit on the side rail and close the locking mechanism by turning down the handle.

WARNING
Make sure the Control Unit is safely locked to the side rail of the treatment couch.

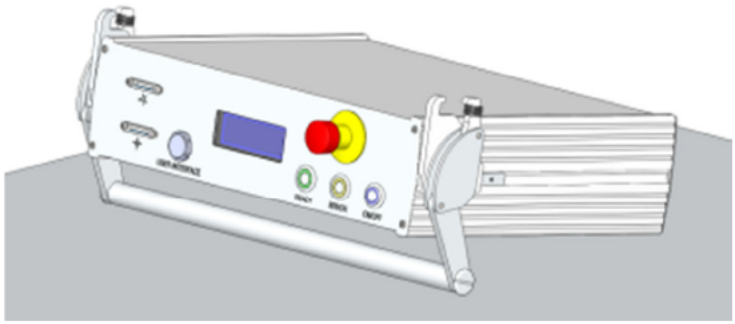
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

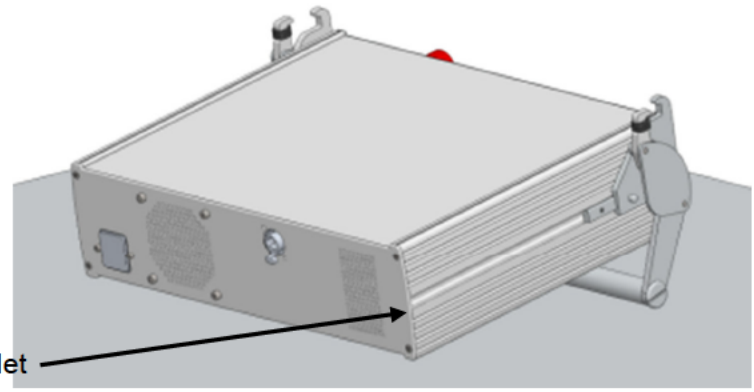
Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Using the Control Unit without Side Rail

When there is no side rail, place the Control Unit on a stable and flat surface that is capable of carrying its weight.

Use the handle as a support as shown in the picture below.





WARNING
Place the Control Unit so that no direct airflow to the patient or sterile areas occur. Otherwise the fan may blow non sterile air to the sterile area.

WARNING
Pay special attention to the placement of the Control Unit and the cable routing. Due to carelessness the components may fall causing harm to the patient or user.

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Adaptation of the Handheld Control Unit to the Side Rail

⚠	**CAUTION** **If iSYS 1 or components are attached to the side rail of a table, ensure that the side rail is capable of carrying the weight. Refer to section 3 for technical data.** **Verify that the side rail connection to the table is tight and does not wobble.**

Press and hold the upper orange button and attach the HCU to the side rail of the treatment couch as shown below.

After release of the upper orange button, the HCU is locked to the side rail.

Now the mechanical setup is finished.

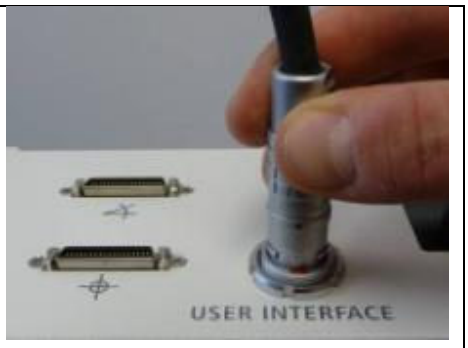
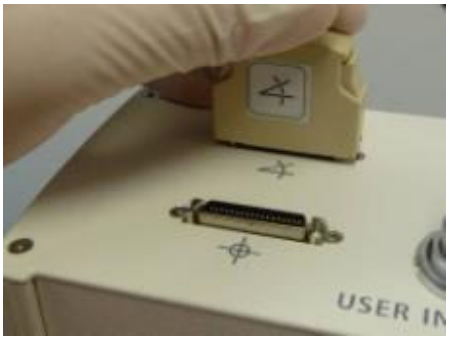
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Connection of the Power and Data Cables

Overview:

Connect the power and data cables like shown in the following table:

Connection between HCU and CU	Connect the circular connector to the socket marked with “USER INTERFACE”. The correct position of the connector is marked with a red dot on both sides of the connector and socket	
Connection of between RPU and CU	Connect the two flat connectors to the sockets on the CU marked with ⌖ and ⌖. The connectors are marked with the same symbols. Please check for the correct orientation of the connectors before inserting. There should be two “clicks” indicating that the connector is firmly affixed.	

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

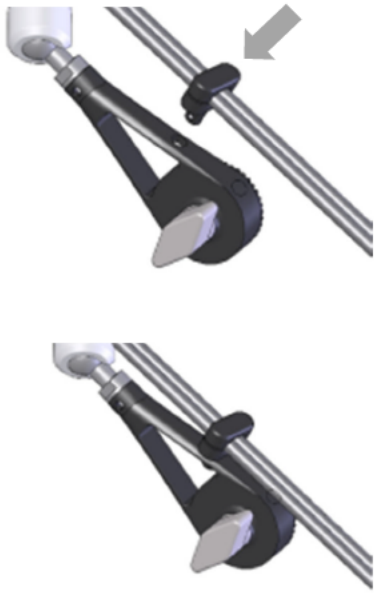
	Connect the two flat connectors to the sockets on the RPU. The connector marked with ⌖ is for the lower robot module (positioning module), whereas the connector marked with ⌖ is for the upper robot module (angulation module). Please check for the correct orientation of the connectors before inserting. For each connector, two clicks shall indicate that the connectors are firmly attached.	

In case of a wrong connection between CU and RPU an error message will be displayed at the CU ("`Check HW(5V,Mod)`", cf. "Error Messages", chapter …

For the cabling between CU and RPU please attach the strain-relief connector to the recess at the MFA accordingly in order to avoid straining the RPU (see picture below).

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016



WARNING
Make sure that the cables do not cross the routes of the patient or the medical staff.
If this is not possible (e.g. no electrical socket nearby), for the safety of the staff and the patient make sure that the cables are taped to the floor.

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

WARNING
In order to avoid RPU movement, attach the strain-relief connector to the recess at the MFA. If the strain relief is not connected properly this may cause damage to the RPU or may harm the patient.

WARNING
Do not pull at the cables, especially when setting up the patient! This may cause the components to fall, interfere with the mechanical setup and potentially harm the patient or user.

Bringing the RPU into the "Parking position"

After the mechanical system setup, the RPU has to be parked in a safe parking position.

Reasons for the parking position:

- The parking position allows the easy attachment of the sterile cover.
- The parking position makes room for setting up the patient.
- The parking position allows access to the region of interest for preparing the surgical intervention (disinfection of the skin, sterile covering of the patient etc.)

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

WARNING
The MFA joints progressively lock, allowing for precise positioning and preventing sudden movements when opened.
Always be aware that opening the MFA too fast can lead to uncontrolled movements of the arm itself or attached components (i.e. the Robotic Positioning Unit).
Always open the MFA slowly and carefully with one hand and hold the MFA or the attached device (Robotic Positioning Unit) carfully with the other hand!

WARNING
Do not misuse iSYS 1 as an armrest or tablet. This can lead to mechanical failures and serious injuries.

Start-up Procedure of the iSYS 1 Robot

1

Follow the Setup – Procedure (mounting of devices and establishing of cable connections) according to chapter …

2

Switch-on the system using the POWER switch.

Remark: Ensure that the joystick of the HCU is in its center position.

During boot-up the following message is shown.

```
iSYS1 - Needle
Guidance Platform
--------------------
System Bootup...
```


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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

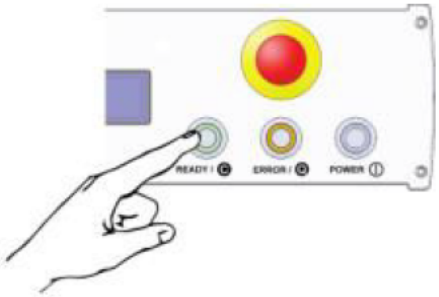
3

The system is now ready to perform the self-test.

```
### iSYS1 C-ARM  ###
* Running SELFTEST *
Rev1:C1.1/M1.6/W1.5
Press C to start  ->
```

4

Press the **C** (Confirm) button to start the self-test.
CAUTION: All axes of the robot will move approximately 1mm during self-test.



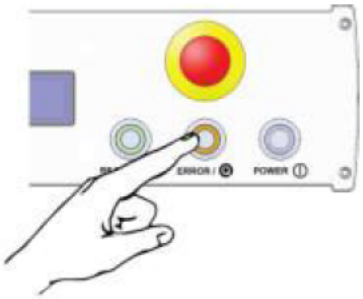
5

After the first step of the self-test you are asked to start the next step.

```
### iSYS1 C-ARM  ###
* Running SELFTEST *
Execute Step 2 of 5
Press Quit-Error  ->
```

6

Press the **Q** (Quit) button to start the next step of the self-test.



Repeat **step 6** until all steps are performed.

7

You will get the following message if the self-test was successfully executed.

```
### iSYS1 C-ARM  ###
Selftest PASSED
```

See instructions at **step 7A + 7B** if the self-test fails.

8

Once the self-test is passed you will get the operation screen.

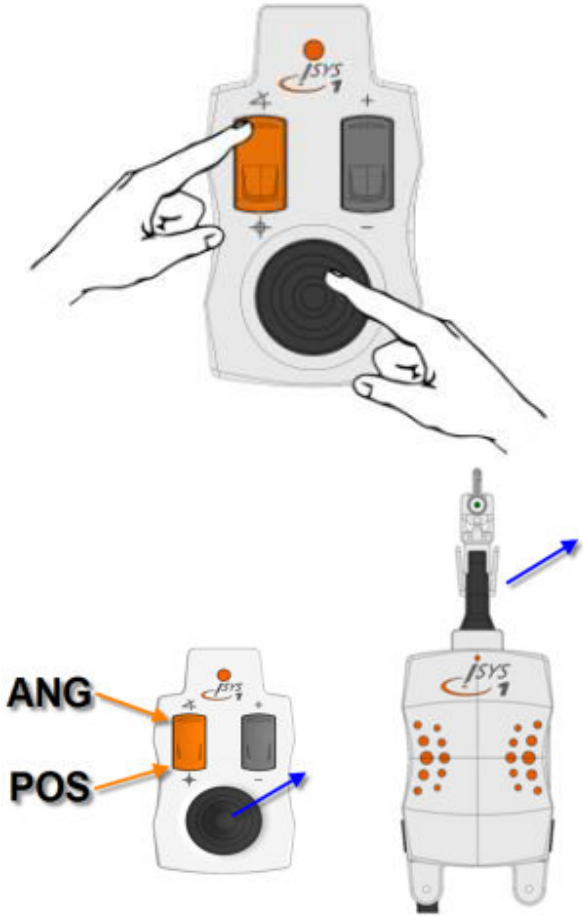
```
### iSYS1 C-ARM  ###

Speedlevel: fast
Joystick Mode  [   ]
```


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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

9

The system is now ready for operation. Use the Handheld Control Unit (HCU) to activate the desired mode (ANG or POS). During activation you can use the joystick to move the robot. The elongation of the joystick is proportional to the motion speed.
You can change the maximum speed using the +/- rocker-switch on the HCU.



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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

7A

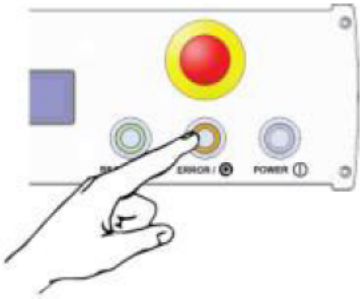
If the self-test fails you will get the following message.

```
### iSYS1 C-ARM  ###
* Running SELFTEST *
Selftest FAILED
Press Q to reset  ->
```

Remark: There are some possible reasons where the self-test fails, even though no critical failure is present (e.g. a module is very close to its motion limit).

7B

Press the **Q** (Quit) button to restart the self-test and continue the procedure at step **3**.



If the self-test still fails after another trial, please contact the manufacturer.

Use of iSYS 1

The surgical procedure can be divided into several steps. The following workflow, for example, shows the use of the iSYS 1 system for a typical needle procedure under C-arm fluoroscopy.

Position the patient on the treatment table. Before covering the patient and the robot with a sterile cover, make sure that the region of interest is in the field of view of the imaging machine and within the mechanical range of the iSYS 1. Therefore the MFA has to be opened and the RPU roughly positioned manually in the region of interest. During opening of the MFA and checking the range the RPU has to be supported by the physician. The following pictures show different possibilities of potential positions. Please consider the movement of the gantry during imaging to avoid collisions of the iSYS 1 with the gantry.

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

In case the robot cannot reach the region of interest, re-position the patient or re-setup the mechanical parts of the system (e.g. mounting the MFA on a different Starburst-adapter or moving the TTA) so that all (potential) entry-points and target points can be reached.

WARNING
The MFA joints progressively lock, allowing for precise positioning preventing sudden movements when opening.
Always be aware that opening the MFA too fast can lead to uncontrolled movements of the arm itself or attached components (i.e. the Robotic Positioning Unit).
Always open the MFA slowly and carefully with one hand and hold the MFA or the attached device (Robotic Positioning Unit) carfully with the other hand!

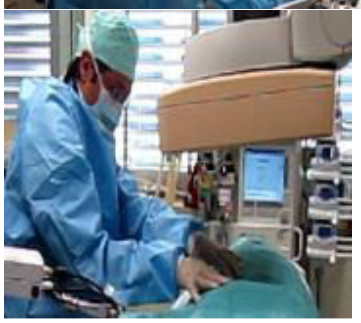
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Setup and Preparing the Patient

Setup and prepare the patient for the interventional procedure following the steps below:

Note:	*Let the patient enter the table from the opposite table site of the iSYS 1 setup. Make sure the patient does not collide with any component of iSYS 1.*



Note:	*The following paragraphs describe only the use of the iSYS 1 system. The use of the iSYS 1 system is just a small part of the workflow of an interventional needle procedure.*

This user manual does not discuss all the other important steps (like e.g. preparation of the non-iSYS disposables, cleaning and disinfection of the patient, sterile covering of the patient, use of the imaging machine, use of the planning software etc.). The general workflow for the specific intervention is in the responsibility of the physician.

Depending on the region of interest and of the compliance of the patient, the need for immobilization devices may occur. There are several - commercially available - immobilization devices on the market that can be used for precise patient immobilization.

Depending on the region of interest, respiratory motion may lead to organ movement and therefore to inaccuracy during the targeting process. There are several - commercially available - devices for respiratory motion control available on the market that might be used to overcome this problem.

In some cases - e.g. non cooperative patient - it might even be necessary to sedate/anesthetize the patient.

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

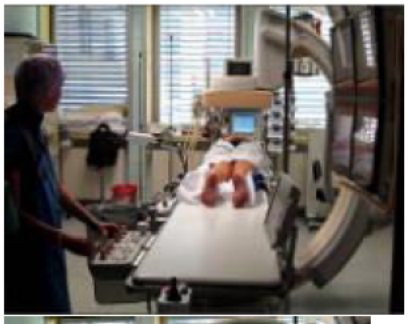
WARNING
It is in the full responsibility of the physician to use aids e.g. for immobilization, respiratory motion control etc. and/or to sedate the patient.
Criteria for the physician include the physical constitution of the patient, the region of interest, the critical (surrounding) structures/anatomy around the path and the target point and the relation of the region of interest to the lung and other moving organs.

iSYS does not take any responsibility for non-iSYS components and treatment steps e.g.correct patient setup, imaging and planning!

Image Acquisition and Treatment Planning

Before image acquisition, make sure that the gantry does not collide with iSYS 1.

To test this, drive the gantry manually and carefully (slow motion) in all necessary extreme positions and make sure that there are no collisions with the setup.

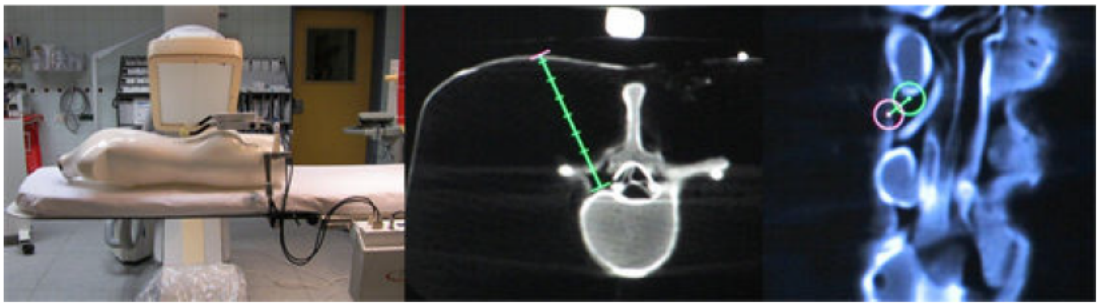


Imaging and planning can be performed with or without the RPU being in the field of view of the imaging device. In case the RPU is placed in the field of view of the imaging device, make sure that only the non-metal parts (plastic NGEs) are in the beam/field of view of the imaging device.

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

WARNING
Only the plastic NGEs ("fingers") do not cause imaging artifacts. If the whole RPU or other parts of the mechanical setup are in the field of view, imaging artifacts may occur!



After imaging of the patient, the planning of the path (entrance and target point) can be done with the planning tool of the imaging machine (not part of the iSYS System!).

Note:	*Imaging and planning are not in the responsibility of iSYS.* *Always keep in mind that the iSYS 1 system has only a certain range of movement for gross positioning and micro positioning (see specifications)* *In case imaging and planning is not done correctly, it might become necessary at a later point of the workflow to redo these steps (potential consequence: bigger time gap between (re-planning) and treatment and thereof (potentially less accuracy and/or additional radiation cause of the need of re-imaging)*

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Working with the sterile disposables (Bioseal/Preferred Medical):

WARNING
All sterile iSYS 1 disposables are intended for single use only. (Re-) Sterilization of these components is not allowed.

WARNING
Do not attempt to clean, sterilize or reuse single use components of the iSYS 1 system. Reuse of single use components might lead to a malfunction of the system and/or an infection of the patient.

WARNING
According to our present state of knowledge, we want to inform you about following known characteristics and technical factors that can lead to hazardous situations in case of reuse of the disposables.

Sterile Covers:
1. **Improper Folding**
2. **Conglutination of the tapes with the foil**
3. **Labels and stickers no longer usable due to opening**

NGE:
1. **Possibility of cross-contamination**
2. **Mechanical damage**

WARNING
Only labeled sterile products are allowed to be used.

WARNING
The single use components are sterile products intended for single use only. Sterility is guaranteed for unopened and intact packaging up to the indicated expiration date. Do not use sterile products if the package is damaged.

Remark: The disposables that are needed for the intervention are supplied by Bioseal/Preferred Medical.

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Preparation of the sterile iSYS Disposables:

To guarantee a quick and safe workflow, take the iSYS disposables – handed over by a non-sterile assistant – out of the sterile cover and deposit the sterile components on a sterile table/plate.

The following disposables are needed for intervention:

Picture	Number of pieces needed	Single Use / Accessories
	1	**Sterile Cover Robotic Positioning Unit** It is a disposable sterile component to cover the RPU and part of the MFA and RPU Cable Set. This assembly consists of a Sterile Drape and the Needle Guide Kit (including 2 Needle Guide Joints with Fixation Rings). Needle Guide Joints allow a quick and reversible connection of the Needle Guide Adapter to the Needle Guide Extension. Order number and name: 4874US Sterile Cover RPU - sterile for US
	Depending on how many needles are placed	**Sterile Needle Guide Insert**: During the intervention the tool is inserted and guided by the (sterile) Needle Guide Insert. NGIs are available for needle diameters given below. The needle diameter of a NGI is printed on the cover bag as well as embossed to the handle of the NGI. Order number and name: 6289G10US Sterile Needle Guide Insert – 10G 5990G11US Sterile Needle Guide Insert – 11G 5991G12US Sterile Needle Guide Insert – 12G 5992G13US Sterile Needle Guide Insert – 13G 5993G14US Sterile Needle Guide Insert – 14G 4877G15US Sterile Needle Guide Insert – 15G 4878G16US Sterile Needle Guide Insert – 16G 4879G17US Sterile Needle Guide Insert – 17G 4880G18US Sterile Needle Guide Insert – 18G 5989G19US Sterile Needle Guide Insert – 19G 4881G20US Sterile Needle Guide Insert – 20G 4882G21US Sterile Needle Guide Insert – 21G
	1	**Sterile Needle Guide Marker Insert:** The Needle Guide Marker Insert allows precise and remote-controlled alignment of the Needle Guide Insert based on real-time imaging data. Order number and name: 4876US NGMI centered - sterile for US

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

	1	**Sterile Cover Handheld Control Unit:** It is a disposable sterile component to cover the HCU during intervention. Order number and name: 4883US Sterile Cover HCU - sterile for US

Make sure all needed disposables are available. Also ensure that extra disposables are available in case a sterile piece is dropped in the non-sterile area (e.g. floor).

WARNING
Be sure the diameter of your instrument complies with the diameter of the Needle Guide Insert.

Attaching the Sterile Cover over the Robotic Positioning Unit

WARNING
Never continue with your procedure if any sterile cover is damaged. Continuing the procedure might lead to serious infection to patient.

WARNING
Never touch the sterile area in the operating room after touching non-sterile components of the iSYS 1 without respective treatment (according to the local regulations).

WARNING
The patient must not touch the sterile cover.

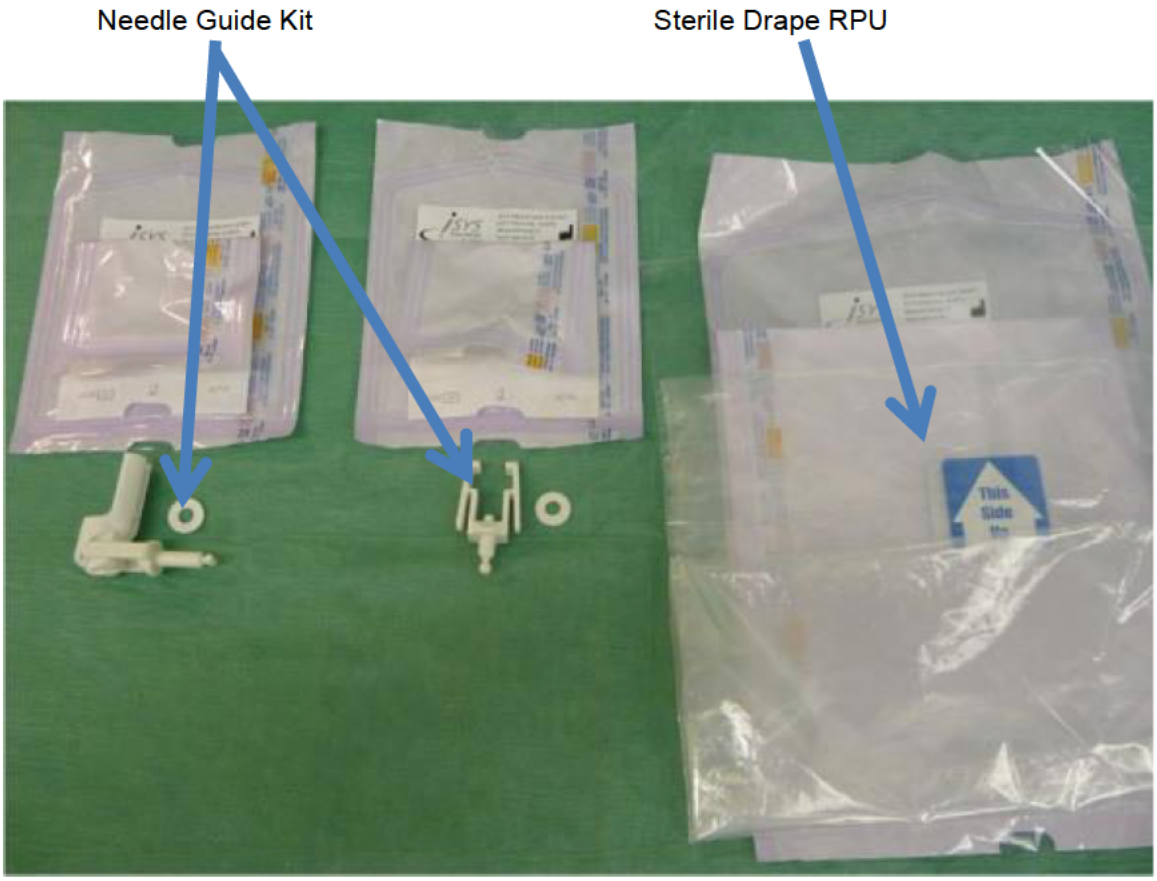
WARNING
Covering the patient's face with the sterile cover can seriously harm the patient.

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

The Robot Positioning Unit and the MFA can be completely covered with a sterile (protective) cover in a simple and safe manner. All non-sterile, reusable parts in the operation area are thereby separated from the sterile parts and the sterile operation area.

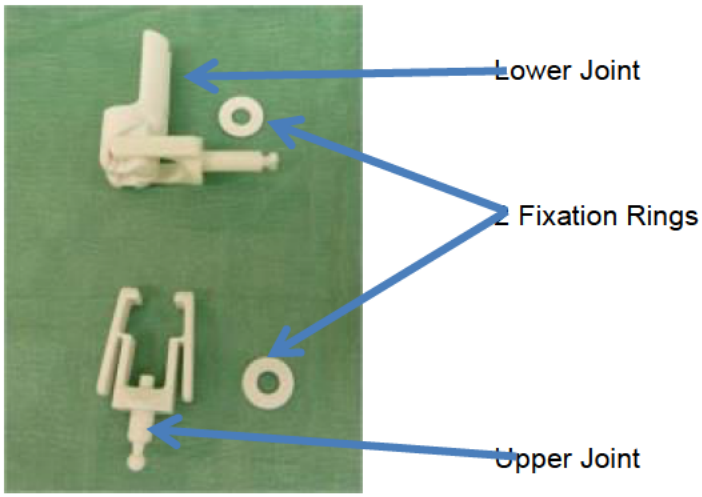
The Sterile Cover RPU consists of 2 parts:



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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

The Needle Guide Kit includes 4 components:



Open the sterile packaging and put all components (Sterile Drape, Lower & Upper Joint & 2 Fixation Rings) on the sterile table.

1. Feed the Upper Joint into the sterile drape and stick it through the upper hole.

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

2. Slip a Fixation Ring onto the Upper Joint

3. Feed the Lower Joint from outside the sterile drape into the lower hole.

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

4. Slip a Fixation Ring onto the Lower Joint from inside the Sterile Drape.

Make sure that both Fixation Rings are properly seated to the Joints!

5. Take the Bowl of the Upper Joint and insert it into the guide rail of the Lower Joint.

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

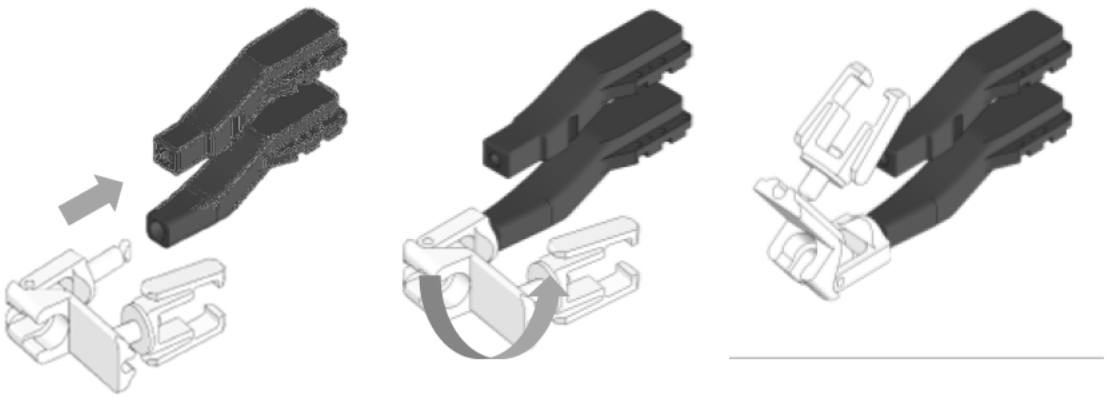
The final Sterile Cover RPU should look as shown in these pictures.

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

The sterile dressed surgeon grabs the end-effector from inside the plastic tube as shown in the picture above.

First the lower joint -is attached to the lower NGE ("finger") by bringing in the pin adapter in a 90 degree angle.

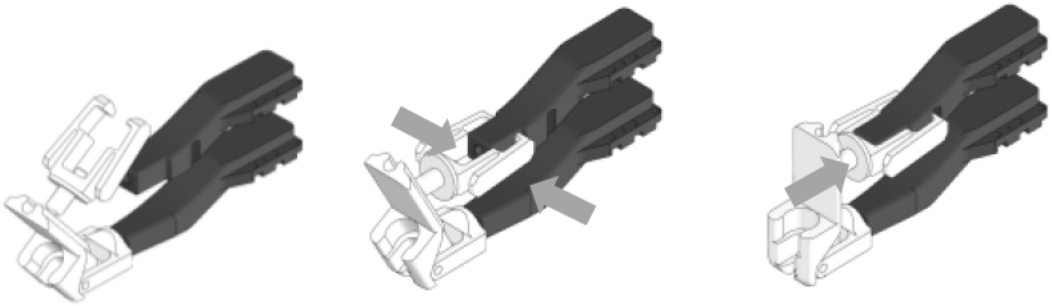


When you have reached the final position, rotate the lower joint counter clockwise 90 degrees and make sure that the pin is locked safely by gently pulling the lower joint.

Attach the upper joint by attaching the clamp adapter as shown in the picture below:

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016



After attachment of the upper joint, let the (non-sterile) assistant catch the white arrow (see blue marking) and pull the cover over the robotic unit.

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

After the RPU and MFA are totally covered with the sterile cover, the sterile surgeon can touch the sterile cover and pull the protuberance part of the cover (on the side of the sterile cover) over the handle of the arm and push it back.

Use the blue tapes to fix the cover in position and to make sure the cover does not slip away.

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Attaching the Sterile Cover to the HCU

WARNING
The patient or other non-sterile persons must not touch the sterile cover.

WARNING
Covering the patient's face with the sterile cover can seriously harm the patient.

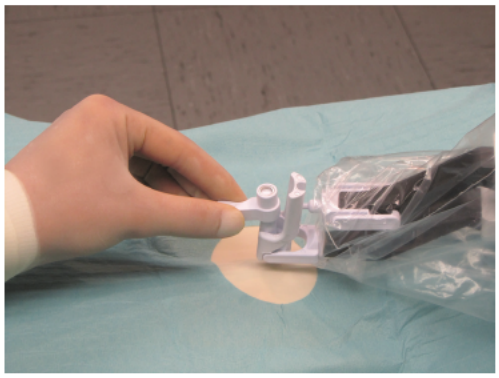
In another simple and safe step, the HCU is completely covered with a sterile protective cover.

The (non-sterile) assistant takes the HCU in his hands. The sterile dressed surgeon takes the Sterile Cover Handheld Control Unit and grabs the HCU from inside the plastic tube.

The (non-sterile) assistant catches the end of the plastic tube and pulls the cover over the HCU and its cable.

Note:	*This step allows the surgeon to later touch and use the HCU with his sterile hands/gloves. In case a second (assistant) non-sterile surgeon can operate the joystick, a sterile cover for the HCU is not needed and this step can be left out!*

Gross-Positioning of the RPU and Insertion of the Sterile Needle Guide Marker Inlay into the Needle Guide Adapter



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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Make sure the entry and target point is in the range of the RU (see specifications above).

Unless it has not already been done before imaging, the RPU needs to be gross-positioned in the region of interest by opening and closing the MFA. To (re-)position the RPU please hold the RPU with one hand and open the MFA handle with the other one.

Please be aware that the MFA offers progressive locking, i.e. the upper link (next to the RPU) opens first, then the middle link and finally the lower link (next to the table/side rail adapter).

WARNING
The MFA joints progressively lock, allowing for precise positioning and preventing sudden movements when opened.
Always be aware that opening the MFA too fast can lead to uncontrolled movements of the arm itself or attached components (i.e. the Robotic Positioning Unit).
Always open the MFA slowly and carefully with one hand and hold the MFA or the attached device (Robotic Positioning Unit) carfully with the other hand!

Although the Robotic Positioning Unit has an ergonomic design, always keep in mind that the sterile cover may decrease the friction forces: Always hold and handle the MFA and the Robotic Positioning Unit carefully and safely!

Move the robot to the desired position/orientation and lock the MFA after positioning. Verify that the MFA handle is securely tightened.

Please check the stability of the setup before proceeding with needle insertion.

To get a rough estimation about the right gross-positioning, you can use standard (skin) markers, the laser cross-hair (or laser pointer) from the imaging device (that visualizes the path) or fluoroscopy.

In case you use fluoroscopy, be aware to step aside to avoid radiation exposure. Always be aware that this method causes additional radiation to the patient.

WARNING
Make sure that the RPU and the NGE is oriented (approximately) parallel to the patient surface.
Always check if there is a risk of touching or colliding with the patient while remotely driving the robot modules (see chapter 4.2.8).
To double check: Drive the robot with the HCU in all extreme positions under direct visual control.
Collisions of the robot with the patient can cause serious injuries.

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

After you have reached and checked the desired position, insert the (sterile) Needle Guide Marker Inlay into the Needle Guide Adapter.

WARNING
Make sure and double check that the Needle Guide Marker Inlay is in the correct position and is free of play in the NGA.

Micro-Positioning and Accurate Alignment of the NGA under fluoroscopy

Use the HCU (as described in chapter 4.5.3) to micro-position the NGA.

WARNING
When using the HCU, be aware not to touch the sterile area with the non-sterile cable of the HCU.

WARNING
Repeat imaging procedure if the Robot Positioning Unit has been accidentally pushed or the power supply has been interrupted after imaging. Failing to do so may lead to mistreatment of the patient.

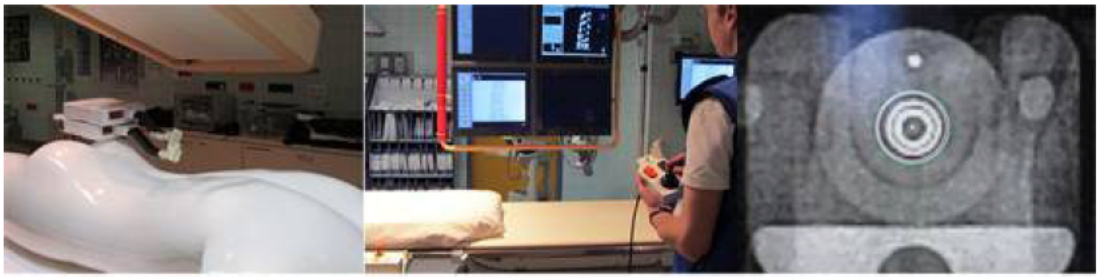
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

WARNING
Be aware not to stand on the cables when moving the Robot Positioning Unit. This can lead to wrong positioning of the instrument and mistreatment of the patient.

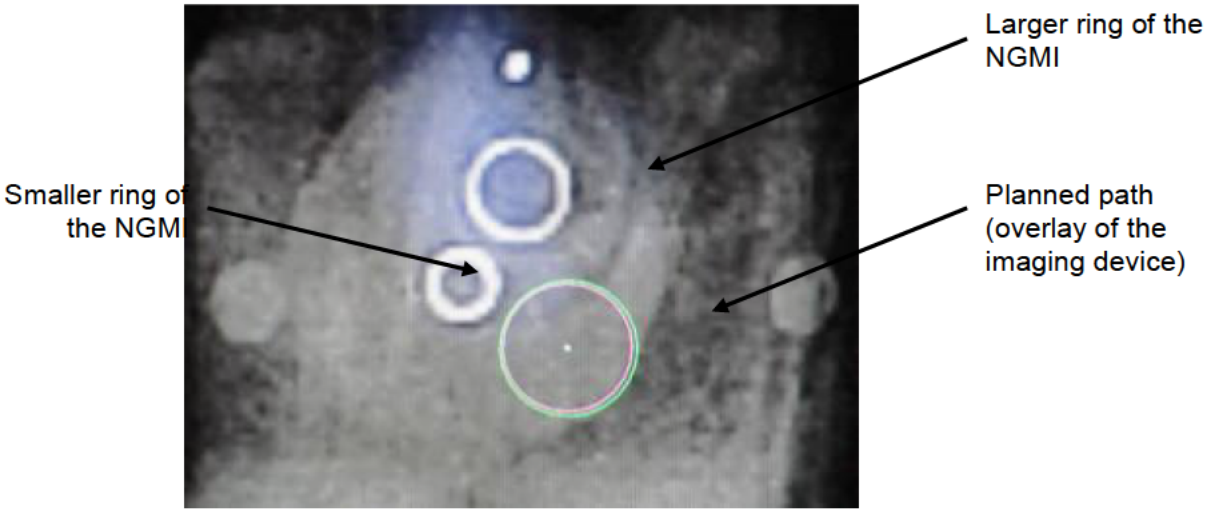
For a first alignment you can use surface markers or the laser cross-hair (or laser pointer) from the imaging device (that visualizes the path). In this case you can stay next to the patient.

If you use real-time-fluoroscopy for the alignment, please stay as far away as possible (minimum 6 feet) from the beam to reduce radiation exposure to a minimum (you just need to have a good view to the monitor that shows the fluoroscopy image).



To avoid unnecessary radiation to the patient, the user can – with the help of the robot – also work "offline" (i.e. without real-time imaging) and use just single Fluoro-Snap-Shots.

For micro-positioning the NG under fluoroscopy the C-Arm has to be orientated perpendicular to the planned path ("entry point view"). To align the Needle Guide with the planned path the user gets the right orientation of the x-, y-, a-, b-axis from the marker insert:

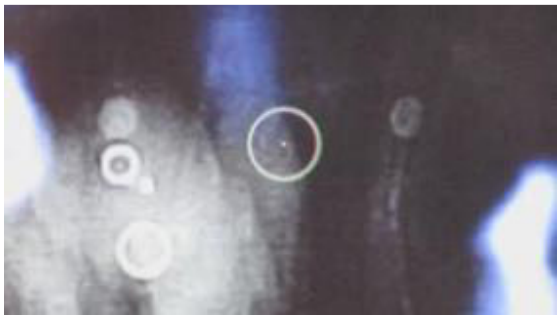
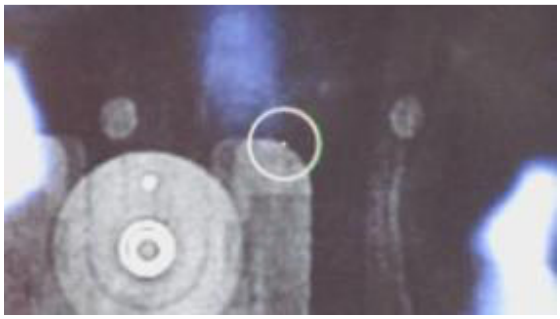


Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

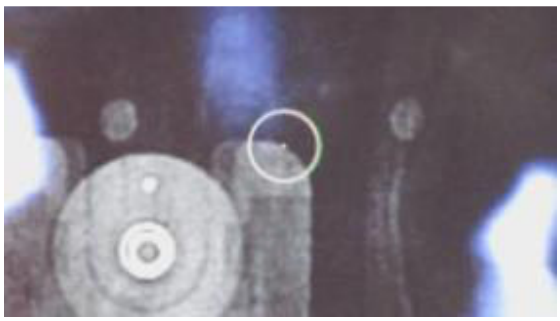
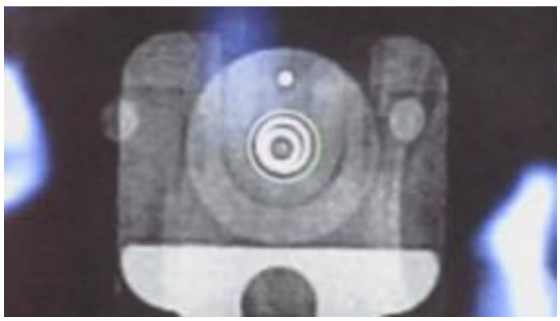
Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

The larger ring of the Needle Guide Marker Inlay marks the position of the Needle Guide. The smaller ring indicates the angulation of the Needle Guide.

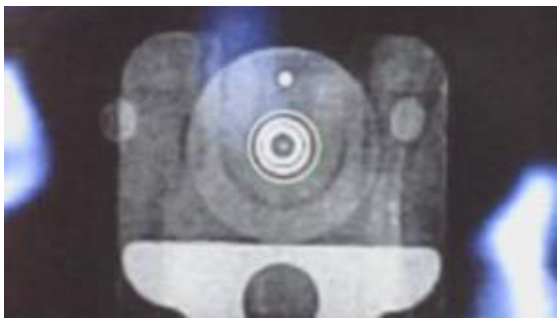
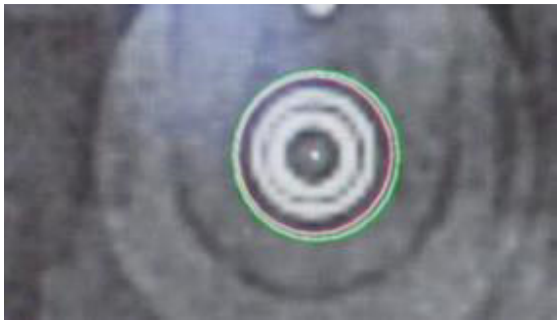
In a first step the smaller ring has to be aligned roughly with the larger ring by moving the RPU in angulation mode. In this mode only the smaller ring moves as shown in the pictures below.

In the next step, both rings have to be aligned with the planned path (indicated by the two rings overlayed by the imaging device) by moving the RPU in positioning mode. When moving the RPU in positioning mode both rings move:

Finally, the alignment has to be optimized by moving the RPU in positioning and angulation mode as shown below. For easy fine positioning the speed level can be set to slow by pushing the MINUS button on the HCU several times unless you hear a beep signal. The speed level is indicated on the display too.

In case the alignment is done under fluoroscopy, a maximum zoom of the fluoro-image, adjustment of the diameters of the ring (in needle entry view, that represents the

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

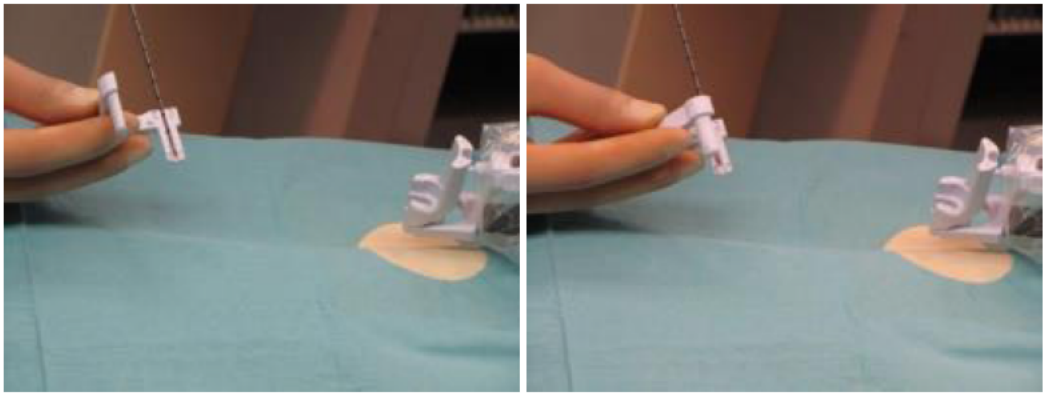
preplanned path) to the diameter of the marker and the resolution of the x-ray image (be careful: higher dose!) may increase the accuracy.

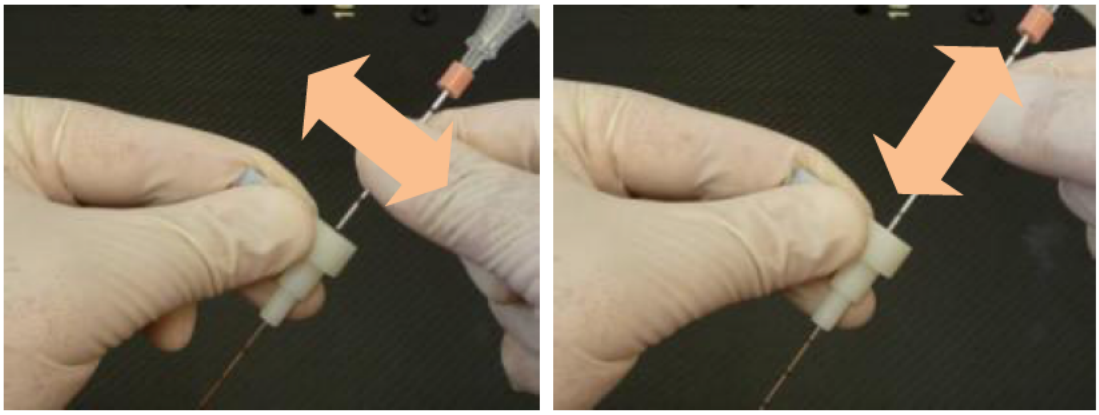
As this is not in the responsibility of iSYS, please contact the manufacturer of the imaging device for further information.

After alignment of the NG, remove the NGMI from the NGA.

Attachment of the Needle Guide Insert and Needle Placement

The NGI has a very important function for needle guidance and quick release. Before attaching the sterile NGI to the NGA, check if the diameter of the needle fits to the NGI and check with the following manual test if the needle has a play-free and friction free guidance in the needle insert:





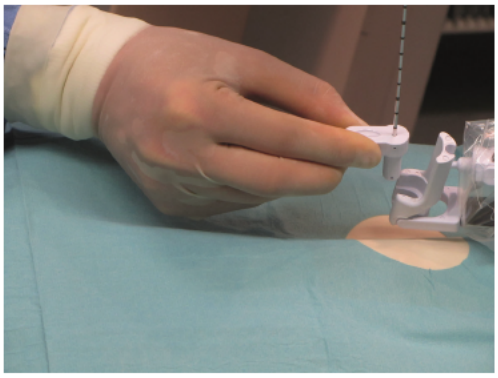
This check takes place in two steps. First insert the needle to the NGI, hold the NGI tightly with one hand (pressing the two halves of the NGI together) and try to move the needle in radial direction with the other hand. There should be no detectable play between NGI and needle. For the second step, try to move the needle in axial direction. The needle should move easily – there should be no blocking of the needle during such axial movement.

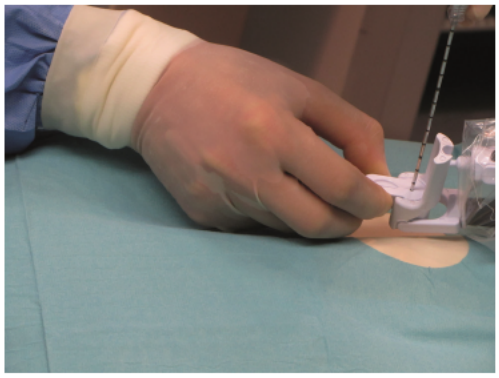
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

WARNING
Check the free and easy movement of the needle in the Needle Guide Insert. Be aware that the needle is not clamped.

After you have checked the functionality of the insert, insert the (sterile) Needle Guide Insert into the Needle Guide Adapter.





WARNING
Make sure and double check that the NGI is in the correct position and that there is no play between NGA and NGI.

WARNING
Precise needle guidance is essential for the accuracy of the needle placement.
Precise needle guidance is only possible if the diameter of the needle is within the specified tolerance over its entire length.
Always check the tolerances of the needle with your needle supplier before using it with the iSYS system!

After attachment of the NGI to the NGA, the needle can be introduced manually in z-axis into the patient. This step must be under full control of the surgeon!

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Depending on the used imaging device, the depth of the needle placement usually is calculated by the planning software and is measured between the defined insertion point and the target point. To verify the correct insertion depth it is recommended that:

- During planning, define the insertion point exactly on the skin surface of the patient.
- Before insertion of the needle, mark the calculated insertion depth (calculated by the planning system) with a sterile ruler and a sterile pen at the needle.
- Insert the needle until the marked insertion depth is at the skin's surface.
- It is highly recommended to check the needle insertion before reaching the final position by means of an intermediate scan (cf also sub-chapter “Verification and quality assurance” below).

Please note that iSYS is not taking any responsibility for the correct insertation depth of the needle or needle-type instrument.

WARNING
Opening the MFA while the needle is being inserted and connected to the RPU can lead to serious patient injuries.

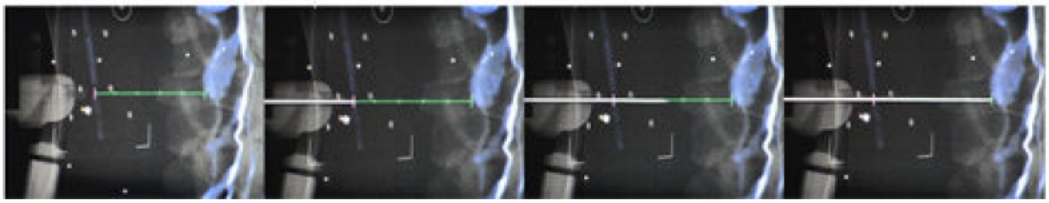
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

WARNING
The iSYS 1 system acts as a guidance system. It is not designed to compensate for external forces.
Forces on the mechanical components of iSYS 1 may lead to inaccuracy of the needle placement!

Verification and quality assurance:

As the NGE is radiolucent, the correct needle position can be verified with lateral scans ("needle progress view", "angulated needle guide view", optional: "needle entry view") before, during and after treatment.



It is in the responsibility of the surgeon to decide how often verification scans are necessary (this may depend on the region of interest, planned accuracy, critical/surrounding tissue, etc).

WARNING
In case of multiple needle procedures, be aware that the needles do not collide with each other or with iSYS 1 compontents! This can seriously harm the patient.

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

WARNING
Be aware that the setup of iSYS 1 does not influence the imaging in the area of interest. If in doubt, repeat the imaging procedure to avoid mistreatment of the patient.

WARNING
In case of an error (emergency stop): the error condition has to be resolved and the system has to be in the ready state to go on. The needle position and angulation has to be verified with the imaging device before inserting the needle/tool.

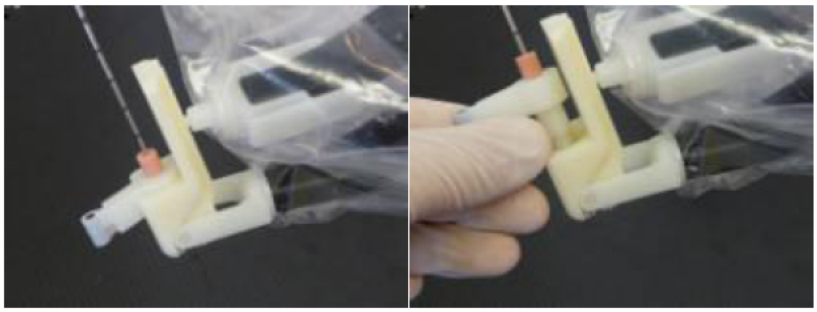
WARNING
The RPU must not be used as a (arm) rest at any time, not even as a support of the surgeons hand while inserting the needle.

WARNING
When inserting the needle avoid excessive pressure on the needle except forces in needle direction. Otherwise it leads to inaccuracies and may lead to mistreatment or injury of the patient.

Removing the NGI and Quick-Release

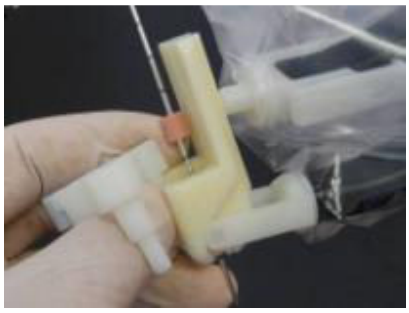
After needle introduction and/or whenever the surgeon steps away from the patient and/or when the diagnosis/treatment with the needle starts, the NGI has to be removed (i.e. the needle gets decoupled from the robot).

Such decoupling can be easily performed by simply lifting the NGI (along the needle axis) until the NGI is no longer connected to the NGA. In this position the NGI can be opened and the needle is no longer attached to the needle guide.



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

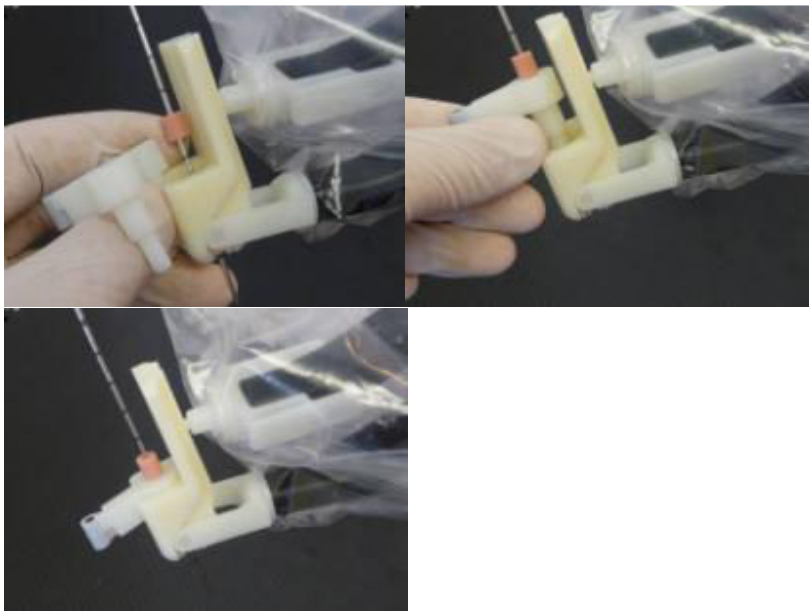
Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016



The decoupling also allows free “swinging” of the needle inside the needle guide and removal of the iSYS 1 system in case of emergency.

For multiple needle placements, decoupling provides for the removal of the RPU from the treatment area and the subsequent gross-positioning of the RPU for placement of additional needles.

If decoupling of the needle is only done temporarily (e.g. because the surgeon had to leave the patient for some time), the re-connection between needle and NGA can be done easily in the reverse order. The opened NGI is placed around the needle and closed afterwards. Then the NGI is moved inside the NGA along the needle axis. Please be sure that the needle is fixed with the other hand during this step in order to avoid unintended needle insertion. For such re-connection the robot must not be moved between decoupling of the needle and re-connection.



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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

WARNING
During manipulation of the NGI for decoupling/coupling the needle from/to the NGA, please be sure that the needle is is in place (e.g. fixation with the other hand) to avoid unintended needle movement.

WARNING
In case of multiple needle procedures, verify that the needles do not collide with each other or with iSYS 1 components! This can seriously harm the patient.

WARNING
The MFA joints progressively lock, allowing for precise positioning and preventing sudden movements when opened.
Always be aware that opening the MFA too fast can lead to uncontrolled movements of the arm itself or attached components (the robotic positioning unit).
Always open the MFA slowly and carefully with one hand and hold the arm or the attached device (robotic positioning unit) carefully with the other hand!

Although the RPU has an ergonomic design, always keep in mind that the sterile cover may decrease the friction forces: Always hold and handle the MFA and the RPU carefully and safely!

Emergency Release/ Removing the system in case of emergency

In case of an emergency (e.g. patient panics), open the MFA, remove the RPU from the patient and bring it into parking position. Before manipulation of the RPU, please make sure to remove the needle from the NGI by either pulling out the needle or de-coupling the needle from the NGI (cf chapter 0).

WARNING
Before removing the system, always check that the NGI (or the needle) has been removed!
In case the needle insert has not been removed, friction forces can pull and/or push the needle and this can seriously harm the patient.

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Dismounting

Before dismounting the system, bring the RPU into the “parking position” and remove the patient from the treatment table.

Remove the disposable parts first and dispose of them according to the clinic guidelines.

Unplug the system, remove the cables, clean the components and dismount the mechanical parts.

For unplugging of the HCU connection cable, please grab the circular connector at the grooved part and simply pull out the plug. For the flat connectors connecting the RPU with the CU, please push the two locking rockers of the connector and then pull out the connector.

Store the components carefully in the iSYS storage boxes.

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Table of Dimensions:

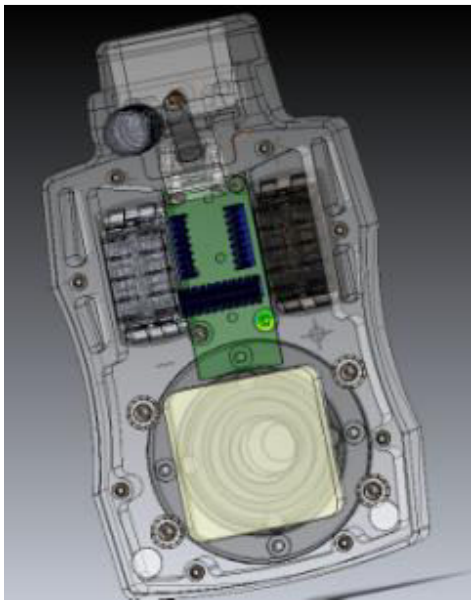
Component	Dimensions
Robotic Positioning Unit	266 x 139 x 68 mm
Needle Guide Extension	120 x 28 x 45 mm
Control Unit	360 x 406 x 147 mm
Handheld Control Unit	187 x 107 x 122 mm
Multi Functional Arm	Max. 500 x 105 x 145 mm
Side Rail Adapter	Side Rail adapter: 230 x 82 x 120 mm Extension Rod: 610 x 45 x 25 mm Max. Setup: 590 x 320 x 82 mm
Table Top Adapter (A and B)	614 x 190 x 45 mm
Needle Guide Adapter	Maximal dimensions: 24 x 25 x 60 mm
Needle Guide Joints	Upper Joint: 60 x 35 x 20 mm Lower Joint: 59 x 25 x 18 mm
Needle Guide Inserts	assembled: 36 x 15 x 30 mm
Drapes	RPU: 30.5 x 122 cm HCU: 30.5 x 198 cm

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

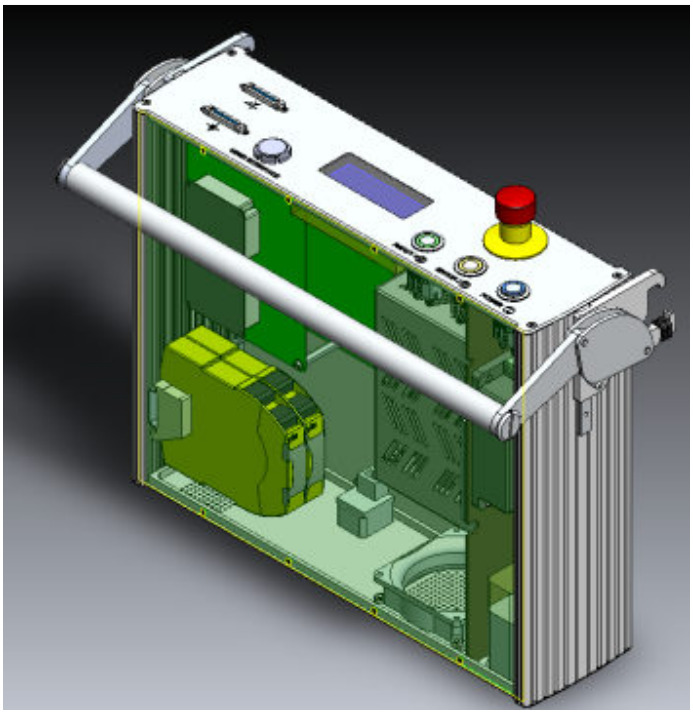
Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Technical Drawings:

Handheld Control Unit



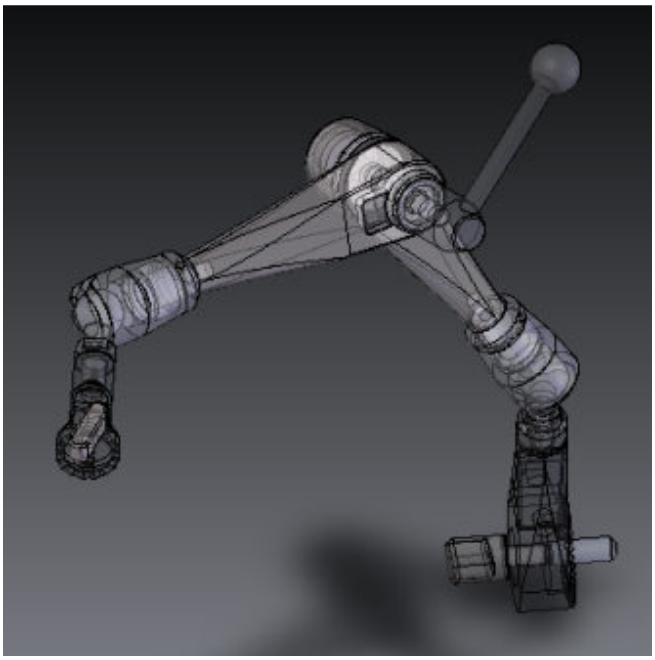
Control Unit



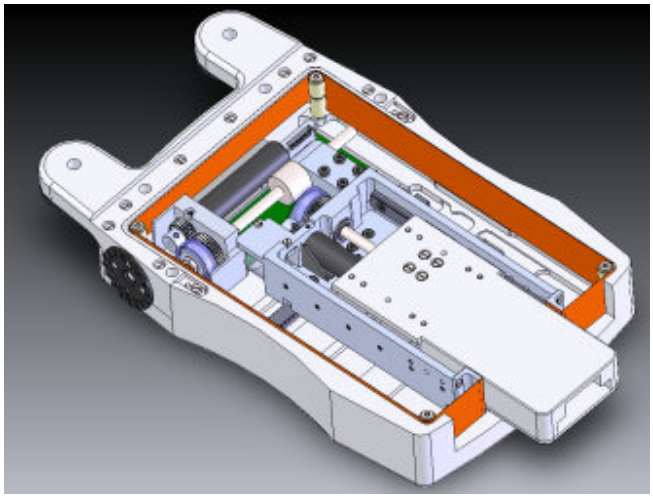
Multi Functional Arm

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016



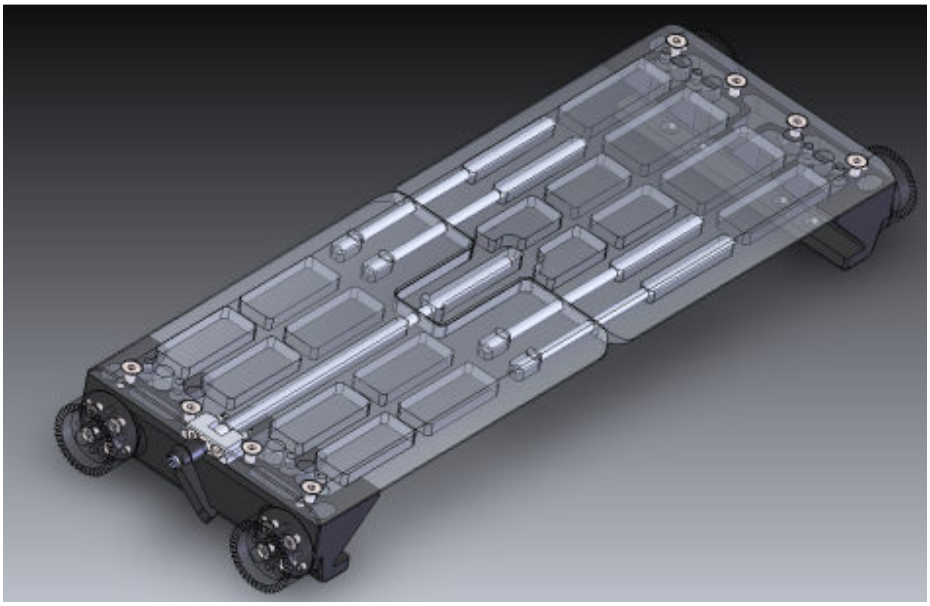
Robotic Positioning Unit



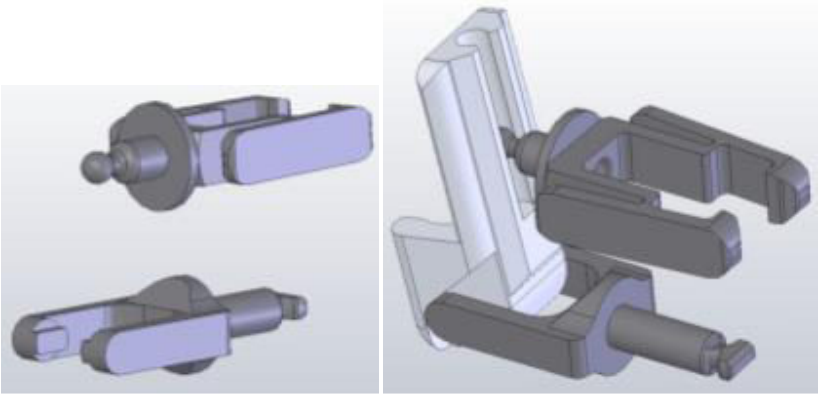
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

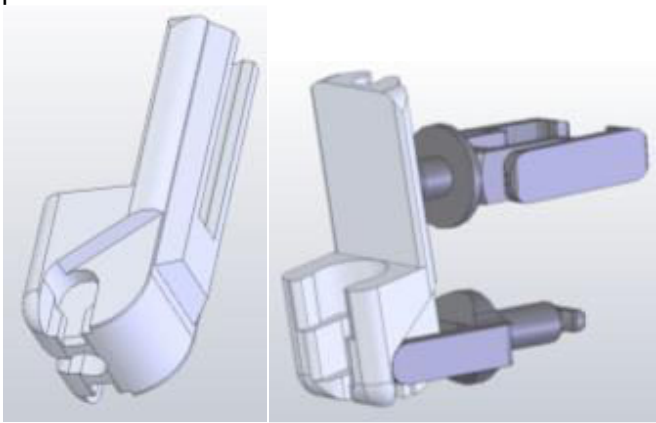
Table Top Adapter



Needle Guide Joints:



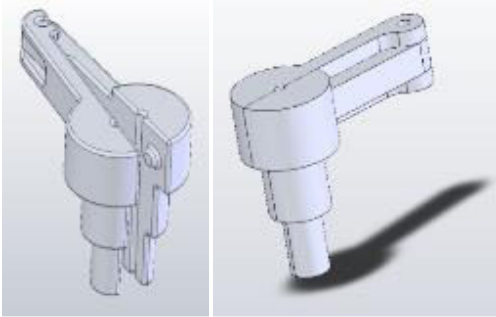
Needle Guide Adapter:



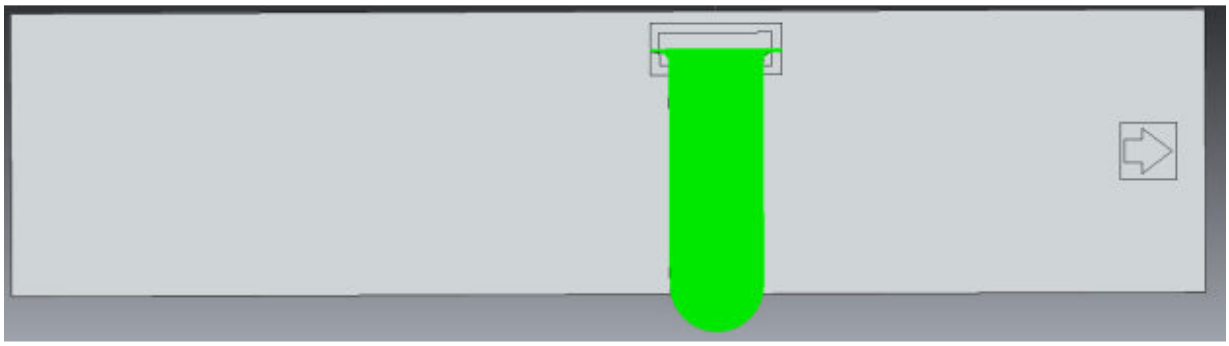
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

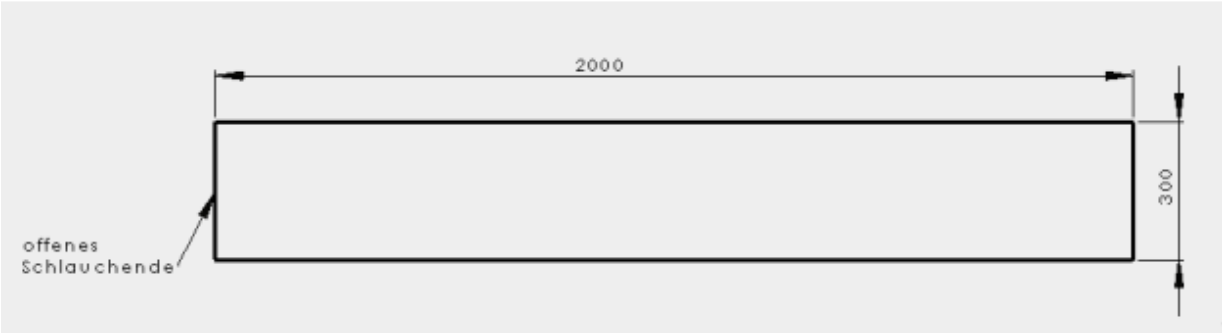
Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Needle Guide Insert:



Sterile Covers:



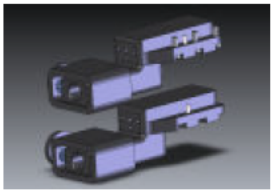
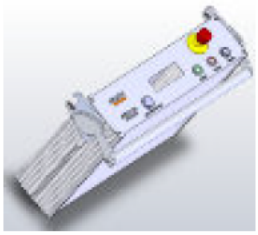


Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Configurations:

iSYS 1 (U.S.)

Name	Picture	Art. No.	Description	Units
Robotic Positioning Unit (RPU)		3908	Robotic Positioning Unit with two 2DOF modules which allows - in combination with the Needle Guide Set - tool angulation (± 30° for both pitch and yaw angle) and needle positioning (± 20 mm for both lateral and longitudinal direction).	1
Needle Guide Extension (NGE)		10820	The Needle Guide Extension comprises two cranked "fingers" which are connected to the Robotic Positioning Unit by screws. This standard version provides an offset of 0mm between the bottom edge of the RPU and the NGE. The "fingers" are mainly made out of radiolucent plastic and do not cause any imaging artifacts.	1
Control Unit US (CU)		6254	The iSYS 1 Control Unit aims to control the iSYS 1 Robotic Positioning Unit. The CU is integrated into a metal rack and can be attached to the side rail of the treatment table by a simple locking mechanism. It is designed to interface with a standard OR siderail with the following dimensions: (W x H) 10 mm x 25 mm.	1
Handheld Control Unit (HCU)		3901	The Handheld Control Unit comprises a 2-axis joystick as well as confirmation and control buttons for remote operation of the RPU from a "safe" distance. A simple locking mechanism allows the attachment to the side rail. A sterile cover for the Handheld Control Unit is also available. It is designed to	1

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

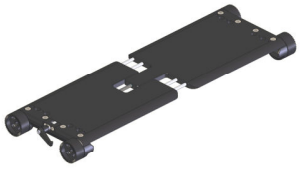
Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

			interface with a standard OR side rail with the following dimensions: (W x H) 10 mm x 25 mm.	
RPU Cable Set 1500 mm		3926	Set of two cables to connect the CU and RPU. Length: 1500 mm	1
RPU Cable Set 3000 mm		5905	Set of two cables to connect the CU and RPU. Length: 3000 mm	1
Power Cord US 2500 mm		6163	Power cord US Length: 2500 mm	1
Transport Box		6098	Transport Box	1

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Accessory, non-sterile:

Name	Picture	Article-No.:	Standard/ Optional/ Disposable	Description
Multi Functional Arm (MFA):		**4271**	Standard	Single-lever passive multi-functional arm for flexible pre-positioning of the iSYS 1 Robotic Positioning Unit. There are two different connectors: the "Starburst"-adapter connects the MFA to the different table adapters; the "Spoon"-adapter connects the MFA to the RPU.
Table Top Adapter Version B - Bottom Mounted (TTAB):		**4120**	Standard	Mechanical adapter for safe and stable connection of the MFA directly to a standard C-Arm Couch Top; It is mounted from the bottom of the Couch Top. This adapter is designed to interface with a carbon fiber table top with the following dimensions: Width between 470 mm and 530 mm Maximal thickness of the table: 6 mm (at the border) and 38mm (in the middle of the table)
Table Top Adapter Version A - Top Mounted (TTAA):		**4117**	Optional	Mechanical adapter for safe and stable connection of the MFA directly to a standard C-Arm Couch Top; The Table Top Adapter Version A – Top Mounted is mounted from the top and provides maximum stability. This adapter is designed to interface with a carbon fiber table top with the following dimensions: Width between 470 mm and 530 mm Maximal thickness of the table: 6 mm (at the border)
Side Rail Adapter (SRA):		**4095**	Optional	Adapter to connect the MFA to a standard side rail. The extension with a metal rod is possible if needed. The rod is inserted and into the adapter and fixed with a screw. The Starburst connector is located at the end of the rod as well as on the adapter itself. This adapter is designed to interface with a standard OR side rail with the following dimensions: (WxH) 10 mm x 25 mm
HCU Cable Extension:		**6162**	Optional	HCU Cable Extension

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Accessory, sterile:

Name	Picture	Article No.	Disposable	Description
Sterile Cover RPU - sterile for US:		4874US	Disposable	It is a disposable sterile component to cover the RPU and part of the MFA and RPU Cable Set. This assembly consists of a sterile drape and two Needle Guide Joints. Needle Guide Joints allow a quick and reversible connection of the Needle Guide Adapter to the Needle Guide Extension.
Sterile Cover HCU - sterile for US:		4883US	Disposable	It is a disposable sterile component to cover the HCU during operation.
Needle Guide Marker Insert centered - sterile for US:		4876US	Disposable	The Needle Guide Marker Insert (sterile) allows precise and remote-controlled alignment of the Needle Guide based on real-time imaging data.
Needle Guide Insert xxG - sterile for US:		6289G10US 5990G11US 5991G12US 5992G13US 5993G14US 4877G15US 4878G16US 4879G17US 4880G18US 5989G19US 4881G20US 4882G21US	Disposable	During the intervention the tool is inserted and guided by the sterile Needle Guide Insert. Needle Guide Insert – 10G Needle Guide Insert – 11G Needle Guide Insert – 12G Needle Guide Insert – 13G Needle Guide Insert – 14G Needle Guide Insert – 15G Needle Guide Insert – 16G Needle Guide Insert – 17G Needle Guide Insert – 18G Needle Guide Insert – 19G Needle Guide Insert – 20G Needle Guide Insert – 21G

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Substantial Equivalence Discussion

Device Comparison Table:

Reference	Frameless Neuromate	ROSA Surgical Device	iSYS 1 (for new submission)
510k-Number	K091081	K101791	-
Manufacturer	INTEGRATED SURGICAL SYSTEMS, INC. 1850 Research Park Dr. Davis, CA 95616 USA	Medtech Surgical Inc. 211 Warren Street Suite 306 Newark, NJ 07103 USA	Submitter
Design			
General device description	Computer controlled electromechanical multi-joined arm indicated for use as a stereotactic instrument	Computer controlled electromechanical multi-joined arm indicated for use as a stereotactic instrument	Computer controlled electromechanical multi-joined arm indicated for invasive procedures
Localization means	Robot arm absolute encoders	Robot arm absolute encoders	Fiducial markers on tool holder.
Image-guided	Yes	Yes	Yes
Planning software	No (third party)	Yes	No (third party)
Registration method	Bone-mounted ultrasound device	Fiducial markers Optical registration device	Fiducial markers
Instrumentation	Laser pointer Tool Holder	Navigation probe Laser pointer Tool Holder	Marker Tool Holder Sterile Covers (third party)
Instrument fixation	Instruments are mounted onto robot arm	Instruments are mounted onto robot arm	Special tool holders for several applications mounted to the Robot
Instrument calibration	Factory Calibration	Factory Calibration	Intra operative
System immobilization between patient and device	Yes	Yes	Yes
Planning and Navigation Software			
N/A.			
System Operation			
Fiducial markers registration with pointer probe	No.	Yes.	No.
Optical registration	No.	Yes.	No.

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Reference	Frameless Neuromate	ROSA Surgical Device	iSYS 1 (for new submission)
Registration with US	Yes.	No.	No.
Accuracy verification	Yes, laser pointer.	Yes, navigation probe, laser beam.	Yes, performed by user
Provide mechanical guidance for tools	Yes.	Yes.	Yes.
Instrument guide position adjustment	Automatic.	Automatic.	Manual.
Surgeon carries out final gesture through tool guide	Yes.	Yes.	Yes.
Indications for Use			
Indication for use	Stereotactic spatial positioning and orientation of an instrument holder or tool guide to be used by a surgeon to manually guide standard neurosurgical instruments (biopsy needle, stimulation or recording electrode, endoscope).	Intended to be used in the operating room for the spatial positioning and orientation of an instrument holder or tool guide, The system is intended to be used by neurosurgeons to guide standard neurosurgical instruments (biopsy needle, stimulation or recording electrode, endoscope). Indicated for any neurosurgical condition in which the use of stereotactic surgery may be appropriate.	The intended use of the iSYS1 device is to function as a remote-operated positioning and guidance system during interventional procedures. Positioning is done in remote control manner; planning of the position/angulation is done based on 2D/3D patient data (CT, cone-beam CT, fluoroscopy) by external planning software – for example using an external navigation system, or planning software coming with the used imaging device. Also verification of the correct position and orientation of the tool prior to/during/after the intervention is done by means of these external devices. The iSYS1-System is then acting as a guideway during the manual insertion of the interventional

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Reference	Frameless Neuromate	ROSA Surgical Device	iSYS 1 (for new submission)
			tool – usually a needle type device, and the like. Applications include, but are not limited to, interventions like biopsy procedures, tumor ablation, nerve blocking, electrode placement, etc.
Anatomical site	Head	Head	total body
User	Neurosurgeon	Neurosurgeon	Surgeon
Accessory	Sterile drapes	Sterile drapes Fiducial markers Head Holder Light source	Sterile Covers Table Adapters Cable Sets
Real-time instrument position	Yes	Yes	Yes
Mechanical Guidance of instruments	Yes	Yes	Yes
Technology			
Powered	Yes	Yes	Yes
CE-Conformity	Yes	Yes	Yes
Computer-controlled	Yes	Yes	Yes

Similarities and Differences:

All three devices are intraoperative instruments used by surgeons for assisting the spatial positioning and orientation of a surgical tool.

iSYS 1 is equivalent to:

- Frameless Neuromate and ROSA Surgical Device for assisting the spatial positioning and orientation of a surgical tool.
- Frameless Neuromate and ROSA Surgical Device for being localized by the navigation or imaging software.
- Frameless Neuromate and ROSA Surgical Device for being guided by an imaging device
- Frameless Neuromate and ROSA Surgical Device for providing a registration method for the imaging device.
- Frameless Neuromate and ROSA Surgical Device for instrumentation and instrument fixation.
- Frameless Neuromate and ROSA Surgical Device for being immobilized in relation to the patient.

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

- Frameless Neuromate and ROSA Surgical Device for providing accuracy verification, tool guidance and position adjustment.
- Frameless Neuromate and ROSA Surgical Device for the physician making the final gesture.
- Frameless Neuromate and ROSA Surgical Device for having the same indications for use, but on a wider field of application for the iSYS 1 (ROI).
- Frameless Neuromate and ROSA Surgical Device for having similar technology.

Differences:
Frameless Neuromate and iSYS 1 do not contain planning software as ROSA Surgical Device does. Position and orientation of the iSYS 1are given by external planning software. This has no effect on safety or effectiveness.

Frameless Neuromate and ROSA Surgical Device provide a factory instrument calibration during intervention while the position of the needle or needle-type instrument (tool) is verified during intervention by the surgeon for the iSYS1. Verification of the tool position requires greater physician effort but provides for exact (depending on the imaging system) tool localization.

ROSA Surgical Device provides registration with pointer probe whereas the Frameless Neuromate provides ultra sound registration. As already described, this is not necessary for the workflow of the iSYS 1 which reduces time and effort for intervention.

Statement of safety and effectiveness:

It is our opinion that the iSYS 1 System (U.S.) does not have technological characteristics that rise additional types of safety or effectiveness questions, and we consider them to be an enhancement to the existing devices.

To validate the accuracy of the iSYS 1 an external reference system has to be used. We have used and tested the iSYS 1 System (U.S.) with the Philips Allura Xper Guide FD 20 X-ray system.

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Proposed Labeling

Content | Page

Product and Packaging Labels	2
User Manual	6
Marketing Material	113
Form FDA 3654	115

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Product and Packaging Labels

Safety Symbols:

STERILE R	Symbol for STERILIZED USING RADIATION
	Symbol for DO NOT USE IF PACKAGE IS DAMAGED
	Symbol for DO NOT REUSE
MR	Symbol for NOT MRI SAFE
	Symbol for ALTERNATING CURRENT
	Symbol for CAUTION, CONSULT ACCOMPANYING DOCUMENTS
	Symbol for TYBE B APPLIED PART
	Symbol for ON/OFF SWITCH (PUSH-PUSH)
	Symbol for PROTECTIVE EARTH
	Symbol for STORAGE TEMPERATURE
	Symbol for DO NOT LITTER IN DOMESTIC WASTE

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Product identification Symbols:

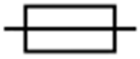
SN	Symbol for SERIAL NUMBER
REF	Symbol for ORDER NUMBER
LOT	Symbol for BATCH NUMBER

Additional Symbols:

CE	Symbol for CE-conformity
+	Symbol for PLUS (increase speed level)
–	Symbol for MINUS (decrease speed level)
	Symbol for POSITIONING
	Symbol for ANGULATION
READY	Label for the ready indicator light
ERROR	Label for the error indicator light
POWER	Label for the power indicator light
USER INTERFACE	Label for the user interface connector
C	Symbol for the confirm push button
Q	Symbol for the quit push button

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

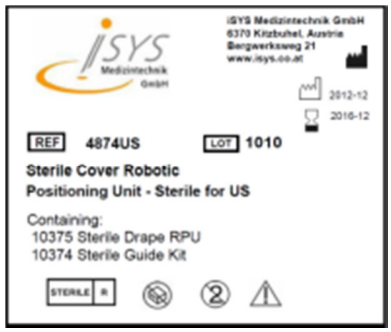
	Symbol for MANUFACTURER
	Symbol for DATE OF MANUFACTURE
	Symbol for USE BY
	Symbol for FUSE
	Symbol for KEEP DRY
	Symbol for THIS SIDE UP
	Label for the Weight
iSYS Medizintechnik GmbH	Company Label

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Examples for Product Labels:

The presented labels are examples for the final product and packaging labels. Lot numbers and dates on these examples are placeholders only. They do not define any format of lot numbers, production or expiry dates.



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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

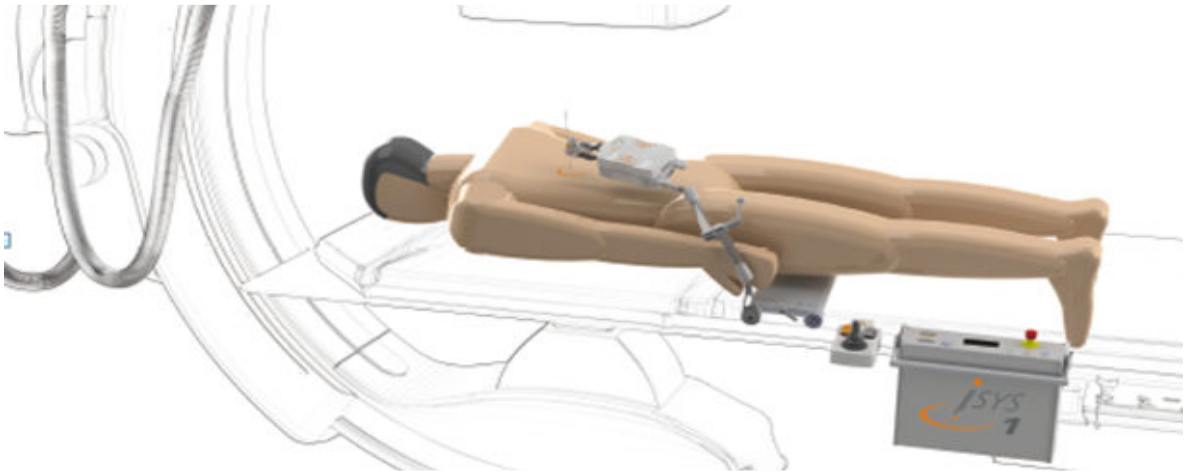
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

PD/B18	Proposed Labeling 510(k) Number:	iSYS Medizintechnik GmbH

User Manual

USER MANUAL US



iSYS Medizintechnik GmbH
Bergwerksweg 21
6370 Kitzbühel
Austria
www.isys.co.at

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Copyright Statement

© 2011 iSYS Medizintechnik GmbH.

All rights reserved. No part of this document may be reproduced in any form without written permission from the copyright holder.

Use of the information contained herein in any form and/or by any means whatsoever is strictly reserved for iSYS and its licensees.

Trademarks

iSYS, iSYS 1 and iSYS Medizintechnik GmbH or its subsidiaries are subject to filed trademark applications.

All rights reserved.

Acknowledgement of Other Trademarks

Other manufacturer's registered trademarks and trade names that appear in this document are hereby acknowledged.

Referenced Documents

Not all documents referred to in this document are part of the scope of delivery for the equipment.

iSYS reserves the right to determine which documents are delivered with a product.

Contact Information

Manufacturer

iSYS Medizintechnik GmbH

Bergwerksweg 21

6370 Kitzbühel

Österreich

Tel +43 (664) 2411140

www.isys.co.at

Representative USA

Cornelia Damsky

56 Westcott Road
Stamford, CT 06902
USA
Phone: +1 (203) 323-7535
Email: cdamsky@att.net

CE 0408

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Table of Contents:

1. Introduction 11
- **1.1. About this Manual 11**
- **1.2. Description of iSYS 1 ..... 11**
- **1.3. Intended Use 13**
- **1.4. Abbreviations 13**
- **1.5. Glossary 14**
- **1.6. Text Formats 15**

2. Safety 16
- **2.1. Warnings, Cautions and Notes 16**
- **2.2. Manual Handling Procedures 16**
- **2.3. Warning Labels 17**
  - *2.3.1. Safety Symbols 17*
  - *2.3.2. Product Identification Symbols 18*
  - *2.3.3. Additional Symbols 18*
- **2.4. Final Disposal 20**
- **2.5. EMC and Mobile Telephones 21**
- **2.6. Compatibility 26**
- **2.7. Compliance 26**
  - *2.7.1. IEC Safety Standards 26*
  - *2.7.2. IEC Classification 27*
- **2.8. Training 27**

3. Specifications 29
- **3.1. Environmental Conditions 29**
  - *3.1.1. Environmental Conditions for Transport and Storage 29*
  - *3.1.2. Environmental Conditions for the Intended Use 29*
- **3.2. Components 30**
  - *3.2.1. System iSYS 1 U.S. (Art.No. 6224) 30*
  - *3.2.2. Accessory – non sterile 33*
  - *3.2.3. Accessory - sterile: 34*
- **3.3. Technical Specifications 35**
  - *3.3.1. Robotic Positioning Unit 35*
  - *3.3.2. Control Unit 35*
  - *3.3.3. RPU Cable Set 1500 ..... 35*
  - *3.3.4. RPU Cable Set 3000 ..... 35*
  - *3.3.5. Handheld Control Unit 35*
  - *3.3.6. HCU Cable Extension 35*

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

3.3.7. Multi Functional Arm 35
3.3.8. Table Top Adapter Version B 36
3.3.9. Table Top Adapter Version A 36
3.3.10. Side Rail Adapter 36

4. Operating iSYS 1 37

4.1. Set-Up and Installation 38

4.1.1. Mounting of the (Radiolucent) Needle Guide Extension to the Robotic Positioning 39
4.1.2. Adaptation of the Table Adapters 41
4.1.3. Mounting of the Multi Functional Arm (MFA) 46
4.1.4. Mounting the Robotic Positioning Unit 48
4.1.5. Mounting the Control Unit to the Side Rail 49
4.1.6. Using the Control Unit without Side Rail 50
4.1.7. Adaptation of the Handheld Control Unit to the Side Rail 51
4.1.8. Connection of the Power and Data Cables 52
4.1.9. Bringing the RPU into the "Parking position" 56
4.1.10. Start-up Procedure of the iSYS 1 Robot 58

4.2. Use of iSYS 1 62

4.2.1. Checking the Mechanical Setup and the Range of iSYS 1 62
4.2.2. Setup and Preparing the Patient 63
4.2.3. Image Acquisition and Treatment Planning 65
4.2.4. Working with the sterile iSYS 1 Disposables 66
4.2.5. Attaching the Sterile Cover over the Robotic Positioning Unit 71
4.2.6. Attaching the Sterile Cover to the HCU 82
4.2.7. Gross-Positioning of the RPU and Insertion of the Sterile Needle Guide Marker Insert into the Needle Guide Adapter 83
4.2.8. Micro-Positioning and Accurate Alignment of the NGA under fluoroscopy 85
4.2.9. Attachment of the Needle Guide Insert and Needle Placement 90
4.2.10. Removing the NGI and Quick-Release 95

4.3. Emergency Release/ Removing the system in case of emergency 98

4.4. Dismounting 98

4.5. User Interface 100

4.5.1. Alarms 100
4.5.2. Front-Panel of the Control Unit 101
4.5.3. Handheld Control Unit 102
4.5.4. Display Messages 104

5. Maintenance 107

5.1. Safety-relevant inspections 108

6. Cleaning and Disinfection 110

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

1. Introduction

1.1. About this Manual

This manual is intended to assist users in the safe and effective operation of the equipment described. The term 'user' is used throughout this manual for both the body that has the authority over the equipment and those persons, who actually handle the equipment.

a) The term clinical user means a qualified person who uses any part of the device and its accessories for the purpose of treating patients, and who has been specifically trained in the safe clinical use of the device. Such treatment is restricted to being therapeutic in nature.

b) The term service user means a qualified service engineer who has been trained in servicing the device, and who operates any part of the device for the purpose of performing tests, adjustments and/or repairs to the equipment without, in any manner, involving the presence or treatment of a patient, and personnel who are involved in site planning and installation of the device.

Before attempting to work with this equipment, you must read, understand, note and, where applicable, strictly observe all danger notices, warnings, cautions and safety markings on the equipment and in this manual paying particular attention to all:

- Warnings
- Cautions
- Notes

Please pay special attention to all the safety information provided, and safety procedures described (see section 2).

The use of this equipment by unauthorized persons is strictly prohibited.

1.2. Description of iSYS 1

The iSYS 1 Interventional Platform is a modular needle guidance platform for interventional radiology and related fields.

Core components are a 4 DOF Robotic Positioning Unit which allows submillimetric needle positioning as well as angulation and a Control Unit which is controlled by a cable connected Handheld Control Unit.

The passive macro positioning unit and different table adapters allow different setups of the system around the patient in the region of interest by still providing maximum rigidity.

The needle-guide-set provides disposable components that ensure precise and sterile needle guidance.

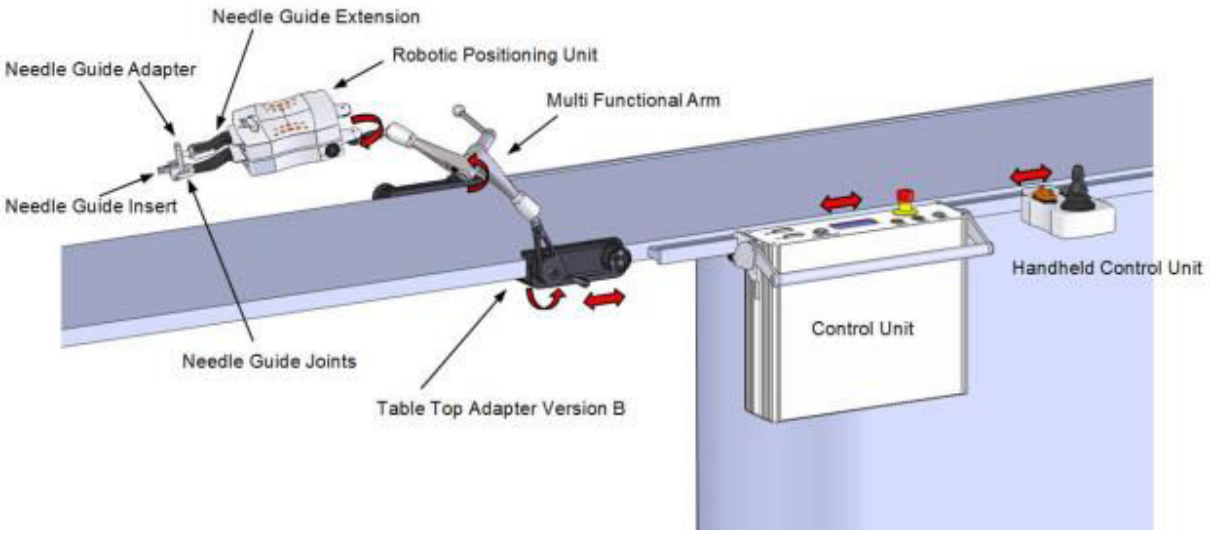
Planning of the intervention is based on digital image data acquired intra-operatively using different kinds of modalities, like CT or fluoroscopy (standard C-arms and/or cone-beam CT systems).

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Planning and verification of both the entry position of the needle-type tool as well as the angulation is performed with the aid of the used imaging device or by an external navigation system.

By using the iSYS 1 Handheld Control Unit the surgeon can remotely move the tool to the desired position and angulation in order to start the clinical procedure.



The system includes the following mechanical parts:

- one Control Unit
- one Table Top Adapter Version B (Bottom Mounted)
- optional: Side Rail Adapter or Table Top Adapter Version A (Top Mounted)
- one Multi Functional Arm
- one Robotic Positioning Unit
- two Needle Guide Extensions

The sterile disposables for each procedure are:

- Sterile Cover Robotic Positioning Unit (not reusable) including Needle Guide Joints and Needle Guide Adapter (not reusable)
- Sterile Cover Handheld Control Unit (not reusable)
- Needle Guide Insert (not reusable)
- Marker Insert (not reusable)

see description in chapter “3.2.4. Accessory – sterile”

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

1.3. Intended Use

The intended use of the iSYS 1 device is to function as a remote-operated positioning and guidance system during interventional procedures. Positioning is done in remote control manner; planning of the position/angulation is done based on 2D/3D patient data (CT, cone-beam CT, fluoroscopy) by external planning software – for example using an external navigation system, or planning software coming with the used imaging device. Also verification of the correct position and orientation of the tool prior to/during/after the intervention is done by means of these external devices. The iSYS 1 system is then acting as a guideway during the manual insertion of the interventional tool – usually a needle type device, and the like. Applications include, but are not limited to, interventions like biopsy procedures, tumor ablation, nerve blocking, electrode placement, etc.

1.4. Abbreviations

The following are abbreviations and acronyms which are used in this document. Their definition is explained below.

Abbreviation	Definition
AC	Alternating current
ASCII	American Standard Code for Information Interchange
AM	Amplitude modulation
CT	Computed tomography
CU	Control Unit
DOF	Degree of Freedom
EMC	Electromagnetic compatibility
FM	Frequency modulation
HCU	Handheld Control Unit
IEC	International Electrotechnical Commission
iSYS	iSYS Medizintechnik GmbH
LCD	Liquid crystal display
LED	Light emitting diode
MFA	Multi Functional Arm
MRI	Magnet resonance imaging
N/A	Not applicable

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Abbreviation	Definition
NGA	Needle Guide Adapter
NGE	Needle Guide Extension
NGI	Needle Guide Insert
NGMI	Needle Guide Marker Insert centered
OR	Operating room
ÖVE	Österreichischer Verband für Elektrotechnik (*Austrian* Electrotechnical Committee)
RF	Radio frequency
RM	Robotic Module
RPU	Robotic Positioning Unit
SRA	Side Rail Adapter
TTAA	Table Top Adapter Version A - Top Mounted
TTAB	Table Top Adapter Version B - Bottom Mounted
TV	Tele-vision
WxH	Width and height

Table 1-1: Abbreviations and Acronyms

1.5. Glossary

Throughout this manual, the following terms have the specific meaning listed below.

Term	Definition
Imaging device	(Medical) Imaging devices are devices used to create images of the human body (or parts and function thereof) for clinical purposes. Imaging modalities for iSYS 1 include CT or fluoroscopy (standard C-arms and/or cone-beam CT systems).
Gantry	In medical imaging, the Gantry is a circular assembly that allows sensors, and possibly energy sources, to rotate around a patient.
Treatment Table	Also called “Imaging Table” or “Treatment Couch”. Table system of the imaging device. Usually this table has a number of degrees of freedom (DOF) – e.g. for vertical and horizontal movement – in order to preposition the

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Term	Definition
	patient relatively to the imaging arm.
(Carbon fiber) Table Top	Upper part of the Treatment Table. This part of the table usually is made of radiolucent material – in most cases CFRP (carbon-fiber-reinforced plastic).
Side Rail	Most Treatment Tables have a (metal) on the rail left and right side along the table in order to fix components. Depending on the producer of the table these Side Rail setups may differ from each other, for most of the table systems the Side Rail has a rectangular cross section.
Treatment Planning	During Treatment Planning, the surgeon is using pre-operative or intra-operative imaging in order to select the target position for the tool (e.g. the tumor to be treated) as well as the tool trajectory from the skin entry point to the target position. Depending on the used Imaging device such Treatment Planning can be done using 2D or 3D images.

Table 1-2: Glossary

1.6. Text Formats

The following text formats may be found in this document. Their definitions are explained below.

Text Format	Definition
italic	notes
CAPS	symbol names
courier	text displayed on screens

Table 1-3: Text Formats

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

2. Safety

2.1. Warnings, Cautions and Notes

The following are examples of how warnings, cautions and notes will appear throughout this document. The text within the examples explains their purpose.

WARNING
Warnings are directions which, if not followed, could constitute a health hazard or cause injury, including fatal or serious injury, or could lead to clinical mistreatment.

CAUTION
Cautions are directions which, if not followed, could cause damage to the equipment described in this manual, and/or any other equipment or goods, and/or could cause environmental damage.

Note:	*Notes provide advice and highlight unusual points. A note is not intended as an instruction.*

2.2. Manual Handling Procedures

WARNING
When lifting heavy components, it is important that the correct procedures are adhered to. Local regulations and procedures regarding manual handling must be observed at all times. Failure to do so may lead to fatal or serious personal injury.

WARNING
If any liquids are spilled over components of the iSYS 1, the component needs to be dried in a drying case for at least 24 hours.

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

2.3. Warning Labels

2.3.1. Safety Symbols

STERILE R	Symbol for STERILIZED USING RADIATION
	Symbol for DO NOT USE IF PACKAGE IS DAMAGED
	Symbol for DO NOT REUSE
MR	Symbol for NOT MRI SAFE
	Symbol for ALTERNATING CURRENT
	Symbol for CAUTION, CONSULT ACCOMPANYING DOCUMENTS
	Symbol for TYBE B APPLIED PART
	Symbol for ON/OFF SWITCH (PUSH-PUSH) Power Switch
	Symbol for PROTECTIVE EARTH
	Symbol for STORAGE TEMPERATURE

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

	Symbol for DO NOT LITTER IN DOMESTIC WASTE

2.3.2. Product Identification Symbols

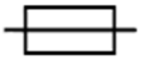
SN	Symbol for SERIAL NUMBER
REF	Symbol for ORDER NUMBER
LOT	Symbol for BATCH NUMBER

2.3.3. Additional Symbols

CE	Symbol for CE-conformity
+	Symbol for PLUS (increase speed level)
–	Symbol for MINUS (decrease speed level)
	Symbol for POSITIONING
	Symbol for ANGULATION
READY	Label for the ready indicator light
ERROR	Label for the error indicator light
POWER	Label for the power indicator light

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

USER INTERFACE	Label for the user interface connector
	Symbol for the confirm push button
	Symbol for the quit push button
	Symbol for MANUFACTURER
	Symbol for DATE OF MANUFACTURE
	Symbol for USE BY
	Symbol for FUSE
	Symbol for KEEP DRY
	Symbol for THIS SIDE UP
	Label for the Weight
iSYS Medizintechnik GmbH	Company Label

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

2.4. Final Disposal

Final disposal means the disposal of the equipment or any part of it in such a way that it can no longer be used for its intended use.

Disposal must always be executed in an environmentally sensitive manner that complies with all local and international regulations and laws. Materials hazardous to human health and the environment must be separately removed and disposed of by competent, licensed facilities. The remaining material may be recycled, where facilities and local regulations permit this.

Never dispose iSYS products in the domestic waste stream.

Prior to disposal, always contact iSYS Medizintechnik GmbH for advice and a list of the substances that require special attention.

WARNING
Incorrect handling or disposal of hazardous material may cause fatal or serious injury and environmental damage. Always disposit iSYS 1 and its components according to the regional regulations.

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

2.5. EMC and Mobile Telephones

The iSYS 1 system is compliant with the requirements according

EN 60601-1-2:2007 and FCC: 47 CFR Part 15:

Guidance and manufacturer's declaration – electromagnetic emissions		
iSYS 1 is intended for use in the electromagnetic environment specified below. The customer or the user of iSYS 1 should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions CISPR 11	Group 1	iSYS 1 uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	iSYS 1 is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Not applicable	

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Guidance and manufacturer's declaration – electromagnetic immunity			
iSYS 1 is intended for use in the electromagnetic environment specified below. The customer or the user of iSYS 1 should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment –guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines ±2 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV line(s) to line(s) ±2 kV line(s) to earth	±1 kV line(s) to line(s) ±2 kV line(s) to earth	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % U_T (>95 % dip in U_T) for 0,5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % UT (>95 % dip in U_T) for 5 sec	<5 % U_T (>95 % dip in U_T) for 0,5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % UT (>95 % dip in U_T) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of iSYS 1 requires continued operation during power mains interruptions, it is recommended that the iSYS 1 be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Note U_T is the AC mains voltage prior to application of the test level.			

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Guidance and manufacturer's declaration – electromagnetic immunity			
iSYS 1 is intended for use in the electromagnetic environment specified below. The customer or the user of iSYS 1 should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment –guidance**
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 Vrms 150 kHz to 80 MHz 3 V/m 80 MHz to 2,5 GHz	10 Vrms 150 kHz to 80 MHz 10 V/m 150 kHz to 80 MHz	Portable and mobile RF communications equipment should be used no closer to any part of iSYS 1 including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d = 0{,}35\sqrt{P}$ $d = 0{,}35\sqrt{P}$ 80 MHz to 800 MHz $d = 0{,}70\sqrt{P}$ 800 MHz to 2,5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[a], should be less than the compliance level in each frequency range[b.] Interference may occur in the vicinity of equipment marked with the following symbol:

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Note 1 At 80 MHz and 800 MHz, the higher frequency range applies.

Note 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which iSYS 1 is used exceeds the applicable RF compliance level above, iSYS 1 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating iSYS 1.

[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 10 V/m.

Recommended separation distances between portable and mobile RF communications equipment and iSYS 1

iSYS 1 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of iSYS 1 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and iSYS 1 as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	**Separation distance according to frequency of transmitter** m		
	150 kHz to 80 MHz $d = 0{,}35\sqrt{P}$	**80 MHz to 800 MHz** $d = 0{,}35\sqrt{P}$	**800 MHz to 2,5 GHz** $d = 0{,}70\sqrt{P}$
0,01	0,035	0,035	0,07
0,1	0,11	0,11	0,22
1	0,35	0,35	0,70
10	1,11	1,11	2,21
100	3,50	3,50	7,00

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

Note 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Note 2	These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

The iSYS 1 system requires special precautions regarding EMC and must be installed and put into service in accordance with the EMC information provided in the accompanying documents.

WARNING
The iSYS 1 system should not be used adjacent to or stacked with other equipment. If the iSYS 1 system is used while positioned adjacent to other equipment, it should be observed to verify normal operation in the configuration in which it will be used.

CAUTION
Class A Equipment – iSYS 1 is not suitable for use in domestic establishments and establishments directly connected to a low voltage power supply network which supplies buildings used for domestic purposes.

WARNING
Portable and mobile RF communications equipment can affect medical electrical equipment.

WARNING
Do not allow any radio-transmitting devices (such as mobile phones, diathermy units, etc.) or devices exceeding the limits defined in the applicable EMC standards in the vicinity of the iSYS 1 system.
Such devices could exceed EMC standards and in unusual circumstances could interfere with the correct functioning of the iSYS 1 system. This could lead to fatal or serious injury, clinical mistreatment, or equipment damage.

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

CAUTION
The use of cables and other components not specified and/or not supplied by iSYS may adversely affect the EMC performance.

2.6. Compatibility

Equipment described in this manual shall only be used in combination with other equipment or components, if these are expressly approved by iSYS as compatible. A list of such equipment and components is available from iSYS upon request.

Changes and/or additions to the equipment shall only be carried out by persons expressly authorized by iSYS to do so. Such changes shall comply with best engineering practice and all applicable laws and regulations that have the force of law within the jurisdiction the equipment will be used within.

WARNING
Changes, additions or maintenance to the equipment carried out by persons without appropriate qualifications and training and/or using unapproved spare parts may lead to fatal or serious personal injury and/or damage to the equipment as well as making the warranty void.

2.7. Compliance

Note:	*The iSYS 1 system has been designed and tested for compliance when used in the clinical environment only.*

The iSYS 1 system is designed to comply with internationally recognized standards for safety and performance.

2.7.1. IEC Safety Standards

The iSYS 1 system complies with the following IEC Safety Standards:

- IEC 60601-1 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2 Medical electrical equipment – Part 1-2: General requirements for safety – Collateral standard: Electromagnetic compatibility – Requirements and tests
- IEC 60601-1-6 Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral Standard: Usability

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

- IEC 60601-1-8 Medical electrical equipment – Part 1-8: General requirements for basic safety and essential performance – Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems

2.7.2. IEC Classification

According to the above listed IEC standards, the iSYS 1 system is classified as set out in the table below:

Type of protection against electric shock	Class I
Degree of protection against electric shock	Type B (the RPU is rated as type B and the needle/tool guided by the system is seen as applied part according IEC 60601-1)
Degree of protection provided by enclosures	IP2X as defined in IEC 60529. (protection against ingress of solid objects with diameter larger than 12,5 mm, no protection against ingress of liquids).
Methods of disinfection recommended by the manufacturer	Disinfected equipment (or elements). See section 6 Cleaning and for methods.
Degree of safety of application in the presence of flammable anesthetic mixture with air or with oxygen or with nitrous oxide	Equipment NOT suitable for use in the presence of a flammable anesthetic mixture with air or with oxygen, or nitrous oxide.
Mode of operation	Continuous

Table 2-2: IEC Classification

Explanation of the classification:

A “Class 1 electrical shock classification” means that the iSYS 1 system must be powered via a power cable connected to a protective earth ground.

2.8. Training

Before using the system at the patient, the user must feel confident with the system and therefore adequate training with the system is mandatory.

Training requirements may vary from country to country. Please make sure that you have received enough training without patient and that you are confident with the use of the system (in accordance with local laws or regulations that have the force of law). Information on training is available from the local iSYS representative.

Purpose of the training:

- Learn the safe use of the system.
- Guarantee a safe and fast workflow.

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

- Learn how to manipulate the NGA with the joystick in 3D. This step is crucial for precise needle alignment.
- The user has to learn the functionality of the joystick and to learn the intuitive use of the joystick.

Important note:

- The user needs to understand how she/he wants to integrate the use of iSYS 1 into the overall workflow of the treatment process: Therefore it is mandatory not just to understand how the system works as a standalone, but also how the system interferes with the overall workflow.
- To avoid complications (setup failures for the specific applications, time consuming breaks that lead to inaccuracy and/or additional radiation, etc.) in the overall workflow and overall setup, it is strongly recommended to train the overall workflow as well.

If problems occur or questions remain, please contact iSYS.

WARNING
The iSYS 1 system and its accessories may only be operated by qualified and authorised personnel. 'Qualified' personnel in this case mean personnel which have been approved to operate medical electrical devices by the responsible management of the clinical environment using the iSYS 1 system.

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

3. Specifications

Electrical installations in the room where the iSYS 1 system is used must comply with the following regulations (in other countries the equivalent standards) where applicable:

- ÖVE EN7
- ÖVE EN1
- ÖVE ÖNORM E8007
- ÖVE ÖNORM E8001

3.1. Environmental Conditions

3.1.1. Environmental Conditions for Transport and Storage

CAUTION
Noncompliance with stated transport and storage conditions may result in damage to the iSYS 1 system. In this case it is essential to completely dry the components of the iSYS 1 system for at least 24 hours and check the functionality of the system before using.

The environmental conditions for transport and storage of the iSYS 1 system are specified in table 3-1.

Ambient temperature	+10°C to +50°C (50°F to 122°F)
Relative humidity	30% to 70%, non-condensing (no outdoor storage)
Atmospheric pressure	800 mbar to 1100 mbar

Table 3-1: Environmental conditions for transport and storage

3.1.2. Environmental Conditions for the Intended Use

The environmental conditions for the intended use of the iSYS 1 system are specified in table 3-2.

Ambient temperature	15°C to 30°C (59°F to 96°F)
Relative humidity	30% to 70%, non-condensing
Atmospheric pressure	800 mbar to 1100 mbar
Max. operating altitude	2000m (6560 ft)

Table 3-2: Environmental conditions for the intended use

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

3.2. Components

WARNING
iSYS 1 must only be used in combination with accessory described in this manual. Other equipment or components shall only be used, if these are expressly approved by iSYS as compatible. A list of such equipment and components is available from iSYS upon request.

The following tables show the single components of the iSYS 1 system, including optional components for variation of the system according to the user's particular requirements. For further details regarding these optional components please contact iSYS Medizintechnik GmbH.

3.2.1. System iSYS 1 U.S. (Art.No. 6224)

Name	Picture	Article-No.:	Standard/ Optional/	Description
Robotic Positioning Unit (RPU):		3908	Standard	Robotic Positioning Unit with two 2DOF modules which allows - in combination with the Needle Guide Set - tool angulation (± 30° for both pitch and yaw angle) and needle positioning (± 20 mm for both lateral and longitudinal direction).
Needle Guide Extension 20mm (NGE)		4965	Standard	The Needle Guide Extension comprises two cranked "fingers" which are connected to the Robotic Positioning Unit by screws. This standard version provides an offset of 20mm between the bottom edge of the RPU and the NGE. The "fingers" are made out of radiolucent plastic and thus do not cause imaging artifacts.
Control Unit (CU):		6254	Standard	The iSYS 1 Control Unit aims to control the iSYS 1 Robotic Positioning Unit. The CU is integrated into a metal rack and can be attached to the side rail of the treatment table by a simple locking mechanism. It is designed to interface with a standard OR siderail with the following

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

				dimensions: (WxH) 10 mm x 25 mm.
RPU Cable Set:		3926 5905	Standard Standard	Set of two cables to connect the CU and RPU. 3926 - RPU Cable Set 1500 mm 5905 - RPU Cable Set 3000 mm
Handheld Control Unit (HCU):		3901	Standard	The Handheld Control Unit comprises a 2-axis joystick as well as confirmation and control buttons for remote operation of the RPU from "safe" distance. A simple locking mechanism allows the attachment to the side rail. A sterile cover for the Handheld Control Unit is also available. It is designed to interface with a standard OR siderail with the following dimensions: (WxH) 10 mm x 25 mm.

Name	Picture	Article-No.:	Standard/ Optional/	Description
Multi Functional Arm (MFA):		4271	Standard	Single-lever passive multi-functional arm for flexible pre-positioning of the iSYS 1 Robotic Positioning Unit. There are two different connectors: the “Starburst”-adapter connects the MFA to the different table adapters; the “Spoon”-adapter connects the MFA to the RPU.
Table Top Adapter Version B - Bottom Mounted (TTAB):		4120	Standard	Mechanical adapter for safe and stable connection of the MFA directly to a standard C-Arm Couch Top; It is mounted from the bottom of the Couch Top. This adapter is designed to interface with a carbon fiber table top with the following dimensions: Width between 470 mm and 530 mm Maximal thickness of the table: 6 mm (at the border)

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

				and 38mm (in the middle of the table)
Table Top Adapter Version A - Top Mounted (TTAA):		4117	Optional	Mechanical adapter for safe and stable connection of the MFA directly to a standard C-Arm Couch Top; The Table Top Adapter Version A – Top Mounted is mounted from the top and provides maximum stability. This adapter is designed to interface with a carbon fiber table top with the following dimensions: Width between 470 mm and 530 mm Maximal thickness of the table: 6 mm (at the border)
Transport box		6098	Standard	Transport box
Power Cord:		6163	Standard	Power cord (U.S.) length 2500 mm

Table 3-3: iSYS 1 U.S. System

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

3.2.2. Accessory – non sterile

Name	Picture	Article-No.:	Standard/ Optional/	Description
Table Top Adapter Version A - Top Mounted (TTAA):		4117	Optional	Mechanical adapter for safe and stable connection of the MFA directly to a standard C-Arm Couch Top; The Table Top Adapter Version A – Top Mounted is mounted from the top and provides maximum stability. This adapter is designed to interface with a carbon fiber table top with the following dimensions: Width between 470 mm and 530 mm Maximal thickness of the table: 6 mm (at the border)
Side Rail Adapter (SRA):		4095	Optional	Adapter to connect the MFA to a standard side rail. The extension with a metal rod is possible if needed. The rod is inserted and into the adapter and fixed with a screw. The Starburst connector is located at the end of the rod as well as on the adapter itself. This adapter is designed to interface with a standard OR side rail with the following dimensions: (WxH) 10 mm x 25 mm
HCU Cable Extension:		6162	Optional	HCU Cable Extension

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

3.2.3. Accessory - sterile:

Name	Picture	Article No.	Disposable	Description
Sterile Cover RPU - sterile for US:		4874US	Disposable	It is a disposable sterile component to cover the RPU and part of the MFA and RPU Cable Set. This assembly consists of a Sterile Drape (Nr. 10375) and the Needle Guide Kit (Nr. 10374) (including 2 Needle Guide Joints with Fixation Rings). Needle Guide Joints allow a quick and reversible connection of the Needle Guide Adapter to the Needle Guide Extension.
Sterile Cover HCU - sterile for US:		4883US	Disposable	It is a disposable sterile component to cover the HCU during operation.
Needle Guide Marker Insert centered - sterile for US:		4876US	Disposable	The Needle Guide Marker Insert (sterile) allows precise and remote-controlled alignment of the Needle Guide based on real-time imaging data.
Needle Guide Insert xxG - sterile for US:		6289G10US 5990G11US 5991G12US 5992G13US 5993G14US 4877G15US 4878G16US 4879G17US 4880G18US 5989G19US 4881G20US 4882G21US	Disposable	During the intervention the tool is inserted and guided by the sterile Needle Guide Insert. Needle Guide Insert – 10G Needle Guide Insert – 11G Needle Guide Insert – 12G Needle Guide Insert – 13G Needle Guide Insert – 14G Needle Guide Insert – 15G Needle Guide Insert – 16G Needle Guide Insert – 17G Needle Guide Insert – 18G Needle Guide Insert – 19G Needle Guide Insert – 20G Needle Guide Insert – 21G

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

3.3. Technical Specifications

3.3.1. Robotic Positioning Unit

Range of Motion: 40 mm x 40 mm (for each Robotic Module)
Max. Force: 35 N
Dimensions: 266 mm x 139 mm x 68,5 mm
Weight: 1,35 kg

3.3.2. Control Unit

Dimensions: 360 mm x 406 mm x 147 mm
Side rail dimensions: 10 mm x 25 mm
Weight: 5,8 kg
Power rating: 230 V ~
50-60 Hz
50 VA
Fuse rating: 2x T1AL 250 V
Alarm Beeper: approx. 55 dB (A) in a distance of 1 m
Power supply cord: 3x min. 1 mm²; max. length 5 m

3.3.3. RPU Cable Set 1500

Cable length: 1,5 m

3.3.4. RPU Cable Set 3000

Cable length: 3,0 m

3.3.5. Handheld Control Unit

Dimensions: 187 mm x 107 mm x 122 mm
Side rail dimensions: 10 mm x 25 mm
Weight: 0,85 kg
Cable length: 3 m

3.3.6. HCU Cable Extension

Cable length: 10 m

3.3.7. Multi Functional Arm

Dimensions: 500 mm x 105 mm x 145 mm
Weight: 1,36 kg

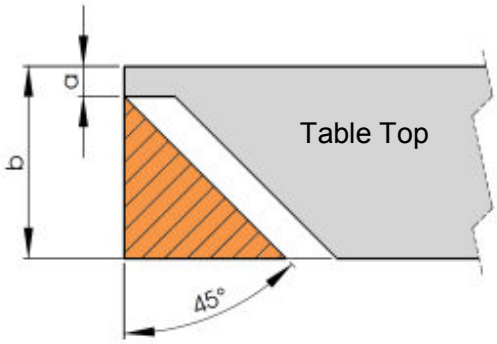
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

3.3.8. Table Top Adapter Version B

Dimensions: 614 mm x 190 mm x 59 mm
Weight: 2,98 kg

Table Top requirements:
Min. table top width: 466 mm
Max. table top width: 535 mm
Min. (a): 3,5 mm
Max. (a): 6 mm
Max. (b): 38 mm



(a) Thickness of the Table Top at the border
(b) Height of the Table Top
Table Top must not reach the orange marked area.

3.3.9. Table Top Adapter Version A

Dimensions: 614 mm x 190 mm x 45 mm
Weight: 2,39 kg

Table Top requirements:
Min. table top width: 466 mm
Max. table top width: 535 mm
Min. (a): 3,5 mm
Max. (a): 6 mm

3.3.10. Side Rail Adapter

Dimensions: 230 mm x 82 mm x 120 mm (without Extension Rod)
610 mm x 45 mm x 25 mm (with Extension Rod)
Side rail dimensions: 10 mm x 25 mm
Weight: 3,29 kg

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

4. Operating iSYS 1

This chapter describes the assembling and operation of the components of the iSYS 1 system. Please be aware that not every type of setup can be described in detail, but with the possibilities described (see below) you should be able to create your desired setup.

WARNING
Never use equipment that is damaged or appears to be working not properly.

WARNING
Never try to touch parts inside of components when operating iSYS 1. Never put your finger in openings. Danger of damage by mains voltage.

WARNING
Always make sure that all components of the hardware setup of iSYS 1 are not causing any collisions with moving parts and/or the gantry of the imaging device.
Therefore, move the gantry and all other moving parts of the imaging device carefully and manually in all desired positions and check for potential collisions before you start the treatment.
Repeat this whenever you have changed the hardware setup of iSYS 1.

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

4.1. Set-Up and Installation

For correct system use and an efficient clinical workflow, please follow the Set-Up and Installation instructions below.

WARNING
Check the power supply cord and plug. Should the power supply cord or plug be damaged, the iSYS 1 system must not be used!

CAUTION
Check the mechanical stability of the setup while setting up the iSYS 1 system!

WARNING
Do not use the iSYS 1 setup in MRI environment.

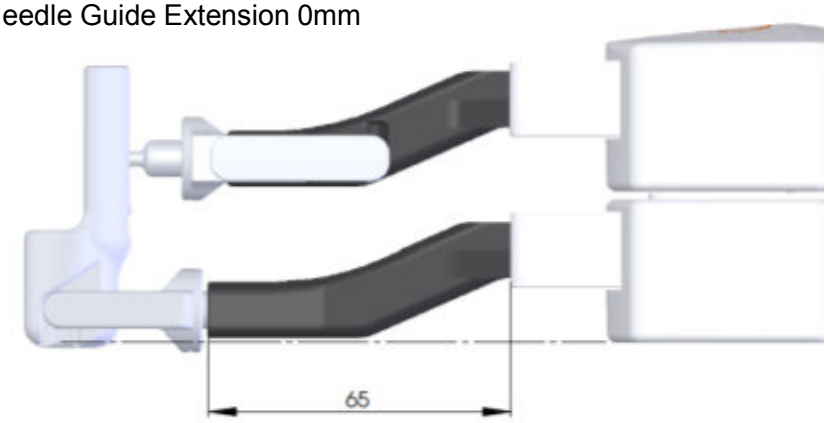
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

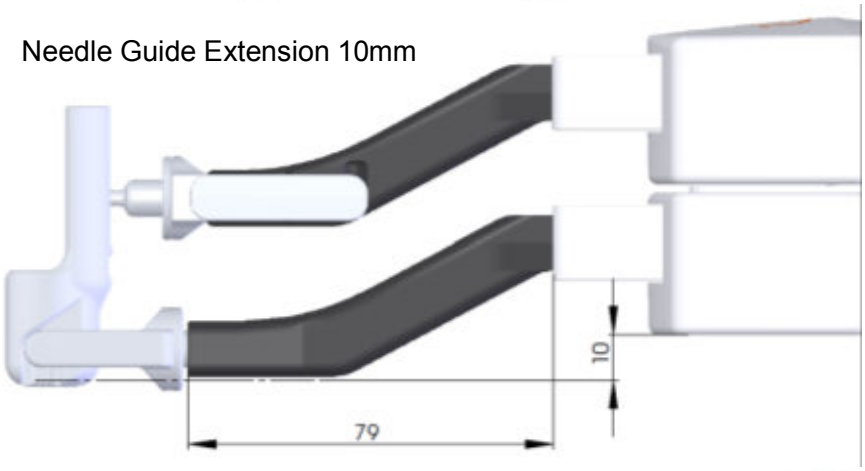
4.1.1. Mounting of the (Radiolucent) Needle Guide Extension to the Robotic Positioning

For the iSYS 1 system different types of Needle Guide Extension are available that differ in offset and length. The system is delivered ready for use with already mounted NGE.

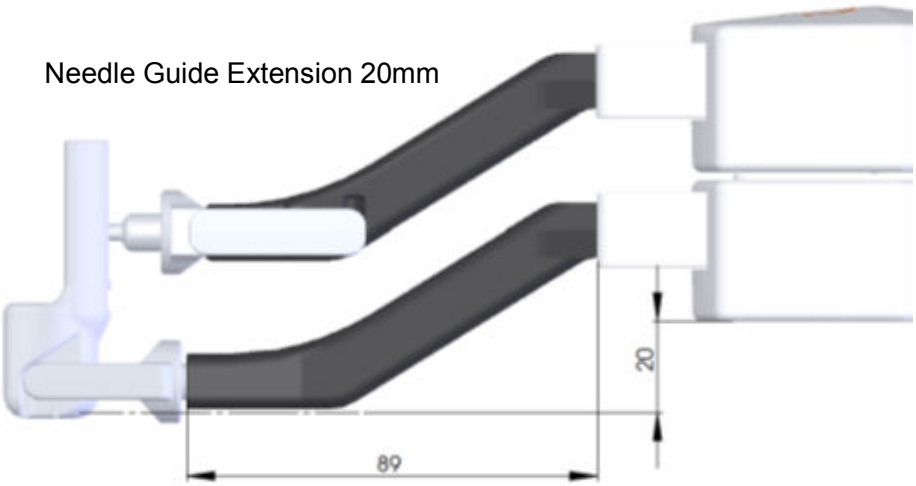
Needle Guide Extension 0mm



Needle Guide Extension 10mm



Needle Guide Extension 20mm



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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Note:	*This setup step is only optional and needs to be done in case the user wants to use a different type of NGE (see descriptions of the NGE above).* *This procedure is performed with the robotic unit only, and can be done outside the treatment room.*

WARNING
The mounting of the (radiolucent) Needle Guide Extension to the Robotic Positioning Unit can only be done by a professional iSYS technician. There has to be done a SW-modification. If you want to change the needle NGE, please contact iSYS Medizintechnik GmbH.

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

4.1.2. Adaptation of the Table Adapters

For attachment of the Robotic Positioning Unit to the imaging table, iSYS is offering three solutions (a, b and c).

Depending on the type of imaging table and the (carbon fiber) table top, one or more of the below described adapter solutions (a, b and c) can be used.

Note:	*Every table adapter offers different features and setup possibilities, depending on the region of interest and the type of intervention.*

CAUTION
Make sure that the treatment couch and/or the table top fulfills the interface requirements for the adapters!
- **Side rail payload: min. 20 kg**
- **Side rail size: 10 mm x 25 mm (WxH)**

In case you are not sure which adapter you can use (or the user manual of the treatment couch and/or the table top manufacturer does not give you the required information), please ask the service technician of the table/couch top manufacturer or contact iSYS for professional advice!

CAUTION
Be aware that the setup does not block intended movements of the table.

WARNING
All table adapters contain metal parts/material and thereof cause imaging artefacts if they are in the field of view of the X-ray beam. Make sure the adapters are outside the field of view of the imaging device!

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

WARNING
For all types of adapters, the following setup rules are essential:

- **Always make sure that the levers are locked properly and that the adapter provides a solid, clearance-free connection to the table!**
  This is not only essential for the accuracy of the final tool placement – any undesired movement of the mechanical setup also is a potential risk for mistreatment or may cause injuriy to the patient!

- **Always perform a manual stability-test (by pushing or pulling the adapter in different directions):**
  The adapter must maintain the position, must not slip and the setup must not wobble!

- **Make sure that the treatment couch and the adapter are permanently fixed to each other. In case you want to move the table with the patient on it, the adapter has to follow this movement!**
  This is not only essential for the accuracy of the tool placement. Failures in the mechanical setup are a potential risk for mistreatment and may cause injuriy to the patient!

- **Be aware that other devices mounted nearby the Table Adapter or the influence of persons may decrease the mechanical stability.**

- **Be aware, that by opening the locking-levers too far, the adapter may not be safely locked and the adapter/setup may drop and this can cause damage to the system or harm the patient!**

WARNING
Make sure that the table is properly fixed before attaching the components of the iSYS 1 system.

WARNING
If the Side Rail Adapter is being used please make sure that the side rail is firmly connected to the treatment table before attaching any of the iSYS 1 components.

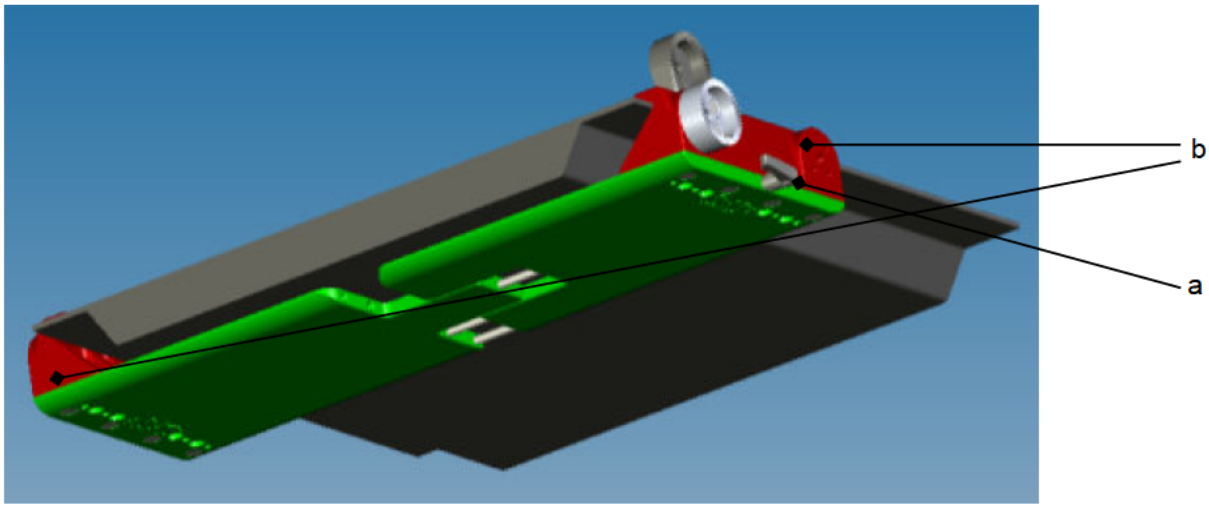
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

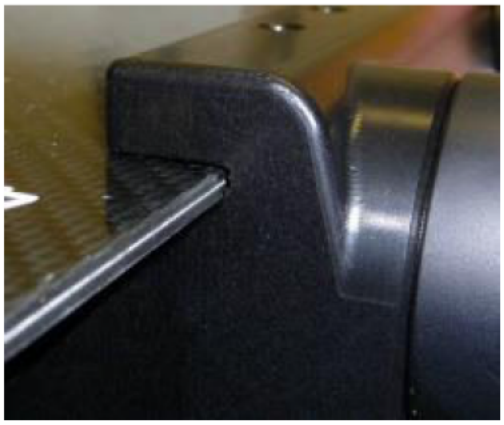
a. Mounting of the Table Top Adapter (Version B - Bottom Mounted)

Open the lever (a) of the Table Top Adapter as far that the clamping jaws (b) can grab the edges of the couch top of the treatment table as shown in the picture below.

By turning the lever clockwise, the clamping jaws (b) of the Table Top Adapter clutch the lateral edges of the table top and thus the adapter is fixed to the table.



The following picture shows the connection between the clamping jaw and the lateral edge of the (carbon) table top.



Once the adapter is locked to the table, it functions as a rigid adapter for the MFA.

If the adapter is not tightened, it can glide and be positioned easily in different positions on the table top.

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

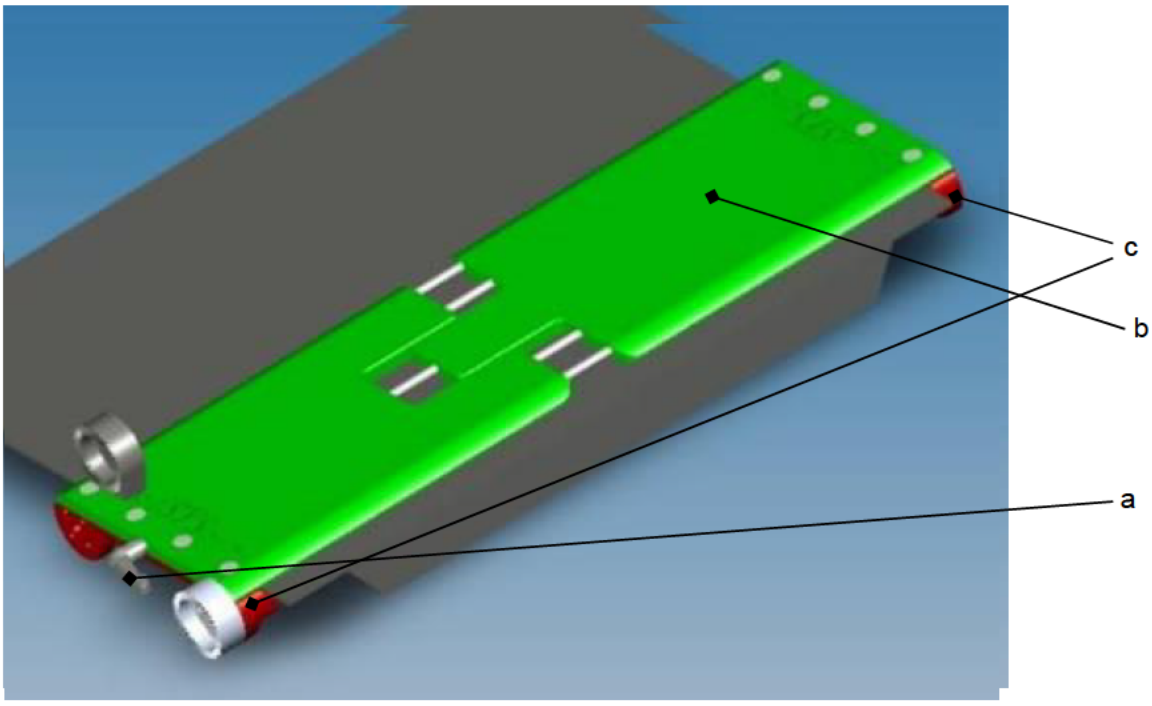
Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

WARNING
Never open the adapter so far that the adapter can fall down.

b. Mounting of the Table Top Adapter (Version A - Top Mounted)

Open the lever (a) of the Table Top Adapter so that the adapter plate (b) can be located on top of the couch top of the treatment table.

By turning the lever (a) clockwise, the clamping jaws (c) of the Table Top Adapter clench the lateral edges of the table top and the adapter is fixed to the table.



Once the adapter is locked to the table, it functions as a rigid adapter for the MFA.

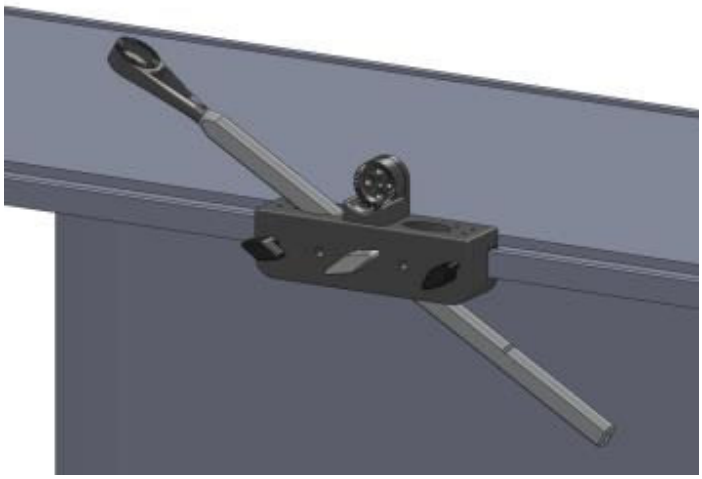
If the adapter is not tightened, it can glide and be positioned easily in different positions on the table

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

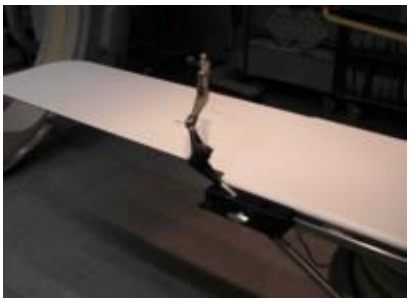
Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

c. Mounting the Side Rail Adapter to the Side Rail of the Imaging Table

Attach the Side Rail Adapter to the side rail of the treatment table as shown below:



By turning the black levers clockwise, the adapter is rigidly attached to the side rail.

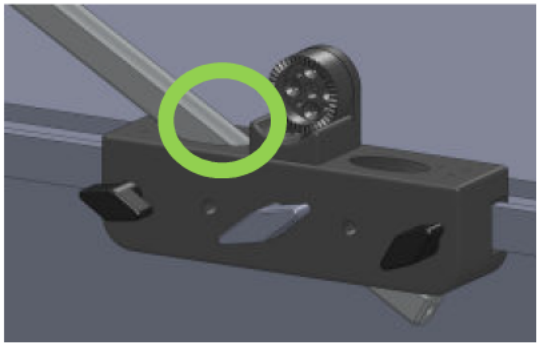


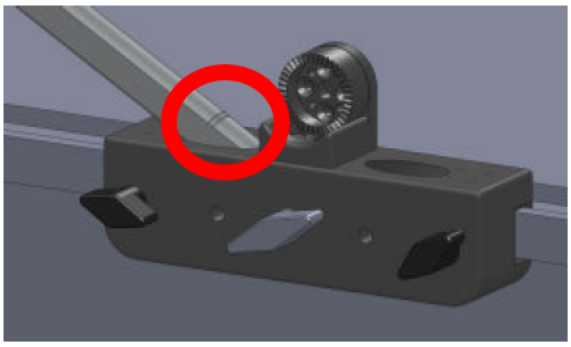
The height of the extension rod can be adjusted by opening and locking the middle lever.

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

WARNING
Make sure that the markings on the extension rod are not visible!





4.1.3. Mounting of the Multi Functional Arm (MFA)

Attach the MFA to one of the Starburst-adapters available on the Table Top Adapter or Side Rail Adapter.

Starburst-adapter

Turn the lever of the Starburst-adapter till the arm is tightly locked to the table adapter.

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

WARNING
Whenever the MFA is mounted or the position of the MFA is being changed (opening and locking) the stability has to be verified with a simple test:
push/pull the Spoon of the MFA or the Robotic Unit gently and check if the MFA and the attached components remain in their position.
Always be aware that the stability of the setup depends on the tightening force of the lever at the MFA.

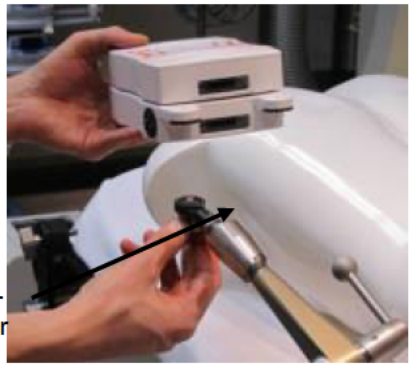
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

4.1.4. Mounting the Robotic Positioning Unit

Attach the Spoon-adapter at the Robot Positioning Unit to the MFA as shown below:

Spoon-adapter



Turn the lever of the Spoon-adapter till the Robot Positioning Unit is tightly locked to the MFA.

WARNING
Always make sure that the levers are locked strong enough and that the mechanical interfaces guarantee a solid, clearance-free connection to each other! This is essential for the treatment, because without high mechanical stability no high accuracies can be achieved with the Robot Positioning Unit!
With a simple manual stability test (by pushing or pulling the RPU carfully in different directions) the rigidity of the mechanical setup can be tested:
The RPU must maintain its position, must not slip and it must not wobble!

WARNING
Whenever the mechanical setup is changed, make sure that the components of iSYS 1 do not cause collisions with the gantry, with the treatment table or with any other part of the imaging device!

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

4.1.5. Mounting the Control Unit to the Side Rail

CAUTION
If iSYS 1 or components are attached to the side rail of a table, ensure that the side rail is capable of carrying the weight. Refer to section 3 for technical data.
Please verify also if the connection of the side rail to the table is tight and does not wobble.

WARNING
Do not cover the front panel of the Control Unit or the display to make sure that any safety-relevant information can be recognized.

Move the CU to the side rail of the table with the handle in straight up position. Hang the unit on the side rail and close the locking mechanism by turning down the handle.

WARNING
Make sure the Control Unit is safely locked to the side rail of the treatment couch.

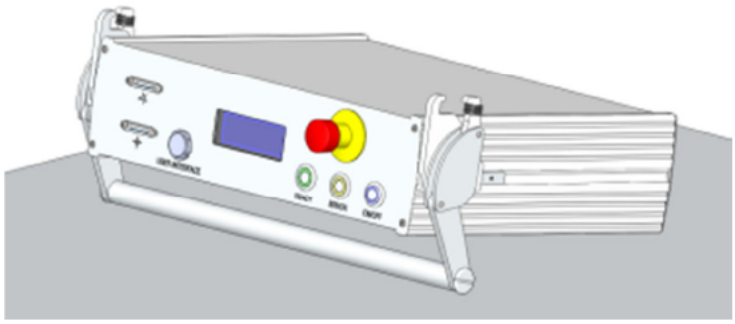
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

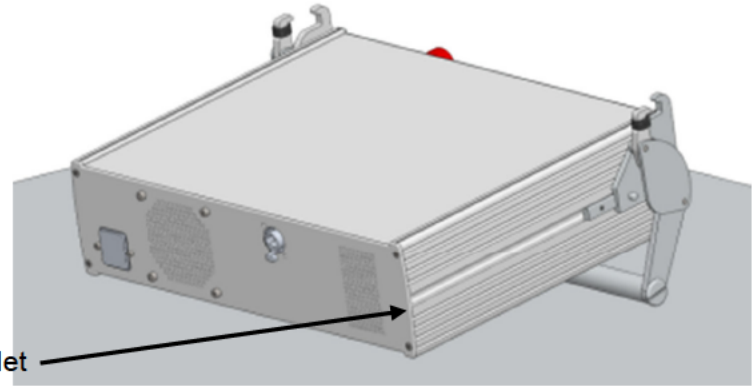
Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

4.1.6. Using the Control Unit without Side Rail

When there is no side rail available make sure the Control Unit is placed on a stable and flat surface which is capable of carrying its weight.

Use the handle as a support as shown in the picture below.





WARNING
Place the Control Unit so that no direct airflow to the patient or sterile areas occur. Otherwise the fan may blow non sterile air to the sterile area.

WARNING
You must pay special attention to the stability of the placement of the Control Unit and the cable routing. Carelessness may lead to falling down of components and harm patient or user.

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

4.1.7. Adaptation of the Handheld Control Unit to the Side Rail

CAUTION
If iSYS 1 or components are attached to the side rail of a table, ensure that the side rail is capable of carrying the weight. Refer to section 3 for technical data.
Please verify also if the connection of the side rail to the table is tight and does not wobble.

Hold the upper orange button pressed and attach the HCU to the side rail of the treatment couch as shown below.

After release of the upper orange button, the HCU is locked to the side rail.

Now the mechanical setup is finished.

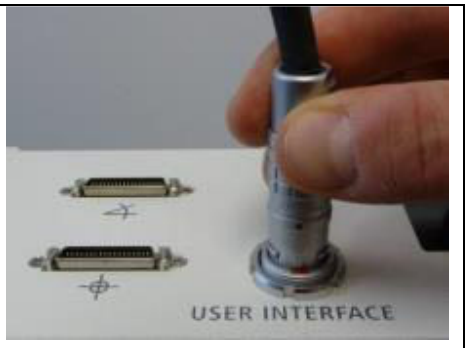
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

4.1.8. Connection of the Power and Data Cables

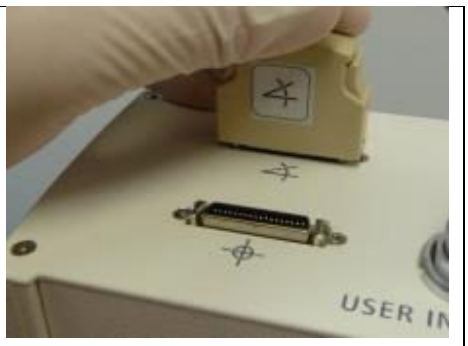
Overview:

Connect the power and data cables like shown in the following table:

Connection between HCU and CU	Connect the circular connector to the socket marked with “USER INTERFACE”. The correct position of the connector is marked with a red dot on both sides, connector and socket	

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

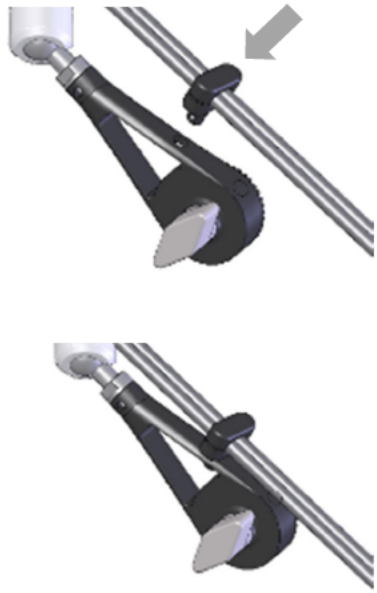
Connection of between RPU and CU	Connect the two flat connectors to the sockets on the CU marked with ⌖ and ⌖. The connectors are marked with the same symbols. Please check for the correct orientation of the connectors before inserting. There should be two “clicks” indicating that the connector is fixed firmly.	
	Connect the two flat connectors to the sockets on the RPU. The connector marked with ⌖ is for the lower robot module (positioning module), whereas the connector marked with ⌖ is for the upper robot module (angulation module). Please check for the correct orientation of the connectors before inserting. There should be two “clicks” indicating that the connector is fixed firmly.	

In case of wrong connection between CU and RPU an error message will be displayed at the CU (“Check HW(5V,Mod)”, cf. “Error Messages”, chapter 0)

For the cabling between CU and RPU please attach the strain-relief connector to the recess at the MFA accordingly in order to avoid pulling forces to the RPU (see picture below).

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016



WARNING
Make sure that the cables do not cross the routes of the patient or the medical staff.
In case this is not avoidable (e.g. no electrical socket nearby), make sure that the cables are taped to the floor so that the patient/medical staff cannot fall over.

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

WARNING
Attach the strain-relief connector to the recess at the MFA accordingly in order to avoid pulling forces to the RPU. If the strain relief is not connected properly this may cause damage to the RPU or may harm the patient.

WARNING
Do not pull at the cables, especially when setting up the patient! This may lead to falling down of components, interference with the mechanical setup and potentially harm patient or user.

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

4.1.9. Bringing the RPU into the "Parking position"

After the mechanical system setup, the RPU has to be parked in a safe parking position.

Reasons for the parking position:

- The parking position allows the easy attachment of the sterile cover.
- The parking position makes room for setting up the patient.
- The parking position allows access to the region of interest for preparing the surgical intervention (disinfection of the skin, sterile covering of the patient etc.)

WARNING
The MFA has progressive locking of the joints to allow precise positioning while locking and to avoid sudden movements when opening.
Always be aware that opening the MFA too fast can lead to uncontrolled movements of the arm itself or attached components (i.e. the Robotic Positioning Unit).
Always open the MFA slowly and carefully with one hand and hold the MFA or the attached device (Robotic Positioning Unit) carfully with the other hand!

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

WARNING
Do not misuse iSYS 1 as an armrest or tablet. This can lead to mechanical failures and serious injuries.

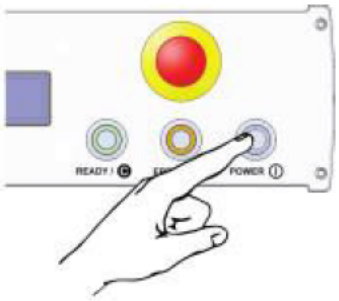
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

4.1.10. Start-up Procedure of the iSYS 1 Robot

1
Follow the Setup – Procedure (mounting of devices and establishing of cable connections) according to chapter 4.1.

2
Switch-on the system using the POWER switch.



Remark: Ensure that the joystick of the HCU is in its center position.

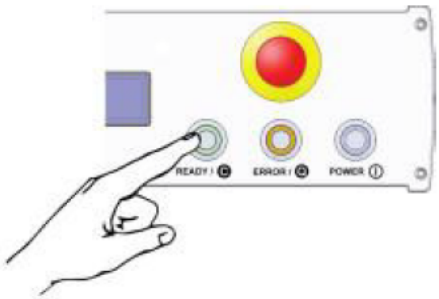
During boot-up the following message is shown.

```
iSYS1 – Needle
Guidance Platform
-------------------
System Bootup...
```

3
The system is now ready to perform the self-test.

```
### iSYS1 C-ARM  ###
* Running SELFTEST *
Rev1:C1.1/M1.6/W1.5
Press C to start  ->
```

4
Press the **C** (Confirm) button to start the self-test.
CAUTION: All axes of the robot will move approximately 1mm during self-test.



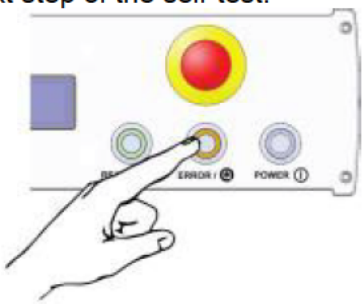
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

5
After the first step of the self-test you are asked to start the next step.

```
### iSYS1 C-ARM  ###
* Running SELFTEST *
Execute Step 2 of 5
Press Quit-Error  ->
```

6
Press the **Q** (Quit) button to start the next step of the self-test.



Repeat **step 6** until all steps are performed.

7
You will get the following message if the self-test was successfully executed.

```
### iSYS1 C-ARM  ###
Selftest PASSED
```

See instructions at **step 7A + 7B** if the self-test fails.

8
Once the self-test is passed you will get the operation screen.

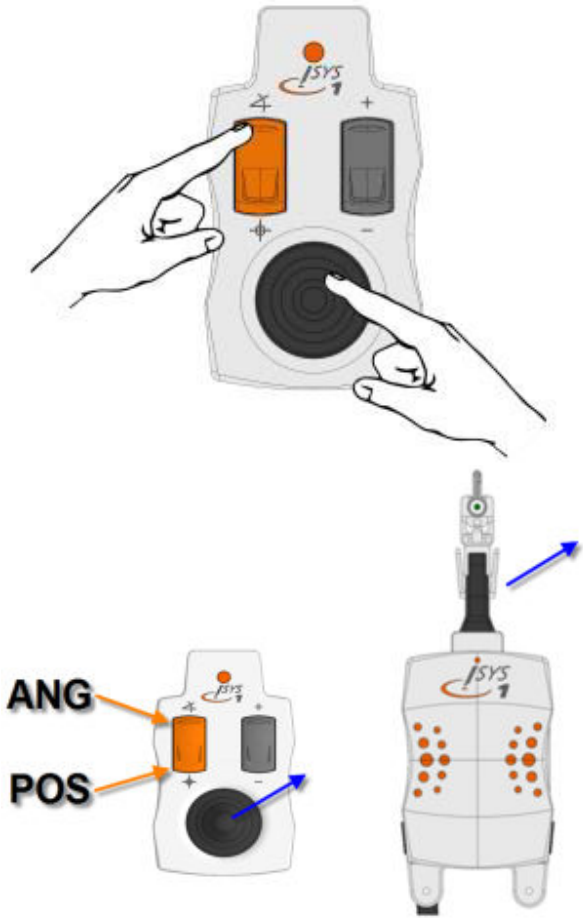
```
### iSYS1 C-ARM  ###

Speedlevel: fast
Joystick Mode  [  ]
```


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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

9

The system is now ready for operation. Use the Handheld Control Unit (HCU) to activate the desired mode (ANG or POS). During activation you can use the joystick to move the robot. The elongation of the joystick is proportional to the motion speed.
You can change the maximum speed using the +/- rocker-switch on the HCU.



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

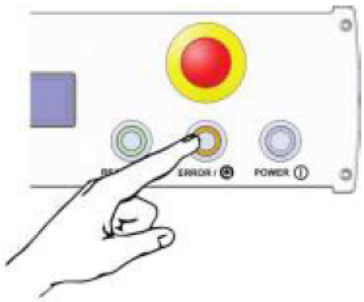
Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

7A
If the self-test fails you will get the following message.

```
### iSYS1 C-ARM  ###
* Running SELFTEST *
Selftest FAILED
Press Q to reset  ->
```

Remark: There are some possible reasons where the self-test fails, even tough no critical failure is present (e.g. a module is very close to its motion limit).

7B
Press the **Q** (Quit) button to restart the self-test and continue the procedure at step **3**.



If the self-test still fails after another trial, please contact the manufacturer.

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

4.2. Use of iSYS 1

The surgical procedure can be divided into several steps. The following workflow, for example, shows the use of the iSYS 1 system for a typical needle procedure under C-arm fluoroscopy.

4.2.1. Checking the Mechanical Setup and the Range of iSYS 1

Position the patient on the treatment table. Before covering the patient and the robot with a sterile cover, make sure that the region of interest is in the field of view of the imaging machine and within the mechanical range of the iSYS 1. Therefore the MFA has to be opened and the RPU roughly positioned manually in the region of interest. During opening of the MFA and checking the range the RPU has to be supported by the physician. The following pictures show different possibilities of potential positions. Please consider the movement of the gantry during imaging to avoid collisions of the iSYS 1 with the gantry.

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

In case the robot cannot reach the region of interest, re-position the patient or re-setup the mechanical parts of the system (e.g. mounting the MFA on a different Starburst-adapter or moving the TTA) so that all (potential) entry-points and target points can be reached.

WARNING
The MFA has progressive locking of the joints to allow precise positioning while locking and to avoid sudden movements when opening.
Always be aware that opening the MFA too fast can lead to uncontrolled movements of the arm itself or attached components (i.e. the Robotic Positioning Unit).
Always open the MFA slowly and carefully with one hand and hold the MFA or the attached device (Robotic Positioning Unit) carfully with the other hand!

4.2.2. Setup and Preparing the Patient

Setup and prepare the patient for the interventional procedure following the steps below:

Note:	*Let the patient enter the table from the opposite table site of the iSYS 1 setup. Make sure the patient does not collide with any component of iSYS 1.*

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Note:	*The following paragraphs describe only the use of the iSYS 1 system. The use of the iSYS 1 system is just a small part of the workflow of an interventional needle procedure.*

This user manual does not take care of all the other important steps (like e.g. preparation of the non-iSYS disposables, cleaning and disinfection of the patient, sterile covering of the patient, use of the imaging machine, use of the planning software etc.). The general workflow for the specific intervention is in the responsibility of the physician.

Depending on the region of interest and of the compliance of the patient, the need of immobilization devices may occur. There are several - commercially available - immobilization devices on the market that can be used for precise patient immobilization.

Depending on the region of interest, respiratory motion may lead to organ movement and therefore to inaccuracy during the targeting process. There are several - commercially available - devices for respiratory motion control available on the market that might be used to overcome this problem.

In some cases - e.g. non cooperative patient - it might even be necessary to sedate/anesthetize the patient.

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

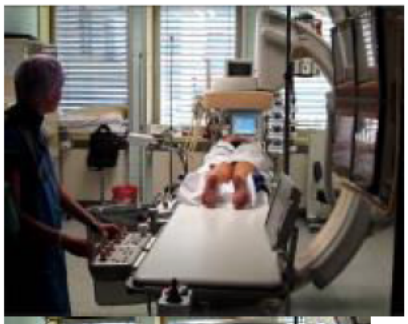
WARNING
It is in the full responsibility of the physician to use aids e.g. for immobilization, respiratory motion control etc. and/or to sedate the patient.
Criteria for the physician include the physical constitution of the patient, the region of interest, the critical (surrounding) structures/anatomy around the path and the target point and the relation of the region of interest to the lung and other moving organs.

iSYS does not take any responsibility for non-iSYS components and treatment steps e.g. correct patient setup, imaging and planning!

4.2.3. Image Acquisition and Treatment Planning

Before image acquisition, make sure that the gantry does not collide with iSYS 1.

To test this, drive the gantry manually and carefully (slow motion) in all necessary extreme positions and make sure that there are no collisions with the setup.

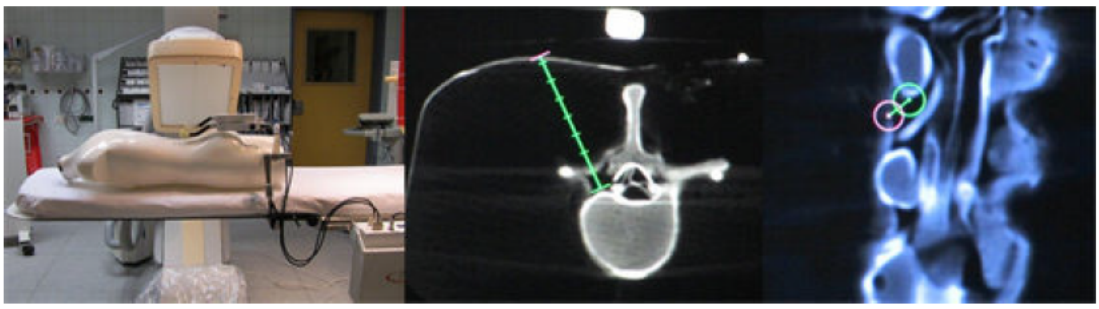


Imaging and planning can be performed with or without the RPU being in the field of view of the imaging device. In case the RPU is placed in the field of view of the imaging device, make sure that only the non-metal parts (plastic NGEs) are in the beam/field of view of the imaging device.

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

WARNING
Only the plastic NGEs ("fingers") do not cause imaging artifacts. If the whole RPU or other parts of the mechanical setup are in the field of view, imaging artifacts may occur!



After imaging of the patient, the planning of the path (entrance and target point) can be done with the planning tool of the imaging machine (not part of the iSYS System!).

Note:	*Imaging and planning are not in the responsibility of iSYS.* *Always keep in mind that the iSYS 1 system has only a certain range of movement for gross positioning and micro positioning (see specifications)* *In case imaging and planning is not done correctly, it might become necessary at a later point of the workflow to redo these steps (potential consequence: bigger time gap between (re-planning) and treatment and thereof (potentially less accuracy and/or additional radiation cause of the need of re-imaging)*

4.2.4. Working with the sterile iSYS 1 Disposables

a. General Information on sterile iSYS 1 Disposables

WARNING
In general, all sterile iSYS 1 disposables are intended for single use for one patient. (Re-) Sterilization of these components is not allowed.

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

WARNING
Do not attempt to clean, sterilize or reuse single use components of the iSYS 1 system. Reuse of single use components might lead to a malfunction of the system and/or an infection of the patient.

WARNING
According to our present state of knowledge, we want to inform you about following known characteristics and technical factors that can lead to hazardous situations in case of reuse of the disposables.

Sterile Covers:
1. **Improper Folding**
2. **Conglutination of the tapes with the foil**
3. **Labels and stickers no longer usable due to opening**

NGE:
1. **Possibility of cross-contamination**
2. **Mechanical damage**

WARNING
Only labeled sterile products are allowed to be used.

WARNING
The single use components are sterile products intended for single use only. Sterility is guaranteed for unopened and intact packaging up to the indicated expiration date. Do not use sterile products if the package is damaged.

Check the Sterilization Indicator Label to make sure the peel pack bag (sterile package) has been processed.

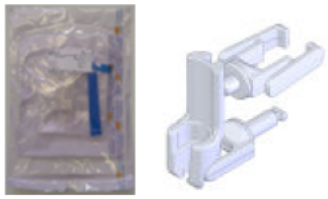
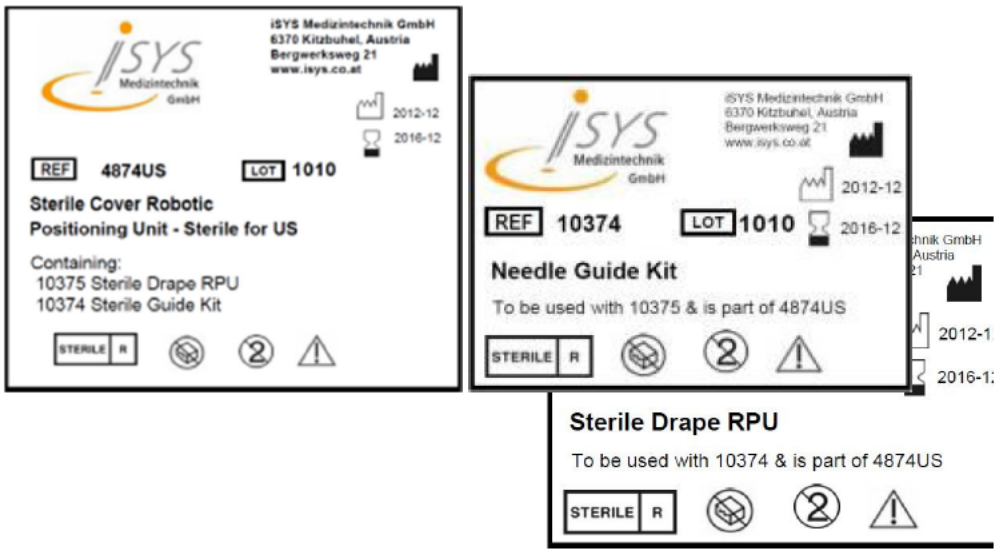
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

b. Preparation of the Sterile iSYS Disposables

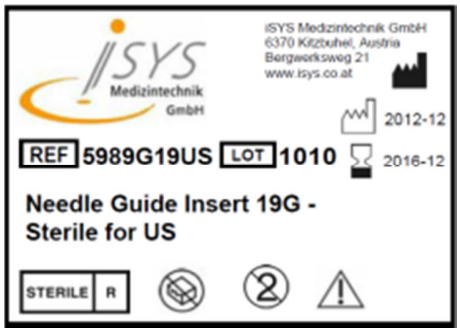
To guarantee a quick and safe workflow, take the iSYS disposables – handed over by a non-sterile assistant – out of the sterile cover and deposit the sterile components on a sterile table/plate.

The following disposables are needed for intervention:

Picture	Number of pieces needed	Single Use / Accessories
	1	**Sterile Cover Robotic Positioning Unit** It is a disposable sterile component to cover the RPU and part of the MFA and RPU Cable Set. This assembly consists of a Sterile Drape (Nr. 10375) and the Needle Guide Kit (Nr. 10374) (including 2 Needle Guide Joints with Fixation Rings). Needle Guide Joints allow a quick and reversible connection of the Needle Guide Adapter to the Needle Guide Extension. Order number and name: 4874US Sterile Cover RPU - sterile for US
		
	Depending on how many needles are placed	**Sterile Needle Guide Insert**: During the intervention the tool is inserted and guided by the (sterile) Needle Guide Insert. NGIs are available for needle diameters given below. The needle diameter of a NGI is printed on the cover bag as well as embossed to the handle of the NGI.

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

		Order number and name: 6289G10US Sterile Needle Guide 5990G11US Insert – 10G 5991G12US Sterile Needle Guide 5992G13US Insert – 11G 5993G14US Sterile Needle Guide 4877G15US Insert – 12G 4878G16US Sterile Needle Guide 4879G17US Insert – 13G 4880G18US Sterile Needle Guide 5989G19US Insert – 14G 4881G20US Sterile Needle Guide 4882G21US Insert – 15G Sterile Needle Guide Insert – 16G Sterile Needle Guide Insert – 17G Sterile Needle Guide Insert – 18G Sterile Needle Guide Insert – 19G Sterile Needle Guide Insert – 20G Sterile Needle Guide Insert – 21G
	1	**Sterile Needle Guide Marker Insert:** The Needle Guide Marker Insert allows precise and remote-controlled alignment of the Needle Guide Insert based on real-time imaging data. Order number and name: 4876US NGMI centered - sterile for US
	1	**Sterile Cover Handheld Control Unit:** It is a disposable sterile component to cover the HCU during intervention. Order number and name: 4883US Sterile Cover HCU - sterile for US

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Make sure all needed disposables are available. Also ensure that extra disposables are available in case a sterile piece is dropped in the non-sterile area (e.g. floor).

WARNING
Be sure the diameter of your instrument complies with the diameter of the Needle Guide Insert.

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

4.2.5. Attaching the Sterile Cover over the Robotic Positioning Unit

WARNING
Never continue with your procedure if any of the sterile covers is or gets damaged. Continuing the procedure might lead to serious infection of patient.

WARNING
Never touch the sterile area in the operating room after touching non-sterile components of the iSYS 1 without respective treatment (according to the local regulations).

WARNING
The patient must not touch the sterile cover.

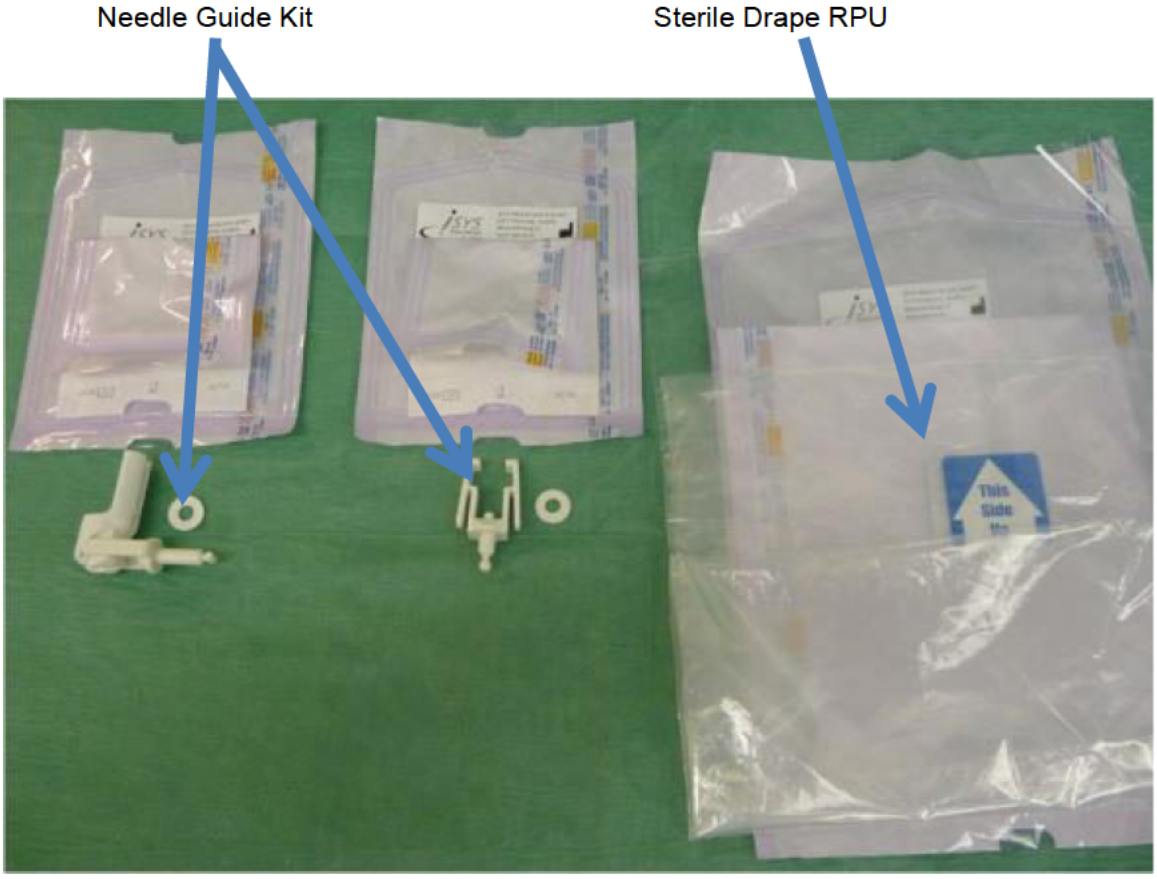
WARNING
Covering the patient's face with the sterile cover can seriously harm the patient.

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

The Robot Positioning Unit and the MFA can be completely covered with a sterile (protective) cover in a simple and safe manner. All non-sterile, reusable parts in the operation area are thereby separated from the sterile parts and the sterile operation area.

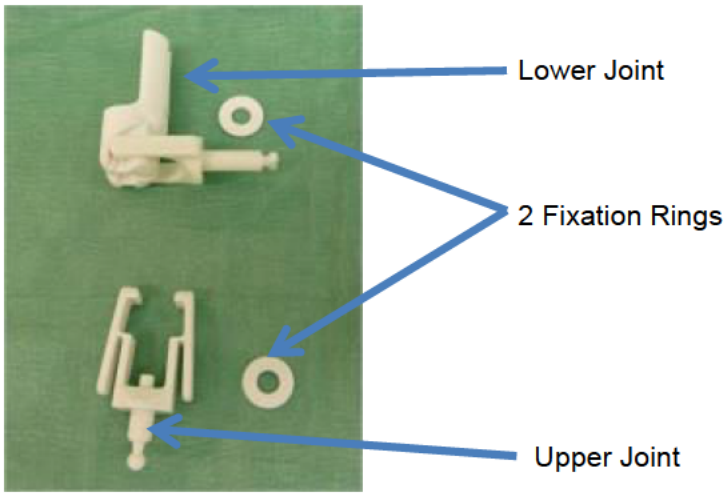
The Sterile Cover RPU consists of 2 parts:



The Needle Guide Kit includes 4 components:

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016



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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Open the sterile packaging and put all components (Sterile Drape, Lower & Upper Joint & 2 Fixation Rings) on the sterile table.

1. Feed the Upper Joint into the sterile drape and stick it through the upper hole.

2. Slip a Fixation Ring onto the Upper Joint

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

3. Feed the Lower Joint from outside the sterile drape into the lower hole.

4. Slip a Fixation Ring onto the Lower Joint from inside the Sterile Drape.

Make sure that both Fixation Rings fixed tight to the Joints!

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

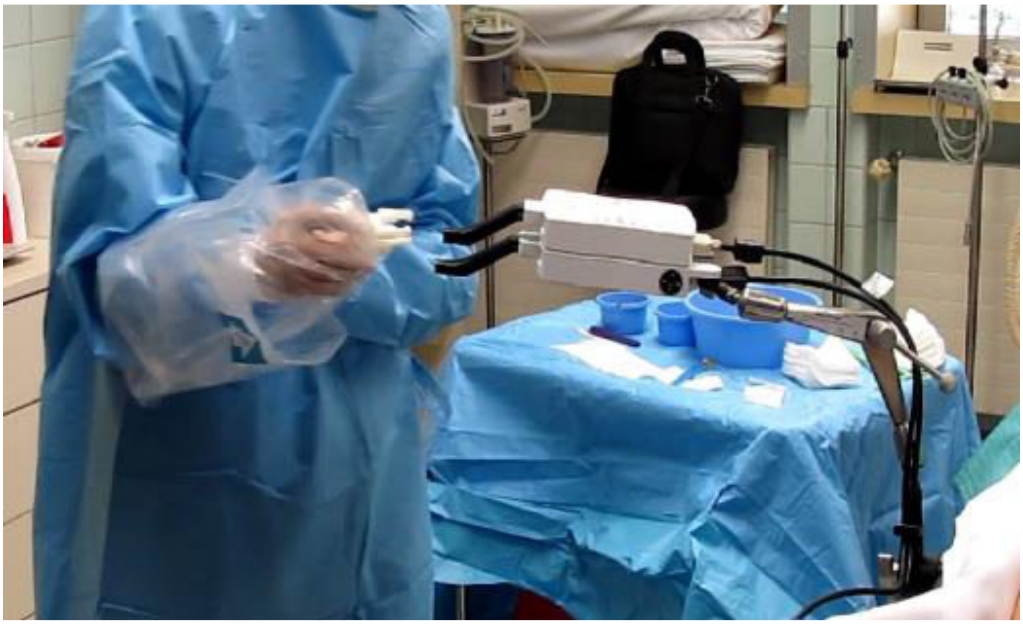
Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

5. Take the Bowl of the Upper Joint and insert it into the guide rail of the Lower Joint.

The final Sterile Cover RPU should look like shown on the pictures.

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

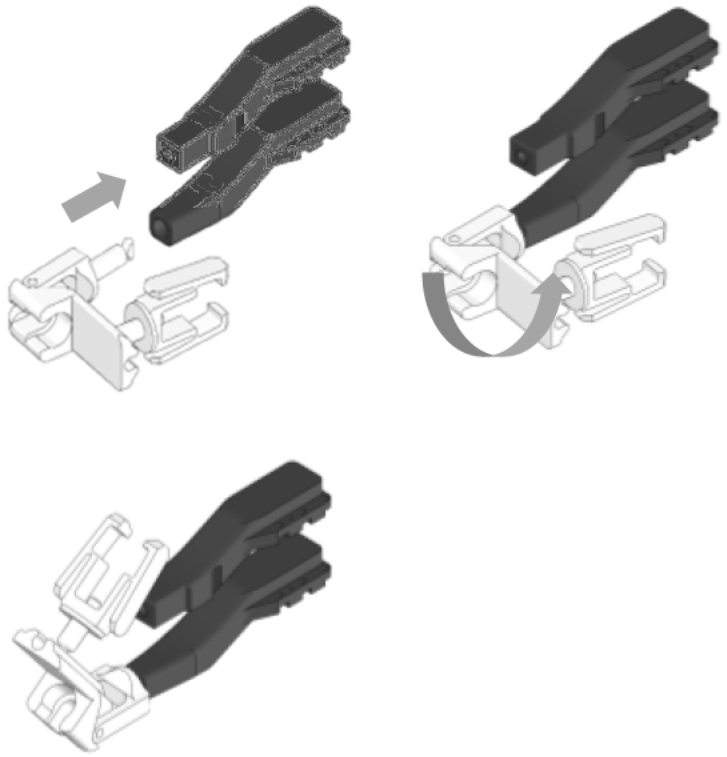


The sterile dressed surgeon grabs the end-effector from inside the plastic tube like shown in the picture above.

First the lower joint -is attached to the lower NGE ("finger") by bringing in the pin adapter in a 90 degree angle.

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

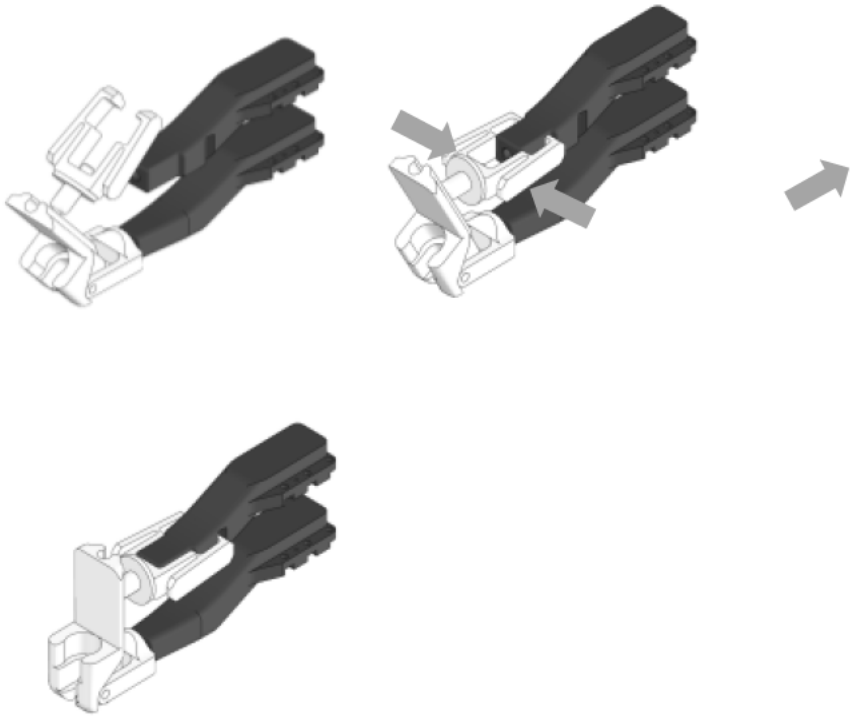


When you have reached the final position, rotate the lower joint 90 degrees up and make sure that the pin is locked safely by gently pulling the lower joint.

Attach the upper joint by attaching the clamp adapter as shown in the picture below:

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016



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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

After attachment of the upper joint, let the (non-sterile) assistant catch the white arrow (see blue marking) and pull the cover over the robotic unit.

After the RPU and MFA is totally covered with the sterile cover, the sterile surgeon can touch the sterile cover and pull the protuberance part of the cover (on the side of the sterile cover) over the handle of the arm and push it back.

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Use the blue tapes to fix the cover in position and to make sure the cover does not slip away.

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

4.2.6. Attaching the Sterile Cover to the HCU

WARNING
The patient or other non-sterile persons must not touch the sterile cover.

WARNING
Covering the patient's face with the sterile cover can seriously harm the patient.

In another simple and safe step, the HCU is completely covered with a sterile protective cover.

The (non-sterile) assistant takes the HCU in his hands. The sterile dressed surgeon takes the Sterile Cover Handheld Control Unit and grabs the HCU from inside the plastic tube.

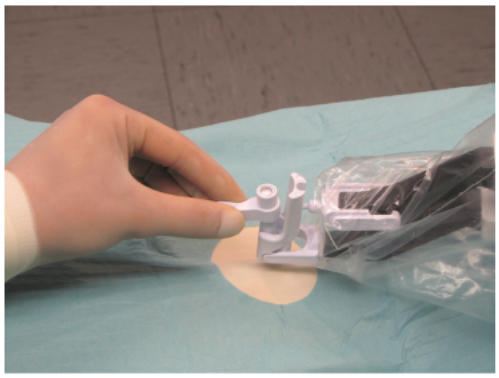
The (non-sterile) assistant catches the end of the plastic tube and pulls the cover over the HCU and its cable.

Note:	*This step allows the surgeon to later touch and use the HCU with his sterile hands/gloves. In case a second (assistant) non-sterile surgeon can operate the joystick, a sterile cover for the HCU is not needed and this step can be left out!*

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

4.2.7. Gross-Positioning of the RPU and Insertion of the Sterile Needle Guide Marker Insert into the Needle Guide Adapter



Make sure the entry and target point is in the range of the RU (see specifications above).

Unless it has not already been done before imaging, the RPU needs to be gross-positioned in the region of interest by opening and closing the MFA. To (re-)position the RPU please hold the RPU with one hand and open the MFA handle with the other one.

Please be aware that the MFA offers progressive locking, i.e. the upper link (next to the RPU) opens first, then the middle link and finally the lower link (next to the table/side rail adapter).

WARNING
The MFA has progressive locking of the joints to allow precise positioning while locking and to avoid sudden movements when opening.
Always be aware that opening the MFA too fast can lead to uncontrolled movements of the arm itself or attached components (i.e. the Robotic Positioning Unit).
Always open the MFA slowly and carefully with one hand and hold the MFA or the attached device (Robotic Positioning Unit) carfully with the other hand!

Although the Robotic Positioning Unit has an ergonomic design, always keep in mind that the steril cover may decrease the friction forces: Always hold and handle the MFA and the Robotic Positioning Unit carefully and safely!

Move the robot to the desired position/orientation and lock the MFA after positioning. The MFA handle needs to be tightened firmly so that the MFA can offer its full payload.

Please check the stability of the setup before proceeding with needle insertion.

To get a rough estimation about the right gross-positioning, you can use standard (skin) markers, the laser cross-hair (or laser pointer) from the imaging device (that visualizes the path) or fluoroscopy.

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

In case you use fluoroscopy, be aware to step aside to avoid radiation exposure. Be always aware that this method causes additional radiation to the patient.

WARNING
Make sure that the RPU and the NGE is oriented (approximately) parallel to the patient surface.
Always check if there is a risk of touching or colliding with the patient while remotely driving the robot modules (see chapter 4.2.8).
To double check: Drive the robot with the HCU in all extreme positions under direct visual control.
Collisions of the robot with the patient can cause serious injuries.

After you have reached and checked the desired position, insert the (sterile) Needle Guide Marker Insert into the Needle Guide Adapter.

WARNING
Make sure and double check that the Needle Guide Marker Insert is in the right endposition and is free of play in the NGA.

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

4.2.8. Micro-Positioning and Accurate Alignment of the NGA under fluoroscopy

Use the HCU (as described in chapter 4.5.3) to micro-position the NGA.

WARNING
When using the HCU, be aware not to touch the sterile area with the non-sterile cable of the HCU.

WARNING
Repeat imaging procedure if the Robot Positioning Unit has been accidental pushed or the power supply has been interrupted after imaging. Failing to do so may lead to mistreatment of the patient.

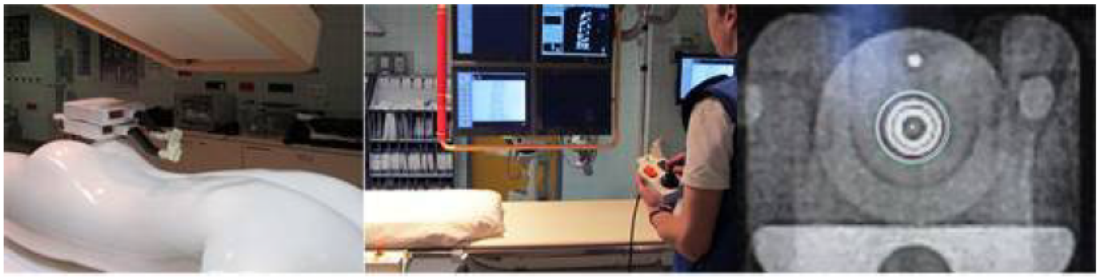
WARNING
Be aware you do not stand on the cables when moving the Robot Positioning Unit. This can lead to wrong positioning of the instrument and mistreatment of the patient.

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

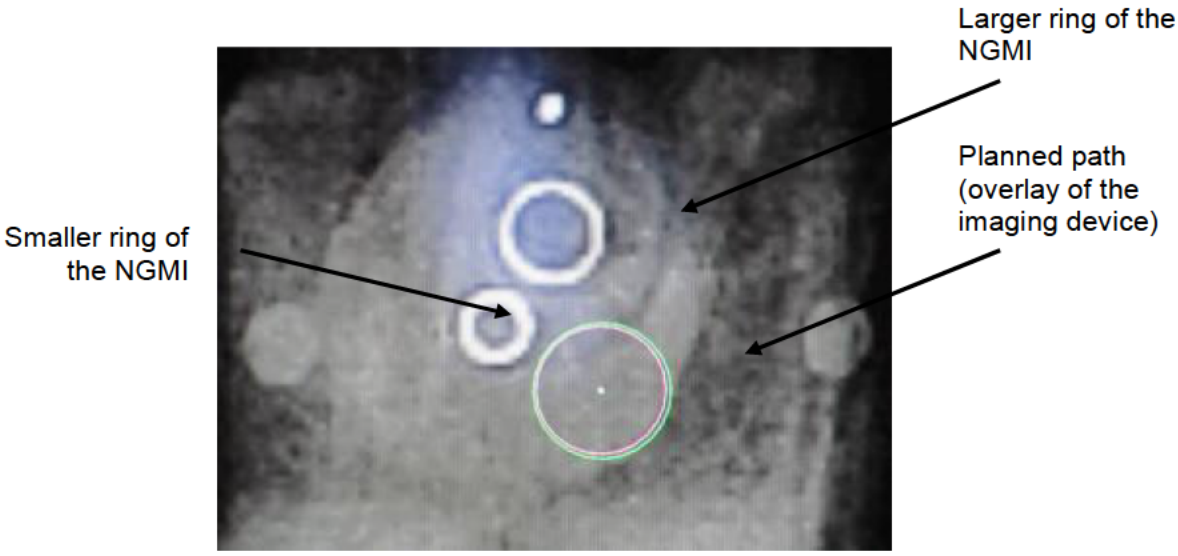
For a first alignment you can use surface markers or the laser cross-hair (or laser pointer) from the imaging device (that visualizes the path). In this case you can stay next to the patient.

If you use real-time-fluoroscopy for the alignment, please stay as far away as possible (minimum 6 feet) from the beam to reduce radiation exposure to a minimum (you just need to have a good view to the monitor that shows the fluoroscopy image).



To avoid unnecessary radiation to the patient, the user can – with the help of the robot – also work "offline" (i.e. without real-time imaging) and use just single Fluoro-Snap-Shots.

For micro-positioning the NG under fluoroscopy the C-Arm has to be orientated perpendicular to the planned path ("entry point view"). To align the Needle Guide with the planned path the user gets the right orientation of the x-, y-, a-, b-axis from the marker Insert:

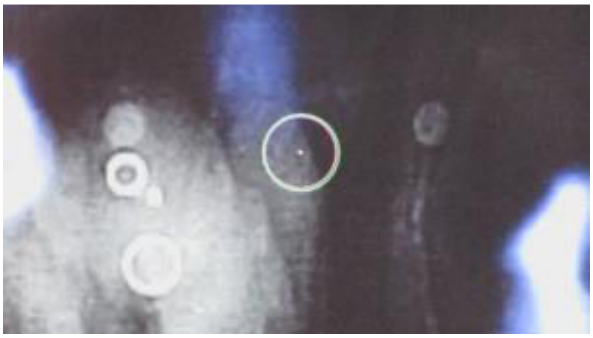


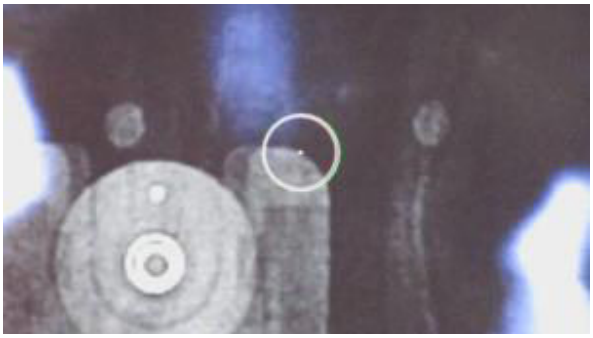
The larger ring of the Needle Guide Marker Insert marks the position of the Needle Guide. The smaller ring indicates the angulation of the Needle Guide.

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

In a first step the smaller ring has to be aligned roughly with the larger ring by moving the RPU in angulation mode. In this mode only the smaller ring moves as shown in the pictures below.

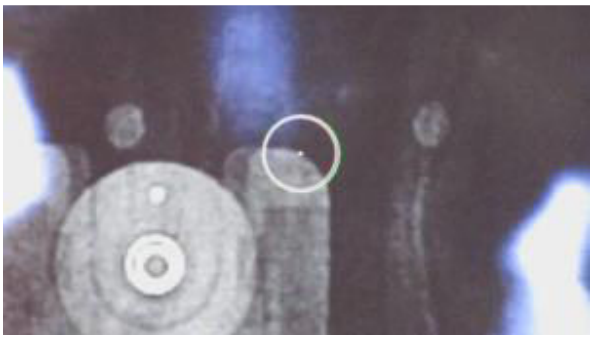


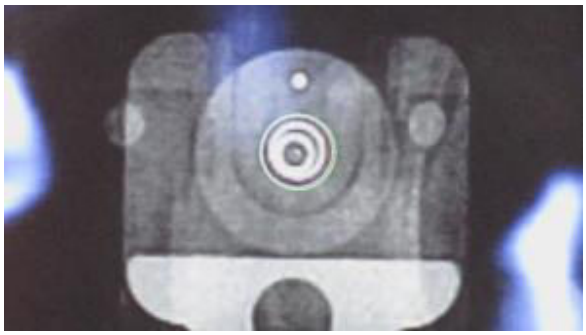


In the next step, both rings have to be aligned with the planned path (indicated by the two rings overlayed by the imaging device) by moving the RPU in positioning mode. When moving the RPU in positioning mode both rings move:

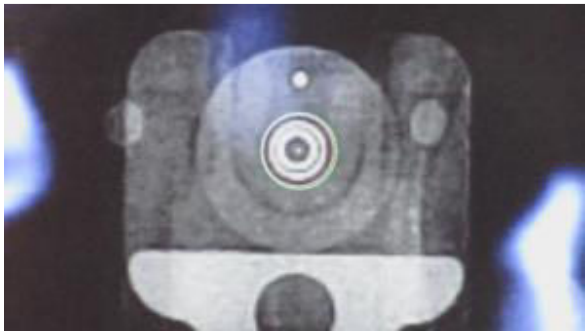
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

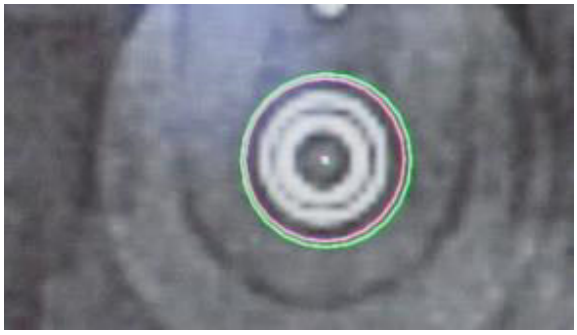
Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016





Finally the alignment has to be optimized by moving the RPU in positioning and angulation mode as shown below. For easy fine positioning the speed level can be set to slow by pushing the MINUS button on the HCU several times unless you hear a beep signal. The speed level is indicated on the display too.





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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

In case the alignment is done under fluoroscopy, a maximum zoom of the fluoro-image, adjustment of the diameters of the ring (in needle entry view, that represents the preplanned path) to the diameter of the marker and the resolution of the x-ray image (be careful: higher dose!) may increase the accuracy.

As this is not in the responsibility of iSYS, please contact the manufacturer of the imaging device for further information.

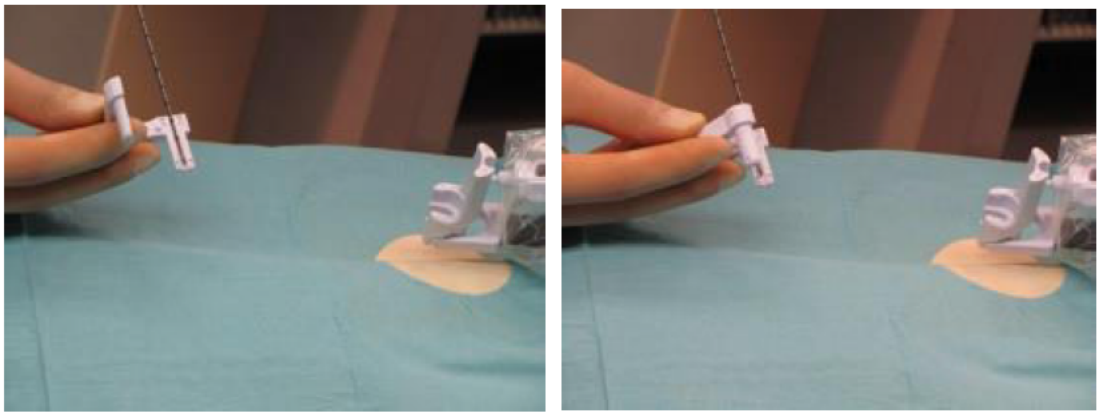
After alignment of the NG, remove the NGMI from the NGA.

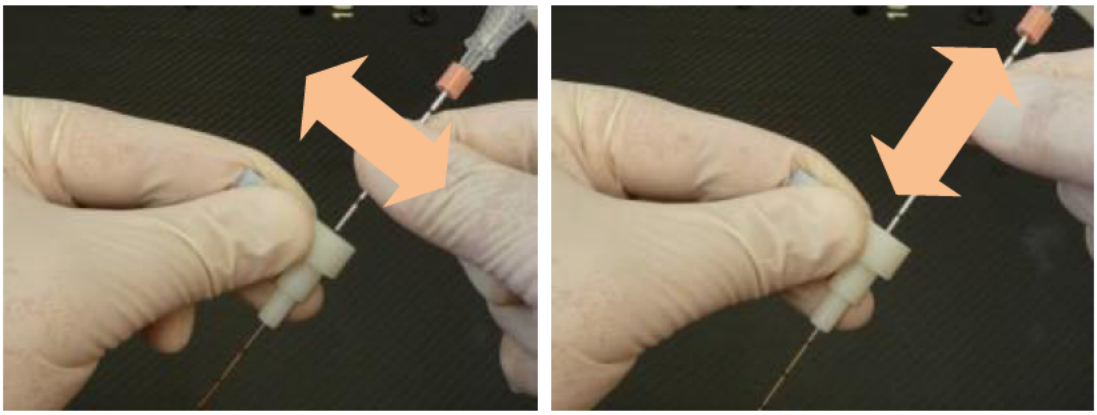
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

4.2.9. Attachment of the Needle Guide Insert and Needle Placement

The NGI has a very important function for needle guidance and quick release. Before attaching the sterile NGI to the NGA, check if the diameter of the needle fits to the NGI and check with the following manual test if the needle has a play-free and friction free guidance in the needle insert:





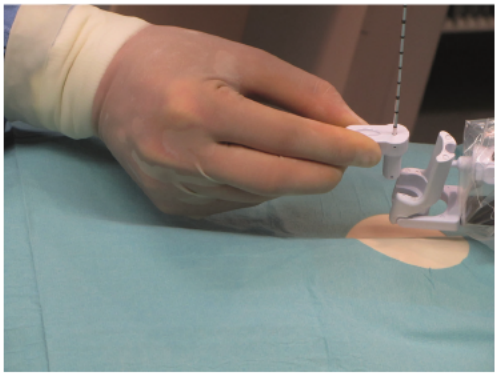
This check takes place in two steps. First insert the needle to the opened NGI, hold the NGI tightly with one hand (pressing the two halves of the NGI together) and try to move the needle in radial direction with the other hand. There should be no detectable play between NGI and needle. For the second step, try to move the needle in axial direction. The needle should move easily – there should be no blocking of the needle during such axial movement.

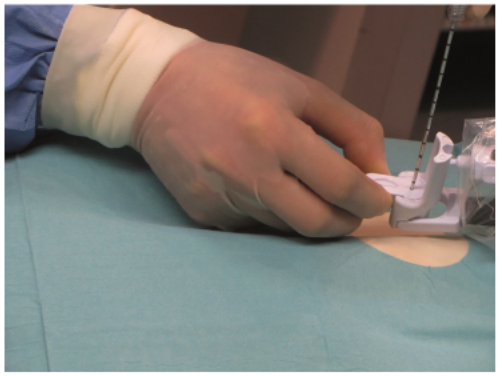
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

WARNING
Check the free and easy movement of the needle in the Needle Guide Insert. Be aware that the needle is not clamped.

After you have checked the functionality of the insert, insert the (sterile) Needle Guide Insert into the Needle Guide Adapter.





WARNING
Make sure and double check that the NGI is in the right endposition and that there is no play between NGA and NGI.

WARNING
Precise needle guidance is essential for the accuracy of the needle placement.
Precise needle guidance is only possible, if the needle diameter is in a certain tolerance over the whole length of the needle.
Always check the tolerances of the needle with your needle supplier before using it with the iSYS system!

After attachment of the NGI to the NGA, the needle can be introduced manually in z-axis into the patient. This step must be under full control of the surgeon!

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Depending on the used imaging device, the depth of the needle placement usually is being calculated by the planning software and is measured between the defined insertion point and the target point. For realization of the correct inserting depth the following procedure is being recommended:

- During planning, define the insertion point exactly on the skin surface of the patient.
- Before insertion of the needle, mark the calculated insertion depth (calculated by the planning system) with a sterile ruler and a sterile pen at the needle.
- Insert the needle until the marked insertion depth is reaching the skin surface
- It is highly recommended to check the needle insertion before reaching the final position by means of an intermediate scan (cf also sub-chapter "Verification and quality assurance" below).

Please note that iSYS is not taking any responsibility for realization of the correct inserting depth!

WARNING
Opening the MFA during the needle being inserted and connected to the RPU can lead to serious injuries at the patient.

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

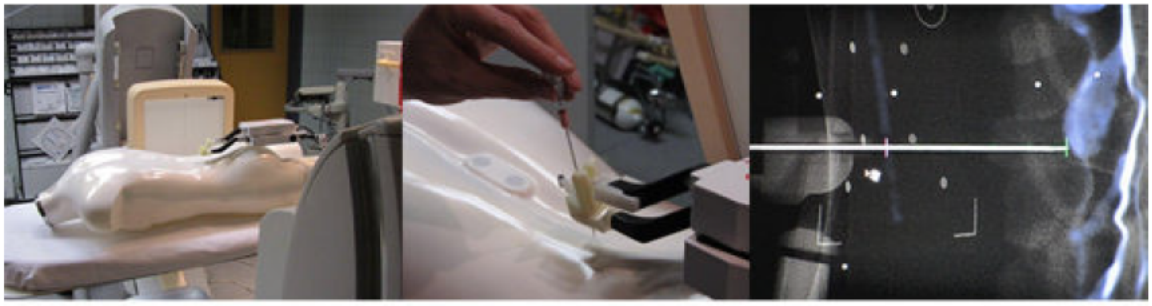
Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

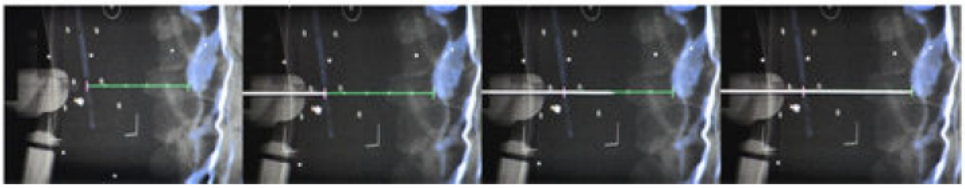
WARNING
The iSYS 1 system acts as a guidance system. It is not designed to compensate high forces from the needle or the user.

Forces on the mechanical components of iSYS 1 may lead to inaccuracy of the needle placement!

Verification and quality assurance:

As the NGE is radiolucent, the correct needle position can be verified with lateral scans ("needle progress view", "angulated needle guide view", optional: "needle entry view") before, during and after treatment.





It is in the responsibility of the surgeon to decide how often verification scans are necessary (this may depend on the region of interest, planned accuracy, critical/surrounding tissue, etc).

WARNING
In case of multiple needle procedures, be aware that the needles do not collide with each other or with iSYS 1 compontents! This can seriously harm the patient.

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

WARNING
Be aware that the setup of iSYS 1 does not influence the imaging in the area of interest. In case of doubts repeat the imaging procedure to avoid mistreatment of the patient.

WARNING
In case of an error (emergency stop): the error condition has to be resolved and the system has to be in the ready state to go on. The needle position and angulation has to be verified with the imaging device before inserting the needle/tool.

WARNING
The RPU must not be use as a (arm) rest at any time, not even as a support of the surgeons hand while inserting the needle.

WARNING
When inserting the needle avoid forces on the needle except for forces along the needle axis. Otherwise it leads to inaccuracies an may lead to mistreatment or injury of the patient.

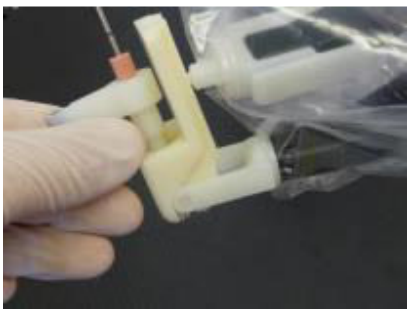
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

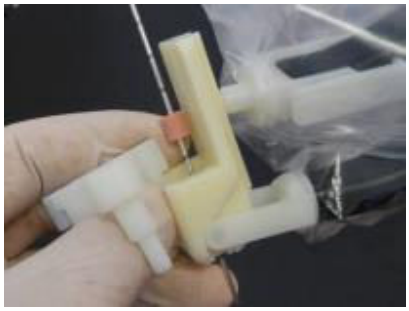
Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

4.2.10. Removing the NGI and Quick-Release

After needle introduction and/or whenever the surgeon steps apart from the patient and/or when the diagnosis/treatment with the needle starts, the NGI has to be removed (i.e. the needle gets decoupled from the robot).

Such decoupling can be easily performed by simply lifting the NGI (along the needle axis) until the NGI is no longer connected to the NGA. In this position the NGI can be opened and the needle is no longer attached to the needle guide.





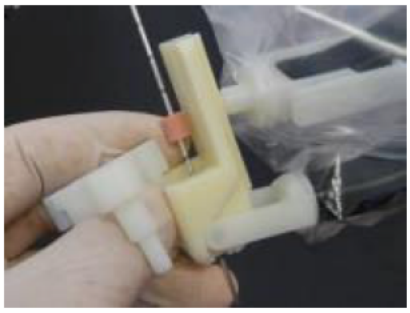
The decoupling also allows free “swinging” of the needle inside the needle guide and a removal of the iSYS 1 system in case of emergency.

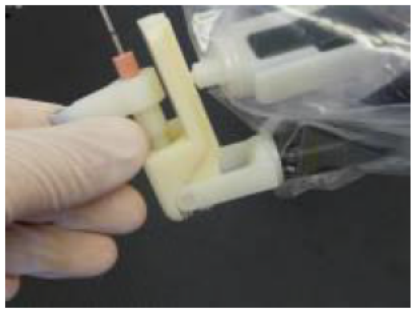
In case of multiple needle placements in larger distance to each other (bigger than the range of the robot), the decoupling also allows the removal of the RPU from the treatment area and a subsequent gross-positioning of the RPU for placement of the next needles.

If decoupling of the needle is only done temporarily (e.g. because the surgeon had to leave the patient for some time), the re-connection between needle and NGA can be done easily in the reverse order. The open NGI is being placed around the needle and being closed afterwards. Then the NGI is moved inside the NGA along the needle axis. Please be sure that the needle is fixed with the other hand during this step in order to avoid unintended needle insertion. For such re-connection the robot must not be moved between decoupling of the needle and re-connection.

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016





WARNING
During manipulation of the NGI for decoupling/coupling the needle from/to the NGA, please be sure that the needle is keeping in place (e.g. fixation with the other hand) in order to avoid unintended needle movement.

WARNING
In case of multiple needle procedures, be aware the needles do not collide with each other or with iSYS 1 compontents! This can seriously harm the patient.

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

WARNING
The MFA has progressive locking of the joints to allow precise positioning while locking and to avoid sudden movements when opening.
Always be aware that opening the MFA too fast can lead to uncontrolled movements of the arm itself or attached components (the robotic positioning unit).
Always open the MFA slowly and carefully with one hand and hold the arm or the attached device (robotic positioning unit) carefully with the other hand!

Although the RPU has an ergonomic design, always keep in mind that the steril cover may decrease the friction forces: Always hold and handle the MFA and the RPU carefully and safely!

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

4.3. Emergency Release/ Removing the system in case of emergency

In case of an emergency (e.g. patient panics), open the MFA, remove the RPU from the patient and bring it into parking position. Before manipulation of the RPU, please make sure to remove the needle from the NGI by either pulling out the needle or de-coupling the needle from the NGI (cf chapter 4.2.10).

WARNING
Before removing the system, always check that the NGI (or the needle) has been removed!
In case the needle insert has not been removed, friction forces can pull and/or push the needle and this can seriously harm the patient.

4.4. Dismounting

Before dismounting the system, bring the RPU into the "parking position" and remove the patient from the treatment table.

Remove the disposable parts first and dispose them according to the clinic guidelines.

Unplug the system, remove the cables, clean the components and dismount the mechanical parts.

For unplugging of the HCU connection cable please grab the circular connector at the grooved part and simply pull out the plug. For the flat connectors connecting the RPU with the CU please push the two locking rockers of the connector and then pull out the connector.

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Store the components carefully in the iSYS storage boxes.

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

4.5. User Interface

4.5.1. Alarms

This chapter describes the iSYS 1 alarms and what you should do if an alarm occurs.

The device provides only one alarm level, i.e. a technical alarm with low priority. Such a low priority alarm/alert warns you about a condition that prevents the system from operating normally. If, for example, the HCU is not connected to the CU, a runtime error is being detected and reported by triggering a dedicated low priority alarm/alert.

These alarms require your awareness. The alarm signal consists of a yellow LED and a sound that repeats a pattern of two beeps. The display has the message ***EMERGENCY STOP*** and an explanation of the alarm. The tables in Section 4.5.4 explain the alarm conditions and messages in more detail.

LCD Display

Error LED indicator

Alarm beeper

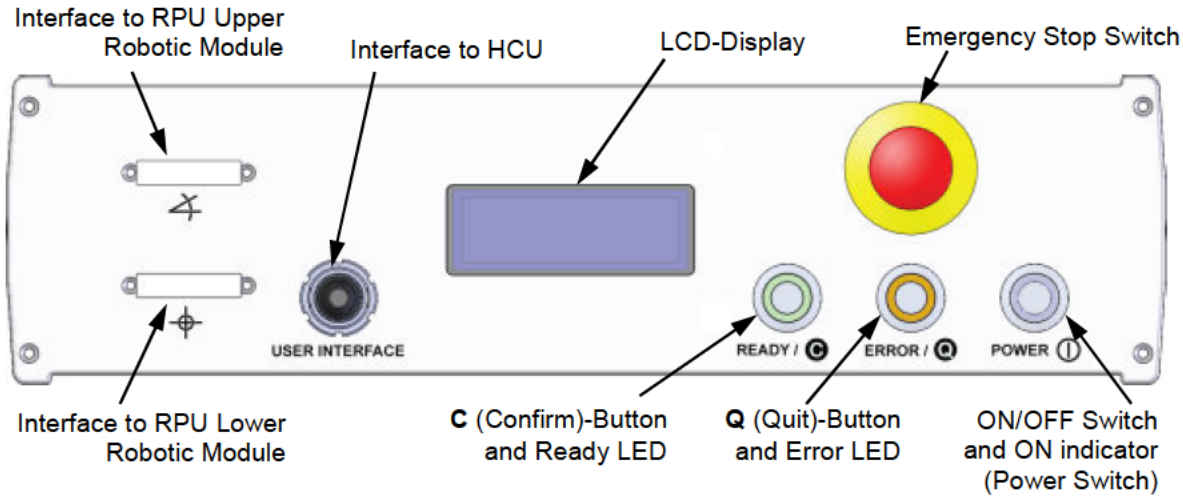
During a low priority alarm/alert:

- Look at the display for text.
- Look up the alarm in the alarm tables in Section 4.5.4 and perform the action specified.
- If the alarm can be cleared: Verify the position and angulation of the tool before you proceed.
- If the alarm persists: Stop the procedure or continue without using iSYS 1. Contact the manufacturer.

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

4.5.2. Front-Panel of the Control Unit



The front panel of the iSYS 1 Control Unit contains the following elements:

Buttons:

- ON/OFF Switch — Used to power the system (not accessible via software)
- **C** (Confirm) Button — Used to confirm triggered actions
- **Q** (Quit) Button — Used for controlled error recovering
- Emergency Stop Switch — Used for user initiated emergency stops

Indicators:

- Ready LED (green) — Indicates the system ready state (lighting) or prompts for confirmation input (flashing)
- Error LED (yellow) — Indicates error situations
- ON Indicator (blue) — Indicates if system is powered (not accessible via software)

LCD Display (4rows x 20 ASCII characters)

The LCD Display shows different states of the system.

Interface socket for Handheld Control Unit

The USER INTERFACE socket provides an electrical interface to control elements on the Handheld Control Unit.

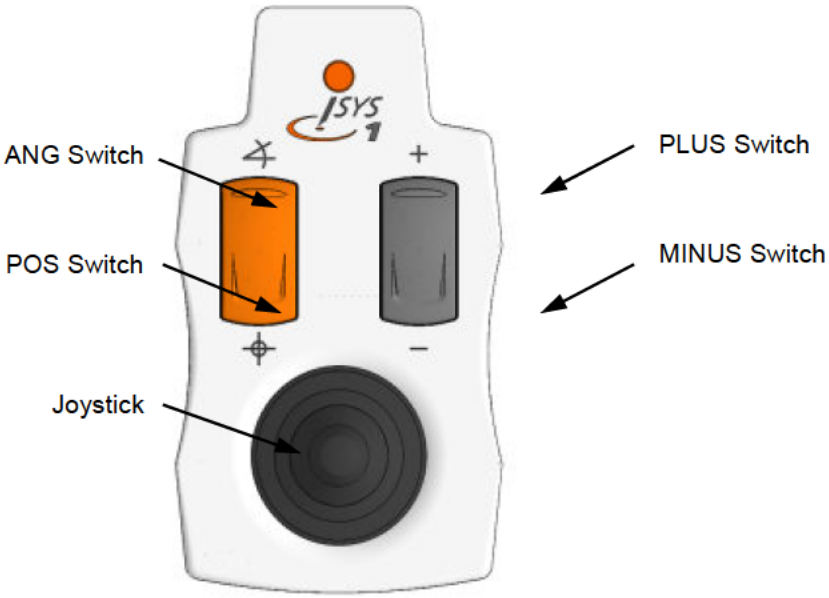
Interface sockets for angulation and positioning module.

..... These sockets provide an electrical interface to the robotic unit.

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

4.5.3. Handheld Control Unit



Left Rocker switch:

- ANG Switch — To activate angulation mode of the RPU
- POS Switch — To activate positioning mode of the RPU

Right Rocker switch:

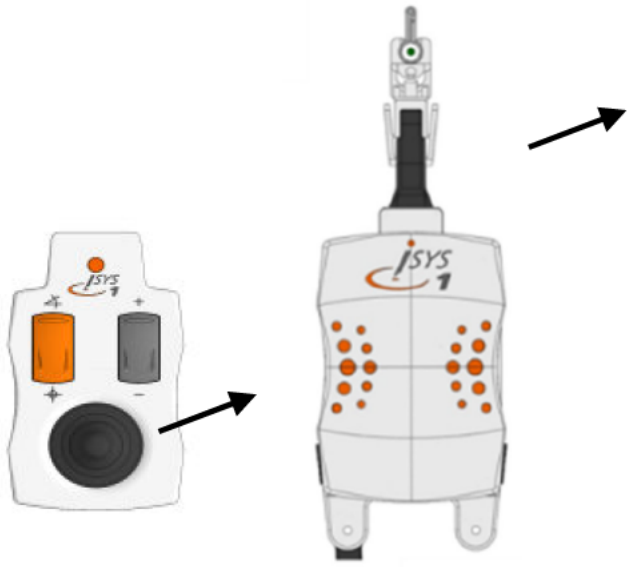
- PLUS Switch (+) — Used to increase the speed limit
- MINUS Switch (-) — Used to decrease the speed limit

Using the PLUS and MINUS button the overall speed level can be switched between 3 levels (100%, 60%, 20%), and thus scales the speed according to the joystick displacement to 100%, 60% or 20%.

Joystick:
The joystick initiates movement of the RPU according to the activated mode (POS or ANG). The shape of the HCU is based on the design of the RPU so that the desired direction of movement can be easily identified.

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016



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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

4.5.4. Display Messages

Boot-up screen

```
 iSYS1 - Needle
Guidance Platform
-------------------
System Bootup....
```

Operation Screen

```
### iSYS1 C-ARM  ###

Speedlevel: fast   *
Joystick Mode  [POS]
```

… Header
… Current Actions (Info Messages)
… Speedlevel and MotionInfo
… Joystickinfo

Message text	Description
Joystickinfo	
Joystick Mode [POS]	The positioning mode is active. Any joystick motion leads to an appropriate motion of the positioning module (lower RM).
Joystick Mode [ANG]	The angulation mode is active. Any joystick motion leads to an appropriate motion of the angulation module (upper RM).
Joystick Mode [ ]	The system is not enabled to perform motions. This steady state is supervised by an electronic circuit.
Speed level+Motion Info	
Speedlevel: {slow|medium|fast} [*] Example: Speedlevel: fast *	The currently active speed level is shown (slow| medium| fast). The asterisk "*" appears if the robotic unit is actually moving. It indicates that the elongation of the joystick is big enough to effectively move the robotic unit.
Info Messages	
Enable System...	The system is activated
Init System	The system is initialized
Starting APP	iSYS 1 application is starting
Rev2 C1.1/M1.6/W1.5	Version info
* Running SELFTEST *	The self-test is running now
Selftest PASSED	The self-test has been completed successfully
Selftest FAILED	Error during self-test

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Error Messages / Emergency Stop Screen

```
### iSYS1 C-ARM  ###
***Emergency Stop***
Stationary Error
Press Q to reset  ->
```

… Header
… ***Emergency Stop***
… Error in Detail (see table below)
… What to do? (e.g. press the Q-button to reset)

Emergency Stop Reasons:

Error Message	Description	Fault correction
Error Init Axis	The axis controller cannot be initialized.	Press Q to recover the system. If the error still arises, please contact the manufacturer.
Error Detect UI	There is no, or a wrong user interface (HCU) connected to the control unit.	Connect the right user interface to the control unit. Check the connection if already connected. Then press Q to recover the system.
Runtime Err Axis	A runtime error in an axis controller was detected.	Press Q to recover the system (if this error arises frequently, please contact the manufacturer).
Runtime Err Ctrl	A runtime error in the master controller was detected.	Press Q to recover the system (if this error arises frequently, please contact the manufacturer).
Prog Abort Axis	The axis controller program was aborted.	Press Q to recover the system (if this error arises frequently, please contact the manufacturer).
Watchdog Error	The watchdog reports a bad response behavior of the master controller.	Press Q to recover the system (if this error arises frequently, please contact the manufacturer).
Wrong App Config	There are wrong or invalid configuration data detected.	Press Q to recover the system (if this error arises frequently, please contact the manufacturer).
Check HW(5V,Mod)	The modules are not connected properly or the cable for angulation and positioning are switched. There is a problem with the internal power supply.	Check the connection of the module - cables. Press Q to recover the system. If the error still arises, please contact the manufacturer.
Emerg-Stop	No special emergency reason was detected by the system. Probably the Emergency Stop	Check the emergency stop switch (release). Press Q to recover the

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Error Message	Description	Fault correction
	Switch was pressed.	system.
Encoder SigError	An encoder signal error occurred.	Press Q to recover the system. If the error still arises, please contact the manufacturer.
Encoder CmpError	An encoder compare error occurred.	Press Q to recover the system. If the error still arises, please contact the manufacturer.
Axis Param Error	The parameters of an axis controller are invalid.	Press Q to recover the system. If the error still arises, please contact the manufacturer.
APP Config Error	The system parameter configuration is invalid.	Press Q to recover the system. If the error still arises, please contact the manufacturer.
Stationary Error	A motion was detected while the enable button (rocker POS/ANG) was not pressed.	Press Q to recover the system. If the error still arises, please contact the manufacturer.
Motor Fault	A motor fault was detected.	Press Q to recover the system. If the error still arises, please contact the manufacturer.
Overload	The applied load on the robotic unit is beyond the defined threshold.	Check the reason for the overload. Press Q to recover the system. If the error still arises, please contact the manufacturer.
Check HCU Center	The joystick of the HCU is not in its center position (is checked during startup). The change of the HCU can also be the reason for this message.	Ensure that the joystick of the HCU is in its center position during startup. Press Q to recover the system. If the error still arises, please contact the manufacturer.

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

5. Maintenance

The product life of the iSYS 1 Unit is **10 years** including a regular service on the device. The service is intended to be performed every year, starting from the 3rd year of use of the device (e.g. device was sold in June 2008; the first service is performed in June 2011). The service includes:

- Detecting wear on the main components
- Detecting failures in the system
- Ensuring the accuracy of the device
- Checking the functionality of the safety relevant components

During the complete lifetime of iSYS 1, all parts and components can be supplied. This means, starting from the end of sale of iSYS 1, the spare parts are available for another ten years.

The lifetime, and thus the end of sales and end of service, might be subject to changes due to growing experience with the product.

For service purposes, iSYS 1 will be sent to iSYS where the service is organized. During that time, the customer will receive a substitute iSYS 1.

WARNING
Changes, additions or maintenance to the equipment carried out by persons without appropriate qualifications and training and/or using unapproved spare parts may lead to fatal or serious personal injury and/or damage to the equipment as well as making the warranty void.

WARNING
Obey the maintenance and service times as given in this section. Disobeying maintanance and service causes loss of warranty and may cause damage of the system and harm of the patient.

WARNING
The housings of the different components may only be opened by an authorized qualified electrician. Before opening a housing, disconnect the iSYS 1 from the main supply.

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

5.1. Safety-relevant inspections

Recurrent testing of safety relevant parameters of the iSYS 1 system as given below has to be done every 24 month. When national laws or regulations prescribe further and/or more frequent inspections or maintenance these rules have to be followed. If the iSYS 1 system fails any step of the inspection/testing the iSYS 1 system must not be used and the manufacturer must be contacted.

WARNING
Measurements are only to be performed by a qualified electrician or under supervision of a qualified electrician.

The mentioned inspections are minimum requirements:

Test/Inspection	Item	Inspection
Functional testing	Emergency stop	When the emergency stop button is activated, no motions of the RPU should be possible
	Drive motors	Smooth operation, abnormal noise development
	Strain relief of RPU Cable Set	Secure hold
	CU and HCU	Side rail: safe locking / secure hold / safe unlocking
	TTAA and TTAB	Table top mounting: safe locking / secure hold / safe unlocking
	CU	Check indicators, beeper and display
Visual inspection	Housing enclosure	Look for damage, cracks etc.
	Contamination	Look for obstruction of moving parts, connector pins etc.
	Cabling	Look for cuts etc.
	Fuse rating	Check correct values after replacement
	Markings and Labeling	Check the integrity of safety markings
	Integrity of mechanical parts	Check for any obstructions

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Protective earth testing	Protective earth connection	According IEC 62353
Insulation resistance test	Insulation between mains parts, accessible parts and earth	According IEC 62353
Leakage measurements	Leakage current	According IEC 62353

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

6. Cleaning and Disinfection

It is important that any part of the equipment which may come into direct contact with patients is cleaned and disinfected on a regular basis. Cleaning is an important requirement for a successful chemical disinfection.

WARNING
Only persons instructed in the use of this medical device are allowed to clean the iSYS 1 system.

WARNING
Always clean and disinfect the reusable components of iSYS 1 according to this manual. Never use equipment that is contaminated or uncleaned as this can lead to serious infections.

WARNING
Do not sterilize the re-usable components of the iSYS 1. Sterilizing of any components of iSYS 1 causes loss of warranty and may cause damage of the system and harm to the patient. If components of iSYS 1 are sterilized by mistake contact the manufacturer.

The system must be cleaned and disinfected prior and after to each use. For cleaning and disinfection use appropriate agents which are proofed for compatibility. iSYS has proofed the following agents as compatible:

Approved disinfection agents:	Active agent
Incidin® Liquid	2-Propanol, 1-Propanol
Mikrozid® AF Liquid	94% Ethanol, 1-Propanol

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

CAUTION
Before beginning cleaning and disinfection, please note:

- **Unplug the power cable**
- **Make sure all other plugs are properly connected.**
- **None of the (electrical) components must show any visible damage; otherwise water or cleaning/disinfection solution could penetrate. This could lead to malfunction or damage to the electrical components.**
- **Before operating the system again, make sure that there is no residual moisture on the electrical contacts.**
- **All iSYS 1 components must not be cleaned with a water jet, a high pressure cleaner or other similar device! Do not use dipping method for cleaning and disinfection!**
- **Clean/disinfect all iSYS 1 components only with a moist towel!**
- **If you suspect that water or any other form of moisture has penetrated the electrical components, disconnect the power plug immediately. If already disconnected from the power supply, make sure it is not plugged in again. Clearly mark the device as "Defective" and take it immediately out of service. Report this to the operator promptly.**
- **Failure to follow these directions could lead to major damage of the system!**

WARNING
After cleaning and disinfection iSYS 1 has to be dried sufficiently. Follow the specific instructions for use and recommended contact times of the used cleaning and disinfection agents.

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

iSYS Medizintechnik GmbH
Bergwerksweg 21
6370 Kitzbühel
Austria
www.isys.co.at

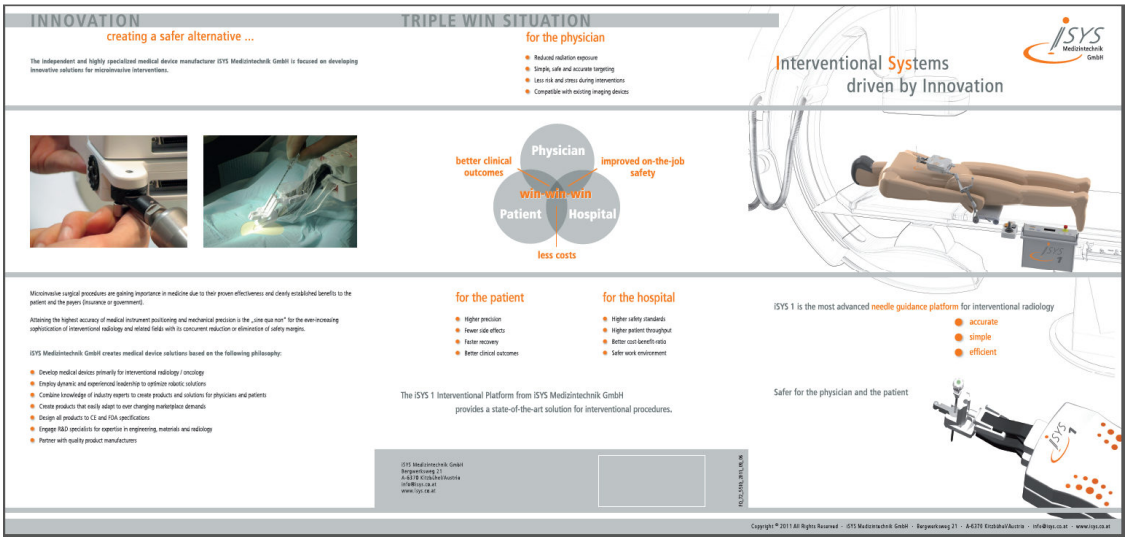
Order Nr.: 9567

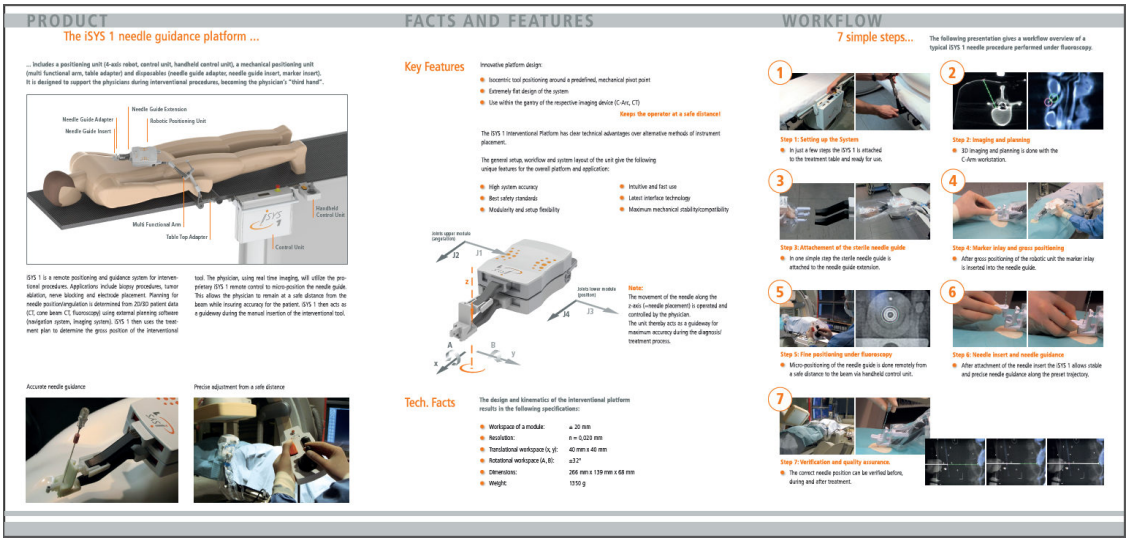
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Marketing Material

Flyer (6 pages):





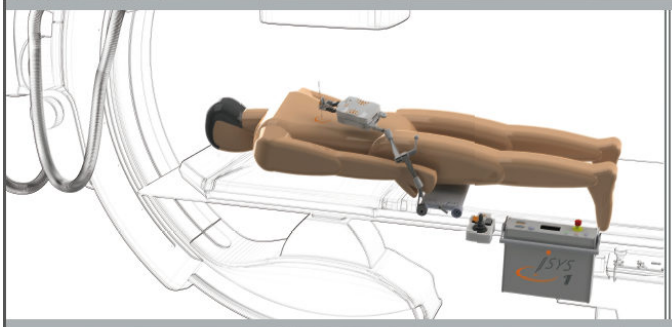
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

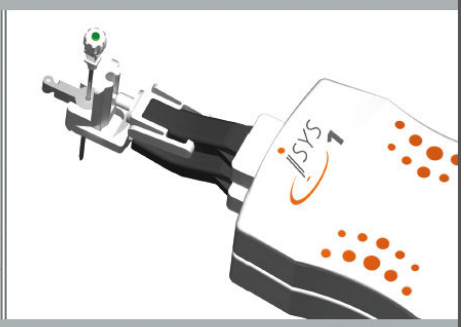
Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Product Flyer (2 pages):

Interventional Systems
driven by Innovation

iSYS Medizintechnik GmbH





iSYS 1 is the most advanced needle guidance platform for interventional radiology

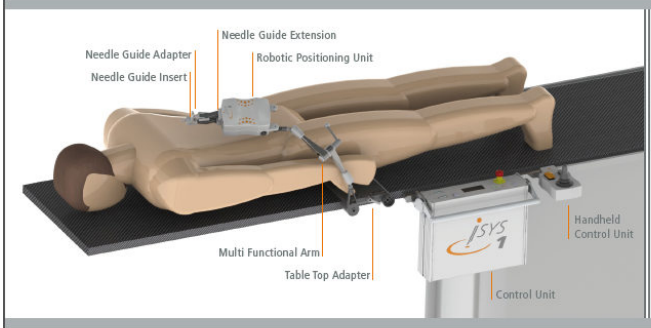
- accurate
- simple
- efficient

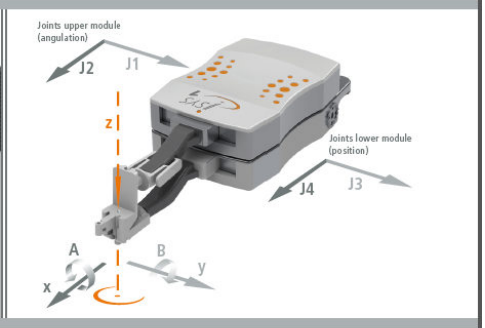
Safer for the physician and the patient

Copyright © 2011 All Rights Reserved · iSYS Medizintechnik GmbH · Bergwerksweg 21 · A-6370 Kitzbühel/Austria · info@isys.co.at · www.isys.co.at

On target from a safe distance.

iSYS Medizintechnik GmbH





System description:

The intended use of the iSYS 1 device is to function as a remote-operated positioning and guidance system during interventional procedures.

Core component is a robotic-positioning unit with 4 degrees of freedom which allows submillimetric needle positioning in x, y (range +/- 20mm) and angulation in A, B (range +/- 35°) around a fixed pivot point.

The passive gross positioning unit and variety of table adaptors allow for different system configurations of the system around the patient in the region of interest while providing maximum rigidity.
Planning of the desired position/angulation is done based on 2D/3D patient data (CT, cone-beam CT, fluoroscopy).

Fine positioning/angulation is done remotely from a safe distance.

After adjustment of the needle guide, the iSYS 1 acts as a guideway during the manual insertion of the interventional tool.

System benefits:

- High system accuracy — better clinical outcomes
- Small and lightweight robot — high safety standards
- Modularity and compatibility — maximum setup flexibility
- Intuitive use — easy and fast handling
- Latest technology — good cost-benefit ratio
- Extremely flat design — use inside the gantry

Keeps the operator at a safe distance!

FO_72_2051 Form 16.03.2011

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Form FDA 3654

Form Approved: OMB No. 0910-0120; Expiration Date: 12/31/13

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

ISO 15223-1 Second Edition 2012-07-01, Medical devices - Symbols to be used with medical device labels, labelling, and informati

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	#5-73	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☐	☒
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☒
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☒	☐
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☒	☐
If yes, was the guidance document followed in preparation of this 510k?	☒	☐

Title of guidance: Guidance for the Content of Premarket Submissions, Guidance for Off-the-Shelf Software, et. al.

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

[5] The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[6] The online search for CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html

FORM FDA 3654 (12/10) Page 1

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE
ISO 15223-1 Second Edition 2012-07-01, Medical devices - Symbols to be used with medical device labels, labelling, and informati

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
5	Symbols	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *
Symbol 5.2.8. is used although not recognized (see SIS)

DESCRIPTION

JUSTIFICATION
Symbol is common and used in the U.S. Use of it does not bear any risk. The meaning is described in the User Manual.

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

* Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

Paperwork Reduction Act Statement

Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and 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:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
1350 Piccard Drive, Room 400
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 number.

FORM FDA 3654 (12/10) Page 2

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Sterilization and Shelf Life

Table of Content

	Page
In General	2
Proposed Labeling	3
Validation Report (Packaging)	7
Summary Report (b)(4) [redacted]	17
Summary Report Preferred Medical	23
Bioburden Routine Report	25
Validation of (b)(4) [redacted] Determination	39
Data Sheets	50
Certificates	75

Following documents can be found on the appendix CD respectively in the Misc.-Files of the eCopy:

Document	Filename
(b)(4) [redacted]	
(b)(4) [redacted] Hygiene Monitoring Plan 2011	009_PM_Hygiene Monitoring plan_RDP 0500_2011
(b)(4) [redacted] Clean room Monitoring Results2012	010_PM_Clean room Monitoring_Results2012
Gamma validation test plan	011_PM_Gamma validation Prüfplan_PRD0400_2010
(b)(4) [redacted]	

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

1. Drapes:

The drapes for iSYS 1 are no longer part of this submission but will be supplied and manufactured by Preferred Medical Products and packaged and sterilized by Bioseal under their own responsibility.

The drapes are supplied b (b)(4) [redacted] under 510(k) K863853 and packaged and sterilized by (b)(4) [redacted] under 510(k) K893814.

For a comparison of the iSYS devices with the existing products from (b)(4) [redacted] and (b)(4) [redacted] see below (Summary Reports).

2. Needle Guide Adapter and Needle Guide Inserts:

The Needle Guide Adapters are part of the robotic system manufactured by iSYS. Bioseal performs packaging and sterilization.

Sterilization method:

(b)(4) [redacted]

Description of packaging:

All components are double packed and sealed. For details of packaging material see below (Data Sheets).

The packaging is performed with the (b)(4) [redacted] For validation see report below.

Validation Method: ANSI/AAMI/ISO 11607-2:2006, ASTM F1886:1998, ASTM F1929-98:2004, ASTM F88, ASTM F2096-11

Shelf-Life:

Shelf-life for all sterile components and validation method:

Lifetime/Shelf-life: 3 years

Validation Method: ASTM F 1980:2011

Device Description

Details see above (page 55 and following).

For technical data sheets see below.

Flammability:

See TDS below: according to UL 94, IEC 60695-2-12 and FMVSS 302.

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Proposed Labeling

The labeling is performed with the Colimatic Thera 450 a (b)(4) For retails see validation report below.

Safety Symbols:

STERILE EO	Symbol for STERILIZED USING ETHYLENE OXIDE
STERILE R	Symbol for STERILIZED USING RADIATION
	Symbol for DO NOT USE IF PACKAGE IS DAMAGED
	Symbol for DO NOT REUSE
MR	Symbol for NOT MRI SAFE
	Symbol for CAUTION, CONSULT ACCOMPANYING DOCUMENTS
	Symbol for STORAGE TEMPERATURE
	Symbol for DO NOT LITTER IN DOMESTIC WASTE

Product Identification:

SN	Symbol for SERIAL NUMBER
REF	Symbol for ORDER NUMBER

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

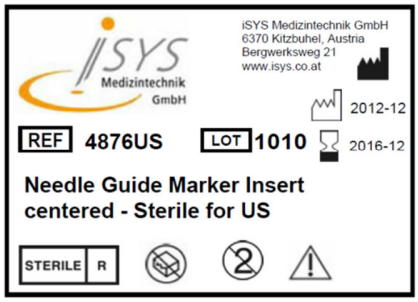
LOT	Symbol for BATCH NUMBER

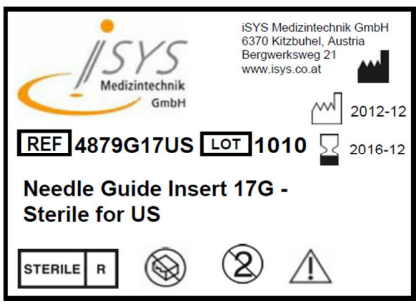
Additional Information

CE	Symbol for CE-conformity
	Symbol for MANUFACTURER
	Symbol for DATE OF MANUFACTURE
	Symbol for USE BY

Samples of Labels:

The presented labels are examples for the final product and packaging labels. Lot numbers and dates on these examples are placeholders only. They do not define any format of lot numbers, production or expiry dates.





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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

iSYS Medizintechnik GmbH
6370 Kitzbuhel, Austria
Bergwerksweg 21
www.isys.co.at
2012-12
REF 4881G20US LOT 1010 2016-12
Needle Guide Insert 20G - Sterile for US
STERILE R

iSYS Medizintechnik GmbH
6370 Kitzbuhel, Austria
Bergwerksweg 21
www.isys.co.at
2012-12
REF 4882G21US LOT 1010 2016-12
Needle Guide Insert 21G - Sterile for US
STERILE R

iSYS Medizintechnik GmbH
6370 Kitzbuhel, Austria
Bergwerksweg 21
www.isys.co.at
2012-12
REF 4880G18US LOT 1010 2016-12
Needle Guide Insert 18G - Sterile for US
STERILE R

iSYS Medizintechnik GmbH
6370 Kitzbuhel, Austria
Bergwerksweg 21
www.isys.co.at
2012-12
REF 5989G19US LOT 1010 2016-12
Needle Guide Insert 19G - Sterile for US
STERILE R

iSYS Medizintechnik GmbH
6370 Kitzbuhel, Austria
Bergwerksweg 21
www.isys.co.at
2012-12
REF 4878G16US LOT 1010 2016-12
Needle Guide Insert 16G - Sterile for US
STERILE R

iSYS Medizintechnik GmbH
6370 Kitzbuhel, Austria
Bergwerksweg 21
www.isys.co.at
2012-12
REF 5992G13US LOT 1010 2016-12
Needle Guide Insert 13G - Sterile for US
STERILE R

iSYS Medizintechnik GmbH
6370 Kitzbuhel, Austria
Bergwerksweg 21
www.isys.co.at
2012-12
REF 6289G10US LOT 1010 2016-12
Needle Guide Insert 10G - Sterile for US
STERILE R

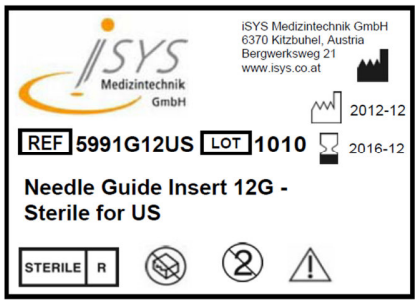
iSYS Medizintechnik GmbH
6370 Kitzbuhel, Austria
Bergwerksweg 21
www.isys.co.at
2012-12
REF 5990G11US LOT 1010 2016-12
Needle Guide Insert 11G - Sterile for US
STERILE R

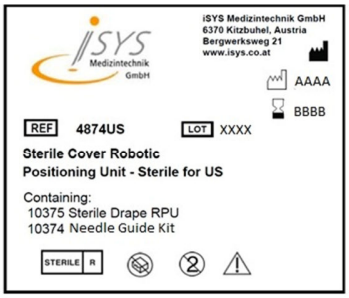
iSYS Medizintechnik GmbH
6370 Kitzbuhel, Austria
Bergwerksweg 21
www.isys.co.at
2012-12
REF 5993G14US LOT 1010 2016-12
Needle Guide Insert 14G - Sterile for US
STERILE R

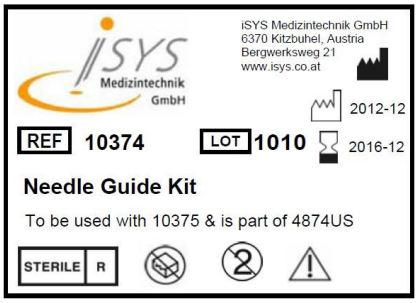
iSYS Medizintechnik GmbH
6370 Kitzbuhel, Austria
Bergwerksweg 21
www.isys.co.at
2012-12
REF 4877G15US LOT 1010 2016-12
Needle Guide Insert 15G - Sterile for US
STERILE R

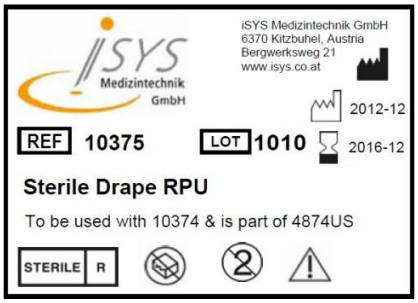
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016









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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

PD/B18	Sterilization and Shelf Life 510(k) Number:	ISYS Medizintechnik GmbH

Validation Report (Packaging)

(b)(4) Third Party Test Data

[redacted]

Qu

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

PD/B18	Sterilization and Shelf Life 510(k) Number:	iSYS Medizintechnik GmbH

(b)(4)

[redacted]

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Biocompatibility

No patient contact, thus not applicable.

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Software

The iSYS 1 (U.S.) is controlled by software, used with the help of a Handheld Control Unit (HCU) and user relevant information is displayed on the Control Unit.

According to the *Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices*, published on May 11, 2005 by *Center for Devices and Radiological Health (CDRH) – Office of Device Evaluation*, the software validation of medical devices containing software must be carried out in a specified way.

Therefore the guidance documents to be used are:

- *General Principles of Software Validation*
- *Guidance for Off-the-Shelf Software Use in Medical Devices*

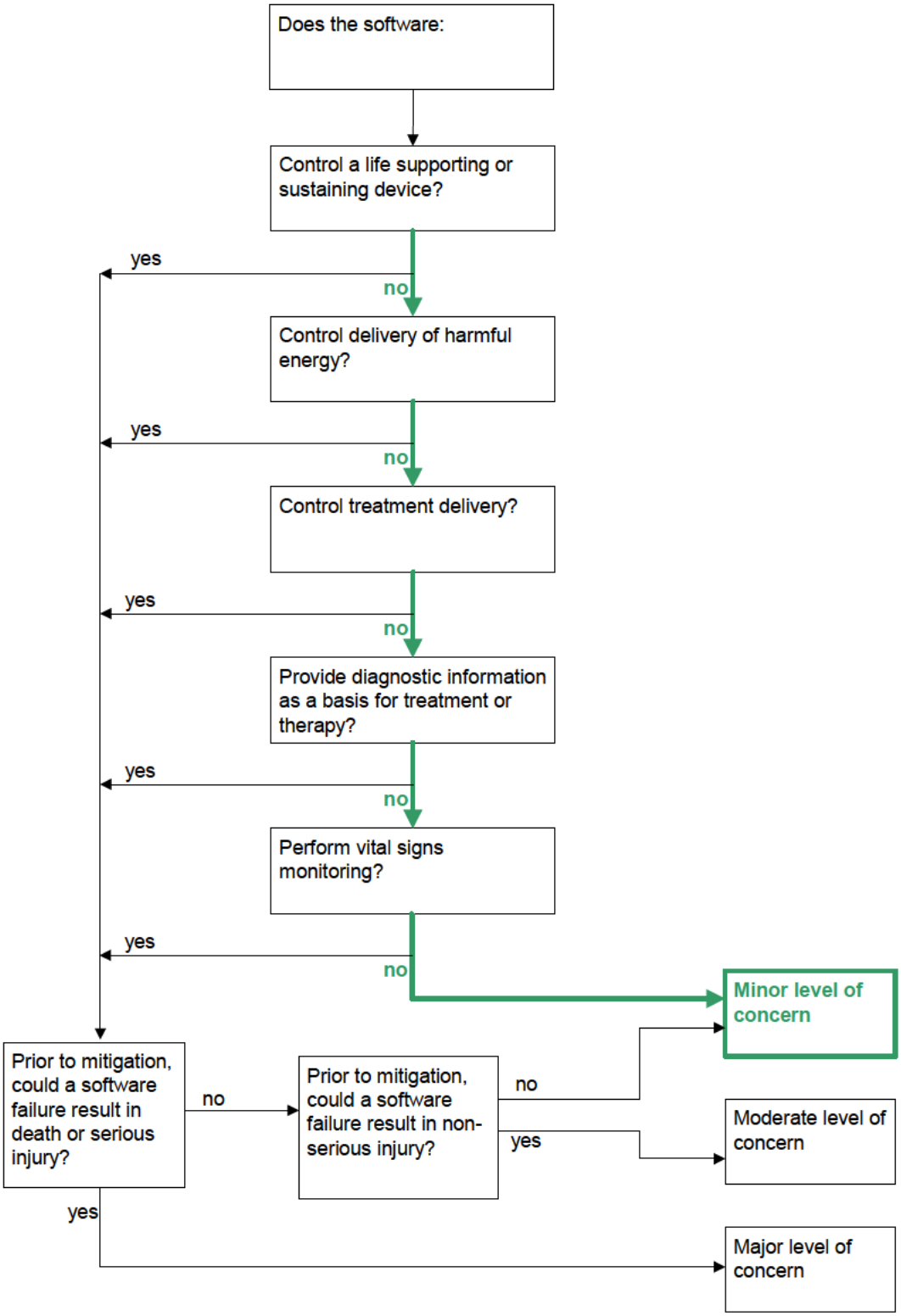
The standard report forms can be found at the end of the document (pages 13 and 14). The documentation of the design process for usability is part of the risk management and can be found in section “009 Declarations of Conformity and Summary Reports”.

Level of concern:

According to the figure below the determination of the Level of Concern for the iSYS1 software results in a “**Minor level of concern**”.

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016



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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

According to Chapter 3 of the *Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices* and the *Level of Concern* of this product, the following documentation will provide the following content:

SOFTWARE DOCUMENTATION	MINOR CONCERN	MODERATE CONCERN	MAJOR CONCERN
Level of Concern	A statement indicating the Level of Concern and a description of the rationale for that level.		
Software Description	A summary overview of the features and software operating environment.		
Device Hazard Analysis	Tabular description of identified hardware and software hazards, including severity assessment and mitigations.		
Software Requirements Specification (SRS)	Summary of functional requirements from SRS.	The complete SRS document.	
Architecture Design Chart	No documentation is necessary in the submission.	Detailed depiction of functional units and software modules. May include state diagrams as well as flow charts.	
Software Design Specification (SDS)	No documentation is necessary in the submission.	Software design specification document.	
Traceability Analysis	Traceability among requirements, specifications, identified hazards and mitigations, and Verification and Validation testing.		
Software Development Environment Description	No documentation is necessary in the submission.	Summary of software life cycle development plan, including a summary of the configuration management and maintenance activities.	Summary of software life cycle development plan. Annotated list of control documents generated during development process. Include the configuration management and maintenance plan documents.
Verification and Validation Documentation	Software functional test plan, pass / fail criteria, and results.	Description of V&V activities at the unit, integration, and system level. System level test protocol, including pass/fail criteria, and tests results.	Description of V&V activities at the unit, integration, and system level. Unit, integration and system level test protocols, including pass/fail criteria, test report, summary, and tests results.
Revision Level History	Revision history log, including release version number and date.		
Unresolved Anomalies (Bugs or Defects)	No documentation is necessary in the	List of remaining software anomalies, annotated with an explanation of the	

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

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Form Approved: OMB No. 0910-0120; Expiration Date: 12/31/13

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

IEC 62366, Medical devices - Application of usability engineering to medical devices

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	#5-50	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☐	☒
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☒
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☒	☐
If yes, was the guidance document followed in preparation of this 510k?	☒	☐

Title of guidance: Medical Device Use-Safety: Incorporating Human Factors into Risk Management

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

[5] The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[6] The online search for CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html

FORM FDA 3654 (12/10) Page 1

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Form Approved: OMB No. 0910-0120; Expiration Date: 12/31/13

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

IEC 62304 First edition 2006-05, Medical device software - Software life cycle processes

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	#13-8	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☐	☒
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☒
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☒	☐
If yes, was the guidance document followed in preparation of this 510k?	☒	☐

Title of guidance: Guidance for the Content of Premarket Submissions, Guidance for Off-the-Shelf Software, et. al.

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

[5] The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[6] The online search for CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html

FORM FDA 3654 (12/10) Page 1

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Electromagnetic Compatibility and Electrical Safety

Table of Content

General	2
Forms FDA 3654	3
Test Report “Electrical Safety”	6
Test Report “Electromagnetic Compatibility”	8
Certificates	23

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Electromagnetic Compatibility:

Tests according to ÖNORM EN ISO 60601-1-2 and FCC requirements performed at seibersdorf laboratories. For test report and certificates see below.

Electrical Safety:

At the **present and until April 2013** (EN ISO 60601-1 2nd edition becoming invalid) testing of each individual system at the Notified Body 0408 (TUV Austria) according to:

- EN 60601-1:1990 + A1:1993 + A2:1995
- EN 60601-1-8:2004 + A1:2006

Example of test report and certificates can be found in below.

Starting from **QIII/2013** type testing including CB-test report and UL-listing at the Notified Body 0408 (TUV Austria) according to:

- IEC 60601-1 3rd Edition
- IEC 60601-1-8

Test strategy is prepared and a risk analysis is already running.

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Forms FDA 3654

Form Approved: OMB No. 0910-0120; Expiration Date: 12/31/13

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

IEC 60601-1, Medical Electrical Equipment - Part 1: General Requirements for Safety, 1988; Amendment 1, 1991-11, Amendment

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	#5-4	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☒
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: _____

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

[5] The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[6] The online search for CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html

FORM FDA 3654 (12/10) Page 1

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Form Approved: OMB No. 0910-0120; Expiration Date: 12/31/13

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

IEC 60601-1-2, Medical Electrical Equipment - Part 1-2: General Requirements for Safety - Collateral standard: Electromagnetic C

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	#5-34	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☒
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☒	☐
If yes, was the guidance document followed in preparation of this 510k?	☐	☒

Title of guidance: _____

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

[5] The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[6] The online search for CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html

FORM FDA 3654 (12/10) Page 1

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Form Approved: OMB No. 0910-0120; Expiration Date: 12/31/13

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

IEC 60601-1-8 Ed. 1, Medical electrical equipment - Part 1-8: General requirements for safety - Collateral Standard: Alarm System

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3] #5-49		
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☒
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510k?	☐	☐
Title of guidance:		

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

[5] The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[6] The online search for CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html

FORM FDA 3654 (12/10) Page 1

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

(b)(4)Third Party Test Data

(b)(4)Third Party Test Data

(b)(4)Third Party Test Data

(b)(4)Third Party Test Data

(b)(4)Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4)Third Party Test Data

(b)(4)Test Report

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

PD/B18	Performance Testing Bench 510(k) Number:	iSYS Medizintechnik GmbH

(b)(4)

[redacted]

Q

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Performance Testing – Animal

Not applicable

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Performance Testing – Clinical

Content Page

Clinical Evaluation Summary 2

Form FDA 3674 37

Clinical studies as provided with the last submission can be found on the appendix CD and the section “Statistical Data and Misc Files” of the eSubmission.

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Table of Content:

1 Introduction 4
1.1 Claimed benefit of the medical product 5
1.2 Risks and side effects connected with the medical product 5
1.3 List of clinical performance and safety 6
2 Reference to former Clinical Data 8
2.1 Treatment Improvement for the Patient 8
2.2 Negative effects on the patient 9
2.3 Workflow 10
2.4 Limitations 10
2.5 Cost Effectiveness 12
2.6 Conclusion 12
2.7 References 12
3 Performed Evaluations 13
3.1 Description of Evaluation #1 13
3.1.1 Method 13
3.1.2 Procedure 13
3.1.3 Evaluation of the Improvement 14
3.1.4 Results 14
3.2 Description of Evaluation #2 14
3.2.1 Method 14
3.2.2 Procedure 14
3.2.3 Evaluation of the Improvement 14
3.2.4 Results 15
3.2.5 Evaluation 21
3.3 Description of Evaluation #3 23
3.3.1 Method 23
3.3.2 Procedure 23
3.3.3 Evaluation of the Improvement 24
3.3.4 Results 24
3.4 Description of Evaluation #4 25
3.4.1 Method 25
3.4.2 Procedure 25
3.4.3 Evaluation of the Improvement 25

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

3.4.4 Results **25**
3.4.5 Evaluation **27**
3.5 Description of Evaluation #5 ..... **28**
3.5.1 Method **29**
3.5.2 Procedure **29**
3.5.3 Evaluation of the Improvement **29**
3.5.4 Results **29**
3.6 Description of Evaluation #6 ..... **29**
3.6.1 Method **29**
3.6.2 Procedure **29**
3.6.3 Evaluation of the Improvement **30**
3.6.4 Results **30**
4 Discussion and summarizing clinical validation **31**
4.1 Clinical Evaluator **31**
4.2 Suitability of the data **31**
4.3 Summary **31**
4.4 Conclusion **33**
5 Summary of clinical experience in Post Marketing **34**
5.1 Update 2012-01-11 ..... **34**
5.2 Results **35**

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

1 Introduction

Micro-invasive surgical procedures are gaining increasing importance in medicine due to the high efficiency level (clinical outcome) and low socio-economic costs. The **iSYS 1** provides a state-of-the-art solution which is able to fulfill the three main requirements – accurate positioning, easy integration into clinical workflow as well as a simple and fast setup procedure.

The iSYS 1 is a modular needle guidance platform for interventional radiology and related fields. Core components are a 4 DOF micro positioning unit, which allows needle positioning from simple needle angulations up to positioning and angulations with adjustable pivot point, and a control unit which is directed by a cable connected control panel. The passive macro positioning unit and various table adapters allow different setups of the system in the region of interest at the patient by still providing maximum rigidity. The needle guide kit provides disposable components that ensure precise and sterile needle guidance. Planning of the intervention is based on digital image data acquired intra-operatively using different kinds of modalities, like CT or fluoroscopy (standard C-arms and/or cone-beam CT systems). Planning of both the entry position of the needle-type tool as well as the angulation is done by means of the used imaging device or by an external navigation system. By using the iSYS 1 HCU, the surgeon can remotely move the tool into the desired position and angulation in order to start the clinical procedure.

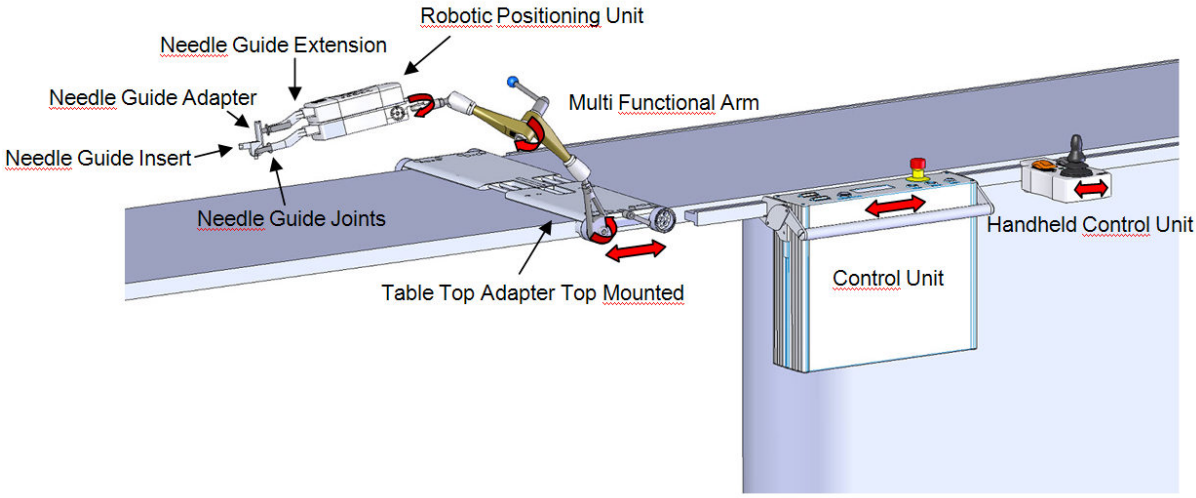


Figure 1: General iSYS system setup

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

The major product parts include the following parts:

- one Control Unit, including a Handheld Control Unit
- one Side Rail or Table Top Adapter
- one Multi Functional Arm
- one Robotic Positioning Unit
- two Needle Guide Extensions
- one Needle Guide coupled with a Sterile Cover (not reusable)
- one Needle Insert (not reusable)

1.1 Claimed benefit of the medical product

The iSYS-1 Interventional Platform has clear advantages over alternative methods of instrument placement:

- The treatment results are markedly improved while the costs of treatment are reduced.
- The radiation exposure for both the patient and the surgical team is being reduced substantially.
- In this way, long-term damage to the surgical team carrying out the treatment will be avoided.

Through the use of the iSYS-1 system, it is no longer necessary to work with the "hand in the beam" and / or in the vicinity of the imaging device. The general setup, the workflow, the system layout and the technical data of the robot give the following key features for the overall system and application:

- High system accuracy
- High safety standards
- Intuitive use - easy and fast handling
- Using the latest technology
- Extremely flat design allows the use inside the gantry of the respective imaging device: The system works in the beam and the operator from safe distance.

1.2 Risks and side effects connected with the medical product

The hazards, and thus the risks, connected with the iSYS 1 are in general:

Hazards to the patient:

- Electrical Shock
- Infection

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

- Burning
- Mechanical Injury
- Mistreatment

Hazards to the operator and other persons, e.g. service technician:

- Electrical shock
- Infection
- Burning
- Mechanical Injury
- Ergonomics

Generic hazards:

- Interference with other medical devices
- Malfunction of other devices
- Environmental hazards

After performing the risk analysis and the risk management process (including mitigations), no further risks remain in connection with the iSYS 1 that can be considered as “not acceptable”. One **purpose of this document** is to proof that the remaining ALARP-Cases after the risk management process are compared to the clinical benefit acceptable and state-of-the-art for comparable interventions.

1.3 List of clinical performance and safety

Performance / Safety Characteristic	Proofed by
The solutions adapted by the manufacturer for the design and construction of the devices must conform to safety principles, taking account of the generally acknowledged state of the art.	Pre-Study and below
The characteristics and performances referred to in Sections 1, 2 and 3 must not be adversely affected to such a degree that the clinical conditions and safety of the patients and, where applicable, of the other persons are compromised during the lifetime of the device as indicated by the manufacturer, when the device is subjected to the stresses which can occur during normal conditions of use.	Pre-Study and below
Risks due to damages by X-Ray radiation of the imaging device (power supply).	Pre-Study
Risks due to damages by X-Ray radiation of the imaging device (data cable, hhc cable).	Pre-Study

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Risks due to malfunction of electronic components due to X-Ray radiation of the imaging device.	Pre-Study
The devices must be designed and manufactured in such a way as to guarantee the characteristics and performances referred to in Section I on the 'General requirements'. These are in particular:	Pre-Study and below
Reduction of radiation	Pre-Study, Seamon
Use in clinical environment	Pre-Study, Rentschler, Maresceaux
Improvement of workflow	Pre-Study, Sarle, Prasad, Zhang, MAS, McIntosh
Reduction of costs	Pre-Study, CADTH, MAS, McIntosh, Camberlin
Safety in general	Pre-Study, Chitwood
Feasibility	Pre-Study, Lobe
Performance	Pre-Study, Hanly, Hayashibe, Lum, Mendez, Comite de Evaluation

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

2 Reference to former Clinical Data

During the pre-study for the iSYS 1, a database and a literature analysis has been performed to detect the state-of-the-art and the competitors for the product idea of a telemanipulated robot unit for needle procedures. The analysis are documented in
"QA_73_2750_PD-D02_LitAnalysis" from 2010-09-01
"QA_73_2199_DataBaseAnalysis" from 2010-09-03
The results are summarized in the following chapters. For references in the following chapters, please see also the documents listed above.

2.1 Treatment Improvement for the Patient

Most systems [ref.1, 3, 5, 9, 13] on the market or in the publications show an improvement in the accuracy for this kind of interventions (needle procedures or comparable) by using teleinterventional means, while no additional or unacceptable risks or hazards for patient and users appear. Also, the present systems always allow the change to a manual procedure at any given point during the intervention, in case this should become necessary. Although rarely found in the literature, the improvement in accuracy appears only when comparing minimal invasive surgery with teleinterventional systems. Compared to the open surgery (not minimal invasive surgery), the accuracy and failure rate is also for the described systems significantly higher [ref.3]. The advantages of minimal invasive surgery compared to traditional surgery (pain, infections, scars) are not to be described in this paper (see Literature e.g. for ATLAS Interventional Guidance Platform). With this improvement in accuracy, some negative side effects of surgical interventions, like harming healthy tissue, can be reduced.
Improving the accuracy of applications can involve an increased contact surface of the implant to the region of the human body where it is mounted (hip or knee). This increase in surface contact increases the lifetime of an implant by reducing the forces on body and implant. Therefore, the information gained from pre-operation processes (CT, MRI) must be implemented into the intervention planning and realization. State-of-the-art for manual interventions is an information transfer rate of 30% - 40% for pre-operation planning. With the need to reduce the size of the aditus, the goal to transact more information can only be reached by an automated system that uses the information for intervention planning to realize this approach reliably [ref. 11, 12, 17, 18, 23, 26, 30].

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Thus, putting a robot under control of a surgeon for clinical interventions means combining medical knowledge with the precision of a robot [ref.12, 15].
Another aspect besides the accuracy is the capability of telemanipulation systems to reach certain areas of the human body that could not be reached conventionally or would require a bigger tissue opening. The range of this capacity strongly depends on pre-operative navigation and planning systems [ref.10, 21].
A general advantage of these systems is that they are not depending on the direct visual contact between surgeon and patient. This allows consultancy through other experts during the intervention via the transmission of the video picture to almost any point in the world with the help of modern communication systems, including the problems that arise with the use of modern technology [ref.5, 12].

2.2 Negative effects on the patient

A negative effect for the patient in a psychological manner is the acceptance of a mechanical system preparing interventions instead of a human surgeon. This effect is added by the negative reputation that some systems for teleintervention received in press and public media (e.g. CASPAR) over the last years. Thus, the advantages of the system have to be explained to the patient. In addition, the personal/visual contact between medical doctor and patient helps to reduce this psychological side effect [ref.5, 17].
One reference [28] reports of bigger wounds, a bigger loss of blood and more complications, which was, except for ROBODOC, not verified. Also, the author mentioned that robots are only able to mill curved structures and the exposure to radiation rises due to the required pre-operative CT scan. This is not true since reference scans during a conventional intervention produce the same or more exposure to radiation, different instruments provide several shapes for milling, and the DOFs allow the correct positioning.
Nevertheless, the case of bigger wounds results in respective post-marketing measures at iSYS for the first products sold to customers (first series). The medical device consultant has to contact the customers to receive information about similar experiences with the iSYS 1. This is already fixed in the post marketing actions for the iSYS 1 (see PD_A10).

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

2.3 Workflow

Some interventions were unnecessarily prolonged (up to the factor of four) by complicated set-ups or problems due to repositioning as well as untrained users. This can be a problem for anesthesia or if a heart-lung-machinery is also in use [ref.3, 5, 17. 28]. Also the setting of reference pins needed with some systems requires an extra intervention which of course is an additional burden for the patient [ref.3, 11, 23]. Single references report, that the operation time was not prolonged [ref.22]. As an effect of the new technology, the physicians need to learn the technical aspects with its general limitations (see below) and risks for patient and user [ref.5].

A big advantage for the physician is the possibility to simulate the complete surgical intervention on a digital system. This allows the training of the physician in general (during education), for special interventions or applications [ref. 15] or the transfer of knowledge from one institute to another [ref.12]. Additionally, the possibility of recording the operation allows full and save documentation in case of arising conflicts between patient and surgeon [ref.5, 10]. The discussion of liability during failure occurrence finally leads to the argument, that the medical expert is responsible for the intervention, including the medical devices used for it. This means that in cases of a robotic system failure, the implementation of safety features puts the responsibility of the patient's safety on the leading medical expert that is the user of the system [ref.17].

Additionally, the presence of a trained technician is recommended for a successful intervention and the anesthetic procedures have also become more complicated [ref.3, 5]. The physical stress for the surgeon is minimized as he/she is now able to perform the intervention while seated comfortably, without the physical limitations occurring in conventional surgery [ref.9]. The system can also compensate changes in the (physical) constitution of the human user intervention [ref.31].

2.4 Limitations

The systems that are limited in their degrees of freedom [e.g. URS Evolution I; RoMed needs a pre-positioning system] show an insufficient range of movement for some interventions. Also other systems (Stäubli, ZEUS) with six DOFs cannot reach each point within the area of interest. Thus, the area of interest and the work envelope do not overlap sufficiently [ref.9]. This is one big advantage of the iSYS robotic system. By the combination of two or more robotic modules, up to six degrees of freedom are

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

achievable while the range of movement is limited by a manual pre-positioning with the ATLAS MultifunctionalARM™s.

Most systems (URS; RoMed, Stäubli) are quite big, and therefore not applicable in every situation [ref.11]. The iSYS robotic system weighs about 2kg.

Limitations related to the patient are [ref.5]:

- not for use in emergencies (no planning possible)
- no combination of interventions/applications
- only one or two vessels are to be treated
- the patient is in good physical and mental condition
- the area of interest is the first time the reason for an intervention (no re-operations)

One big problem in the development of robotic systems for the medical use is the missing standards for safety for this kind of systems. It is neither legitimate nor sensible to transfer safety guidelines from industrial robots as they do not allow any person within their working area, with is essential for the medical use of robotic systems. So only some aspects concerning safety can be fixed [ref.17, 18]:

- the speed of the industrial systems, as well as the operating force, have to be reduced in order to minimize damage in cases of failure
- after a certain amount of movement a short break should give the physician the opportunity to check up the intervention
- complex movements should be reduced to simple movements with one DOF only; this reduces harm to the patient, if an error occurs
- a second, redundant and independent system has to be implemented to supervise movements
- safety switches (“dead man switch”) should be used
- sensors for force and torque should control and limit the movements
- the definition of “no-go areas” should be possible for the user
- it should be possible to abort the robotic intervention and continue the intervention conventionally at any given time, should this become necessary (e.g. if the endoscope’s lens is covered with blood and control is no longer possible) [ref. 15].

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

2.5 Cost Effectiveness

Possible disadvantage of the presented systems are the investment costs [ref.1, 5, 12]. While most of the systems burden the hospitals budget with millions for the purchase, the running costs per applications are high as well (ca. 300€ per application for NeuroMate®). Also, some manufacturers keep on arguing, that the saved time and the higher effectiveness of the robotic system will compensate the higher costs for investment. An argumentation, that has yet to be demonstrated [ref.21].

Future projects try to visualize or project the relevant data on the skin of the patient as well as on the monitor. With this combination, supervising a surgery that is performed from the control room next door by standing beside the patient becomes possible. The positioning accuracy at the moment is ± 1.5mm. It should also be possible to visualize the already examined area together with the area of interest to minimize interventions time and reduce endoscope movements [ref.15].

2.6 Conclusion

In summary, the benefits deriving from telemanipulation systems for minimal invasive surgery overweigh the additional costs and risks. The additional risks compared to a manual needle invention are the use of electricity for the robot unit, which is nowadays under control and can be considered as safe if applying the respective standards, and the danger of infections due to the use of additional components.

2.7 References

See “QA_73_2750_PD-D02_LitAnalysis” from 2010-09-01 and “QA_73_2199_DataBaseAnalysis” from 2010-09-03.

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

3 Performed Evaluations

3.1 Description of Evaluation #1

Study number:	**1**	***Study name:***	***Literature Search 1***
Reference:	*See "EX_66_4270_Evaluation1" for search details*		
Short Description:	*Search the data base "Google Scholar" for literature of comparable and own products to define the suitable search parameters.*		
Location:	*IMA* *Viktor-Kaplan-Str. 2* *A-2700 Wiener Neustadt*		
Date:	*2011-05-03*		

3.1.1 Method

The database "Google Scholar" was searched to define the correct search parameters.

3.1.2 Procedure

The following parameters were used:

Artikel finden	mit **allen** Wörtern	surgical, robotics
	mit der **genauen Wortgruppe**	
	mit **irgendeinem** der Wörter	
	ohne die Wörter	
	die meine Wörter enthalten	irgendwo im Artikel
Autor	Artikel geschrieben von	z. B. *"Stephen Hawking"* oder *Hawking*
Veröffentlichung	Artikel veröffentlicht in	z. B. *NJW* oder *Nature*
Datum	Artikel veröffentlicht zwischen	— z.B. *1996*

The number of findings was 46.100. The search parameters were thus changed to…

Artikel finden	mit **allen** Wörtern	surgical, robotics
	mit der **genauen Wortgruppe**	
	mit **irgendeinem** der Wörter	
	ohne die Wörter	
	die meine Wörter enthalten	irgendwo im Artikel
Autor	Artikel geschrieben von	z. B. *"Stephen Hawking"* oder *Hawking*
Veröffentlichung	Artikel veröffentlicht in	z. B. *NJW* oder *Nature*
Datum	Artikel veröffentlicht zwischen	2000 — 2011 z.B. *1996*

…as mainly latest articles are relevant for the literature search. The number of results was then 16.500.

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Afterwards, the search words have been limited to the title of the article. This reduced the number of findings to 177.

Artikel finden	mit **allen** Wörtern	surgical, robotics
	mit der **genauen Wortgruppe**	
	mit **irgendeinem** der Wörter	
	ohne die Wörter	
	die meine Wörter enthalten	im Titel des Artikels
Autor	Artikel geschrieben von	z. B. *"Stephen Hawking"* oder *Hawking*
Veröffentlichung	Artikel veröffentlicht in	z. B. *NJW* oder *Nature*
Datum	Artikel veröffentlicht zwischen	2000 — 2011 z.B. *1996*

3.1.3 Evaluation of the Improvement

Not applicable.

3.1.4 Results

The 177 findings will be analyzed and documented.

3.2 Description of Evaluation #2

Study number:	**2**	***Study name:***	***Literature Search 2***
Reference:	-		
Short Description:	*Analyze the search results from Evaluation 1*		
Location:	*IMA* *Viktor-Kaplan-Str. 2* *A-2700 Wiener Neustadt*		
Date:	*2011-05-03*		

3.2.1 Method

Subject of this clinical investigation is the use of robotic components in a surgical environment with the focus on needle and needle-like procedures.

3.2.2 Procedure

The following table (see 3.2.4) summarizes the results and gives short information about the literature found. Relevant data in literature is then discussed in chapter 3.2.5.

3.2.3 Evaluation of the Improvement

Not applicable.

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

3.2.4 Results

First Author	Title	Reference*	Relevance
Kevin Cleary	State of the art in surgical robotics: Clinical applications and technology challenges	EX_66_2407_wi_CLE-2001	relevant already analyzed in pre-study
Satava, Richard	Surgical Robotics: The Early Chronicles: A Personal Historical Perspective	-	not relevant
Chitwood WR	Minimally invasive videoscopic mitral valve surgery: the current role of surgical robotics	-	relevant
Richard Sarle	Surgical Robotics and Laparoscopic Training Drills	-	minor relevant
Louw, Deon	Surgical Robotics: A Review and Neurosurgical Prototype Development	-	minor relevant
Marohn	Twenty-first century surgery using twenty-first century technology: Surgical robotics* 1	-	*cannot be viewed*
D Stoianovici	Multi-imager compatible actuation principles in surgical robotics	-	not relevant
Thom E Lobe	Novel Uses of Surgical Robotics in Head and Neck Surgery	-	relevant
Pott	Today's state of the art in surgical robotics	-	*page not found*
Hong Gee Sim	Equipment and technology in surgical robotics	-	not relevant, overview only
Gourin, Christine	Surgical robotics in otolaryngology: expanding the technology envelope	-	minor relevant
Hockstein	A history of robots: from science fiction to surgical robotics	-	not relevant

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Patrick A. Finlay	Surgical Robotics	EX_66_4272_wi_FIN-2007	minor relevant
Sunil Prasad	Surgical robotics: Impact of motion scaling on task performance	-	relevant
Hagn	DLR MIROSURGE—towards versatility in surgical robotics	-	not relevant
Satava	The future of sugical simulation and surgical robotics.	-	no abstract available not relevant
Pua, E.C.	3-D ultrasound guidance of surgical robotics: a feasibility study	-	Ultrasound not relevant
Eric J. Hanly	Mentoring Console Improves Collaboration and Teaching in Surgical Robotics	-	relevant
Hayashibe	Preoperative planning system for surgical robotics setup with kinematics and haptics	-	relevant
Rembold	Surgical robotics: An introduction	-	not relevant
Nele Famaey	Soft tissue modelling for applications in virtual surgery and surgical robotics	-	not relevant
Korb	Risk analysis and safety assessment in surgical robotics: A case study on a biopsy robot	EX_66_2398_wi_KOR-2005	relevant already analyzed in pre-study
DU Zhi-jiang	Present status and key techniques of surgical robotics	-	not relevant
Philipp J. Stolka	Improving Navigation Precision of Milling Operations in Surgical Robotics	EX_66_4273_wi_STO-2006	relevant

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Philipp J. Stolka	Building local maps in surgical robotics	-	not relevant
Nifong	Building a surgical robotics program	-	not relevant
J Whitman	Autonomous surgical robotics using 3-D ultrasound guidance: Feasibility study	-	Ultrasound not relevant
MA Connor	Perioperative nurse training in cardiothoracic surgical robotics		minor relevant
RJ Franzino	The Laprotek surgical system and the next generation of robotics	PD_D01	relevant already analyzed in pre-study
P Kazanzides	Surgical and interventional robotics-core concepts, technology, and design	EX_66_2386_wi_FIC-2008	relevant already analyzed in pre-study
Leigh G. Seamon	Minimally invasive comprehensive surgical staging for endometrial cancer: Robotics or laparoscopy?	-	relevant
KA Guru	Impact of robotics and laparoscopy on surgical skills: a comparative study	-	relevant
Wang	Minimally invasive surgical training using robotics and tele-collaboration	-	minor relevant
V. Chandra	Surgical robotics and image guided therapy in pediatric surgery: Emerging and converging minimal access technologies	-	minor relevant
V Musahl	Current opinion on computer-aided surgical navigation and robotics: role in the treatment of sports-related injuries	-	not relevant

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

MA White	Comparative Analysis of Surgical Margins Between Radical Retropubic Prostatectomy and RALP: Are Patients Sacrificed During Initiation of Robotics Program?	-	minor relevant
RD Katz	Robotics in microsurgery: use of a surgical robot to perform a free flap in a pig	-	minor relevant
SE Langenburg	Surgical robotics: Creating a new program	-	not relevant
MJH Lum	Teleoperation in surgical robotics–network latency effects on surgical performance	-	relevant
K. C. Veluvolu	Estimation and filtering of physiological tremor for real-time compensation in surgical robotics applications	-	not relevant
BC Shah	Miniature in vivo robotics and novel robotic surgical platforms	-	relevant
G Hager	Surgical and interventional robotics: part III	EX_66_2386_wi_FIC-2008	relevant already analyzed in pre-study
J Maresceaux	Image fusion, virtual reality, robotics and navigation. Effects on surgical practice	-	very relevant
IAMJ Broeders	Robotics revolutionizing surgery: the Intuitive Surgical “Da Vinci” system	-	relevant no new information
I Sakuma	Surgical Robotics	-	minor relevant
KC Curley	Innovation by committee? Reigniting surgical robotics research and development	-	not relevant

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

JS Dai	Surgical robotics and its development and progress	-	relevant
J Whitman	3-D ultrasound guidance of surgical robotics using catheter transducers: Feasibility study	-	Ultrasound not relevant
S. J. Belsley	1st International Congress of the Minimally Invasive Robotic Association (MIRA), 7–10 December 2006, Innsbruck, Austria. Congress summary: MIRA and the future of surgical robotics	-	minor relevant
GS Lee	Cyber physical systems security applied to surgical robotics	-	page error when loading
P Gomes	Surgical robotics: Reviewing the past, analysing the present, imagining the future	-	not relevant
J Raczkowsky	Karlsruhe Surgical Robotics Research	-	minor relevant
RV Clayman	Surgical robotics: impact of motion scaling on task performance	-	no abstract available
Munoz, V.F	Risk analysis for fail-safe motion control implementation in surgical robotics	-	not relevant
ME Rentschler	In vivo abdominal surgical robotics: Tissue mechanics modeling, robotic design, experimentation, and analysis	-	relevant
Satava	How the future of surgery is changing: Robotics, telesurgery, surgical simulators and other advanced technologies	-	not relevant
A Hattoria	Surgical Robotics and Instrumentation	-	not relevant

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

I Broeders	Robotics in the operating theatre of the future: Advanced technology in an adapted surgical workplace	-	relevant no new information
MA Davis	Robotic-assisted laparoscopic exenteration in recurrent cervical cancer Robotics improved the surgical experience for 2 women with recurrent cervical cancer.	-	relevant
MO Culjat	Tactile Feedback in Surgical Robotics	-	not relevant
JC Bowersox	The Future of Surgical Robotics.	-	not relevant
T Haidegger	Surgical robotics in neurosurgery	-	not relevant
	The following findings provide information on a meta-level only and are minor relevant while the information is presented in the given findings already.		

* either in the same folder of the PDM or in C:\iSYS-Datentresor\06. QUALITÄTSMANAGEMENT\660_WISSENSMANAGEMENT\Literatur

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

3.2.5 Evaluation

Safety:

Chitwood: From this and other work reviewed, we conclude that video-assisted and computer-assisted robotic techniques are safe and may be the pathway to truly endoscopic mitral valve operations. We are encouraged regarding the use of this new technology for mitral valve operations.

Reduction of radiation:

Seamon: Robotic hysterectomy and lymphadenectomy for endometrial carcinoma can be accomplished in heavier patients and results in shorter operating times and hospital length of stay, a lower transfusion rate, and less frequent conversion to laparotomy when compared to laparoscopic hysterectomy and lymphadenectomy.

Use in clinical environment:

Rentschler: Combined with laboratory bench-top testing, this model helped predict a suitable wheel design for traversing the abdominal organs without tissue damage.

Maresceaux: When integrating all of the data recorded during this preoperative stage, an enhanced reality can be made possible to improve intra-operative patient interactions. CAS allows for increased three-dimensional accuracy, improved precision and the reproducibility of procedures. The ability to store the actions of the surgeon as digitized information also allows for universal, rapid distribution: i.e., the surgeon's activity can be transmitted to the other side of the operating room or to a remote site via high-speed communications links, as was recently demonstrated by our own team during the Lindbergh operation. Furthermore, the surgeon will be able to share his expertise and skill through teleconsultation and telemanipulation, bringing the patient closer to the expert surgical team through electronic means and opening the way to advanced and continuous surgical learning. Finally, for postoperative interaction, virtual reality and simulation can provide us with 4 dimensional images, time being the fourth dimension. This should allow physicians to have a better idea of the disease process in evolution, and treatment modifications based on this view can be anticipated. We are presently determining the accuracy and efficacy of 4 dimensional imaging compared to conventional evaluations.

Improvement of workflow:

The improvement of the workflow may also have influence on the reduction of costs as more interventions can be performed a day.

Sarle: The robotic system allowed surgeons to complete drills faster than traditional laparoscopy. Novice laparoscopic surgeons performed three of the four drills faster robotically than did expert laparoscopic surgeons. These findings may indicate that the attributes of the robotic system level

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

the playing field between surgeons of different skill levels. The next generation of surgeons must focus on this evolving technology and its application in the operating room of the future.

Prasad: Motion scaling, rather than tremor filtration, plays the major role in the enhanced accuracy seen in robotic surgical systems. Robotic assistance with MS significantly improved accuracy above laparoscopic instruments alone and robotic assistance with tremor filtration alone. MS also creates ambidexterity in an otherwise unidextrous population, optimizing the surgeon's ability to undertake tasks requiring microsurgical accuracy.

Dai: Surgical robotics is the study and application of advanced robotic technology to diverse surgical procedures, particularly to minimally invasive surgery. The advanced robotic technology in minimally invasive surgery leads to momentous change in and generates a tremendous impact on surgery, resulting in less pain and scarring, reduced blood loss and transfusions, lower risk of complication, shorter hospital stays and faster recovery periods.

Feasibility:

Lobe: Transaxillary, endoscopic, robotically assisted approaches to the head and neck are feasible. The addition of robotics improves surgical dexterity in a difficult-to-reach anatomic region. Patient satisfaction appears high because of the avoidance of a cervical incision.

Improvement of performance:

Hanly: The da Vinci mentoring console greatly facilitates surgeon collaboration during robotic surgery and improves the performance of complex surgical tasks. The mentoring console has the potential to improve resident participation in surgical robotics cases, enhance resident education in surgical training programs engaged in surgical robotics, and improve patient safety during robotic surgery.

Hayashibe: Recently, some useful robotic surgical systems have been developed and applied in many surgical situations. Systems such as the da Vinci™ surgical system of Intuitive Surgical Inc., which facilitates minimally invasive surgery with increased dexterity, are commercially available. Preoperative simulation and planning of surgical robot setups should accompany advanced robotic surgery if their advantages are to be further pursued. Feedback from the planning system will play an essential role in computer-aided robotic surgery in addition to preoperative detailed geometric information from patient CT/MRI images. Surgical robot setup simulation systems for appropriate trocar site placement have been developed especially for abdominal surgery. The motion of the surgical robot can be simulated and rehearsed with kinematic constraints at the trocar site, and the inverse-kinematics of the robot. Results from simulation using clinical patient data verify the effectiveness of the proposed system.

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Lum: There were no statistical differences between experienced surgeons and non-surgeons in the number of errors (block drooping) as well as the completion time and the tool tip path length at different time delays.

Davis: Pelvic exenteration can be used to cure women with a central pelvic recurrence or persistence of gynecologic malignancy after initial definitive therapy. Refinements in patient selection, operative techniques, and surgical instrumentation have significantly improved outcomes over the past 60 years, but the procedure is still associated with significant mortality, morbidity, and recovery time. New technologies have made it possible to approach radical gynecologic surgeries in a minimally invasive fashion.

Limitations:

Shah: Robotic surgical systems, such as the da Vinci Surgical System (Intuitive Surgical, Inc., Sunnyvale, California), have revolutionized laparoscopic surgery but are limited by large size, increased costs, and limitations in imaging. Miniature in vivo robots are being developed that are inserted entirely into the peritoneal cavity for laparoscopic and natural orifice transluminal endoscopic surgical (NOTES) procedures. In the future, miniature camera robots and microrobots should be able to provide a mobile viewing platform.

3.3 Description of Evaluation #3

Study number:	**3**	***Study name:***	***Literature Search 3***
Reference:	*See "EX_66_4274_Evaluation3" for search details*		
Short Description:	*Perform the same search as in Evaluation 1, but change the sequence of search words.*		
Location:	*IMA* *Viktor-Kaplan-Str. 2* *A-2700 Wiener Neustadt*		
Date:	*2011-05-03*		

3.3.1 Method

Perform the same search as in Evaluation 1, but change the sequence of search words.

3.3.2 Procedure

The following parameters were used:

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Artikel finden	mit **allen** Wörtern	robotics surgical
	mit der **genauen Wortgruppe**	
	mit **irgendeinem** der Wörter	
	ohne die Wörter	
	die meine Wörter enthalten	im Titel des Artikels
Autor	Artikel geschrieben von	z. B. *"Stephen Hawking"* oder *Hawking*
Veröffentlichung	Artikel veröffentlicht in	z. B. *NJW* oder *Nature*
Datum	Artikel veröffentlicht zwischen	2000 — 2011 z.B. *1996*

3.3.3 Evaluation of the Improvement

Not applicable.

3.3.4 Results

The search led to the same 177 results as the first search.

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

3.4 Description of Evaluation #4

Study number:	**4**	***Study name:***	***Literature Search 4***
Reference:	*See "EX_66_4281_Evaluation4.1" and "EX_66_4281_Evaluation4.2" for search details*		
Short Description:	*Search the CDR database for literature. Keyword: "robot"*		
Location:	*IMA Viktor-Kaplan-Str. 2 A-2700 Wiener Neustadt*		
Date:	*2011-05-04*		

3.4.1 Method

Search the CDR database for literature.

3.4.2 Procedure

The following parameters were used:

"robot"

3.4.3 Evaluation of the Improvement

Not applicable.

3.4.4 Results

The search led to 35 results.

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

First Author	Title	Reference*	Relevance*
Liu Hongqian	Robotic surgery for benign gynaecological disease	-	not available
Canadian Agency for Drugs and Technologies in Health	Draft report: robot-assisted surgery versus open surgery and laparoscopic surgery: clinical and cost-effectiveness analyses	-	minor relevant costs and effectiveness only
McIntosh H	Open, laparoscopic and robot-assisted laparoscopic radical prostatectomy for localised prostate cancer	-	relevant
Zhang P	Robot-assisted laparoscope fundoplication for gastroesophageal reflux disease: a systematic review of randomized controlled trials	-	minor relevant
Medical Advisory Secretariat	Robotic-assisted minimally invasive surgery for gynecologic and urologic oncology: an evidence-based analaysis	-	relevant
Camberlin C	Robot-assisted surgery: health technology assessment	-	relevant
Pichon-Riviere A	Robot-assisted surgery in prostate cancer	-	published in Spanish
Llanos Mendez A	Robot-assisted surgery using da Vinci robot telemanipulation in prostatectomy	-	relevant
Comite d' Evaluation et de Diffusion des Innovations Technologiques	Stereotactic neurosurgical robot	-	relevant

* literature considered to be not relevant is not listed.

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

3.4.5 Evaluation

Costs and Effectiveness:

CADTH: With respect to robotically-performed radical prostatectomy, this procedure is relatively expensive. The investment made in acquiring this technology is significant, and institutions that choose to adopt it should make efforts to monitor its costs and outcomes in order to maximize cost-effective use within their own centre. To decrease costs, centres should maximize caseloads, consider keeping the robot operational for longer durations if possible, and use the technology for multiple indications, particularly those with greater potential impact on important patient outcomes and savings on institutional costs.

MAS: RAL has diffused in the province with four surgical systems in place in Ontario, two in Toronto and two in London. RAL is a more expensive technology on a per case basis due to more expensive robot specific instrumentation and physician labour reflected by increased OR time reported in the clinical literature. There is also an upfront cost to acquire the machine and maintenance contract. RAL is expected to capture market at 65% with project net impacts by Year 3 of 3.1M and 6.6M for hysterectomy and prostatectomy respectively.

McIntosh: Laparoscopic prostatectomy takes longer to perform than open surgery but is associated with less intraoperative blood loss, lower blood transfusion rates, fewer complications and a shorter hospital stay. Studies comparing laparoscopic prostatectomy with robot-assisted laparoscopic surgery report inconsistent results for perioperative outcomes. There is insufficient evidence to conclude that any of the three surgical approaches is superior with regard to functional and oncological outcomes. The cost effectiveness of alternative surgical approaches to radical prostatectomy has not been established. Robot-assisted surgery may be best suited to high-volume prostatectomy centres to minimise costs associated with the learning curve.

Camberlin: The system is expensive to acquire and use because of the necessary and expensive limited-use equipment. Currently over 20 robotic surgical systems are installed in Belgium. They are used mainly for prostatectomy, and many are not used to full capacity. Despite implicit or explicit claims that this technology is superior, for most indications its distinct advantages are currently unproven and highly dependent on surgical skills and professional experience. Because too many systems are scattered in different hospitals, resulting in underutilization, the required experience is difficult to

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

acquire for many of the surgeons using these devices. Patients often must pay a nonreimbursable supplement for using this innovative technology, and they are not always fairly and clearly informed about the alternatives.

Workflow:

Zhang: The current evidence demonstrates that RAF is safe and effective in treating GERD. The weakness of this treatment method is that it prolongs the time necessary to carry out fundoplication. However, RAF should be the future trend for treating GERD. See also: MAS, McIntosh

Performance/Accuracy:

Mendez: The reviews retrieved conclude that the scientific evidence available does not provide enough information to draw any definitive conclusions regarding the efficacy and safety of robot-assisted surgery compared with conventional laparoscopy or open surgery.

Comite de Evaluation: This robot is seen to meet the requirements of accuracy, innocuity and minimal invasion characterizing neurosurgical practice. No other technique of neuronavigation currently provides this degree of accuracy. The CEDIT recommends the NeuroMate (R) stereotactic robot for centres handling a large number of patients with stereotactic neurosurgery indications, but also recommends a harnessing of expertise (neurology, neuroradiology, neurosurgery, and neurophysiology) with recognized experience in the field. The neurosurgery department of the Henri-Mondor hospital corresponds to these requirements.

3.5 Description of Evaluation #5

Study number:	**5**	***Study name:***	***Literature Search 5***
Reference:	*See "EX_66_4277_HTA_Bericht_17" in the same folder*		
Short Description:	*Search the German website of DIMDI for applicable HTA-Reports.* *Analyze the HTA-Report*		
Location:	*IMA* *Viktor-Kaplan-Str. 2* *A-2700 Wiener Neustadt*		
Date:	*2011-05-04*		

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

3.5.1 Method

Topic of the HTA-Report is the minimal invasive surgery at the spinal disc compared to conservative methods like traditional surgery or methods of treatment. The search was performed at the website of DIMDI with the key word “robot”.

“Robotics”, “Telemanipulation”, “Roboter” and “Biopsie” led to no further results.

3.5.2 Procedure

See HTA-Report for details.

3.5.3 Evaluation of the Improvement

The authors in the HTA-Report saw no evidence for an improvement of the treatment with the help of minimal invasive surgery as there does not exist enough literature comparing the different treatment methods. As this report is from 2005, the information situation has significantly changed and minimal invasive surgery has become more and more popular.

3.5.4 Results

The HTA-Report from 2005 demands further clinical investigations to determine the benefit and risks for minimal invasive surgery. This is now given (see above).

3.6 Description of Evaluation #6

Study number:	**4**	***Study name:***	***Literature Search 6***
Reference:	*n/a*		
Short Description:	*Search the INAHTA database for literature. Keyword: “robot”*		
Location:	*IMA* *Viktor-Kaplan-Str. 2* *A-2700 Wiener Neustadt*		
Date:	*2011-05-04*		

3.6.1 Method

Search the INAHTA database for literature.

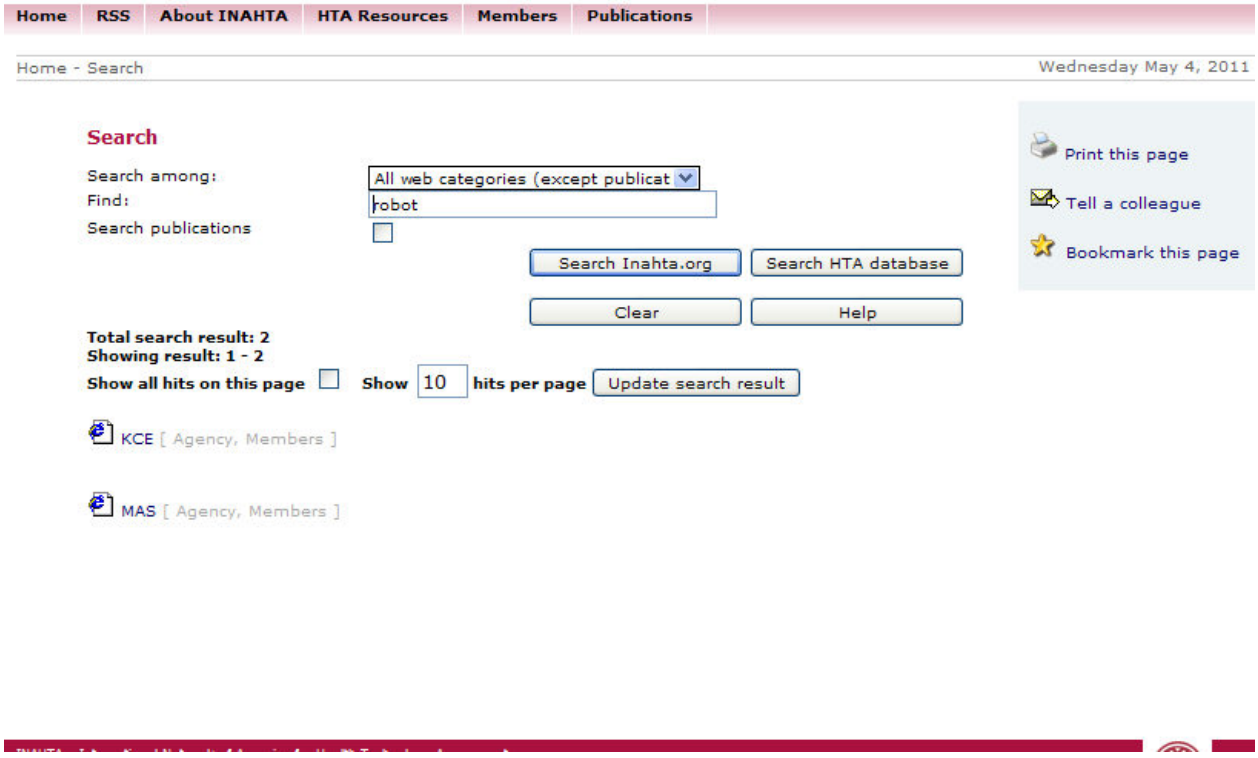
3.6.2 Procedure

The following parameters were used:

“robot”

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016



3.6.3 Evaluation of the Improvement

Not applicable.

3.6.4 Results

The search led to no further results.

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

4 Discussion and summarizing clinical validation

4.1 Clinical Evaluator

The clinical evaluation is reviewed by the following persons:

Dr. Michael **Vogele**, iSYS Medizintechnik GmbH

Relevant Qualifications: medical doctor, working on similar product since 1995, several publications

Prof. Dr. Reto **Bale**, SIPLab Innsbruck

Leading expert for minimal invasive surgery in the radiology in Austria, numerous publications

4.2 Suitability of the data

The suitability of the cited literature is proofed by the clinical evaluators and can be considered as given.

4.3 Summary

From the given literature, we conclude that video-assisted and computer-assisted robotic techniques are safe and may be the pathway to improve minimal invasive operations. The damage to healthy tissue can be significantly reduced which results in shorter operating times and hospital length of stay.

CAS (computer assisted surgery) allows for increased three-dimensional accuracy, improved precision and the reproducibility of procedures. The ability to transmit to the other side of the operating room or to a remote site via high-speed communications links is an additional advantage. Furthermore, the surgeon will be able to share his expertise and skill through teleconsultation and telemanipulation, bringing the patient closer to the expert surgical team.

Surgical robotics is the study and application of advanced robotic technology to diverse surgical procedures, particularly to minimally invasive surgery. The advanced robotic technology in minimally invasive surgery leads to momentous change in and generates a tremendous impact on surgery, resulting in less pain and scarring, reduced blood loss and transfusions, lower risk of complication, shorter hospital stays and faster recovery periods. Systems such as the da Vinci™ surgical system of Intuitive Surgical Inc., which facilitates minimally invasive surgery with increased dexterity, are commercially available. Preoperative simulation and planning of surgical robot setups should

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

accompany advanced robotic surgery if their advantages are to be further pursued. Feedback from the planning system will play an essential role in computer-aided robotic surgery in addition to preoperative detailed geometric information from patient CT/MRI images.

While other authors find no statistical differences between experienced surgeons and non-surgeons in the number of errors (block drooping) as well as the completion time and the tool tip path length at different time delays, the CEDIT considers robots to meet the requirements of accuracy, innocuity and minimal invasion characterizing neurosurgical practice. No other technique of neuronavigation currently provides this degree of accuracy. The CEDIT recommends the NeuroMate (R) stereotactic robot for centres handling a large number of patients with stereotactic neurosurgery indications, but also recommends a harnessing of expertise (neurology, neuroradiology, neurosurgery, and neurophysiology) with recognized experience in the field. The neurosurgery department of the Henri-Mondor hospital corresponds to these requirements.

Limitations:

Robotic surgical systems, such as the da Vinci Surgical System (Intuitive Surgical, Inc., Sunnyvale, California), have revolutionized laparoscopic surgery but are limited by large size, increased costs, and limitations in imaging. Miniature in vivo robots are being developed that are inserted entirely into the peritoneal cavity for laparoscopic and natural orifice transluminal endoscopic surgical procedures. In the future, miniature camera robots and microrobots should be able to provide a mobile viewing platform.

CAS is a more expensive technology on a per case basis due to more expensive robot specific instrumentation and physician labour reflected by increased OR time reported in the clinical literature.

There is insufficient evidence to conclude that any of the three surgical approaches is superior with regard to functional and oncological outcomes.

Despite implicit or explicit claims that this technology is superior, for most indications its distinct advantages are currently unproven and highly dependent on surgical skills and professional experience.

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

4.4 Conclusion

A **clinical investigation is not necessary** as all aspects of the risk management process and the essential requirements are covered by the literature analysis.

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

5 Summary of clinical experience in Post Marketing

The following summarizes the results from different clinical trials and first experiences with the iSYS1 in the field. The interventions have been performed on both, phantom and patients. Most interventions have been performed at the reference sites of iSYS. Referenced files can be found in the same folder (B10).

5.1 Update 2012-01-11

1. Reference: EX_72_6252_Feedback_Strijen

Partner: M.v.Strijen, Philips

Abstract (corrected): “So far we performed 8 cases with the iSYS system. Although we had to find a way to manage the shortage of disposables. In the meantime I also received the alternative table connection and already mounted it on our table. Among the 8 initial cases there was 1 cryo ablation and several other cases that could not have been performed without the robot or might have been really difficult. Needless to say we indeed had an interesting week since my return from CIRSE.”

2. Reference: Email

Partner: Reto Bale, SIPLab Innsbruck

Abstract: Reporting of three clinical cases as a first feedback, performed following interventions.

- Female patient with lower back pain, Technology: Philips C-Arm (+ Xper Guide SW) + iSYS 1 (standard configuration), Needle placements to the point of pain (ganglion), accuracy: 2 mm, patient pain free after drug infiltration.
- Female patient with trigeminus neurolgia. Technology: Philips C-Arm (+ Xper Guide SW) + iSYS 1 (standard configuration), Needle placement into the foramen ovale (skull base), accuracy: submillimetric, patient pain free after RF.
- Male patient with liver metastasis. Technology: Medtronic Stealth Station + iSYS 1 (standard setup with adapter for the Medtronic Biopsy Guide), Multiple needle placements to targets in the liver, accuracy: 1-3 mm, all metastasis treated successfully with RF.

3. Reference: Email

Partner: M.v.Strijen, Philips

Abstract (corrected): The iSYS is still doing a terrific job, although in some patients we have now also encountered some slight limitations. We did get the additional

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

disposables and are using them where indicated. I must admit that I don't have an overview of the remaining disposables, but as you know we still have the escape route of re-using the plastic parts with our own sterile covers…We also performed the first RFA case in Nieuwegein, and of course we performed with use of the iSYS 1, a quick and clean procedure, where we also astounded the witnessing representative of Covidien. I am still awaiting the signal to start the randomization study.

4. Reference: Publication

Partner: Reto Bale, SIPLab Innsbruck

Abstract: Set–up during stereotactic radiofrequency ablation of a CRLM with 8 cm in diameter in the right liver lobe: camera array of the navigation system (a), monitor of navigation system (b). Ten coaxial needles are already in place and the aiming device (c) is adjusted for placement of the 11th needle. The two cameras localize the guide frame of the navigation system (d) and the dynamic reference frame. A median number of 2 lesions (range 1–14) per patient with a median size of 2 cm (range 0.5–13 cm) were treated. 130 lesions were <3 cm (68.8%), 36 lesions were 3–5 cm (19%) and 23 lesions were >5 cm (12.2%) totaling 189 liver lesions. Due to the learning curve with exclusion of patients with tumors adjacent to the central biliary structures and different needle placement planning for tumors in the liver dome avoiding the costophrenic angle the complication rate decreased from 22.6% before to 8.9% after January 2009.

5.2 Results

Update 2012-01-11:

The first clinical trials support our opinion concerning the iSYS 1. Several characteristics have been demonstrated. These are in detail (for reference see above):

- The treatment results are markedly improved (see 3. and 4.)
- High system accuracy (see 2.)
- High safety standards (see 1. And 4.)
- Intuitive use - easy and fast handling (see 1.)

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

- Extremely flat design allows the use inside the gantry of the respective imaging device (see 1.)

The conclusions from chapters 2.6 and 4.4 remain valid.

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Form FDA 3674

See OMB Statement on Reverse. Form Approved: OMB No. 0910-0616, Expiration Date: 2-28-2015

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Certification of Compliance, under 42 U.S.C. § 282(j)(5)(B), with Requirements of ClinicalTrials.gov Data Bank (42 U.S.C. § 282(j))

(For submission with an application/submission, including amendments, supplements, and resubmissions, under §§ 505, 515, 520(m), or 510(k) of the Federal Food, Drug, and Cosmetic Act or § 351 of the Public Health Service Act.)

SPONSOR / APPLICANT / SUBMITTER INFORMATION

1. NAME OF SPONSOR/APPLICANT/SUBMITTER
iSYS Medizintechnik GmbH

2. DATE OF THE APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES
05/07/2013

3. ADDRESS *(Number, Street, State, and ZIP Code)*
Bergwerkswag 21
A-6370 Kitzbuehel

4. TELEPHONE AND FAX NUMBERS *(Include Area Code)*
(Tel.) +43 (0) 664 2411140
(Fax) -

PRODUCT INFORMATION

5. FOR DRUGS/BIOLOGICS: Include Any/All Available Established, Proprietary and/or Chemical/Biochemical/Blood/Cellular/Gene Therapy Product Name(s)
FOR DEVICES: Include Any/All Common or Usual Name(s), Classification, Trade or Proprietary or Model Name(s) and/or Model Number(s)
(Attach extra pages as necessary)

see extra pages

APPLICATION / SUBMISSION INFORMATION

6. TYPE OF APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES
☐ IND ☐ NDA ☐ ANDA ☐ BLA ☐ PMA ☐ HDE ☒ 510(k) ☐ PDP ☐ Other

7. INCLUDE IND/NDA/ANDA/BLA/PMA/HDE/510(k)/PDP/OTHER NUMBER *(If number previously assigned)*

8. SERIAL NUMBER ASSIGNED TO APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES

CERTIFICATION STATEMENT / INFORMATION

9. CHECK ONLY ONE OF THE FOLLOWING BOXES *(See instructions for additional information and explanation)*

☒ A. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act, enacted by 121 Stat. 823, Public Law 110-85, do not apply because the application/submission which this certification accompanies does not reference any clinical trial.

☐ B. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act, enacted by 121 Stat. 823, Public Law 110-85, do not apply to any clinical trial referenced in the application/submission which this certification accompanies.

☐ C. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act, enacted by 121 Stat. 823, Public Law 110-85, apply to one or more of the clinical trials referenced in the application/submission which this certification accompanies and that those requirements have been met.

10. IF YOU CHECKED BOX C, IN NUMBER 9, PROVIDE THE NATIONAL CLINICAL TRIAL (NCT) NUMBER(S) FOR ANY "APPLICABLE CLINICAL TRIAL(S)," UNDER 42 U.S.C. § 282(j)(1)(A)(i), SECTION 402(j)(1)(A)(i) OF THE PUBLIC HEALTH SERVICE ACT, REFERENCED IN THE APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES *(Attach extra pages as necessary)*

NCT Number(s):

The undersigned declares, to the best of her/his knowledge, that this is an accurate, true, and complete submission of information. I understand that the failure to submit the certification required by 42 U.S.C. § 282(j)(5)(B), section 402(j)(5)(B) of the Public Health Service Act, and the knowing submission of a false certification under such section are prohibited acts under 21 U.S.C. § 331, section 301 of the Federal Food, Drug, and Cosmetic Act.
Warning: A willfully and knowingly false statement is a criminal offense, U.S. Code, title 18, section 1001.

11. SIGNATURE OF SPONSOR/APPLICANT/SUBMITTER OR AN AUTHORIZED REPRESENTATIVE (Sign)
Oliver Spitz
Sign

12. NAME AND TITLE OF THE PERSON WHO SIGNED IN NO. 11
(Name) Oliver Spitz
(Title) Manager of Regulatory Affairs

13. ADDRESS *(Number, Street, State, and ZIP Code) (of person identified in Nos. 11 and 12)*
Oberlaenderstrasse 30 1/3
D-86163 Augsburg

14. TELEPHONE AND FAX NUMBERS *(Include Area Code)*
(Tel.) +49 (0) 173 5904978
(Fax) -

15. DATE OF CERTIFICATION
05/06/2013

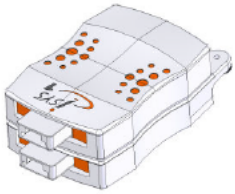
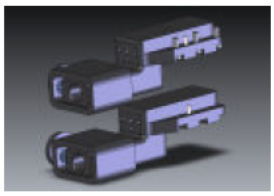
Form FDA 3674 (3/12) (FRONT) PSC Publishing Services (301) 443-6740 EF

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Amendment to section 5 of Form 3674:

iSYS 1 (U.S.), Art. No. 6224

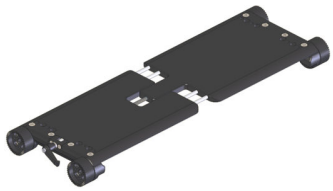
Name	Picture	Art. No.
Robotic Positioning Unit (RPU)		3908
Needle Guide Extension (NGE)		10820
Control Unit US (CU)		6254
Handheld Control Unit (HCU)		3901
Multifunctional Arm (MFA)		4271
RPU Cable Set 1500mm		3926
RPU Cable Set 3000mm		5905

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Power Cord US 2500mm		6163
Transport Box		6098

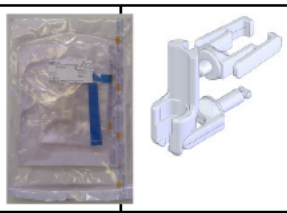
Accessory, non-sterile:

Name	Picture	Art. No.:
Multi Functional Arm (MFA):		4271
Table Top Adapter Version B - Bottom Mounted (TTAB):		4120
Table Top Adapter Version A - Top Mounted (TTAA):		4117
Side Rail Adapter (SRA):		4095

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Accessory, sterile:

Name	Picture	Art. No.
Sterile Cover RPU - sterile for US:		4874US
Sterile Cover HCU - sterile for US:		4883US
Needle Guide Marker Insert centered - sterile for US:		4876US
Needle Guide Insert xxG - sterile for US:		6289G10US 5990G11US 5991G12US 5992G13US 5993G14US 4877G15US 4878G16US 4879G17US 4880G18US 5989G19US 4881G20US 4882G21US

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

K131433/S001

PD/B18	510k Cover Letter 510(k) Number: K131433	iSYS Medizintechnik GmbH

Name *Dr. Michael Vogele*

mobil *+43 (0) 664 2411140*
email *michael.vogele@isys.co.at*
web *www.isys.co.at*

iSYS Medizintechnik GmbH, Bergwerksweg 21, 6370 Kitzbühel, Austria

iSYS Medizintechnik GmbH

FDA CDRH DMC
JUN 06 2013
Received

Food and Drug Administration
Center for Device and Radiological Health
Document Mail Center WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Subject: 510(k) Notification K131433

This is additional information to notify you of the intention of iSYS Medizintechnik GmbH, Bergwerksweg 21, A-6370 Kitzbuehel, Austria to market the following device:

1. **Proprietary Name:** iSYS 1 (U.S.)
2. **Common/Usual Name:** Robotic Positioning Unit
3. **Establishment Registration Number:** pending
4. **Address of manufacturing and packaging facility:** Bergwerksweg 21, A-6370 Kitzbuehel, Austria
5. **Classification Name:** Neurological stereotaxic instrument
6. **Classification:**
   Device Class: Class II
   Classification Panel: Neurology
   Product Code: HAW
   CFR Section: 882.4560
7. **Reason for Submission:** New device
8. **Substantial Equivalence:**

510(k) Number	*Model name*	*Manufacturer*
K101791	ROSA	Medtech
K991081	Neuromate	Integrated Surgical Systems

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

9. **Performance Standards:** ÖNORM EN ISO 60601, ÖNORM EN ISO 62304, ANSI/AAMI/ISO 11737, AAMI TIR33, AAMI TIR35, AAMI ST67, ANSI/AAMI/ISO 11607-2, ISO 11137

10. **Sterile Accessory** Drapes supplied by (b)(4) [redacted] (b)(4) [redacted] under 510(k) K863853 and packaged and sterilized by (b)(4) [redacted] (b)(4) [redacted] under 510(k) **K893814.**

The files coming with this 510k submission file are our response on the Acceptance Checklist of 31/05/2013 and contain the required changes. The following addresses the individual items of the Acceptance Checklist.

Organizational Elements

Item 3: According to page 104 of the User Manual for eSubmission ("Include page numbers only for individual documents.") each section is numbered. Also, each section is clearly identified with the doc-name in the footer (left margin). Each document provides the same scheme and this is uniform throughout the complete submission. Additionally, the submission contains a table of content as required on page 103 of the User Manual for eSubmission ("include a table of content"), which can be found in section 001

Elements of a Complete Submission (RTA Items)

A. Administrative

Item A.1: We have revised the contents on page 3 of the CDRH Premarket Review Submission Cover Sheet. The following changes have been made:

- 510k number of Neuromate corrected
- Classification name: instrument, stereotaxic
- Classification panel: Neurology
- CFR Section: 21 CFR 882.4560

See file "PD_75_11532_002_CDRH Premarket Review Submission Cover Sheet"

Item A.4: Remarks on the comments as they appear in the checklist:

- We don't have a fax
- Please see page 1 of section 5, number 7. iSYS 1 (U.S.) is the common name of the product.
- Please see page 4 of the file. Additionally, the 510k number of Neuromate has been corrected and our 510k number added.
- Brief discussion of the nonclinical tests is added.
- Conclusions drawn from the non-clinical tests are added.

See file PD_75_11535_005_510k Summary

Item A.7: Form 3674 can be found in section 020. As we did not perform clinical trials, forms 3454 or 3455 are not applicable; and therefore we are not registered with clinicaltrials.gov.

Item A.8: The missing forms have been added to section 002 CDRH Premarket Review Submission Cover Sheet.

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Item A.9: The letters from FDA regarding K113495 and our answers have been added. Please see file FDA K113495.zip.

B. Device Description

Item B.11c: The list is complete.

Item B.12: see item B.11c

Item B.13a and b: see item B.11c

Item B.13c: This is correct.

C. Substantial Equivalence Discussion

Item C.15b: Material comparison added to section 012. Please see file PD_75_11542_012_Substantial Equivalence Discussion. Additionally, the 510k-numbers have been corrected.

Item C.16: On page 4, in the first paragraph for "Differences" it states: Frameless Neuromate and the iSYS1 do not contain planning software and ROSA Surgical does. Position and orientation of the iSYS 1 are given by external planning software. This has no effect on safety or effectiveness.

In the second paragraph it states: "Frameless Neuromate and ROSA Surgical Device provide factory calibration during intervention while the position of the needle or needle-type instrument (tool) is verified during intervention by the surgeon for the iSYS1. Verification of the tool position requires greater physician effort but provides for exact (depending on the imaging system) tool localization."

In the third paragraph it states: "ROSA Surgical Device provides registration with pointer probe whereas the Frameless Neuromate provides ultra sound registration. As already discussed, this is not necessary for the workflow of the iSYS 1, which reduces time and effort for intervention." These are the statements concerning the differences between the devices and the reasons why this has no influence on safety and effectiveness.

Item C.16: From our point of view, there is no difference between the indications for use. Our Indications for Use is more detailed as we explain the way of tool positioning and the predicate devices do not.

D Proposed Labeling (see also 21 CFR part 801)

Item D.18: The sentence "Federal law restricts this device to sale by or on the order of a physician" according to 21 CFR 801.109(b)(1) has been added to the user manual. Please see File PD_75_11543_013_Proposed Labeling, page 13.

E. Sterilization

Item E.22a: On page 2 of 89, section 1. Drapes it is stated that the drapes are supplied sterile, and in section 2 Needle Guide Adapters and Needle Guide Inserts we have revised the sentence to read "The Needle guide Adapters and Inserts are part of the robotic system manufactured by iSYS (b)(4) performs the packaging and sterilization." That complies with section 11 page 57.

Item E.22b: The symbol "do not reuse" on each device and in the labeling description should make it clear. The user manual (see section labeling) gives respective warnings to the user.

Item E.22c: See item E.22b. Additionally see User Manual (p. 66/116). This section of the risk management refers to the mechanical components of iSYS 1 (robot unit, adapters, control unit). They have to be cleaned and disinfected as given in the user manual.

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

F. Shelf Life

Item F.26: This is correct.

Item F.27: This is correct.

Item F.28: See 510k of Bioseal. This topic is not part of our submission. See also device comparison from Bioseal. Additionally, our stability samples are stored in a temperature and humidity controlled room; Tests for real time aging are ongoing.

H. Software

Item H.32: Remarks on the comments as they appear in the checklist:

- Please refer to page 2 of 12 of section 016. The analysis shows the reasons for minor level of concern. Additionally, we have implemented hardware safety measures in the system. The level of concern has been confirmed by our notified body.
- No, this is the classification as stated in ISO 62304, The Harmonized Standard for Medical Device Software and is mandatory.
- See above
- See above

Item H.33: Remarks on the comments as they appear in the checklist:

- Software documentation was performed according to Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices, published on May 11, 2005 by Center for Devices and Radiological Health (CDRH) – Office of Device Evaluation. Any required information for this level of concern is included.
- No, this is the way we perform risk analysis. It is according to ISO 14971.
- Not applicable (see item H.32).
- Not applicable (see item H.32).

In case of any questions concerning this application, please contact either Dr. Michael Vogele, CEO at +43 (0) 664 2411140 (michael.vogele@isys.co.at) or Oliver Spitz (Regulatory Consultant) at +49 (0) 173 5904978 (oliver.spitz@isys.co.at).

The eCopy is an exact duplicate of the paper copy.

Sincerely,

Dr. Michael Vogele

CEO

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

iSYS Medizintechnik GmbH

510(k) Premarket Notification

(Basing on “Guidance for Industry and FDA Staff: Format for Traditional and Abbreviated 510(k)s“

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Table of Content

Section	Name	Number of Pages	Appendix/Misc
001	Medical Device User Fee Cover Sheet (Form FDA 3601)	4	No
002	CDRH Premarket Review Submission Cover Sheet	27	Yes
003	510(k) Cover Letter	4	No
004	Indications for Use Statement	1	No
005	510(k) Summary	6	No
006	Premarket Notification Truthful and Accurate Statement	1	No
007	Premarket Notification Class III Certification and Summary	1	No
008	Financial Certification or Disclosure Statement	1	No
009	Declarations of Conformity and Summary Reports (including Risk Management File)	92	No
010	Executive Summary	4	No
011	Device Description	57	No
012	Substantial Equivalence Discussion	4	No
013	Proposed Labeling	116	No
014	Sterilization and Shelf Life	88	Yes
015	Biocompatibility	1	No
016	Software	14	No
017	Electromagnetic Compatibility and Electrical Safety	24	No
018	Performance Testing – Bench	22	No
019	Performance Testing – Animal	1	No
020	Performance Testing – Clinical	40	Yes

* Highlighted sections are subject to changes due to FDA Acceptance Checklist of 05/31/2013.

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

PD/B18	Medical Device User Fee Cover Sheet (Form FDA 3601) 510(k) Number: K131433	iSYS Medizintechnik GmbH

Following files are on the Appendix CD for the paper version of this submission respectively in the Miscellaneous Files for the eCopy:

Filename	Document	Applies to Section
001_HamlynSymposium_iSYS Workflow_final	Workflow presented on the Hamlyn Symposium	020
002_Clinical cases	Summary of Clinical Cases	020
003_Dissertation-Schamberger	Dissertation Dr. Schamberger	020
004_ECR2013_C-2559	Presentation of Clinical Case	020
005_iSys robot iGuide	Phantom Study on Accuracy	020
006_Multi Center Study	Multi-Center Study	020
007_Zeego Schulz Zangos	Report Radiation Exposure	020
008 (b)(4) VDMax Final Report.zip	(b)(4) Sterilization Report (b)(4)	014
009_PM_Hygiene Monitoring plan_RDP 0500_2011	(b)(4) Hygiene Monitoring Plan 2011	014
010_PM_Clean room Monitoring_Results2012	(b)(4) lean room Monitoring Results2012	014
011_PM_Gamma validation Prüfplan_PRD0400_2010	Gamma validation test plan	014
012_PM_Bioburden_SC-80_report904377_2012	(b)(4) Bioburden Report 2012	014
013_FDA K113495	Correspondence of former submission	002

* Highlighted sections are subject to changes due to FDA Acceptance Checklist of 05/31/2013.

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Form Approved: OMB No. 0910-511 Expiration Date: February 28, 2013. 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) [redacted]
Write the Payment Identification number on your check.

A completed cover sheet must accompany each original application or supplement subject to fees. If payment is sent by U.S. mail or courier, please include a copy of this completed form with payment. Payment and mailing instructions can be found at: http://www.fda.gov/oc/mdufma/coversheet.html

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

ISYS MEDIZINTECHNIK GMBH
Bergwerksweg 21

KITZBUEHEL
6370
AT

1.1 EMPLOYER IDENTIFICATION NUMBER (EIN)

2. CONTACT NAME
Oliver Spitz
2.1 E-MAIL ADDRESS
oliver.spitz@isys.co.at
2.2 TELEPHONE NUMBER (include Area code)
0049 173 5904978
2.3 FACSIMILE (FAX) NUMBER (Include Area code)

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/oc/mdufma

Select an application type:
[X] Premarket notification(510(k)); except for third party
[ ] 513(g) Request for Information
[ ] Biologics License Application (BLA)
[ ] Premarket Approval Application (PMA)
[ ] Modular PMA
[ ] Product Development Protocol (PDP)
[ ] Premarket Report (PMR)
[ ] Annual Fee for Periodic Reporting (APR)
[ ] 30-Day Notice

3.1 Select a center
[X] CDRH
[ ] CBER
3.2 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)
[X] YES, I meet the small business criteria and have submitted the required qualifying documents to FDA
NO, I am not a small business
4.1 If Yes, please enter your Small Business Decision Number: SBD135332

5. FDA WILL NOT ACCEPT YOUR SUBMISSION IF YOUR COMPANY HAS NOT PAID AN ESTABLISHMENT REGISTRATION FEE THAT IS DUE TO FDA. HAS YOUR COMPANY PAID ALL ESTABLISHMENT REGISTRATION FEES THAT ARE DUE TO FDA?
[X] YES (All of our establishments have registered and paid the fee, or this is our first device, and we will register and pay the fee within 30 days of FDA's approval/clearance of this device.)
[ ] NO (If "NO," FDA will not accept your submission until you have paid all fees due to FDA. This submission will not be processed; see http://www.fda.gov/cdrh/mdufma for additional information)

6. 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
[ ] This biologics application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only
[ ] The sole purpose of the application is to support conditions of use for a pediatric population
[ ] The application is submitted by a state or federal government entity for a device that is not to be distributed commercially

7. 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

PAPERWORK REDUCTION ACT STATEMENT
Public reporting burden for this collection of information is estimated to average 18 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and 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 the address below.

Department of Health and Human Services, Food and Drug Administration, Office of Chief Information Officer, 1350 Piccard Drive, 4th Floor Rockville, MD 20850
[Please do NOT return this form to the above address, except as it pertains to comments on the burden estimate.]

8. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION
(b)(4) [redacted]
03-May-2013

Form FDA 3601 (01/2007)

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

CDRH PREMARKET REVIEW SUBMISSION COVER SHEET

Form Approval
OMB No. 0910-0120
Expiration Date: December 31, 2013
See PRA Statement on page 5.

Date of Submission	User Fee Payment ID Number	FDA Submission Document Number *(if known)*
06/04/2013	MD6068500-956733	K131433

SECTION A — TYPE OF SUBMISSION

PMA	PMA & HDE Supplement	PDP	510(k)	Request for Feedback
☐ Original Submission	☐ Regular (180 day)	☐ Original PDP	☒ Original Submission:	☐ Pre-Submission
☐ Premarket Report	☐ Special	☐ Notice of Completion	☒ Traditional	☐ Informational Meeting
☐ Modular Submission	☐ Panel Track (PMA Only)	☐ Amendment to PDP	☐ Special	☐ Submission Issue Meeting
☐ Amendment	☐ 30-day Supplement		☐ Abbreviated (Complete section I, Page 5)	☐ Day 100 Meeting
☐ Report	☐ 30-day Notice		☐ Additional Information	☐ Agreement Meeting
☐ Report Amendment	☐ 135-day Supplement		☐ Third Party	☐ Determination Meeting
☐ Licensing Agreement	☐ Real-time Review			☐ Study Risk Determination
	☐ 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 ISYS MEDIZINTECHNIK GMBH	Establishment Registration Number *(if known)*
Division Name *(if applicable)*	Phone Number *(including area code)* +43 (0) 664 2411140
Street Address BERGWERKSWEG 21	FAX Number *(including area code)* Not available
City KITZBUEHEL	State / Province: TIROL; ZIP/Postal Code: 6370; Country: AUSTRIA
Contact Name OLIVER SPITZ	
Contact Title MANAGER REGULATORY AFFAIRS	Contact E-mail Address OLIVER.SPITZ@ISYS.CO.AT

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

(b)(4)

[redacted]

FORM FDA 3514 (1/13) Page 1 of 5 Pages

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

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

- ☐ New Device
- ☐ 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
- ☐ Process change:
  - ☐ Manufacturing ☐ Packaging
  - ☐ Sterilization
  - ☐ Other *(specify below)*
- ☐ Response to FDA correspondence:
- ☐ Change in design, component, or specification:
  - ☐ Software / Hardware
  - ☐ Color Additive
  - ☐ Material
  - ☐ Specifications
  - ☐ Other *(specify below)*
- ☐ Labeling change:
  - ☐ Indications
  - ☐ Instructions
  - ☐ Performance Characteristics
  - ☐ Shelf Life
  - ☐ Trade Name
  - ☐ Other *(specify below)*
- ☐ Location change:
  - ☐ Manufacturer
  - ☐ Sterilizer
  - ☐ Packager
- ☐ Report Submission:
  - ☐ Annual or Periodic
  - ☐ Post-approval Study
  - ☐ Adverse Reaction
  - ☐ Device Defect
  - ☐ Amendment
- ☐ 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
- ☐ Response 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)*:

FORM FDA 3514 (1/13) Page 2 of 5 Pages

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

SECTION E — ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS

Product codes of devices to which substantial equivalence is claimed

1	HAW	2		3		4	
5		6		7		8	

Summary of, or statement concerning, safety and effectiveness information

- [x] 510 (k) summary attached
- [ ] 510 (k) statement

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

	510(k) Number		Trade or Proprietary or Model Name		Manufacturer
1	K101791	1	ROSA SURGICAL DEVICE	1	MEDTECH SAS
2	K991081	2	FRAMELESS NEUROMATE	2	INTEGRATED SURGICAL SYSTEMS, INC:
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 name

Instrument, stereotaxic

	Trade or Proprietary or Model Name for This Device		Model Number
1	iSYS 1 (U.S.)	1	6224
2	Accessory, non-sterile	2	div
3	Accessory, sterile	3	div
4		4	
5		5	

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

1 K113495	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
HAW	882.4560	[ ] Class I [x] Class II [ ] Class III [ ] Unclassified
Classification Panel: Neurology		

Indications *(from labeling)*

The intended use of the iSYS1 device is to function as a remote-operated positioning and guidance system during interventional procedures. Positioning is done in remote control manner; planning of the position/angulation is done based on 2D/3D patient data (CT, cone-beam CT, fluoroscopy) by external planning software – for example using an external navigation system, or planning software coming with the used imaging device. Also verification of the correct position and orientation of the tool prior to/during/after the intervention is done by means of these external devices. The iSYS1-System is then acting as a guideway during the manual insertion of the interventional tool – usually a needle type device, and the like. Applications include, but are not limited to, interventions like biopsy procedures, tumor ablation, nerve blocking, electrode placement, etc.

FORM FDA 3514 (1/13) — Page 3 of 5 Pages

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Note: Submission of the information entered in Section H does not affect the need to submit device establishment registration.	FDA Document Number *(if known)* K131433

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

☐ Original ☒ Add ☐ Delete	Facility Establishment Identifier (FEI) Number isy83218	☒ Manufacturer ☐ Contract Sterilizer ☐ Contract Manufacturer ☐ Repackager / Relabeler
Company / Institution Name ISYS MEDIZINTECHNIK GMBH		Establishment Registration Number PENDING
Division Name *(if applicable)*		Phone Number *(including area code)* +43 (0) 664 2411140
Street Address BERGWERKSWEG 21		FAX Number *(including area code)* NOT AVAILABLE
City KITZBUEHEL		State / Province: TIROL; ZIP Code: 6370; Country: AUSTRIA
Contact Name OLIVER SPITZ	Contact Title MANAGER REGULATORY AFFAIRS	Contact E-mail Address OLIVER.SPITZ@ISYS.CO.AT

(b)(4) [redacted]

☐ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number	☐ Manufacturer ☐ Contract Sterilizer ☐ Contract Manufacturer ☐ Repackager / Relabeler
Company / Institution Name		Establishment Registration Number
Division Name *(if applicable)*		Phone Number *(including area code)*
Street Address		FAX Number *(including area code)*
City		State / Province; ZIP Code; Country
Contact Name	Contact Title	Contact E-mail Address

FORM FDA 3514 (1/13) Add Continuation Page Page 4 of 5 Pages

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

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	60601-1	IEC	Medical Electrical Equipment - Part 1: General Requirements for Safety	Amendment 1 Amendment 2	10/01/2005
2	60601-1-2	IEC	Medical Electrical Equipment - Part 1-2: General Requirements for Safety - Collateral standard: Electromagnetic Compatibility - Requirements and Tests	Edition 2.1 consolidated with Amendment 1	3/3/2008
3	60601-1-8	IEC	Medical electrical equipment - Part 1-8: General requirements for safety - Collateral Standard: Alarm Systems - Requirements, tests and guidances - General requirements and guidelines for alarm systems in medical equipment	Edition 1	08/08/2006
4	62366	IEC	Medical devices - Application of usability engineering to medical devices	First Edition	08/08/2009
5	62304	IEC	Medical device software - Software life cycle processes.	First Edition	08/20/2008
6	15223-1	ISO	Medical devices - Symbols to be used with medical device labels, labelling, and information to be supplied - Part 1: General requirements	Second Edition	07/01/2012
7					

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

This section applies only to requirements of the Paperwork Reduction Act of 1995.

"DO NOT SEND YOUR COMPLETED FORM TO THE FDA STAFF ADDRESS BELOW."

The burden time for this collection of information is estimated to average 0.5 hour per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
1350 Piccard Drive, Room 400
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 number.

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

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	11137-1	AAMI / ANSI / ISO	Sterilization of health care products - Radiation - Part 1: Requirements for development, validation, and routine control of a sterilization process for medical devices		03/16/2012
2	11137-2	AAMI / ANSI / ISO	Sterilization of health care products - Radiation - Part 2: Establishing the sterilization dose		01/15/2013
3	11137-3	AAMI / ANSI / ISO	Sterilization of health care products - Radiation - Part 3: Guidance on dosimetric aspects		03/16/2012
4	11607-1	AAMI / ANSI / ISO	Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems		03/16/2012
5	11607-2	AAMI / ANSI / ISO	Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes		03/16/2012
6	11737-1	AAMI / ANSI / ISO	Sterilization of medical devices - Microbiological methods Part 1: Determination of the population of microorganisms on product, 2ed	Second Edition	08/20/2012
7	D4169-09	ASTM	Standard Practice for Performance Testing of Shipping Containers and Systems		01/15/2013

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

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF ADDRESS BELOW.

The burden time for this collection of information is estimated to average 0.5 hour per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
1350 Piccard Drive, Room 400
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 number.

FORM FDA 3514 (1/13) Page 5 of 5 Pages

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

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	D-4332-01	ASTM	Standard practice for conditioning containers, packages, or packaging components for testing		05/05/2010
2	F88/F88M-09	ASTM	Standard Test Method for Seal Strength of Flexible Barrier Materials		01/15/2013
3	F1886/F1886M-09	ASTM	Standard Test Method for Determining Integrity of Seals for Flexible Packaging by Visual Inspection		01/15/2013
4	F1929-98	ASTM	Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration		01/15/2013
5	F1980-07	ASTM	Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices		01/15/2013
6	F2096-11	ASTM	Standard Test Method for Detecting Gross Leaks in Packaging by Internal Pressurization (Bubble Test		01/15/2013
7					

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

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF ADDRESS BELOW.

The burden time for this collection of information is estimated to average 0.5 hour per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
1350 Piccard Drive, Room 400
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 number.

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Forms FDA 3654

Form Approved: OMB No. 0910-0120; Expiration Date: 12/31/13

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

IEC 60601-1, Medical Electrical Equipment - Part 1: General Requirements for Safety, 1988; Amendment 1, 1991-11, Amendment

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	#5-4	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☒
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: _____

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

[5] The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[6] The online search for CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html

FORM FDA 3654 (12/10) Page 1

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Form Approved: OMB No. 0910-0120; Expiration Date: 12/31/13

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

IEC 60601-1-2, Medical Electrical Equipment - Part 1-2: General Requirements for Safety - Collateral standard: Electromagnetic C

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3] #5-34		
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☒
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☒	☐
If yes, was the guidance document followed in preparation of this 510k?	☐	☒

Title of guidance: _____

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

[5] The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[6] The online search for CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html

FORM FDA 3654 (12/10) Page 1

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Form Approved: OMB No. 0910-0120; Expiration Date: 12/31/13

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

IEC 60601-1-8 Ed. 1, Medical electrical equipment - Part 1-8: General requirements for safety - Collateral Standard: Alarm System

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	#5-49	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☒
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: _____

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

[5] The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[6] The online search for CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html

FORM FDA 3654 (12/10) Page 1

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Form Approved: OMB No. 0910-0120; Expiration Date: 12/31/13

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

IEC 62366, Medical devices - Application of usability engineering to medical devices

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	#5-50	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☐	☒
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☒
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☒	☐
If yes, was the guidance document followed in preparation of this 510k?	☒	☐

Title of guidance: Medical Device Use-Safety: Incorporating Human Factors into Risk Management

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

[5] The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[6] The online search for CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html

FORM FDA 3654 (12/10) Page 1

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Form Approved: OMB No. 0910-0120; Expiration Date: 12/31/13

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

IEC 62304 First edition 2006-05, Medical device software - Software life cycle processes

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	#13-8	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☐	☒
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☒
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☒	☐
If yes, was the guidance document followed in preparation of this 510k?	☒	☐

Title of guidance: Guidance for the Content of Premarket Submissions, Guidance for Off-the-Shelf Software, et. al.

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

[5] The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[6] The online search for CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html

FORM FDA 3654 (12/10) Page 1

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Form Approved: OMB No. 0910-0120; Expiration Date: 12/31/13

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

ISO 15223-1 Second Edition 2012-07-01, Medical devices - Symbols to be used with medical device labels, labelling, and informati

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	#5-73	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☐	☒
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☒
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☒	☐
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☒	☐
If yes, was the guidance document followed in preparation of this 510k?	☒	☐

Title of guidance: Guidance for the Content of Premarket Submissions, Guidance for Off-the-Shelf Software, et. al.

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

[5] The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[6] The online search for CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html

FORM FDA 3654 (12/10) Page 1

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE
ISO 15223-1 Second Edition 2012-07-01, Medical devices - Symbols to be used with medical device labels, labelling, and informati

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
5	Symbols	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *
Symbol 5.2.8. is used although not recognized (see SIS)

DESCRIPTION

JUSTIFICATION
Symbol is common and used in the U.S. Use of it does not bear any risk. The meaning is described in the User Manual.

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

* Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

Paperwork Reduction Act Statement

Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and 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:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
1350 Piccard Drive, Room 400
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 number.

FORM FDA 3654 (12/10) Page 2

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Form Approved: OMB No. 0910-0120; Expiration Date: 12/31/13

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

ANSI/AAMI/ISO 11137-1 Sterilization of health care products - Radiation Part 1

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	#14-297	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☒
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☒	☐
If yes, was the guidance document followed in preparation of this 510k?	☒	☐

Title of guidance: AAMI TIR 33:2005 Sterilization of health care products- Method VDmax

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

[5] The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[6] The online search for CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html

FORM FDA 3654 (12/10) Page 1

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Form Approved: OMB No. 0910-0120; Expiration Date: 12/31/13

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

ISO 11137-2:2012 Sterilization of health care products- Radiation Part 2: Establishing the sterilization dose

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	#14-364	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☒
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☒	☐
If yes, was the guidance document followed in preparation of this 510k?	☒	☐

Title of guidance: AAMI TIR 33: 2005 Sterilization of health care products-radiation sterilization - Method VDmax

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

[5] The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[6] The online search for CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html

FORM FDA 3654 (12/10) Page 1

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Form Approved: OMB No. 0910-0120; Expiration Date: 12/31/13

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

ANSI/AAMI/ISO 11137-3 :2006 Sterilization of health care products - Radiation Part 3

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2] ?	☒	☐
FDA Recognition number [3]	#14-298	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☒
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5] ?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☒	☐
If yes, was the guidance document followed in preparation of this 510k?	☒	☐

Title of guidance: AAMI TIR 33: 2005 Sterilization of health care products- Radiation sterilization - Method VDmax

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

[5] The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[6] The online search for CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html

FORM FDA 3654 (12/10) Page 1

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Form Approved: OMB No. 0910-0120; Expiration Date: 12/31/13

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

ANSI/AAMI/ISO 11607-1 Packaging for terminally sterilized medical devices - Part 1 Requirements for materials, sterile barrier

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	#14-193	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☒
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☒	☐
If yes, was the guidance document followed in preparation of this 510k?	☒	☐

Title of guidance: AAMI TIR 22: 2007 Guidance for ANSI/AAMI/ISO 11607, Part 1 and Part 2:2006

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

[5] The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[6] The online search for CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html

FORM FDA 3654 (12/10) Page 1

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Form Approved: OMB No. 0910-0120; Expiration Date: 12/31/13

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

ANSI/AAMI/ISO 11607-2:2006 Packaging for terminally sterilized medical devices - Part 2 Validation requirements

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	#14-194	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☒
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☒	☐
If yes, was the guidance document followed in preparation of this 510k?	☒	☐

Title of guidance: AAMI TIR 22:2007 Guidance for ANSI/AAMI/ISO 11607 - Part1 and Part 2:2006

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

[5] The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[6] The online search for CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html

FORM FDA 3654 (12/10) Page 1

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Form Approved: OMB No. 0910-0120; Expiration Date: 12/31/13

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

ANSI/AAMI/ISO 11737-1:2006 Sterilization of Medical Devices-Microbiological methods Part 1

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	#14-227	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☒
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: _____

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

[5] The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[6] The online search for CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html

FORM FDA 3654 (12/10) Page 1

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Form Approved: OMB No. 0910-0120; Expiration Date: 12/31/13

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

ASTM D4169:2001 Practice for Performance Testing of Shipping Containers and Systems

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	#14-300	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☒
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☒	☐
If yes, was the guidance document followed in preparation of this 510k?	☒	☐

Title of guidance: ANSI/AAMI/ISO 11607-1:2006 -Packaging for terminally sterilized medical devices -Part 1

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

[5] The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[6] The online search for CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html

FORM FDA 3654 (12/10) Page 1

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Form Approved: OMB No. 0910-0120; Expiration Date: 12/31/13

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

ASTM D-4332-01:2996 Standard practice for conditioning containers, packages, or packaging components for testing

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	#5-51	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☒
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: _____

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

[5] The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[6] The online search for CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html

FORM FDA 3654 (12/10) Page 1

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Form Approved: OMB No. 0910-0120; Expiration Date: 12/31/13

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

ASTM F88 Standard test method for Seal Strength of Flexible Barrier Materials

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	#14-283	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☒
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☒	☐
If yes, was the guidance document followed in preparation of this 510k?	☒	☐

Title of guidance: ANSI/AAMI/ISO 11607-1:2006 Packaging for terminally sterilized medical devices- Part 1

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

[5] The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[6] The online search for CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html

FORM FDA 3654 (12/10) Page 1

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Form Approved: OMB No. 0910-0120; Expiration Date: 12/31/13

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

ASTM F1886:1998 Standard Test Method for Determining Integrity of Seals for Flexible Packaging by Visual Inspection

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	#14-288	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☒
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☒	☐
If yes, was the guidance document followed in preparation of this 510k?	☒	☐

Title of guidance: ANSI/AAMI/ISO 11607-1:2006 Packaging of terminally sterilized medical devices- Part 2

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

[5] The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[6] The online search for CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html

FORM FDA 3654 (12/10) Page 1

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Form Approved: OMB No. 0910-0120; Expiration Date: 12/31/13

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

ASTM F1929-98:2004 Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	#14-64	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☒
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☒	☐
If yes, was the guidance document followed in preparation of this 510k?	☒	☐

Title of guidance: AAMI TIR 22:2007 Guidance for ANSI/AAMI/ISO 11607 Part 1 and Part 2: 2006

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

[5] The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[6] The online search for CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html

FORM FDA 3654 (12/10) Page 1

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Form Approved: OMB No. 0910-0120; Expiration Date: 12/31/13

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

ASTM F2096-11 Standard test method for detecting gross leaks in porous medical packaging by internal pressurizing

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	#14-359	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☒
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☒	☐
If yes, was the guidance document followed in preparation of this 510k?	☒	☐

Title of guidance: TIR 22:2007 Guidance for ANSI/AAMI/ISO 11607- Part1 and Part 2: 2006

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

[5] The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[6] The online search for CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html

FORM FDA 3654 (12/10) Page 1

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Form Approved: OMB No. 0910-0120; Expiration Date: 12/31/13

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

ASTM F1980:2011 Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	#14-229	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☒
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☒	☐
If yes, was the guidance document followed in preparation of this 510k?	☒	☐

Title of guidance: AAMI TIR 22:2007 Guidance for ANSI/AAMI/ISO 11607 -Part 1 and Part 2

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

[5] The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[6] The online search for CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html

FORM FDA 3654 (12/10) Page 1

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Name ***Dr. Michael Vogele***

mobil ***+43 (0) 664 2411140***
email *michael.vogele@isys.co.at*
web *www.isys.co.at*

iSYS Medizintechnik GmbH, Bergwerksweg 21, 6370 Kitzbühel, Austria

Food and Drug Administration
Center for Device and Radiological Health
Document Mail Center WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Subject: 510(k) Notification K131433

This is additional information to notify you of the intention of iSYS Medizintechnik GmbH, Bergwerksweg 21, A-6370 Kitzbuehel, Austria to market the following device:

1.	**Proprietary Name:**	iSYS 1 (U.S.)
2.	**Common/Usual Name:**	Robotic Positioning Unit
3.	**Establishment Registration Number:**	pending
4.	**Address of manufacturing and packaging facility:**	Bergwerksweg 21, A-6370 Kitzbuehel, Austria
5.	**Classification Name:**	Neurological stereotaxic instrument
6.	**Classification:**	Device Class: Class II Classification Panel: Neurology Product Code: HAW CFR Section: 882.4560
7.	**Reason for Submission:**	New device
8.	**Substantial Equivalence:**	

510(k) Number	***Model name***	***Manufacturer***
K101791	ROSA	Medtech
K991081	Neuromate	Integrated Surgical Systems

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

9.	**Performance Standards:**	ÖNORM EN ISO 60601, ÖNORM EN ISO 62304, ANSI/AAMI/ISO 11737, AAMI TIR33, AAMI TIR35, AAMI ST67, ANSI/AAMI/ISO 11607-2, ISO 11137
10.	**Sterile Accessory**	Drapes supplied by (b)(4) [redacted] (b)(4) [redacted] nder 510(k) **K863853** and packaged and sterilized by (b)(4) [redacted] (b)(4) [redacted] (b)(4) [redacted] under 510(k) **K893814**.

The files coming with this 510k submission file are our response on the Acceptance Checklist of 31/05/2013 and contain the required changes. The following addresses the individual items of the Acceptance Checklist.

Organizational Elements

Item 3: According to page 104 of the User Manual for eSubmission ("Include page numbers only for individual documents.") each section is numbered. Also, each section is clearly identified with the doc-name in the footer (left margin). Each document provides the same scheme and this is uniform throughout the complete submission. Additionally, the submission contains a table of content as required on page 103 of the User Manual for eSubmission ("include a table of content"), which can be found in section 001

Elements of a Complete Submission (RTA Items)

A. Administrative

Item A.1: We have revised the contents on page 3 of the CDRH Premarket Review Submission Cover Sheet. The following changes have been made:

- 510k number of Neuromate corrected
- Classification name: instrument, stereotaxic
- Classification panel: Neurology
- CFR Section: 21 CFR 882.4560

See file "PD_75_11532_002_CDRH Premarket Review Submission Cover Sheet"

Item A.4: Remarks on the comments as they appear in the checklist:

- We don't have a fax
- Please see page 1 of section 5, number 7. iSYS 1 (U.S.) is the common name of the product.
- Please see page 4 of the file. Additionally, the 510k number of Neuromate has been corrected and our 510k number added.
- Brief discussion of the nonclinical tests is added.
- Conclusions drawn from the non-clinical tests are added.

See file PD_75_11535_005_510k Summary

Item A.7: Form 3674 can be found in section 020. As we did not perform clinical trials, forms 3454 or 3455 are not applicable; and therefore we are not registered with clinicaltrials.gov.

Item A.8: The missing forms have been added to section 002 CDRH Premarket Review Submission Cover Sheet.

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Item A.9: The letters from FDA regarding K113495 and our answers have been added. Please see file FDA K113495.zip.

B. Device Description

Item B.11c: The list is complete.

Item B.12: see item B.11c

Item B.13a and b: see item B.11c

Item B.13c: This is correct.

C. Substantial Equivalence Discussion

Item C.15b: Material comparison added to section 012. Please see file PD_75_11542_012_Substantial Equivalence Discussion. Additionally, the 510k-numbers have been corrected.

Item C.16: On page 4, in the first paragraph for "Differences" it states: Frameless Neuromate and the iSYS1 do not contain planning software and ROSA Surgical does. Position and orientation of the iSYS 1 are given by external planning software. This has no effect on safety or effectiveness.

In the second paragraph it states: "Frameless Neuromate and ROSA Surgical Device provide factory calibration during intervention while the position of the needle or needle-type instrument (tool) is verified during intervention by the surgeon for the iSYS1. Verification of the tool position requires greater physician effort but provides for exact (depending on the imaging system) tool localization."

In the third paragraph it states: "ROSA Surgical Device provides registration with pointer probe whereas the Frameless Neuromate provides ultra sound registration. As already discussed, this is not necessary for the workflow of the iSYS 1, which reduces time and effort for intervention." These are the statements concerning the differences between the devices and the reasons why this has no influence on safety and effectiveness.

Item C.16: From our point of view, there is no difference between the indications for use. Our Indications for Use is more detailed as we explain the way of tool positioning and the predicate devices do not.

D Proposed Labeling (see also 21 CFR part 801)

Item D.18: The sentence "Federal law restricts this device to sale by or on the order of a physician" according to 21 CFR 801.109(b)(1) has been added to the user manual. Please see File PD_75_11543_013_Proposed Labeling, page 13.

E. Sterilization

Item E.22a: On page 2 of 89, section 1. Drapes it is stated that the drapes are supplied sterile, and in section 2 Needle Guide Adapters and Needle Guide Inserts we have revised the sentence to read "The Needle guide Adapters and Inserts are part of the robotic system manufactured by iSYS (b)(4) performs the packaging and sterilization." That complies with section 11 page 57.

Item E.22b: The symbol "do not reuse" on each device and in the labeling description should make it clear. The user manual (see section labeling) gives respective warnings to the user.

Item E.22c: See item E.22b. Additionally see User Manual (p. 66/116). This section of the risk management refers to the mechanical components of iSYS 1 (robot unit, adapters, control unit). They have to be cleaned and disinfected as given in the user manual.

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

F. Shelf Life

Item F.26: This is correct.

Item F.27: This is correct.

Item F.28: See 510k of (b)(4) This topic is not part of our submission. See also device comparison from (b)(4). Additionally, our stability samples are stored in a temperature and humidity controlled room; Tests for real time aging are ongoing.

H. Software

Item H.32: Remarks on the comments as they appear in the checklist:

- Please refer to page 2 of 12 of section 016. The analysis shows the reasons for minor level of concern. Additionally, we have implemented hardware safety measures in the system. The level of concern has been confirmed by our notified body.
- No, this is the classification as stated in ISO 62304, The Harmonized Standard for Medical Device Software and is mandatory.
- See above
- See above

Item H.33: Remarks on the comments as they appear in the checklist:

- Software documentation was performed according to Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices, published on May 11, 2005 by Center for Devices and Radiological Health (CDRH) – Office of Device Evaluation. Any required information for this level of concern is included.
- No, this is the way we perform risk analysis. It is according to ISO 14971.
- Not applicable (see item H.32).
- Not applicable (see item H.32).

In case of any questions concerning this application, please contact either Dr. Michael Vogele, CEO at +43 (0) 664 2411140 (michael.vogele@isys.co.at) or Oliver Spitz (Regulatory Consultant) at +49 (0) 173 5904978 (oliver.spitz@isys.co.at).

The eCopy is an exact duplicate of the paper copy.

Sincerely,

Dr. Michael Vogele

CEO

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

510(k) SUMMARY

1.	Applicant:	iSYS Medizintechnik GmbH
2.	Address:	Bergwerksweg 21 6370 Kitzbühel / Austria
3.	Contact Person:	Dr. Michael Vogele Tel. +43 (0) 664 2411140
4.	Preparation Date:	April 30, 2013
5.	Device Submitted:	iSYS 1 (U.S.)
6.	Proprietary Name:	iSYS 1 (U.S.)
7.	Common Name:	iSYS 1 (U.S.)
8.	Classification Name:	Neurological Stereotaxic Instrument Product Code HAW, Reg.No. 882.4560
9.	Substantial Equivalence:	The iSYS 1 is substantially equivalent to the following legally marketed devices: Rosa Surgical Device manufactured by Medtech Surgical Inc. and Frameless Neuromate manufactured by Integrated Surgical Systems. The characteristics of this device are similar to those of the predicate devices identified on the comparison chart, which follows. It is our opinion that the iSYS 1 does not have technological characteristics that raise additional types of questions related to terms of safety and effectiveness.
10.	Device Description:	The iSYS 1 is a modular needle guidance platform for interventional radiology and related fields. Core components are a 4 DOF micro positioning unit which allows the submillimetric needle positioning from simple needle angulations up to positioning and angulations with adjustable pivot point and a control unit which is directed by a cable connected control panel. The passive macro positioning unit and different table adapters allow different setups of the system around the patient in the region of interest. The needle-guide-kit (manufactured by ECOLAB) provides disposable components that ensure precise and sterile needle guidance. Planning of the tool position/orientation as well as validation of the correctness of the tool position must be performed with an external planning and measurement system which is not part of the iSYS-1 Interventional Platform. The position of iSYS 1 is

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

visible for most imaging systems due to the used markers. During treatment the tool is controlled by the user.

11. Intended Use:

The intended use of the iSYS1 device is to function as a remote-operated positioning and guidance system during interventional procedures. Positioning is done in remote control manner; planning of the position/angulation is done based on 2D/3D patient data (CT, cone-beam CT, fluoroscopy) by external planning software – for example using an external navigation system, or planning software coming with the used imaging device. Also verification of the correct position and orientation of the tool prior to/during/after the intervention is done by means of these external devices. The iSYS1-System is then acting as a guideway during the manual insertion of the interventional tool – usually a needle type device, and the like. Applications include, but are not limited to, interventions like biopsy procedures, tumor ablation, nerve blocking, electrode placement, etc.

The iSYS 1 System is indicated for any medical condition in which the use of a stable and precise needle/tool guidance system may be appropriate, and where external navigation technology and/or imaging technology (e.g. CB-CT, CT, X-Ray) can be used for exact planning and tracking of the needle/tool.

12. Clinical Use

The Side Rail Adapter is attached to the side rail for the setup; the Table Top Adapter is attached directly onto the CT table. Both Adapters are equipped with a “starburst” connector, to which the Multifunctional Arm can be attached. The MFA is equipped with one “starburst” connector at the bottom and one “spoon” connector at the top. The “spoon” connector has its counterpart on the Robotic Positioning Unit for the setup. The Control Unit is attached directly to the side rail. The Robotic Positioning Unit is connected by a cable to the Control Unit, which has cable connections to both the electric power supply and to a Handheld Control Unit. The Needle Guide Extensions are screw-fixed onto the Robotic Positioning Modules. The Sterile Cover is directly fixed onto the Needle Guide Joints and can be drawn over the robotic parts. The Needle Insert is placed into the appropriate connector of the Needle Guide, to prepare needle usage. The Handheld Control Unit can be clamped onto the side rail and covered with a drape. Planning of the tool position/orientation as well as validation of the correctness of the tool position must be performed with

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

an external planning and measurement system (imaging or navigation software).

13. Biocompatibility: The iSYS 1 is not in contact with patient. At any time when in use a sterile cover sheet is to be placed between the patient and the system. Additionally there are no new materials introduced in the manufacture of the iSYS 1. Therefore, no biocompatibility studies were performed for this device.

14. Performance Data: Operating temperature/humidity range: 15 to 30°C; 30 to 70% relative humidity with no condensation

Storage temperature/humidity range: 10 to 50°C; 30 to 70% relative humidity with no condensation

Power Supply: 50W; 115VAC/230VAC; 50-60Hz; cable: C14 according to IEC/EN 60320-1, US498, CSA C22.2 no. 42;

Sterilization of the sterile accessories has been validated by Bioseal, the company responsible for packaging and sterilizing the iSYS accessories.

The accuracy of the intervention depends on the resolution and capabilities of the imaging device or software. The mechanical accuracy of iSYS1 is below 1 mm, but that gives no accuracy value for treatments.

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Device Comparison Summary:

Reference	Frameless Neuromate	ROSA Surgical Device	iSYS 1 (for new submission)
510k-Number	K991081	K101791	K131433
Manufacturer	INTEGRATED SURGICAL SYSTEMS, INC. 1850 Research Park Dr. Davis, CA 95616 USA	Medtech Surgical Inc. 211 Warren Street Suite 306 Newark, NJ 07103 USA	Submitter
Design			
General device description	Computer controlled electromechanical multi-joined arm indicated for use as a stereotactic instrument	Computer controlled electromechanical multi-joined arm indicated for use as a stereotactic instrument	Computer controlled electromechanical multi-joined arm indicated for invasive procedures
Localization means	Robot arm absolute encoders	Robot arm absolute encoders	Fiducial markers on tool holder.
Image-guided	Yes	Yes	Yes
Planning software	No (third party)	Yes	No (third party)
Instrumentation	Laser pointer Tool Holder	Navigation probe Laser pointer Tool Holder	Marker Tool Holder Sterile Covers
Instrument fixation	Instruments are mounted onto robot arm	Instruments are mounted onto robot arm	Special tool holders for several applications mounted to the Robot
Instrument calibration	Factory Calibration	Factory Calibration	By navigation/imaging software during intervention
System immobilization between patient and device	Yes	Yes	Yes
Indications for Use			
Indication for use	Stereotactic spatial positioning and orientation of an instrument holder or tool guide to be used by a surgeon to manually guide standard neurosurgical instruments (biopsy needle, stimulation or recording electrode, endoscope).	Intended to be used in the operating room for the spatial positioning and orientation of an instrument holder or tool guide, The system is intended to be used by neurosurgeons to guide standard neurosurgical instruments (biopsy needle, stimulation or recording electrode,	The intended use of the iSYS1 device is to function as a remote-operated positioning and guidance system during interventional procedures. Positioning is done in remote control manner; planning of the position/angulation is done based on 2D/3D patient data

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Reference	Frameless Neuromate	ROSA Surgical Device	iSYS 1 (for new submission)
		endoscope). Indicated for any neurosurgical condition in which the use of stereotactic surgery may be appropriate.	(CT, cone-beam CT, fluoroscopy) by external planning software – for example using an external navigation system, or planning software coming with the used imaging device. Also verification of the correct position and orientation of the tool prior to/ during/after the intervention is done by means of these external devices. The iSYS1-System is then acting as a guideway during the manual insertion of the interventional tool – usually a needle type device, and the like. Applications include, but are not limited to, interventions like biopsy procedures, tumor ablation, nerve blocking, electrode placement, etc.
Anatomical site	Head	Head	no restrictions
User	Neurosurgeon	Neurosurgeon	Surgeon
Accessory	Sterile drapes	Sterile drapes Fiducial markers Head Holder Light source	Sterile Covers Table Adapters Cable Sets
Registration	Ultrasound	Marker Optical	Marker
Real-time instrument position	Yes	Yes	Yes
Mechanical Guidance of instruments	Yes	Yes	Yes
Instrument Guide	Manual	Manual	Manual
Technology			
Powered	Yes	Yes	Yes

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Reference	Frameless Neuromate	ROSA Surgical Device	iSYS 1 (for new submission)
CE-Conformity	Yes	Yes	Yes
Computer-controlled	Yes	Yes	Yes
Materials	Metal, electronics and plastics	Metal, electronics and plastics	Metal, electronics Polyamide Polyethylene Bralen

Non-clinical testing has mainly been performed to prove electrical and mechanical safety of the devices. Similar to the predicate devices, iSYS 1 was tested according to EN ISO 60601-1 2nd edition:

- EN 60601-1:1990 + A1:1993 + A2:1995
- EN 60601-1-8:2004 + A1:2006

The Electromagnetic Compatibility of the iSYS1 System has been tested according to FCC, 47 CFR Part15 (Edition 1st October 2010) and ISO 60601-1-2:2007.

Both tests demonstrate that with regards to electrical and mechanical safety, the predicate devices and iSYS 1 are substantially equivalent.

Statement of safety and effectiveness:

It is our opinion that the iSYS 1 System (U.S.) does not have technological characteristics that raise additional types of safety or effectiveness questions, and we consider them to be an enhancement to the existing devices.

To validate the accuracy of the iSYS 1 an external reference system has to be used. We have used and tested the iSYS 1 System (U.S.) with the Philips Allura Xper Guide FD 20 X-ray system.

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Substantial Equivalence Discussion

Device Comparison Table:

Reference	Frameless Neuromate	ROSA Surgical Device	iSYS 1 (for new submission)
510k-Number	K991081	K101791	K131433
Manufacturer	INTEGRATED SURGICAL SYSTEMS, INC. 1850 Research Park Dr. Davis, CA 95616 USA	Medtech Surgical Inc. 211 Warren Street Suite 306 Newark, NJ 07103 USA	Submitter
Design			
General device description	Computer controlled electromechanical multi-joined arm indicated for use as a stereotactic instrument	Computer controlled electromechanical multi-joined arm indicated for use as a stereotactic instrument	Computer controlled electromechanical multi-joined arm indicated for invasive procedures
Localization means	Robot arm absolute encoders	Robot arm absolute encoders	Fiducial markers on tool holder.
Image-guided	Yes	Yes	Yes
Planning software	No (third party)	Yes	No (third party)
Registration method	Bone-mounted ultrasound device	Fiducial markers Optical registration device	Fiducial markers
Instrumentation	Laser pointer Tool Holder	Navigation probe Laser pointer Tool Holder	Marker Tool Holder Sterile Covers (third party)
Instrument fixation	Instruments are mounted onto robot arm	Instruments are mounted onto robot arm	Special tool holders for several applications mounted to the Robot
Instrument calibration	Factory Calibration	Factory Calibration	Intra operative
System immobilization between patient and device	Yes	Yes	Yes
Planning and Navigation Software			
N/A.			
System Operation			
Fiducial markers registration with pointer probe	No.	Yes.	No.
Optical registration	No.	Yes.	No.

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Reference	Frameless Neuromate	ROSA Surgical Device	iSYS 1 (for new submission)
Registration with US	Yes.	No.	No.
Accuracy verification	Yes, laser pointer.	Yes, navigation probe, laser beam.	Yes, performed by user
Provide mechanical guidance for tools	Yes.	Yes.	Yes.
Instrument guide position adjustment	Automatic.	Automatic.	Manual.
Surgeon carries out final gesture through tool guide	Yes.	Yes.	Yes.
Indications for Use			
Indication for use	Stereotactic spatial positioning and orientation of an instrument holder or tool guide to be used by a surgeon to manually guide standard neurosurgical instruments (biopsy needle, stimulation or recording electrode, endoscope).	Intended to be used in the operating room for the spatial positioning and orientation of an instrument holder or tool guide, The system is intended to be used by neurosurgeons to guide standard neurosurgical instruments (biopsy needle, stimulation or recording electrode, endoscope). Indicated for any neurosurgical condition in which the use of stereotactic surgery may be appropriate.	The intended use of the iSYS1 device is to function as a remote-operated positioning and guidance system during interventional procedures. Positioning is done in remote control manner; planning of the position/angulation is done based on 2D/3D patient data (CT, cone-beam CT, fluoroscopy) by external planning software – for example using an external navigation system, or planning software coming with the used imaging device. Also verification of the correct position and orientation of the tool prior to/during/after the intervention is done by means of these external devices. The iSYS1-System is then acting as a guideway during the manual insertion of the interventional

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Reference	Frameless Neuromate	ROSA Surgical Device	iSYS 1 (for new submission)
			tool – usually a needle type device, and the like. Applications include, but are not limited to, interventions like biopsy procedures, tumor ablation, nerve blocking, electrode placement, etc.
Anatomical site	Head	Head	total body
User	Neurosurgeon	Neurosurgeon	Surgeon
Accessory	Sterile drapes	Sterile drapes Fiducial markers Head Holder Light source	Sterile Covers Table Adapters Cable Sets
Real-time instrument position	Yes	Yes	Yes
Mechanical Guidance of instruments	Yes	Yes	Yes
Technology			
Powered	Yes	Yes	Yes
CE-Conformity	Yes	Yes	Yes
Computer-controlled	Yes	Yes	Yes
Materials	Metal, electronics and plastics	Metal, electronics and plastics	Metal, electronics Polyamide Polyethylene Bralen

Similarities and Differences:

All three devices are intraoperative instruments used by surgeons for assisting the spatial positioning and orientation of a surgical tool.

iSYS 1 is equivalent to:

- Frameless Neuromate and ROSA Surgical Device for assisting the spatial positioning and orientation of a surgical tool.
- Frameless Neuromate and ROSA Surgical Device for being localized by the navigation or imaging software.
- Frameless Neuromate and ROSA Surgical Device for being guided by an imaging device
- Frameless Neuromate and ROSA Surgical Device for providing a registration method for the imaging device.

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

- Frameless Neuromate and ROSA Surgical Device for instrumentation and instrument fixation.
- Frameless Neuromate and ROSA Surgical Device for being immobilized in relation to the patient.
- Frameless Neuromate and ROSA Surgical Device for providing accuracy verification, tool guidance and position adjustment.
- Frameless Neuromate and ROSA Surgical Device for the physician making the final gesture.
- Frameless Neuromate and ROSA Surgical Device for having the same indications for use, but on a wider field of application for the iSYS 1 (ROI).
- Frameless Neuromate and ROSA Surgical Device for having similar technology.

Non-clinical testing has mainly been performed to prove electrical and mechanical safety of the devices. Similar to the predicate devices, iSYS 1 was tested according to EN ISO 60601-1 2nd edition:

- EN 60601-1:1990 + A1:1993 + A2:1995
- EN 60601-1-8:2004 + A1:2006

The Electromagnetic Compatibility of the iSYS1 System has been tested according to FCC, 47 CFR Part15 (Edition 1st October 2010) and ISO 60601-1-2:2007.

Both tests demonstrate that with regards to electrical and mechanical safety, the predicate devices and iSYS 1 are substantially equivalent.

Differences:
Frameless Neuromate and iSYS 1 do not contain planning software as ROSA Surgical Device does. Position and orientation of the iSYS 1are given by external planning software. This has no effect on safety or effectiveness.

Frameless Neuromate and ROSA Surgical Device provide a factory instrument calibration during intervention while the position of the needle or needle-type instrument (tool) is verified during intervention by the surgeon for the iSYS1. Verification of the tool position requires greater physician effort but provides for exact (depending on the imaging system) tool localization.

ROSA Surgical Device provides registration with pointer probe whereas the Frameless Neuromate provides ultra sound registration. As already described, this is not necessary for the workflow of the iSYS 1 which reduces time and effort for intervention.

Statement of safety and effectiveness:

It is our opinion that the iSYS 1 System (U.S.) does not have technological characteristics that raise additional types of safety or effectiveness questions, and we consider them to be an enhancement to the existing devices.

To validate the accuracy of the iSYS 1 an external reference system has to be used. We have used and tested the iSYS 1 System (U.S.) with the Philips Allura Xper Guide FD 20 X-ray system.

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Proposed Labeling

Content | Page

Product and Packaging Labels	2
User Manual	6
Marketing Material	113
Form FDA 3654	115

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Product and Packaging Labels

Safety Symbols:

STERILE R	Symbol for STERILIZED USING RADIATION
	Symbol for DO NOT USE IF PACKAGE IS DAMAGED
	Symbol for DO NOT REUSE
MR	Symbol for NOT MRI SAFE
	Symbol for ALTERNATING CURRENT
	Symbol for CAUTION, CONSULT ACCOMPANYING DOCUMENTS
	Symbol for TYBE B APPLIED PART
	Symbol for ON/OFF SWITCH (PUSH-PUSH)
	Symbol for PROTECTIVE EARTH
	Symbol for STORAGE TEMPERATURE
	Symbol for DO NOT LITTER IN DOMESTIC WASTE

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Product identification Symbols:

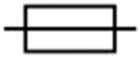
SN	Symbol for SERIAL NUMBER
REF	Symbol for ORDER NUMBER
LOT	Symbol for BATCH NUMBER

Additional Symbols:

CE	Symbol for CE-conformity
+	Symbol for PLUS (increase speed level)
–	Symbol for MINUS (decrease speed level)
	Symbol for POSITIONING
	Symbol for ANGULATION
READY	Label for the ready indicator light
ERROR	Label for the error indicator light
POWER	Label for the power indicator light
USER INTERFACE	Label for the user interface connector
C	Symbol for the confirm push button
Q	Symbol for the quit push button

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

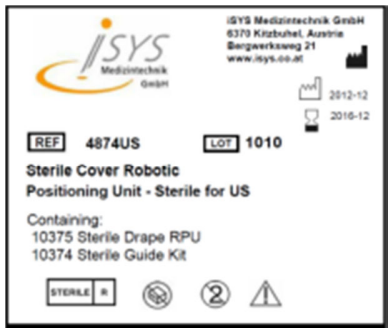
	Symbol for MANUFACTURER
	Symbol for DATE OF MANUFACTURE
	Symbol for USE BY
	Symbol for FUSE
	Symbol for KEEP DRY
	Symbol for THIS SIDE UP
	Label for the Weight
iSYS Medizintechnik GmbH	Company Label

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Examples for Product Labels:

The presented labels are examples for the final product and packaging labels. Lot numbers and dates on these examples are placeholders only. They do not define any format of lot numbers, production or expiry dates.



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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

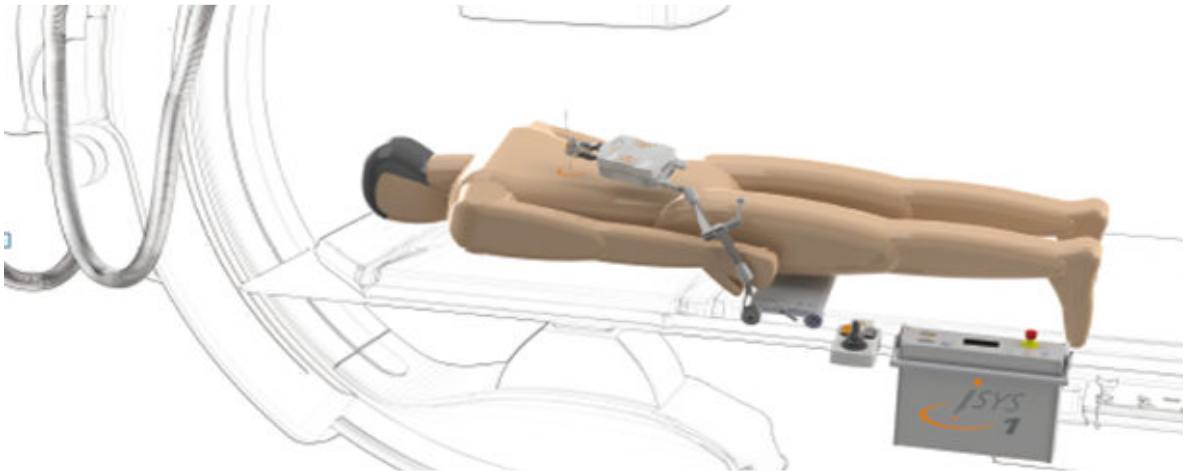
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

PD/B18	Proposed Labeling 510(k) Number: K131433	iSYS Medizintechnik GmbH

User Manual

USER MANUAL US



iSYS Medizintechnik GmbH
Bergwerksweg 21
6370 Kitzbühel
Austria
www.isys.co.at

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Copyright Statement

© 2011 iSYS Medizintechnik GmbH.

All rights reserved. No part of this document may be reproduced in any form without written permission from the copyright holder.

Use of the information contained herein in any form and/or by any means whatsoever is strictly reserved for iSYS and its licensees.

Trademarks

iSYS, iSYS 1 and iSYS Medizintechnik GmbH or its subsidiaries are subject to filed trademark applications.

All rights reserved.

Acknowledgement of Other Trademarks

Other manufacturer's registered trademarks and trade names that appear in this document are hereby acknowledged.

Referenced Documents

Not all documents referred to in this document are part of the scope of delivery for the equipment.

iSYS reserves the right to determine which documents are delivered with a product.

Contact Information

Manufacturer

iSYS Medizintechnik GmbH

Bergwerksweg 21

6370 Kitzbühel

Österreich

Tel +43 (664) 2411140

www.isys.co.at

Representative USA

Cornelia Damsky

56 Westcott Road
Stamford, CT 06902
USA
Phone: +1 (203) 323-7535
Email: cdamsky@att.net

CE 0408

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Table of Contents:

1. Introduction 11

1.1. About this Manual 11

1.2. Description of iSYS 1 11

1.3. Intended Use 13

1.4. Abbreviations 13

1.5. Glossary 14

1.6. Text Formats 15

2. Safety 16

2.1. Warnings, Cautions and Notes 16

2.2. Manual Handling Procedures 16

2.3. Warning Labels 17

2.3.1. Safety Symbols 17

2.3.2. Product Identification Symbols 18

2.3.3. Additional Symbols 18

2.4. Final Disposal 20

2.5. EMC and Mobile Telephones 21

2.6. Compatibility 26

2.7. Compliance 26

2.7.1. IEC Safety Standards 26

2.7.2. IEC Classification 27

2.8. Training 27

3. Specifications 29

3.1. Environmental Conditions 29

3.1.1. Environmental Conditions for Transport and Storage 29

3.1.2. Environmental Conditions for the Intended Use 29

3.2. Components 30

3.2.1. System iSYS 1 U.S. (Art.No. 6224) 30

3.2.2. Accessory – non sterile 33

3.2.3. Accessory - sterile: 34

3.3. Technical Specifications 35

3.3.1. Robotic Positioning Unit 35

3.3.2. Control Unit 35

3.3.3. RPU Cable Set 1500 35

3.3.4. RPU Cable Set 3000 35

3.3.5. Handheld Control Unit 35

3.3.6. HCU Cable Extension 35

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

3.3.7. Multi Functional Arm 35
3.3.8. Table Top Adapter Version B 36
3.3.9. Table Top Adapter Version A 36
3.3.10. Side Rail Adapter 36

4. Operating iSYS 1 37

4.1. Set-Up and Installation 38

4.1.1. Mounting of the (Radiolucent) Needle Guide Extension to the Robotic Positioning 39
4.1.2. Adaptation of the Table Adapters 41
4.1.3. Mounting of the Multi Functional Arm (MFA) 46
4.1.4. Mounting the Robotic Positioning Unit 48
4.1.5. Mounting the Control Unit to the Side Rail 49
4.1.6. Using the Control Unit without Side Rail 50
4.1.7. Adaptation of the Handheld Control Unit to the Side Rail 51
4.1.8. Connection of the Power and Data Cables 52
4.1.9. Bringing the RPU into the "Parking position" 56
4.1.10. Start-up Procedure of the iSYS 1 Robot 58

4.2. Use of iSYS 1 62

4.2.1. Checking the Mechanical Setup and the Range of iSYS 1 62
4.2.2. Setup and Preparing the Patient 63
4.2.3. Image Acquisition and Treatment Planning 65
4.2.4. Working with the sterile iSYS 1 Disposables 66
4.2.5. Attaching the Sterile Cover over the Robotic Positioning Unit 71
4.2.6. Attaching the Sterile Cover to the HCU 82
4.2.7. Gross-Positioning of the RPU and Insertion of the Sterile Needle Guide Marker Insert into the Needle Guide Adapter 83
4.2.8. Micro-Positioning and Accurate Alignment of the NGA under fluoroscopy 85
4.2.9. Attachment of the Needle Guide Insert and Needle Placement 90
4.2.10. Removing the NGI and Quick-Release 95

4.3. Emergency Release/ Removing the system in case of emergency 98

4.4. Dismounting 98

4.5. User Interface 100

4.5.1. Alarms 100
4.5.2. Front-Panel of the Control Unit 101
4.5.3. Handheld Control Unit 102
4.5.4. Display Messages 104

5. Maintenance 107

5.1. Safety-relevant inspections 108

6. Cleaning and Disinfection 110

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

1. Introduction

1.1. About this Manual

This manual is intended to assist users in the safe and effective operation of the equipment described. The term 'user' is used throughout this manual for both the body that has the authority over the equipment and those persons, who actually handle the equipment.

a) The term clinical user means a qualified person who uses any part of the device and its accessories for the purpose of treating patients, and who has been specifically trained in the safe clinical use of the device. Such treatment is restricted to being therapeutic in nature.

b) The term service user means a qualified service engineer who has been trained in servicing the device, and who operates any part of the device for the purpose of performing tests, adjustments and/or repairs to the equipment without, in any manner, involving the presence or treatment of a patient, and personnel who are involved in site planning and installation of the device.

Before attempting to work with this equipment, you must read, understand, note and, where applicable, strictly observe all danger notices, warnings, cautions and safety markings on the equipment and in this manual paying particular attention to all:

- Warnings
- Cautions
- Notes

Please pay special attention to all the safety information provided, and safety procedures described (see section 2).

The use of this equipment by unauthorized persons is strictly prohibited.

1.2. Description of iSYS 1

The iSYS 1 Interventional Platform is a modular needle guidance platform for interventional radiology and related fields.

Core components are a 4 DOF Robotic Positioning Unit which allows submillimetric needle positioning as well as angulation and a Control Unit which is controlled by a cable connected Handheld Control Unit.

The passive macro positioning unit and different table adapters allow different setups of the system around the patient in the region of interest by still providing maximum rigidity.

The needle-guide-set provides disposable components that ensure precise and sterile needle guidance.

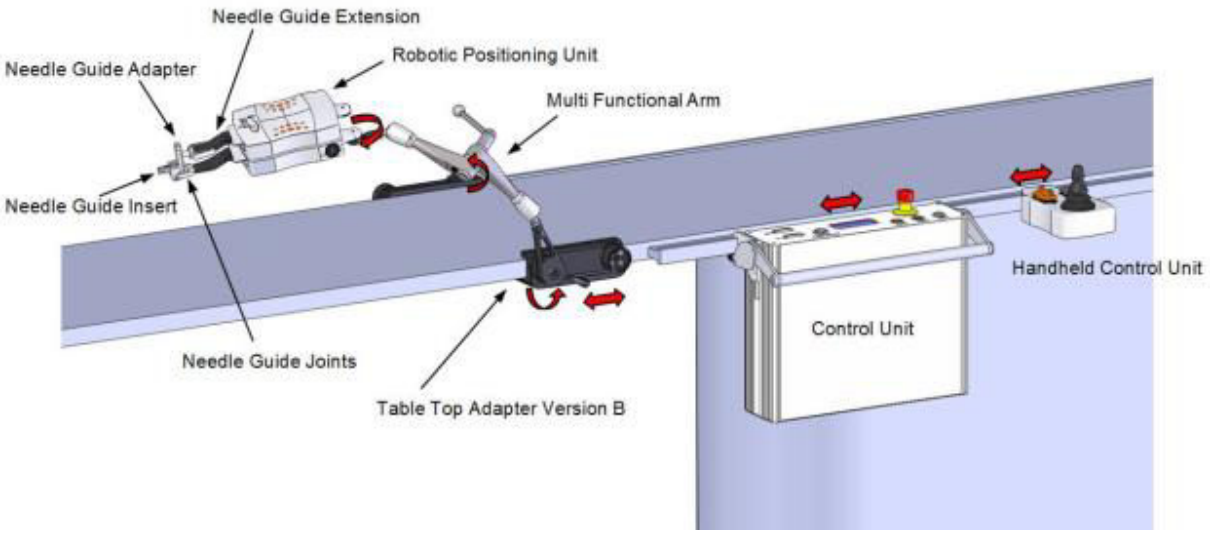
Planning of the intervention is based on digital image data acquired intra-operatively using different kinds of modalities, like CT or fluoroscopy (standard C-arms and/or cone-beam CT systems).

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Planning and verification of both the entry position of the needle-type tool as well as the angulation is performed with the aid of the used imaging device or by an external navigation system.

By using the iSYS 1 Handheld Control Unit the surgeon can remotely move the tool to the desired position and angulation in order to start the clinical procedure.



The system includes the following mechanical parts:

- one Control Unit
- one Table Top Adapter Version B (Bottom Mounted)
- optional: Side Rail Adapter or Table Top Adapter Version A (Top Mounted)
- one Multi Functional Arm
- one Robotic Positioning Unit
- two Needle Guide Extensions

The sterile disposables for each procedure are:

- Sterile Cover Robotic Positioning Unit (not reusable) including Needle Guide Joints and Needle Guide Adapter (not reusable)
- Sterile Cover Handheld Control Unit (not reusable)
- Needle Guide Insert (not reusable)
- Marker Insert (not reusable)

see description in chapter “3.2.4. Accessory – sterile”

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

1.3. Intended Use

The intended use of the iSYS 1 device is to function as a remote-operated positioning and guidance system during interventional procedures. Positioning is done in remote control manner; planning of the position/angulation is done based on 2D/3D patient data (CT, cone-beam CT, fluoroscopy) by external planning software – for example using an external navigation system, or planning software coming with the used imaging device. Also verification of the correct position and orientation of the tool prior to/during/after the intervention is done by means of these external devices. The iSYS 1 system is then acting as a guideway during the manual insertion of the interventional tool – usually a needle type device, and the like. Applications include, but are not limited to, interventions like biopsy procedures, tumor ablation, nerve blocking, electrode placement, etc.

WARNING
In the USA, Federal law restricts this device to sale by or on the order of a physician.

1.4. Abbreviations

The following are abbreviations and acronyms which are used in this document. Their definition is explained below.

Abbreviation	Definition
AC	Alternating current
ASCII	American Standard Code for Information Interchange
AM	Amplitude modulation
CT	Computed tomography
CU	Control Unit
DOF	Degree of Freedom
EMC	Electromagnetic compatibility
FM	Frequency modulation
HCU	Handheld Control Unit
IEC	International Electrotechnical Commission
iSYS	iSYS Medizintechnik GmbH
LCD	Liquid crystal display
LED	Light emitting diode

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Abbreviation	Definition
MFA	Multi Functional Arm
MRI	Magnet resonance imaging
N/A	Not applicable
NGA	Needle Guide Adapter
NGE	Needle Guide Extension
NGI	Needle Guide Insert
NGMI	Needle Guide Marker Insert centered
OR	Operating room
ÖVE	Österreichischer Verband für Elektrotechnik (*Austrian* Electrotechnical Committee)
RF	Radio frequency
RM	Robotic Module
RPU	Robotic Positioning Unit
SRA	Side Rail Adapter
TTAA	Table Top Adapter Version A - Top Mounted
TTAB	Table Top Adapter Version B - Bottom Mounted
TV	Tele-vision
WxH	Width and height

Table 1-1: Abbreviations and Acronyms

1.5. Glossary

Throughout this manual, the following terms have the specific meaning listed below.

Term	Definition
Imaging device	(Medical) Imaging devices are devices used to create images of the human body (or parts and function thereof) for clinical purposes. Imaging modalities for iSYS 1 include CT or fluoroscopy (standard C-arms and/or cone-beam CT systems).
Gantry	In medical imaging, the Gantry is a circular assembly that allows sensors, and possibly energy sources, to

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Term	Definition
	rotate around a patient.
Treatment Table	Also called "Imaging Table" or "Treatment Couch". Table system of the imaging device. Usually this table has a number of degrees of freedom (DOF) – e.g. for vertical and horizontal movement – in order to preposition the patient relatively to the imaging arm.
(Carbon fiber) Table Top	Upper part of the Treatment Table. This part of the table usually is made of radiolucent material – in most cases CFRP (carbon-fiber-reinforced plastic).
Side Rail	Most Treatment Tables have a (metal) on the rail left and right side along the table in order to fix components. Depending on the producer of the table these Side Rail setups may differ from each other, for most of the table systems the Side Rail has a rectangular cross section.
Treatment Planning	During Treatment Planning, the surgeon is using pre-operative or intra-operative imaging in order to select the target position for the tool (e.g. the tumor to be treated) as well as the tool trajectory from the skin entry point to the target position. Depending on the used Imaging device such Treatment Planning can be done using 2D or 3D images.

Table 1-2: Glossary

1.6. Text Formats

The following text formats may be found in this document. Their definitions are explained below.

Text Format	Definition
italic	notes
CAPS	symbol names
courier	text displayed on screens

Table 1-3: Text Formats

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

2. Safety

2.1. Warnings, Cautions and Notes

The following are examples of how warnings, cautions and notes will appear throughout this document. The text within the examples explains their purpose.

WARNING
Warnings are directions which, if not followed, could constitute a health hazard or cause injury, including fatal or serious injury, or could lead to clinical mistreatment.

CAUTION
Cautions are directions which, if not followed, could cause damage to the equipment described in this manual, and/or any other equipment or goods, and/or could cause environmental damage.

Note:	*Notes provide advice and highlight unusual points. A note is not intended as an instruction.*

2.2. Manual Handling Procedures

WARNING
When lifting heavy components, it is important that the correct procedures are adhered to. Local regulations and procedures regarding manual handling must be observed at all times. Failure to do so may lead to fatal or serious personal injury.

WARNING
If any liquids are spilled over components of the iSYS 1, the component needs to be dried in a drying case for at least 24 hours.

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

2.3. Warning Labels

2.3.1. Safety Symbols

STERILE R	Symbol for STERILIZED USING RADIATION
	Symbol for DO NOT USE IF PACKAGE IS DAMAGED
	Symbol for DO NOT REUSE
MR	Symbol for NOT MRI SAFE
	Symbol for ALTERNATING CURRENT
	Symbol for CAUTION, CONSULT ACCOMPANYING DOCUMENTS
	Symbol for TYBE B APPLIED PART
	Symbol for ON/OFF SWITCH (PUSH-PUSH) Power Switch
	Symbol for PROTECTIVE EARTH
	Symbol for STORAGE TEMPERATURE

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

	Symbol for DO NOT LITTER IN DOMESTIC WASTE

2.3.2. Product Identification Symbols

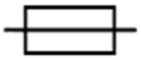
SN	Symbol for SERIAL NUMBER
REF	Symbol for ORDER NUMBER
LOT	Symbol for BATCH NUMBER

2.3.3. Additional Symbols

CE	Symbol for CE-conformity
+	Symbol for PLUS (increase speed level)
–	Symbol for MINUS (decrease speed level)
	Symbol for POSITIONING
	Symbol for ANGULATION
READY	Label for the ready indicator light
ERROR	Label for the error indicator light
POWER	Label for the power indicator light

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

USER INTERFACE	Label for the user interface connector
	Symbol for the confirm push button
	Symbol for the quit push button
	Symbol for MANUFACTURER
	Symbol for DATE OF MANUFACTURE
	Symbol for USE BY
	Symbol for FUSE
	Symbol for KEEP DRY
	Symbol for THIS SIDE UP
	Label for the Weight
	Company Label

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

2.4. Final Disposal

Final disposal means the disposal of the equipment or any part of it in such a way that it can no longer be used for its intended use.

Disposal must always be executed in an environmentally sensitive manner that complies with all local and international regulations and laws. Materials hazardous to human health and the environment must be separately removed and disposed of by competent, licensed facilities. The remaining material may be recycled, where facilities and local regulations permit this.

Never dispose iSYS products in the domestic waste stream.

Prior to disposal, always contact iSYS Medizintechnik GmbH for advice and a list of the substances that require special attention.

WARNING
Incorrect handling or disposal of hazardous material may cause fatal or serious injury and environmental damage. Always disposit iSYS 1 and its components according to the regional regulations.

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

2.5. EMC and Mobile Telephones

The iSYS 1 system is compliant with the requirements according

EN 60601-1-2:2007 and FCC: 47 CFR Part 15:

Guidance and manufacturer's declaration – electromagnetic emissions		
iSYS 1 is intended for use in the electromagnetic environment specified below. The customer or the user of iSYS 1 should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions CISPR 11	Group 1	iSYS 1 uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	iSYS 1 is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Not applicable	

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Guidance and manufacturer's declaration – electromagnetic immunity			
iSYS 1 is intended for use in the electromagnetic environment specified below. The customer or the user of iSYS 1 should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment –guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines ±2 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV line(s) to line(s) ±2 kV line(s) to earth	±1 kV line(s) to line(s) ±2 kV line(s) to earth	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % U_T (>95 % dip in U_T) for 0,5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % UT (>95 % dip in U_T) for 5 sec	<5 % U_T (>95 % dip in U_T) for 0,5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % UT (>95 % dip in U_T) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of iSYS 1 requires continued operation during power mains interruptions, it is recommended that the iSYS 1 be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Note U_T is the AC mains voltage prior to application of the test level.			

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Guidance and manufacturer's declaration – electromagnetic immunity			
iSYS 1 is intended for use in the electromagnetic environment specified below. The customer or the user of iSYS 1 should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment –guidance**
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 Vrms 150 kHz to 80 MHz 3 V/m 80 MHz to 2,5 GHz	10 Vrms 150 kHz to 80 MHz 10 V/m 150 kHz to 80 MHz	Portable and mobile RF communications equipment should be used no closer to any part of iSYS 1 including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d = 0{,}35\sqrt{P}$ $d = 0{,}35\sqrt{P}$ 80 MHz to 800 MHz $d = 0{,}70\sqrt{P}$ 800 MHz to 2,5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[a], should be less than the compliance level in each frequency range[b.] Interference may occur in the vicinity of equipment marked with the following symbol:

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Note 1 At 80 MHz and 800 MHz, the higher frequency range applies.

Note 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which iSYS 1 is used exceeds the applicable RF compliance level above, iSYS 1 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating iSYS 1.

[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 10 V/m.

Recommended separation distances between portable and mobile RF communications equipment and iSYS 1

iSYS 1 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of iSYS 1 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and iSYS 1 as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	**Separation distance according to frequency of transmitter** m		
	150 kHz to 80 MHz $d = 0{,}35\sqrt{P}$	**80 MHz to 800 MHz** $d = 0{,}35\sqrt{P}$	**800 MHz to 2,5 GHz** $d = 0{,}70\sqrt{P}$
0,01	0,035	0,035	0,07
0,1	0,11	0,11	0,22
1	0,35	0,35	0,70
10	1,11	1,11	2,21
100	3,50	3,50	7,00

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

Note 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Note 2	These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

The iSYS 1 system requires special precautions regarding EMC and must be installed and put into service in accordance with the EMC information provided in the accompanying documents.

WARNING
The iSYS 1 system should not be used adjacent to or stacked with other equipment. If the iSYS 1 system is used while positioned adjacent to other equipment, it should be observed to verify normal operation in the configuration in which it will be used.

CAUTION
Class A Equipment – iSYS 1 is not suitable for use in domestic establishments and establishments directly connected to a low voltage power supply network which supplies buildings used for domestic purposes.

WARNING
Portable and mobile RF communications equipment can affect medical electrical equipment.

WARNING
Do not allow any radio-transmitting devices (such as mobile phones, diathermy units, etc.) or devices exceeding the limits defined in the applicable EMC standards in the vicinity of the iSYS 1 system.
Such devices could exceed EMC standards and in unusual circumstances could interfere with the correct functioning of the iSYS 1 system. This could lead to fatal or serious injury, clinical mistreatment, or equipment damage.

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

CAUTION
The use of cables and other components not specified and/or not supplied by iSYS may adversely affect the EMC performance.

2.6. Compatibility

Equipment described in this manual shall only be used in combination with other equipment or components, if these are expressly approved by iSYS as compatible. A list of such equipment and components is available from iSYS upon request.

Changes and/or additions to the equipment shall only be carried out by persons expressly authorized by iSYS to do so. Such changes shall comply with best engineering practice and all applicable laws and regulations that have the force of law within the jurisdiction the equipment will be used within.

WARNING
Changes, additions or maintenance to the equipment carried out by persons without appropriate qualifications and training and/or using unapproved spare parts may lead to fatal or serious personal injury and/or damage to the equipment as well as making the warranty void.

2.7. Compliance

Note:	*The iSYS 1 system has been designed and tested for compliance when used in the clinical environment only.*

The iSYS 1 system is designed to comply with internationally recognized standards for safety and performance.

2.7.1. IEC Safety Standards

The iSYS 1 system complies with the following IEC Safety Standards:

- IEC 60601-1 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2 Medical electrical equipment – Part 1-2: General requirements for safety – Collateral standard: Electromagnetic compatibility – Requirements and tests
- IEC 60601-1-6 Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral Standard: Usability

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

- IEC 60601-1-8 Medical electrical equipment – Part 1-8: General requirements for basic safety and essential performance – Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems

2.7.2. IEC Classification

According to the above listed IEC standards, the iSYS 1 system is classified as set out in the table below:

Type of protection against electric shock	Class I
Degree of protection against electric shock	Type B (the RPU is rated as type B and the needle/tool guided by the system is seen as applied part according IEC 60601-1)
Degree of protection provided by enclosures	IP2X as defined in IEC 60529. (protection against ingress of solid objects with diameter larger than 12,5 mm, no protection against ingress of liquids).
Methods of disinfection recommended by the manufacturer	Disinfected equipment (or elements). See section 6 Cleaning and for methods.
Degree of safety of application in the presence of flammable anesthetic mixture with air or with oxygen or with nitrous oxide	Equipment NOT suitable for use in the presence of a flammable anesthetic mixture with air or with oxygen, or nitrous oxide.
Mode of operation	Continuous

Table 2-2: IEC Classification

Explanation of the classification:

A “Class 1 electrical shock classification” means that the iSYS 1 system must be powered via a power cable connected to a protective earth ground.

2.8. Training

Before using the system at the patient, the user must feel confident with the system and therefore adequate training with the system is mandatory.

Training requirements may vary from country to country. Please make sure that you have received enough training without patient and that you are confident with the use of the system (in accordance with local laws or regulations that have the force of law). Information on training is available from the local iSYS representative.

Purpose of the training:

- Learn the safe use of the system.
- Guarantee a safe and fast workflow.

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

- Learn how to manipulate the NGA with the joystick in 3D. This step is crucial for precise needle alignment.
- The user has to learn the functionality of the joystick and to learn the intuitive use of the joystick.

Important note:

- The user needs to understand how she/he wants to integrate the use of iSYS 1 into the overall workflow of the treatment process: Therefore it is mandatory not just to understand how the system works as a standalone, but also how the system interferes with the overall workflow.
- To avoid complications (setup failures for the specific applications, time consuming breaks that lead to inaccuracy and/or additional radiation, etc.) in the overall workflow and overall setup, it is strongly recommended to train the overall workflow as well.

If problems occur or questions remain, please contact iSYS.

WARNING
The iSYS 1 system and its accessories may only be operated by qualified and authorised personnel. 'Qualified' personnel in this case mean personnel which have been approved to operate medical electrical devices by the responsible management of the clinical environment using the iSYS 1 system.

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

3. Specifications

Electrical installations in the room where the iSYS 1 system is used must comply with the following regulations (in other countries the equivalent standards) where applicable:

- ÖVE EN7
- ÖVE EN1
- ÖVE ÖNORM E8007
- ÖVE ÖNORM E8001

3.1. Environmental Conditions

3.1.1. Environmental Conditions for Transport and Storage

CAUTION
Noncompliance with stated transport and storage conditions may result in damage to the iSYS 1 system. In this case it is essential to completely dry the components of the iSYS 1 system for at least 24 hours and check the functionality of the system before using.

The environmental conditions for transport and storage of the iSYS 1 system are specified in table 3-1.

Ambient temperature	+10°C to +50°C (50°F to 122°F)
Relative humidity	30% to 70%, non-condensing (no outdoor storage)
Atmospheric pressure	800 mbar to 1100 mbar

Table 3-1: Environmental conditions for transport and storage

3.1.2. Environmental Conditions for the Intended Use

The environmental conditions for the intended use of the iSYS 1 system are specified in table 3-2.

Ambient temperature	15°C to 30°C (59°F to 96°F)
Relative humidity	30% to 70%, non-condensing
Atmospheric pressure	800 mbar to 1100 mbar
Max. operating altitude	2000m (6560 ft)

Table 3-2: Environmental conditions for the intended use

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

3.2. Components

WARNING
iSYS 1 must only be used in combination with accessory described in this manual. Other equipment or components shall only be used, if these are expressly approved by iSYS as compatible. A list of such equipment and components is available from iSYS upon request.

The following tables show the single components of the iSYS 1 system, including optional components for variation of the system according to the user's particular requirements. For further details regarding these optional components please contact iSYS Medizintechnik GmbH.

3.2.1. System iSYS 1 U.S. (Art.No. 6224)

Name	Picture	Article-No.:	Standard/ Optional/	Description
Robotic Positioning Unit (RPU):		3908	Standard	Robotic Positioning Unit with two 2DOF modules which allows - in combination with the Needle Guide Set - tool angulation (± 30° for both pitch and yaw angle) and needle positioning (± 20 mm for both lateral and longitudinal direction).
Needle Guide Extension 20mm (NGE)		4965	Standard	The Needle Guide Extension comprises two cranked "fingers" which are connected to the Robotic Positioning Unit by screws. This standard version provides an offset of 20mm between the bottom edge of the RPU and the NGE. The "fingers" are made out of radiolucent plastic and thus do not cause imaging artifacts.
Control Unit (CU):		6254	Standard	The iSYS 1 Control Unit aims to control the iSYS 1 Robotic Positioning Unit. The CU is integrated into a metal rack and can be attached to the side rail of the treatment table by a simple locking mechanism. It is designed to interface with a standard OR siderail with the following

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

				dimensions: (WxH) 10 mm x 25 mm.
RPU Cable Set:		3926 5905	Standard Standard	Set of two cables to connect the CU and RPU. 3926 - RPU Cable Set 1500 mm 5905 - RPU Cable Set 3000 mm
Handheld Control Unit (HCU):		3901	Standard	The Handheld Control Unit comprises a 2-axis joystick as well as confirmation and control buttons for remote operation of the RPU from "safe" distance. A simple locking mechanism allows the attachment to the side rail. A sterile cover for the Handheld Control Unit is also available. It is designed to interface with a standard OR siderail with the following dimensions: (WxH) 10 mm x 25 mm.

Name	Picture	Article-No.:	Standard/ Optional/	Description
Multi Functional Arm (MFA):		4271	Standard	Single-lever passive multi-functional arm for flexible pre-positioning of the iSYS 1 Robotic Positioning Unit. There are two different connectors: the “Starburst”-adapter connects the MFA to the different table adapters; the “Spoon”-adapter connects the MFA to the RPU.
Table Top Adapter Version B - Bottom Mounted (TTAB):		4120	Standard	Mechanical adapter for safe and stable connection of the MFA directly to a standard C-Arm Couch Top; It is mounted from the bottom of the Couch Top. This adapter is designed to interface with a carbon fiber table top with the following dimensions: Width between 470 mm and 530 mm Maximal thickness of the table: 6 mm (at the border)

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

				and 38mm (in the middle of the table)
Table Top Adapter Version A - Top Mounted (TTAA):		4117	Optional	Mechanical adapter for safe and stable connection of the MFA directly to a standard C-Arm Couch Top; The Table Top Adapter Version A – Top Mounted is mounted from the top and provides maximum stability. This adapter is designed to interface with a carbon fiber table top with the following dimensions: Width between 470 mm and 530 mm Maximal thickness of the table: 6 mm (at the border)
Transport box		6098	Standard	Transport box
Power Cord:		6163	Standard	Power cord (U.S.) length 2500 mm

Table 3-3: iSYS 1 U.S. System

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

3.2.2. Accessory – non sterile

Name	Picture	Article-No.:	Standard/ Optional/	Description
Table Top Adapter Version A - Top Mounted (TTAA):		4117	Optional	Mechanical adapter for safe and stable connection of the MFA directly to a standard C-Arm Couch Top; The Table Top Adapter Version A – Top Mounted is mounted from the top and provides maximum stability. This adapter is designed to interface with a carbon fiber table top with the following dimensions: Width between 470 mm and 530 mm Maximal thickness of the table: 6 mm (at the border)
Side Rail Adapter (SRA):		4095	Optional	Adapter to connect the MFA to a standard side rail. The extension with a metal rod is possible if needed. The rod is inserted and into the adapter and fixed with a screw. The Starburst connector is located at the end of the rod as well as on the adapter itself. This adapter is designed to interface with a standard OR side rail with the following dimensions: (WxH) 10 mm x 25 mm
HCU Cable Extension:		6162	Optional	HCU Cable Extension

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

3.2.3. Accessory - sterile:

Name	Picture	Article No.	Disposable	Description
Sterile Cover RPU - sterile for US:		4874US	Disposable	It is a disposable sterile component to cover the RPU and part of the MFA and RPU Cable Set. This assembly consists of a Sterile Drape (Nr. 10375) and the Needle Guide Kit (Nr. 10374) (including 2 Needle Guide Joints with Fixation Rings). Needle Guide Joints allow a quick and reversible connection of the Needle Guide Adapter to the Needle Guide Extension.
Sterile Cover HCU - sterile for US:		4883US	Disposable	It is a disposable sterile component to cover the HCU during operation.
Needle Guide Marker Insert centered - sterile for US:		4876US	Disposable	The Needle Guide Marker Insert (sterile) allows precise and remote-controlled alignment of the Needle Guide based on real-time imaging data.
Needle Guide Insert xxG - sterile for US:		6289G10US 5990G11US 5991G12US 5992G13US 5993G14US 4877G15US 4878G16US 4879G17US 4880G18US 5989G19US 4881G20US 4882G21US	Disposable	During the intervention the tool is inserted and guided by the sterile Needle Guide Insert. Needle Guide Insert – 10G Needle Guide Insert – 11G Needle Guide Insert – 12G Needle Guide Insert – 13G Needle Guide Insert – 14G Needle Guide Insert – 15G Needle Guide Insert – 16G Needle Guide Insert – 17G Needle Guide Insert – 18G Needle Guide Insert – 19G Needle Guide Insert – 20G Needle Guide Insert – 21G

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

3.3. Technical Specifications

3.3.1. Robotic Positioning Unit

Range of Motion: 40 mm x 40 mm (for each Robotic Module)
Max. Force: 35 N
Dimensions: 266 mm x 139 mm x 68,5 mm
Weight: 1,35 kg

3.3.2. Control Unit

Dimensions: 360 mm x 406 mm x 147 mm
Side rail dimensions: 10 mm x 25 mm
Weight: 5,8 kg
Power rating: 230 V ~
50-60 Hz
50 VA
Fuse rating: 2x T1AL 250 V
Alarm Beeper: approx. 55 dB (A) in a distance of 1 m
Power supply cord: 3x min. 1 mm²; max. length 5 m

3.3.3. RPU Cable Set 1500

Cable length: 1,5 m

3.3.4. RPU Cable Set 3000

Cable length: 3,0 m

3.3.5. Handheld Control Unit

Dimensions: 187 mm x 107 mm x 122 mm
Side rail dimensions: 10 mm x 25 mm
Weight: 0,85 kg
Cable length: 3 m

3.3.6. HCU Cable Extension

Cable length: 10 m

3.3.7. Multi Functional Arm

Dimensions: 500 mm x 105 mm x 145 mm
Weight: 1,36 kg

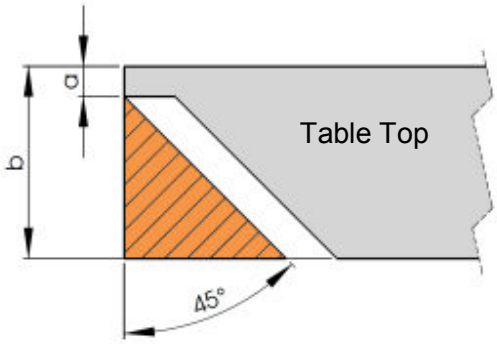
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

3.3.8. Table Top Adapter Version B

Dimensions: 614 mm x 190 mm x 59 mm
Weight: 2,98 kg

Table Top requirements:
Min. table top width: 466 mm
Max. table top width: 535 mm
Min. (a): 3,5 mm
Max. (a): 6 mm
Max. (b): 38 mm



(a) Thickness of the Table Top at the border
(b) Height of the Table Top
Table Top must not reach the orange marked area.

3.3.9. Table Top Adapter Version A

Dimensions: 614 mm x 190 mm x 45 mm
Weight: 2,39 kg

Table Top requirements:
Min. table top width: 466 mm
Max. table top width: 535 mm
Min. (a): 3,5 mm
Max. (a): 6 mm

3.3.10. Side Rail Adapter

Dimensions: 230 mm x 82 mm x 120 mm (without Extension Rod)
610 mm x 45 mm x 25 mm (with Extension Rod)
Side rail dimensions: 10 mm x 25 mm
Weight: 3,29 kg

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

4. Operating iSYS 1

This chapter describes the assembling and operation of the components of the iSYS 1 system. Please be aware that not every type of setup can be described in detail, but with the possibilities described (see below) you should be able to create your desired setup.

WARNING
Never use equipment that is damaged or appears to be working not properly.

WARNING
Never try to touch parts inside of components when operating iSYS 1. Never put your finger in openings. Danger of damage by mains voltage.

WARNING
Always make sure that all components of the hardware setup of iSYS 1 are not causing any collisions with moving parts and/or the gantry of the imaging device.
Therefore, move the gantry and all other moving parts of the imaging device carefully and manually in all desired positions and check for potential collisions before you start the treatment.
Repeat this whenever you have changed the hardware setup of iSYS 1.

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

4.1. Set-Up and Installation

For correct system use and an efficient clinical workflow, please follow the Set-Up and Installation instructions below.

WARNING
Check the power supply cord and plug. Should the power supply cord or plug be damaged, the iSYS 1 system must not be used!

CAUTION
Check the mechanical stability of the setup while setting up the iSYS 1 system!

WARNING
Do not use the iSYS 1 setup in MRI environment.

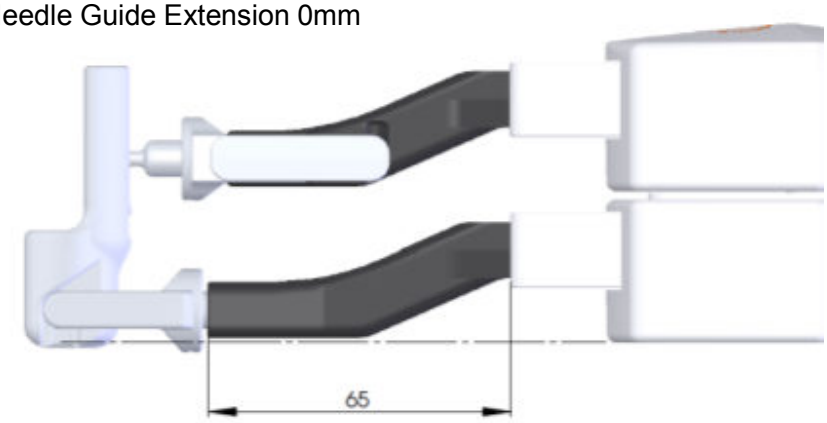
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

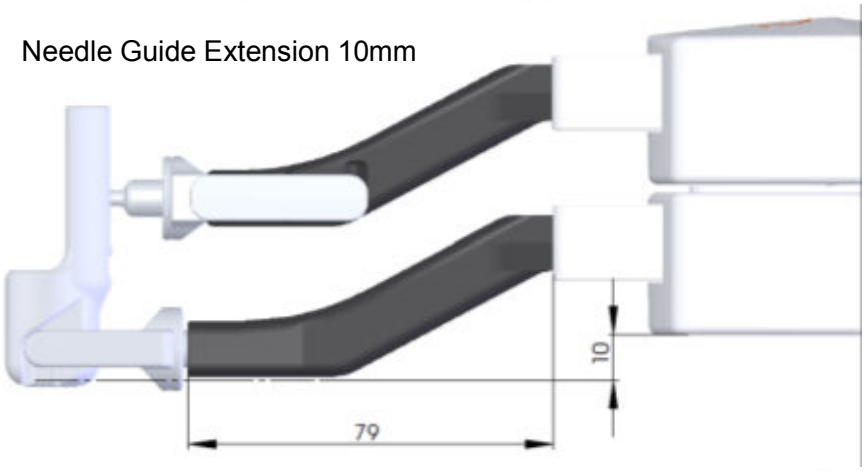
4.1.1. Mounting of the (Radiolucent) Needle Guide Extension to the Robotic Positioning

For the iSYS 1 system different types of Needle Guide Extension are available that differ in offset and length. The system is delivered ready for use with already mounted NGE.

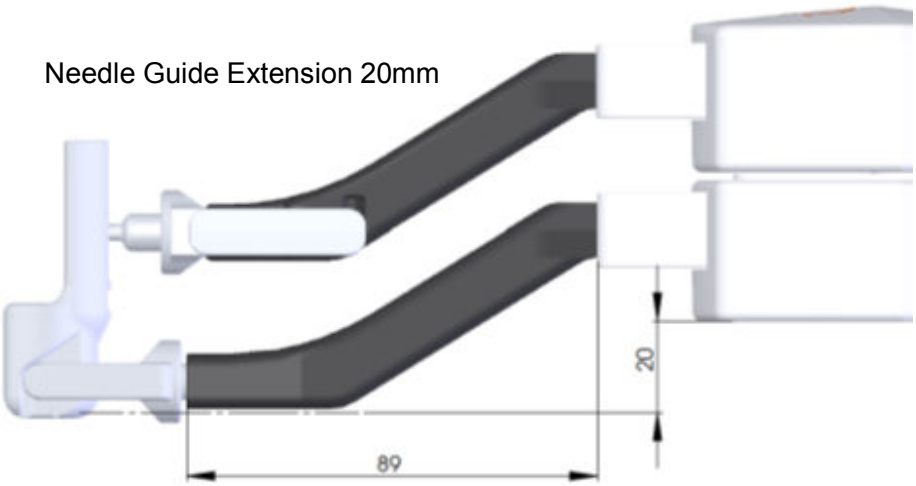
Needle Guide Extension 0mm



Needle Guide Extension 10mm



Needle Guide Extension 20mm



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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Note: *This setup step is only optional and needs to be done in case the user wants to use a different type of NGE (see descriptions of the NGE above).*

This procedure is performed with the robotic unit only, and can be done outside the treatment room.

WARNING
The mounting of the (radiolucent) Needle Guide Extension to the Robotic Positioning Unit can only be done by a professional iSYS technician. There has to be done a SW-modification. If you want to change the needle NGE, please contact iSYS Medizintechnik GmbH.

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

4.1.2. Adaptation of the Table Adapters

For attachment of the Robotic Positioning Unit to the imaging table, iSYS is offering three solutions (a, b and c).

Depending on the type of imaging table and the (carbon fiber) table top, one or more of the below described adapter solutions (a, b and c) can be used.

Note:	*Every table adapter offers different features and setup possibilities, depending on the region of interest and the type of intervention.*

CAUTION
Make sure that the treatment couch and/or the table top fulfills the interface requirements for the adapters!
- **Side rail payload: min. 20 kg**
- **Side rail size: 10 mm x 25 mm (WxH)**

In case you are not sure which adapter you can use (or the user manual of the treatment couch and/or the table top manufacturer does not give you the required information), please ask the service technician of the table/couch top manufacturer or contact iSYS for professional advice!

CAUTION
Be aware that the setup does not block intended movements of the table.

WARNING
All table adapters contain metal parts/material and thereof cause imaging artefacts if they are in the field of view of the X-ray beam. Make sure the adapters are outside the field of view of the imaging device!

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

WARNING
For all types of adapters, the following setup rules are essential:

- **Always make sure that the levers are locked properly and that the adapter provides a solid, clearance-free connection to the table!**
  This is not only essential for the accuracy of the final tool placement – any undesired movement of the mechanical setup also is a potential risk for mistreatment or may cause injuriy to the patient!

- **Always perform a manual stability-test (by pushing or pulling the adapter in different directions):**
  The adapter must maintain the position, must not slip and the setup must not wobble!

- **Make sure that the treatment couch and the adapter are permanently fixed to each other. In case you want to move the table with the patient on it, the adapter has to follow this movement!**
  This is not only essential for the accuracy of the tool placement. Failures in the mechanical setup are a potential risk for mistreatment and may cause injuriy to the patient!

- **Be aware that other devices mounted nearby the Table Adapter or the influence of persons may decrease the mechanical stability.**

- **Be aware, that by opening the locking-levers too far, the adapter may not be safely locked and the adapter/setup may drop and this can cause damage to the system or harm the patient!**

WARNING
Make sure that the table is properly fixed before attaching the components of the iSYS 1 system.

WARNING
If the Side Rail Adapter is being used please make sure that the side rail is firmly connected to the treatment table before attaching any of the iSYS 1 components.

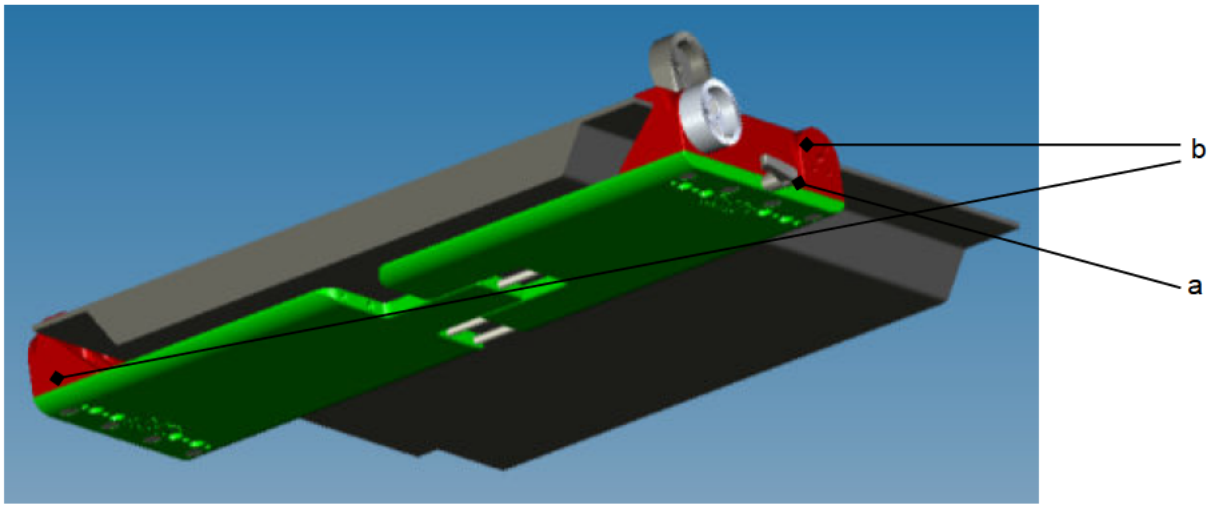
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

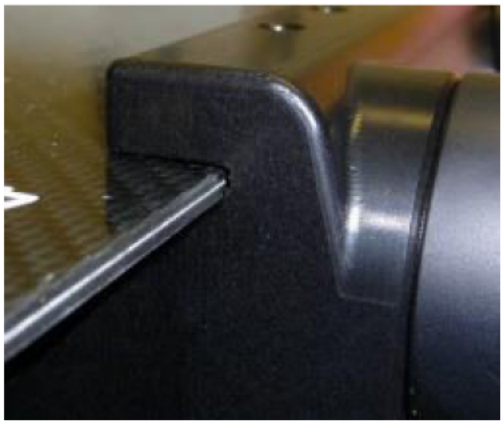
a. Mounting of the Table Top Adapter (Version B - Bottom Mounted)

Open the lever (a) of the Table Top Adapter as far that the clamping jaws (b) can grab the edges of the couch top of the treatment table as shown in the picture below.

By turning the lever clockwise, the clamping jaws (b) of the Table Top Adapter clutch the lateral edges of the table top and thus the adapter is fixed to the table.



The following picture shows the connection between the clamping jaw and the lateral edge of the (carbon) table top.



Once the adapter is locked to the table, it functions as a rigid adapter for the MFA.

If the adapter is not tightened, it can glide and be positioned easily in different positions on the table top.

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

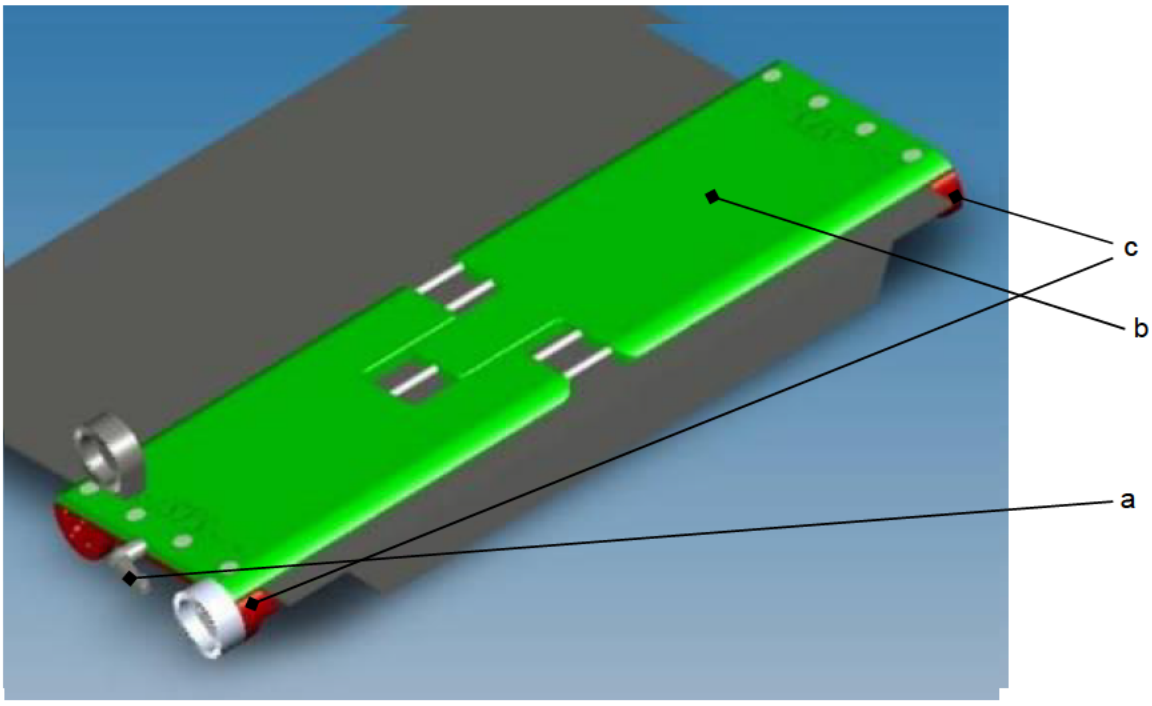
Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

WARNING
Never open the adapter so far that the adapter can fall down.

b. Mounting of the Table Top Adapter (Version A - Top Mounted)

Open the lever (a) of the Table Top Adapter so that the adapter plate (b) can be located on top of the couch top of the treatment table.

By turning the lever (a) clockwise, the clamping jaws (c) of the Table Top Adapter clench the lateral edges of the table top and the adapter is fixed to the table.



Once the adapter is locked to the table, it functions as a rigid adapter for the MFA.

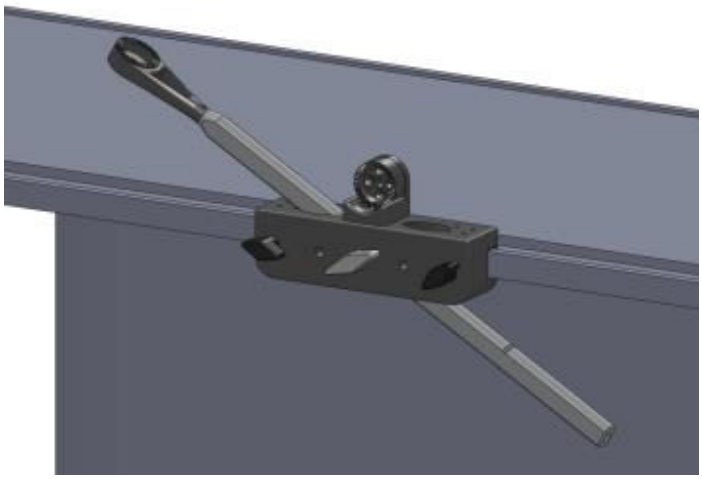
If the adapter is not tightened, it can glide and be positioned easily in different positions on the table

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

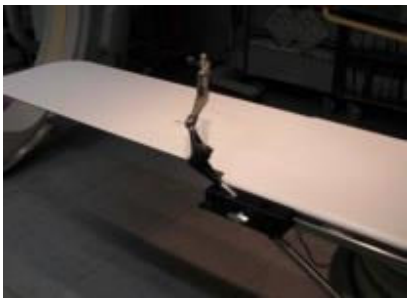
Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

c. Mounting the Side Rail Adapter to the Side Rail of the Imaging Table

Attach the Side Rail Adapter to the side rail of the treatment table as shown below:



By turning the black levers clockwise, the adapter is rigidly attached to the side rail.

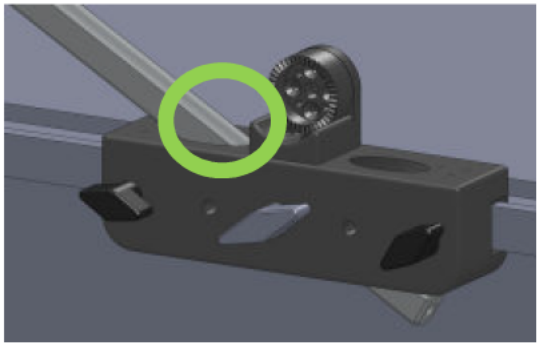


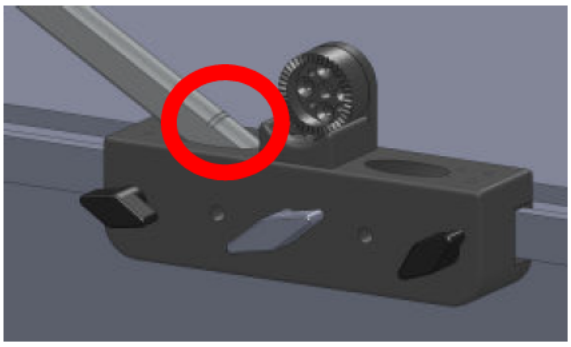
The height of the extension rod can be adjusted by opening and locking the middle lever.

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

WARNING
Make sure that the markings on the extension rod are not visible!





4.1.3. Mounting of the Multi Functional Arm (MFA)

Attach the MFA to one of the Starburst-adapters available on the Table Top Adapter or Side Rail Adapter.

Starburst-adapter

Turn the lever of the Starburst-adapter till the arm is tightly locked to the table adapter.

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

WARNING
Whenever the MFA is mounted or the position of the MFA is being changed (opening and locking) the stability has to be verified with a simple test:
push/pull the Spoon of the MFA or the Robotic Unit gently and check if the MFA and the attached components remain in their position.
Always be aware that the stability of the setup depends on the tightening force of the lever at the MFA.

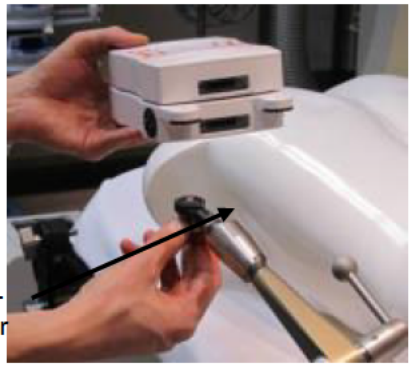
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

4.1.4. Mounting the Robotic Positioning Unit

Attach the Spoon-adapter at the Robot Positioning Unit to the MFA as shown below:

Spoon-adapter



Turn the lever of the Spoon-adapter till the Robot Positioning Unit is tightly locked to the MFA.

WARNING
Always make sure that the levers are locked strong enough and that the mechanical interfaces guarantee a solid, clearance-free connection to each other! This is essential for the treatment, because without high mechanical stability no high accuracies can be achieved with the Robot Positioning Unit!
With a simple manual stability test (by pushing or pulling the RPU carfully in different directions) the rigidity of the mechanical setup can be tested:
The RPU must maintain its position, must not slip and it must not wobble!

WARNING
Whenever the mechanical setup is changed, make sure that the components of iSYS 1 do not cause collisions with the gantry, with the treatment table or with any other part of the imaging device!

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

4.1.5. Mounting the Control Unit to the Side Rail

CAUTION
If iSYS 1 or components are attached to the side rail of a table, ensure that the side rail is capable of carrying the weight. Refer to section 3 for technical data.
Please verify also if the connection of the side rail to the table is tight and does not wobble.

WARNING
Do not cover the front panel of the Control Unit or the display to make sure that any safety-relevant information can be recognized.

Move the CU to the side rail of the table with the handle in straight up position. Hang the unit on the side rail and close the locking mechanism by turning down the handle.

WARNING
Make sure the Control Unit is safely locked to the side rail of the treatment couch.

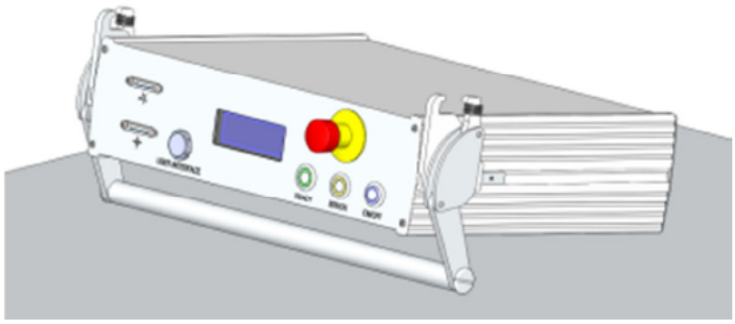
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

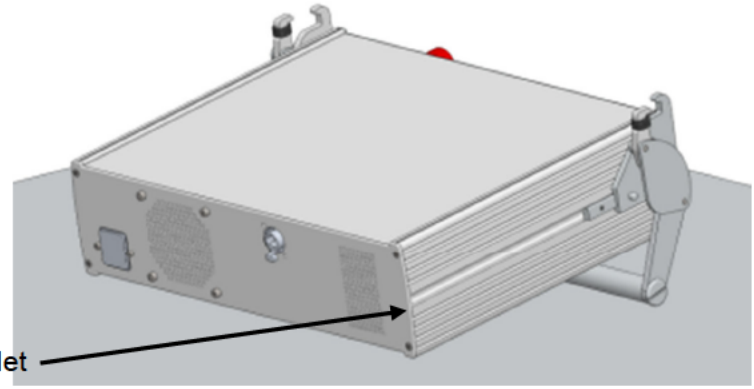
Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

4.1.6. Using the Control Unit without Side Rail

When there is no side rail available make sure the Control Unit is placed on a stable and flat surface which is capable of carrying its weight.

Use the handle as a support as shown in the picture below.





WARNING
Place the Control Unit so that no direct airflow to the patient or sterile areas occur. Otherwise the fan may blow non sterile air to the sterile area.

WARNING
You must pay special attention to the stability of the placement of the Control Unit and the cable routing. Carelessness may lead to falling down of components and harm patient or user.

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

4.1.7. Adaptation of the Handheld Control Unit to the Side Rail

CAUTION
If iSYS 1 or components are attached to the side rail of a table, ensure that the side rail is capable of carrying the weight. Refer to section 3 for technical data.
Please verify also if the connection of the side rail to the table is tight and does not wobble.

Hold the upper orange button pressed and attach the HCU to the side rail of the treatment couch as shown below.

After release of the upper orange button, the HCU is locked to the side rail.

Now the mechanical setup is finished.

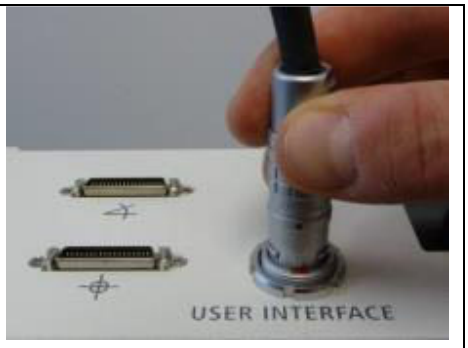
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

4.1.8. Connection of the Power and Data Cables

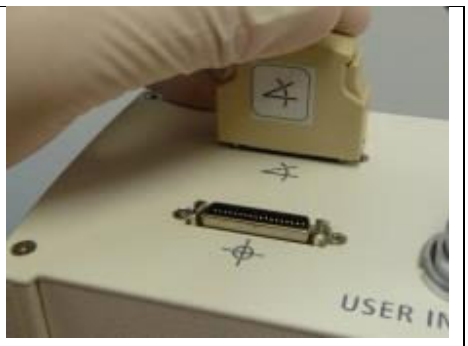
Overview:

Connect the power and data cables like shown in the following table:

Connection between HCU and CU	Connect the circular connector to the socket marked with “USER INTERFACE”. The correct position of the connector is marked with a red dot on both sides, connector and socket	

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

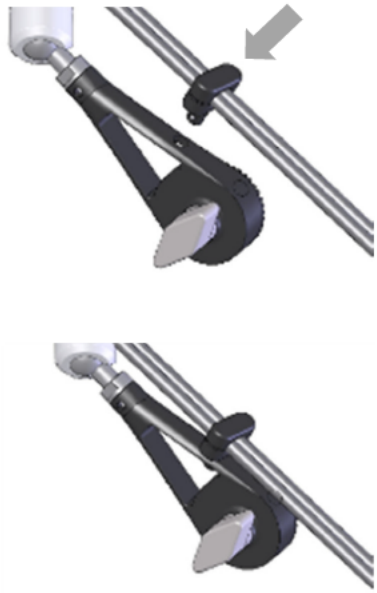
Connection of between RPU and CU	Connect the two flat connectors to the sockets on the CU marked with ⌖ and ⌖. The connectors are marked with the same symbols. Please check for the correct orientation of the connectors before inserting. There should be two “clicks” indicating that the connector is fixed firmly.	
	Connect the two flat connectors to the sockets on the RPU. The connector marked with ⌖ is for the lower robot module (positioning module), whereas the connector marked with ⌖ is for the upper robot module (angulation module). Please check for the correct orientation of the connectors before inserting. There should be two “clicks” indicating that the connector is fixed firmly.	

In case of wrong connection between CU and RPU an error message will be displayed at the CU (“Check HW(5V,Mod)”, cf. “Error Messages”, chapter 0)

For the cabling between CU and RPU please attach the strain-relief connector to the recess at the MFA accordingly in order to avoid pulling forces to the RPU (see picture below).

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016



WARNING
Make sure that the cables do not cross the routes of the patient or the medical staff.
In case this is not avoidable (e.g. no electrical socket nearby), make sure that the cables are taped to the floor so that the patient/medical staff cannot fall over.

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

WARNING
Attach the strain-relief connector to the recess at the MFA accordingly in order to avoid pulling forces to the RPU. If the strain relief is not connected properly this may cause damage to the RPU or may harm the patient.

WARNING
Do not pull at the cables, especially when setting up the patient! This may lead to falling down of components, interference with the mechanical setup and potentially harm patient or user.

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

4.1.9. Bringing the RPU into the "Parking position"

After the mechanical system setup, the RPU has to be parked in a safe parking position.

Reasons for the parking position:

- The parking position allows the easy attachment of the sterile cover.
- The parking position makes room for setting up the patient.
- The parking position allows access to the region of interest for preparing the surgical intervention (disinfection of the skin, sterile covering of the patient etc.)

WARNING
The MFA has progressive locking of the joints to allow precise positioning while locking and to avoid sudden movements when opening.
Always be aware that opening the MFA too fast can lead to uncontrolled movements of the arm itself or attached components (i.e. the Robotic Positioning Unit).
Always open the MFA slowly and carefully with one hand and hold the MFA or the attached device (Robotic Positioning Unit) carfully with the other hand!

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

WARNING
Do not misuse iSYS 1 as an armrest or tablet. This can lead to mechanical failures and serious injuries.

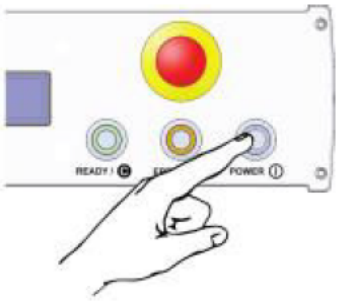
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

4.1.10. Start-up Procedure of the iSYS 1 Robot

1
Follow the Setup – Procedure (mounting of devices and establishing of cable connections) according to chapter 4.1.

2
Switch-on the system using the POWER switch.



Remark: Ensure that the joystick of the HCU is in its center position.

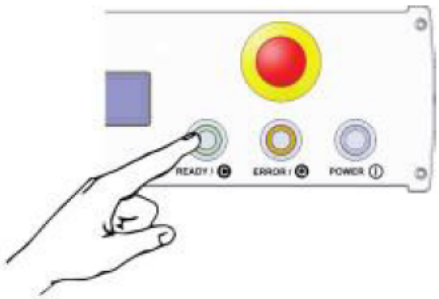
During boot-up the following message is shown.

```
iSYS1 – Needle
Guidance Platform
-------------------
System Bootup...
```

3
The system is now ready to perform the self-test.

```
### iSYS1 C-ARM  ###
* Running SELFTEST *
Rev1:C1.1/M1.6/W1.5
Press C to start  ->
```

4
Press the **C** (Confirm) button to start the self-test.
CAUTION: All axes of the robot will move approximately 1mm during self-test.



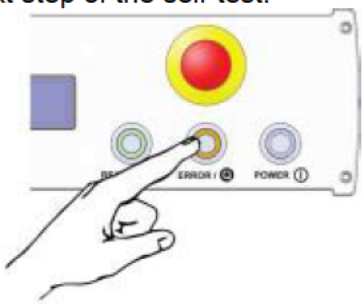
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

5
After the first step of the self-test you are asked to start the next step.

```
### iSYS1 C-ARM  ###
* Running SELFTEST *
Execute Step 2 of 5
Press Quit-Error  ->
```

6
Press the **Q** (Quit) button to start the next step of the self-test.



Repeat **step 6** until all steps are performed.

7
You will get the following message if the self-test was successfully executed.

```
### iSYS1 C-ARM  ###
Selftest PASSED
```

See instructions at **step 7A + 7B** if the self-test fails.

8
Once the self-test is passed you will get the operation screen.

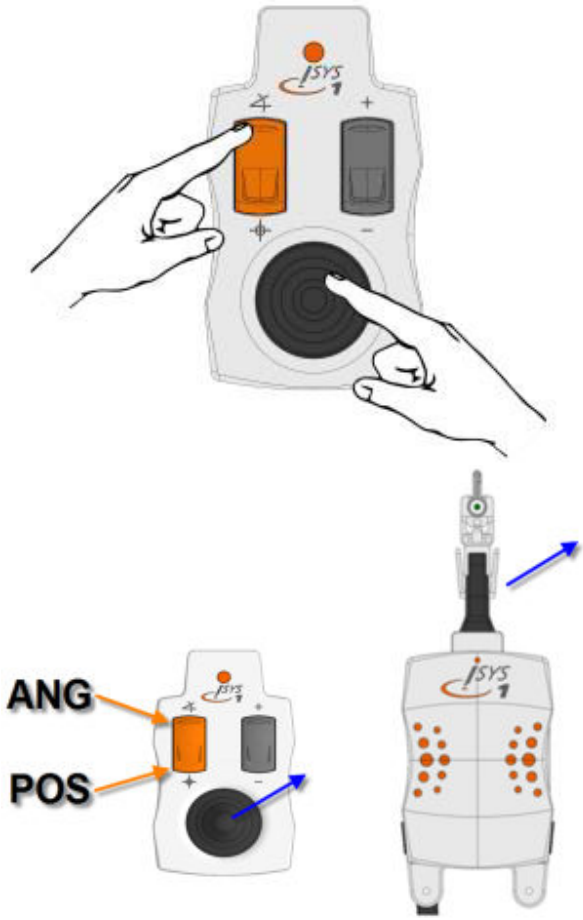
```
### iSYS1 C-ARM  ###

Speedlevel: fast
Joystick Mode  [  ]
```


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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

9

The system is now ready for operation. Use the Handheld Control Unit (HCU) to activate the desired mode (ANG or POS). During activation you can use the joystick to move the robot. The elongation of the joystick is proportional to the motion speed.
You can change the maximum speed using the +/- rocker-switch on the HCU.



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

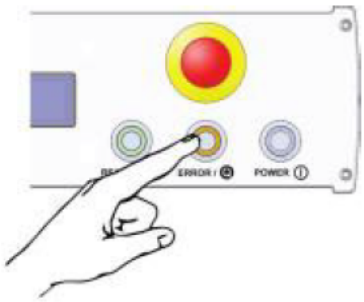
Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

7A
If the self-test fails you will get the following message.

```
### iSYS1 C-ARM  ###
* Running SELFTEST *
Selftest FAILED
Press Q to reset  ->
```

Remark: There are some possible reasons where the self-test fails, even tough no critical failure is present (e.g. a module is very close to its motion limit).

7B
Press the **Q** (Quit) button to restart the self-test and continue the procedure at step **3**.



If the self-test still fails after another trial, please contact the manufacturer.

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

4.2. Use of iSYS 1

The surgical procedure can be divided into several steps. The following workflow, for example, shows the use of the iSYS 1 system for a typical needle procedure under C-arm fluoroscopy.

4.2.1. Checking the Mechanical Setup and the Range of iSYS 1

Position the patient on the treatment table. Before covering the patient and the robot with a sterile cover, make sure that the region of interest is in the field of view of the imaging machine and within the mechanical range of the iSYS 1. Therefore the MFA has to be opened and the RPU roughly positioned manually in the region of interest. During opening of the MFA and checking the range the RPU has to be supported by the physician. The following pictures show different possibilities of potential positions. Please consider the movement of the gantry during imaging to avoid collisions of the iSYS 1 with the gantry.

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

In case the robot cannot reach the region of interest, re-position the patient or re-setup the mechanical parts of the system (e.g. mounting the MFA on a different Starburst-adapter or moving the TTA) so that all (potential) entry-points and target points can be reached.

WARNING
The MFA has progressive locking of the joints to allow precise positioning while locking and to avoid sudden movements when opening.
Always be aware that opening the MFA too fast can lead to uncontrolled movements of the arm itself or attached components (i.e. the Robotic Positioning Unit).
Always open the MFA slowly and carefully with one hand and hold the MFA or the attached device (Robotic Positioning Unit) carfully with the other hand!

4.2.2. Setup and Preparing the Patient

Setup and prepare the patient for the interventional procedure following the steps below:

Note:	*Let the patient enter the table from the opposite table site of the iSYS 1 setup. Make sure the patient does not collide with any component of iSYS 1.*

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Note:	*The following paragraphs describe only the use of the iSYS 1 system. The use of the iSYS 1 system is just a small part of the workflow of an interventional needle procedure.*

This user manual does not take care of all the other important steps (like e.g. preparation of the non-iSYS disposables, cleaning and disinfection of the patient, sterile covering of the patient, use of the imaging machine, use of the planning software etc.). The general workflow for the specific intervention is in the responsibility of the physician.

Depending on the region of interest and of the compliance of the patient, the need of immobilization devices may occur. There are several - commercially available - immobilization devices on the market that can be used for precise patient immobilization.

Depending on the region of interest, respiratory motion may lead to organ movement and therefore to inaccuracy during the targeting process. There are several - commercially available - devices for respiratory motion control available on the market that might be used to overcome this problem.

In some cases - e.g. non cooperative patient - it might even be necessary to sedate/anesthetize the patient.

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

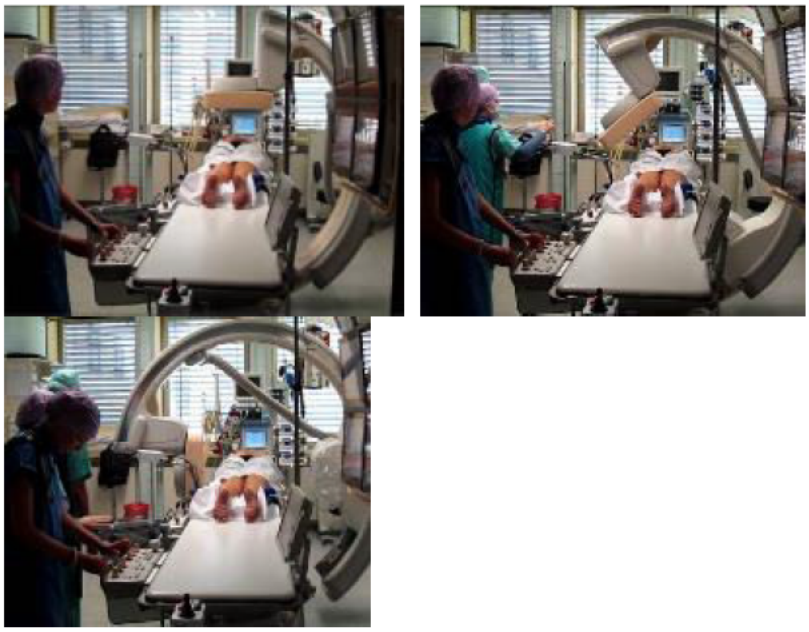
WARNING
It is in the full responsibility of the physician to use aids e.g. for immobilization, respiratory motion control etc. and/or to sedate the patient.
Criteria for the physician include the physical constitution of the patient, the region of interest, the critical (surrounding) structures/anatomy around the path and the target point and the relation of the region of interest to the lung and other moving organs.

iSYS does not take any responsibility for non-iSYS components and treatment steps e.g. correct patient setup, imaging and planning!

4.2.3. Image Acquisition and Treatment Planning

Before image acquisition, make sure that the gantry does not collide with iSYS 1.

To test this, drive the gantry manually and carefully (slow motion) in all necessary extreme positions and make sure that there are no collisions with the setup.

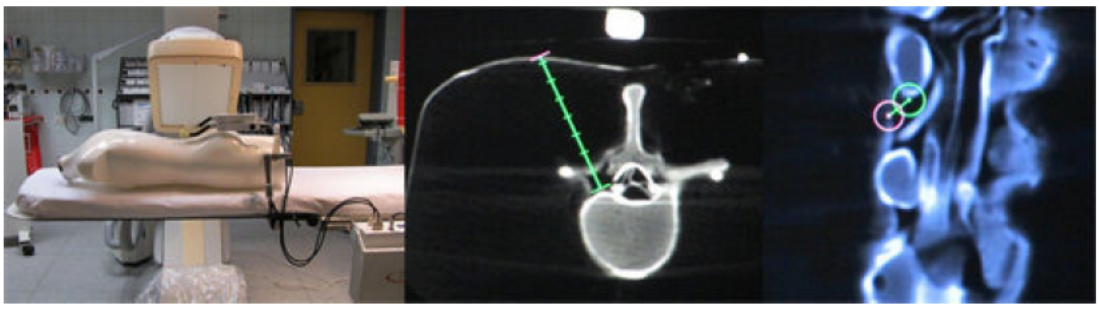


Imaging and planning can be performed with or without the RPU being in the field of view of the imaging device. In case the RPU is placed in the field of view of the imaging device, make sure that only the non-metal parts (plastic NGEs) are in the beam/field of view of the imaging device.

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

WARNING
Only the plastic NGEs ("fingers") do not cause imaging artifacts. If the whole RPU or other parts of the mechanical setup are in the field of view, imaging artifacts may occur!



After imaging of the patient, the planning of the path (entrance and target point) can be done with the planning tool of the imaging machine (not part of the iSYS System!).

Note: *Imaging and planning are not in the responsibility of iSYS.*

Always keep in mind that the iSYS 1 system has only a certain range of movement for gross positioning and micro positioning (see specifications)

In case imaging and planning is not done correctly, it might become necessary at a later point of the workflow to redo these steps (potential consequence: bigger time gap between (re-planning) and treatment and thereof (potentially less accuracy and/or additional radiation cause of the need of re-imaging)

4.2.4. Working with the sterile iSYS 1 Disposables

a. General Information on sterile iSYS 1 Disposables

WARNING
In general, all sterile iSYS 1 disposables are intended for single use for one patient. (Re-) Sterilization of these components is not allowed.

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

WARNING
Do not attempt to clean, sterilize or reuse single use components of the iSYS 1 system. Reuse of single use components might lead to a malfunction of the system and/or an infection of the patient.

WARNING
According to our present state of knowledge, we want to inform you about following known characteristics and technical factors that can lead to hazardous situations in case of reuse of the disposables.

Sterile Covers:
1. **Improper Folding**
2. **Conglutination of the tapes with the foil**
3. **Labels and stickers no longer usable due to opening**

NGE:
1. **Possibility of cross-contamination**
2. **Mechanical damage**

WARNING
Only labeled sterile products are allowed to be used.

WARNING
The single use components are sterile products intended for single use only. Sterility is guaranteed for unopened and intact packaging up to the indicated expiration date. Do not use sterile products if the package is damaged.

Check the Sterilization Indicator Label to make sure the peel pack bag (sterile package) has been processed.

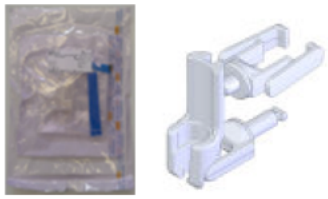
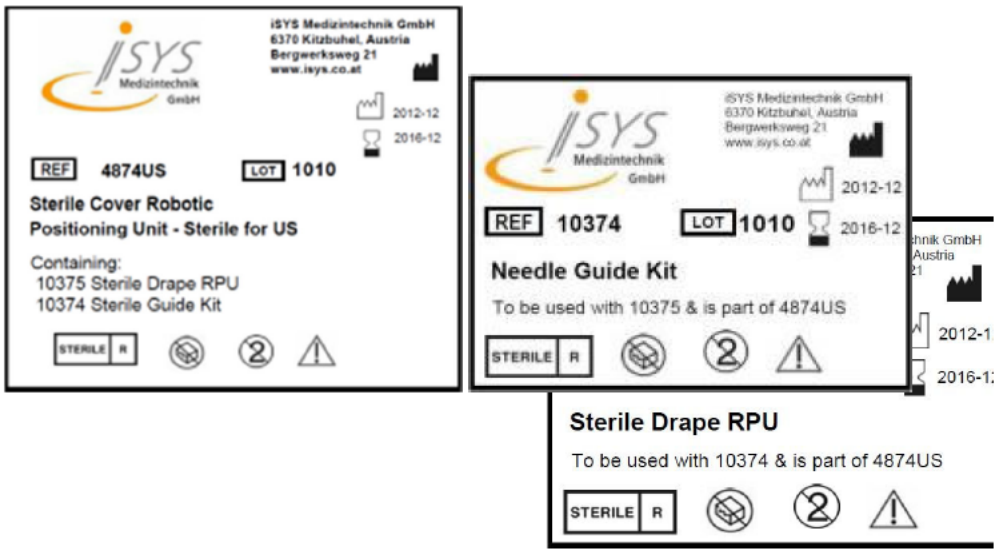
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

b. Preparation of the Sterile iSYS Disposables

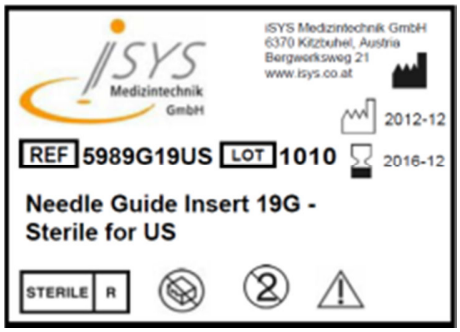
To guarantee a quick and safe workflow, take the iSYS disposables – handed over by a non-sterile assistant – out of the sterile cover and deposit the sterile components on a sterile table/plate.

The following disposables are needed for intervention:

Picture	Number of pieces needed	Single Use / Accessories
	1	**Sterile Cover Robotic Positioning Unit** It is a disposable sterile component to cover the RPU and part of the MFA and RPU Cable Set. This assembly consists of a Sterile Drape (Nr. 10375) and the Needle Guide Kit (Nr. 10374) (including 2 Needle Guide Joints with Fixation Rings). Needle Guide Joints allow a quick and reversible connection of the Needle Guide Adapter to the Needle Guide Extension. Order number and name: 4874US Sterile Cover RPU - sterile for US
		
	Depending on how many needles are placed	**Sterile Needle Guide Insert**: During the intervention the tool is inserted and guided by the (sterile) Needle Guide Insert. NGIs are available for needle diameters given below. The needle diameter of a NGI is printed on the cover bag as well as embossed to the handle of the NGI.

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

		Order number and name: 6289G10US Sterile Needle Guide Insert – 10G 5990G11US Sterile Needle Guide Insert – 11G 5991G12US Sterile Needle Guide Insert – 12G 5992G13US Sterile Needle Guide Insert – 13G 5993G14US Sterile Needle Guide Insert – 14G 4877G15US Sterile Needle Guide Insert – 15G 4878G16US Sterile Needle Guide Insert – 16G 4879G17US Sterile Needle Guide Insert – 17G 4880G18US Sterile Needle Guide Insert – 18G 5989G19US Sterile Needle Guide Insert – 19G 4881G20US Sterile Needle Guide Insert – 20G 4882G21US Sterile Needle Guide Insert – 21G
	1	**Sterile Needle Guide Marker Insert:** The Needle Guide Marker Insert allows precise and remote-controlled alignment of the Needle Guide Insert based on real-time imaging data. Order number and name: 4876US NGMI centered - sterile for US
	1	**Sterile Cover Handheld Control Unit:** It is a disposable sterile component to cover the HCU during intervention. Order number and name: 4883US Sterile Cover HCU - sterile for US

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Make sure all needed disposables are available. Also ensure that extra disposables are available in case a sterile piece is dropped in the non-sterile area (e.g. floor).

WARNING
Be sure the diameter of your instrument complies with the diameter of the Needle Guide Insert.

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

4.2.5. Attaching the Sterile Cover over the Robotic Positioning Unit

WARNING
Never continue with your procedure if any of the sterile covers is or gets damaged. Continuing the procedure might lead to serious infection of patient.

WARNING
Never touch the sterile area in the operating room after touching non-sterile components of the iSYS 1 without respective treatment (according to the local regulations).

WARNING
The patient must not touch the sterile cover.

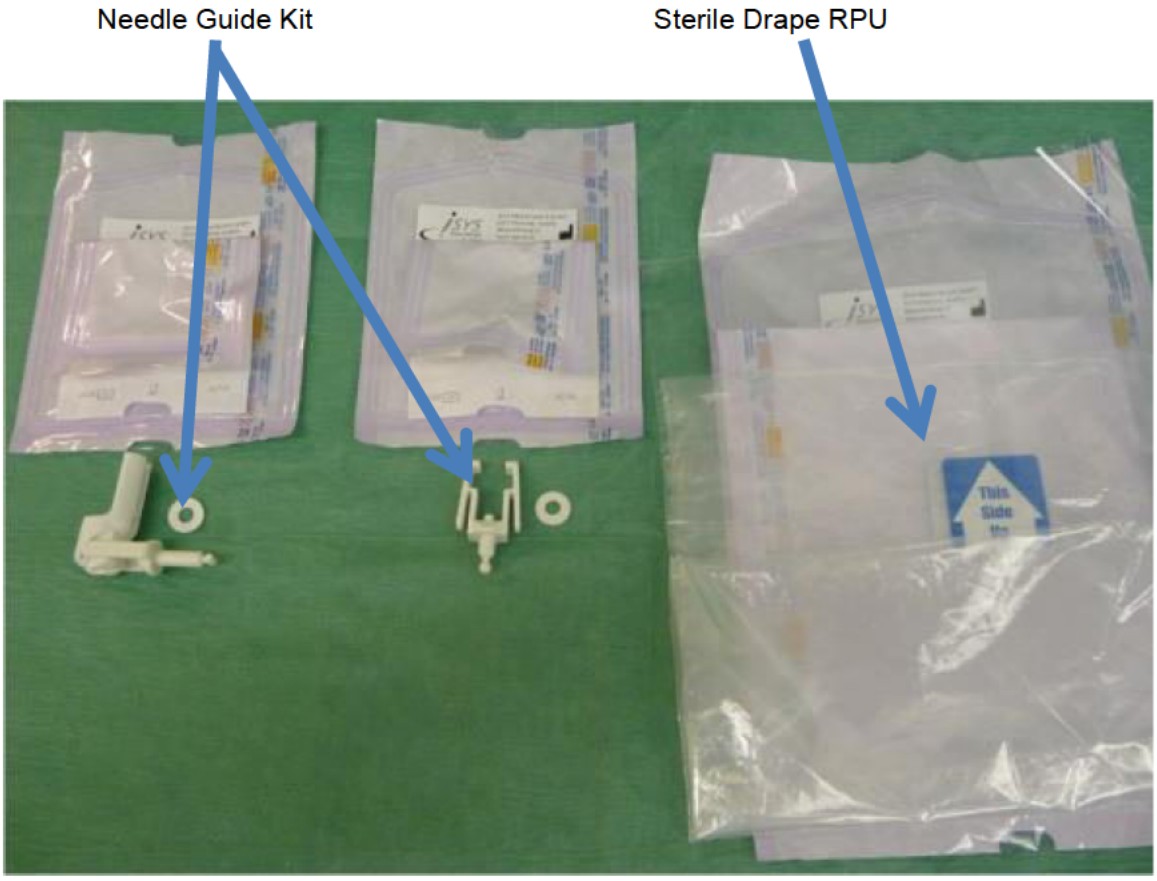
WARNING
Covering the patient's face with the sterile cover can seriously harm the patient.

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

The Robot Positioning Unit and the MFA can be completely covered with a sterile (protective) cover in a simple and safe manner. All non-sterile, reusable parts in the operation area are thereby separated from the sterile parts and the sterile operation area.

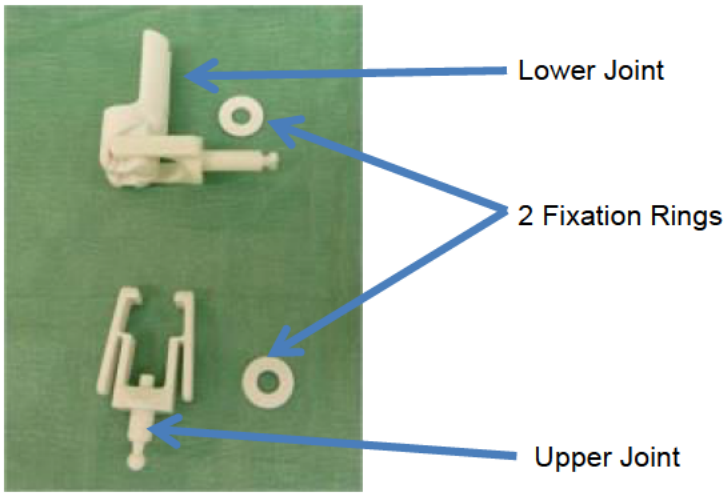
The Sterile Cover RPU consists of 2 parts:



The Needle Guide Kit includes 4 components:

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016



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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Open the sterile packaging and put all components (Sterile Drape, Lower & Upper Joint & 2 Fixation Rings) on the sterile table.

1. Feed the Upper Joint into the sterile drape and stick it through the upper hole.

2. Slip a Fixation Ring onto the Upper Joint

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

3. Feed the Lower Joint from outside the sterile drape into the lower hole.

4. Slip a Fixation Ring onto the Lower Joint from inside the Sterile Drape.

Make sure that both Fixation Rings fixed tight to the Joints!

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

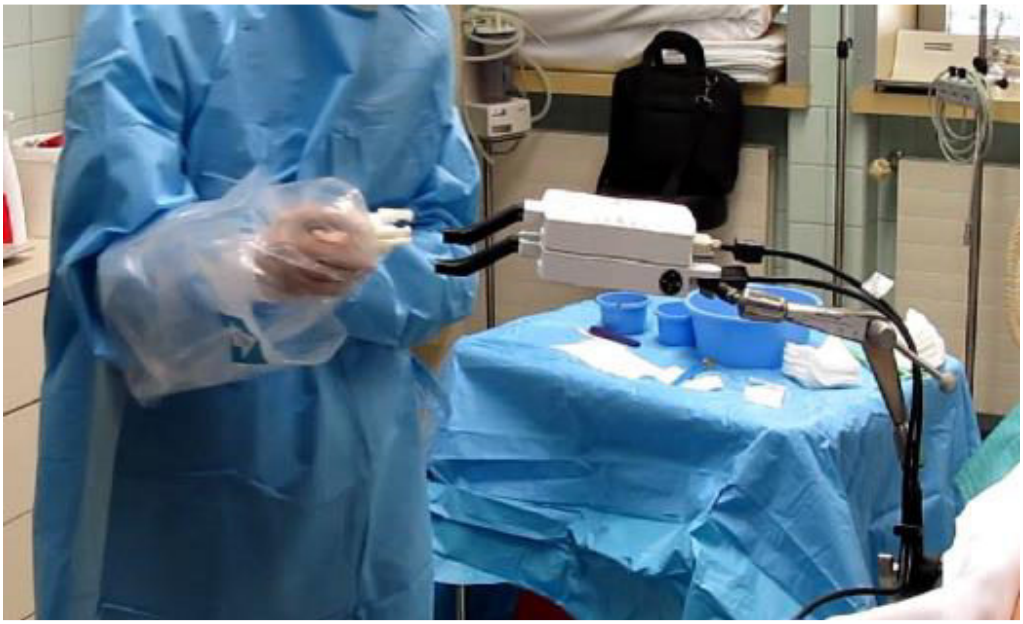
Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

5. Take the Bowl of the Upper Joint and insert it into the guide rail of the Lower Joint.

The final Sterile Cover RPU should look like shown on the pictures.

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

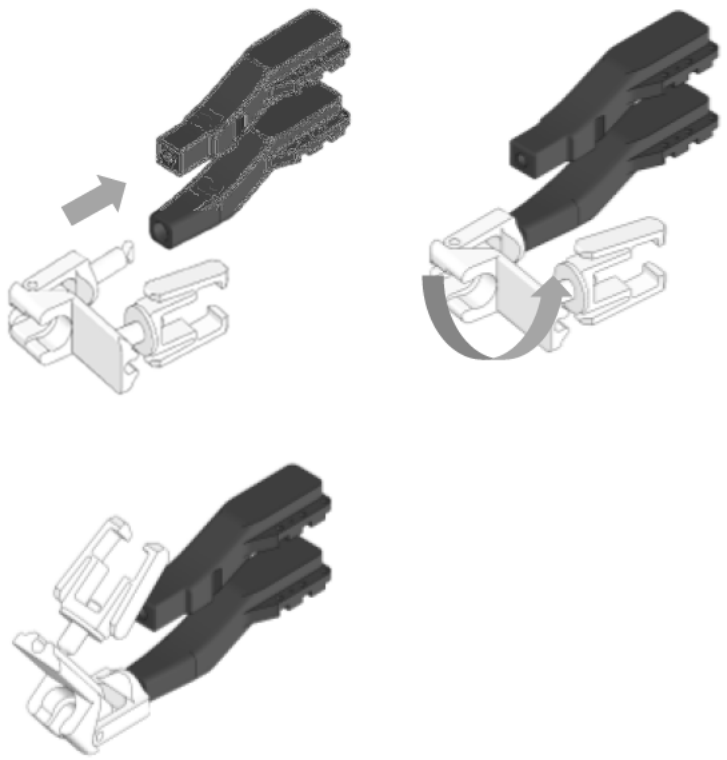


The sterile dressed surgeon grabs the end-effector from inside the plastic tube like shown in the picture above.

First the lower joint -is attached to the lower NGE ("finger") by bringing in the pin adapter in a 90 degree angle.

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

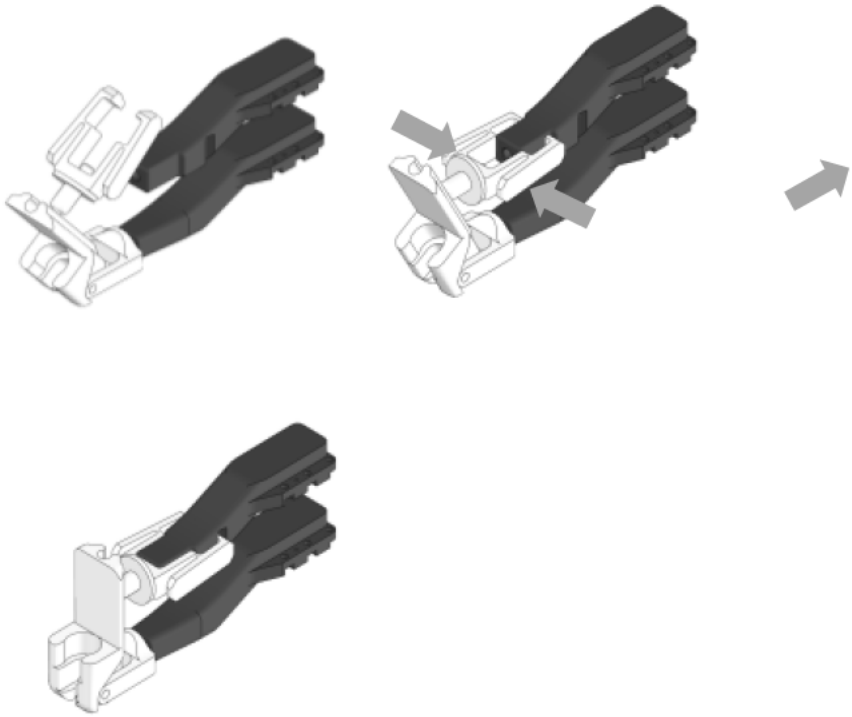


When you have reached the final position, rotate the lower joint 90 degrees up and make sure that the pin is locked safely by gently pulling the lower joint.

Attach the upper joint by attaching the clamp adapter as shown in the picture below:

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016



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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

After attachment of the upper joint, let the (non-sterile) assistant catch the white arrow (see blue marking) and pull the cover over the robotic unit.

After the RPU and MFA is totally covered with the sterile cover, the sterile surgeon can touch the sterile cover and pull the protuberance part of the cover (on the side of the sterile cover) over the handle of the arm and push it back.

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Use the blue tapes to fix the cover in position and to make sure the cover does not slip away.

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

4.2.6. Attaching the Sterile Cover to the HCU

WARNING
The patient or other non-sterile persons must not touch the sterile cover.

WARNING
Covering the patient's face with the sterile cover can seriously harm the patient.

In another simple and safe step, the HCU is completely covered with a sterile protective cover.

The (non-sterile) assistant takes the HCU in his hands. The sterile dressed surgeon takes the Sterile Cover Handheld Control Unit and grabs the HCU from inside the plastic tube.

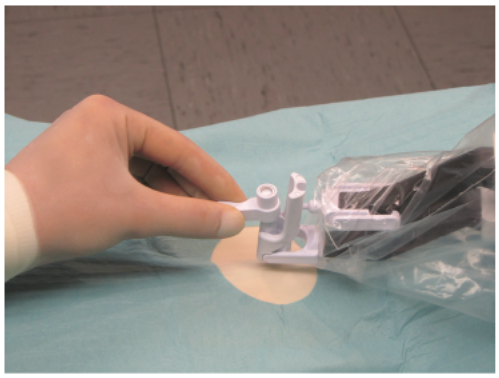
The (non-sterile) assistant catches the end of the plastic tube and pulls the cover over the HCU and its cable.

Note:	*This step allows the surgeon to later touch and use the HCU with his sterile hands/gloves. In case a second (assistant) non-sterile surgeon can operate the joystick, a sterile cover for the HCU is not needed and this step can be left out!*

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

4.2.7. Gross-Positioning of the RPU and Insertion of the Sterile Needle Guide Marker Insert into the Needle Guide Adapter



Make sure the entry and target point is in the range of the RU (see specifications above).

Unless it has not already been done before imaging, the RPU needs to be gross-positioned in the region of interest by opening and closing the MFA. To (re-)position the RPU please hold the RPU with one hand and open the MFA handle with the other one.

Please be aware that the MFA offers progressive locking, i.e. the upper link (next to the RPU) opens first, then the middle link and finally the lower link (next to the table/side rail adapter).

WARNING
The MFA has progressive locking of the joints to allow precise positioning while locking and to avoid sudden movements when opening.
Always be aware that opening the MFA too fast can lead to uncontrolled movements of the arm itself or attached components (i.e. the Robotic Positioning Unit).
Always open the MFA slowly and carefully with one hand and hold the MFA or the attached device (Robotic Positioning Unit) carfully with the other hand!

Although the Robotic Positioning Unit has an ergonomic design, always keep in mind that the steril cover may decrease the friction forces: Always hold and handle the MFA and the Robotic Positioning Unit carefully and safely!

Move the robot to the desired position/orientation and lock the MFA after positioning. The MFA handle needs to be tightened firmly so that the MFA can offer its full payload.

Please check the stability of the setup before proceeding with needle insertion.

To get a rough estimation about the right gross-positioning, you can use standard (skin) markers, the laser cross-hair (or laser pointer) from the imaging device (that visualizes the path) or fluoroscopy.

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

In case you use fluoroscopy, be aware to step aside to avoid radiation exposure. Be always aware that this method causes additional radiation to the patient.

WARNING
Make sure that the RPU and the NGE is oriented (approximately) parallel to the patient surface.
Always check if there is a risk of touching or colliding with the patient while remotely driving the robot modules (see chapter 4.2.8).
To double check: Drive the robot with the HCU in all extreme positions under direct visual control.
Collisions of the robot with the patient can cause serious injuries.

After you have reached and checked the desired position, insert the (sterile) Needle Guide Marker Insert into the Needle Guide Adapter.

WARNING
Make sure and double check that the Needle Guide Marker Insert is in the right endposition and is free of play in the NGA.

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

4.2.8. Micro-Positioning and Accurate Alignment of the NGA under fluoroscopy

Use the HCU (as described in chapter 4.5.3) to micro-position the NGA.

WARNING
When using the HCU, be aware not to touch the sterile area with the non-sterile cable of the HCU.

WARNING
Repeat imaging procedure if the Robot Positioning Unit has been accidental pushed or the power supply has been interrupted after imaging. Failing to do so may lead to mistreatment of the patient.

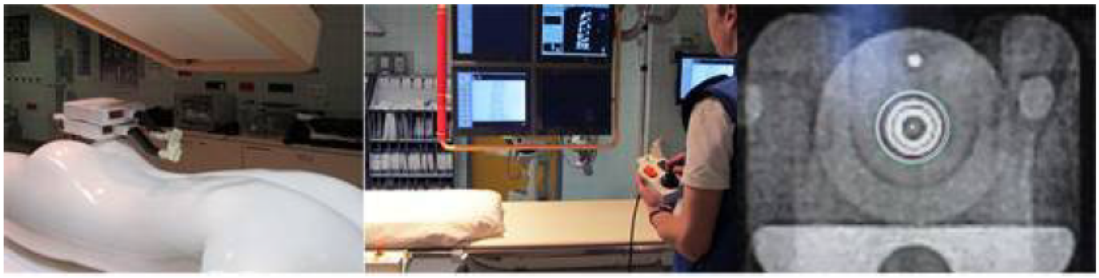
WARNING
Be aware you do not stand on the cables when moving the Robot Positioning Unit. This can lead to wrong positioning of the instrument and mistreatment of the patient.

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

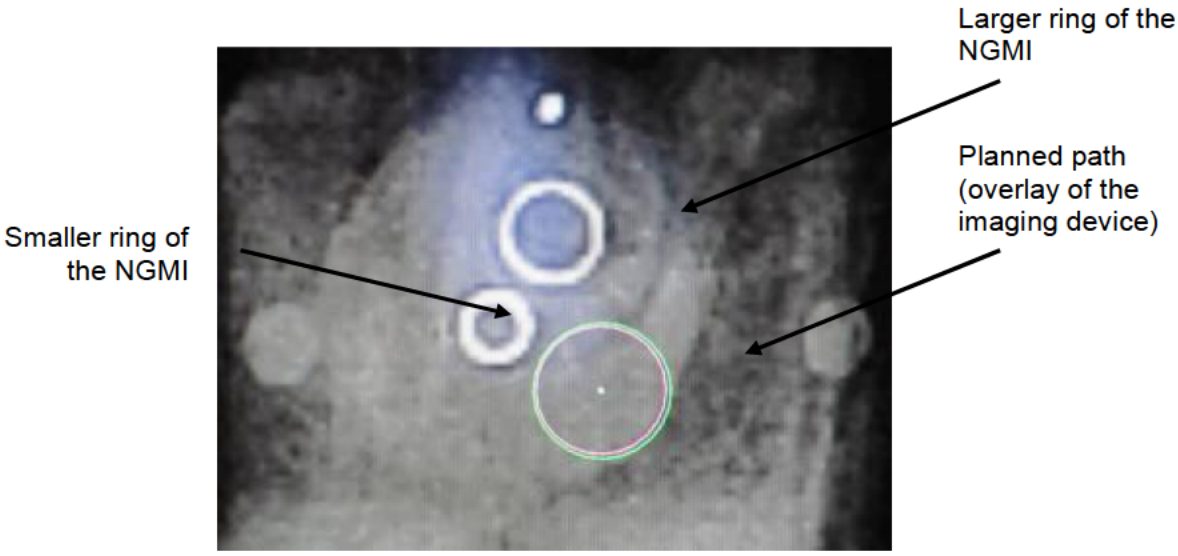
For a first alignment you can use surface markers or the laser cross-hair (or laser pointer) from the imaging device (that visualizes the path). In this case you can stay next to the patient.

If you use real-time-fluoroscopy for the alignment, please stay as far away as possible (minimum 6 feet) from the beam to reduce radiation exposure to a minimum (you just need to have a good view to the monitor that shows the fluoroscopy image).



To avoid unnecessary radiation to the patient, the user can – with the help of the robot – also work "offline" (i.e. without real-time imaging) and use just single Fluoro-Snap-Shots.

For micro-positioning the NG under fluoroscopy the C-Arm has to be orientated perpendicular to the planned path ("entry point view"). To align the Needle Guide with the planned path the user gets the right orientation of the x-, y-, a-, b-axis from the marker Insert:

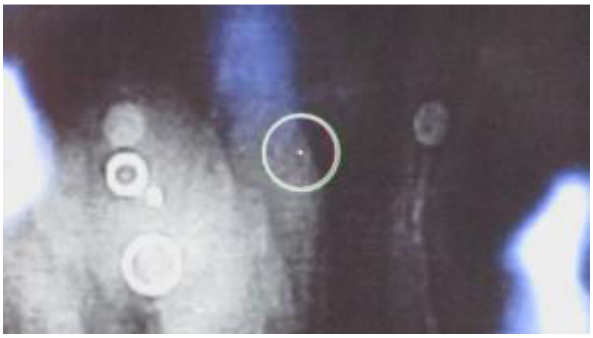


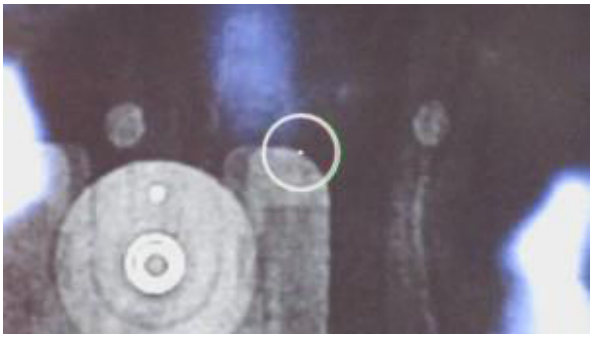
The larger ring of the Needle Guide Marker Insert marks the position of the Needle Guide. The smaller ring indicates the angulation of the Needle Guide.

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

In a first step the smaller ring has to be aligned roughly with the larger ring by moving the RPU in angulation mode. In this mode only the smaller ring moves as shown in the pictures below.

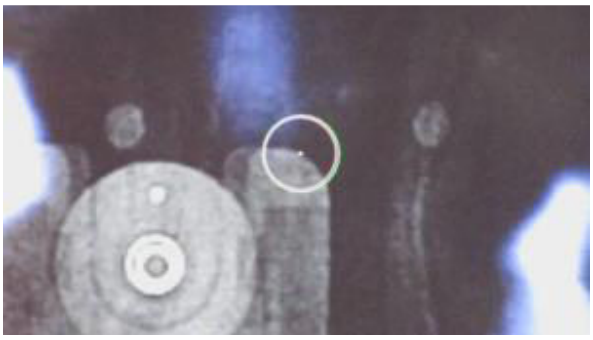


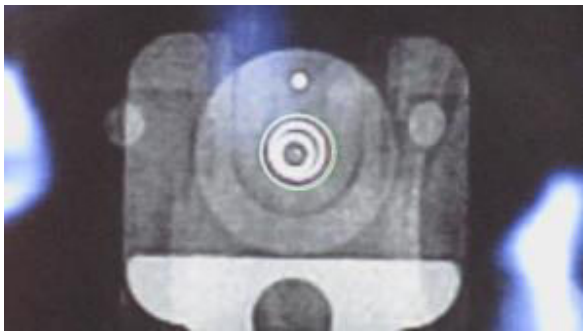


In the next step, both rings have to be aligned with the planned path (indicated by the two rings overlayed by the imaging device) by moving the RPU in positioning mode. When moving the RPU in positioning mode both rings move:

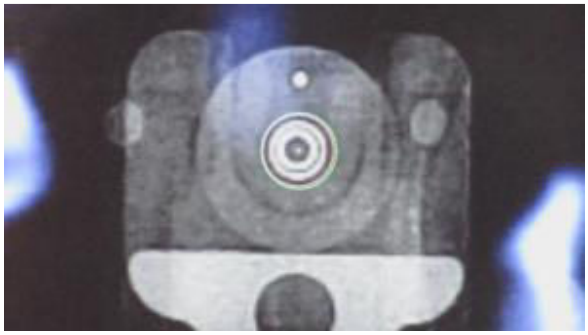
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

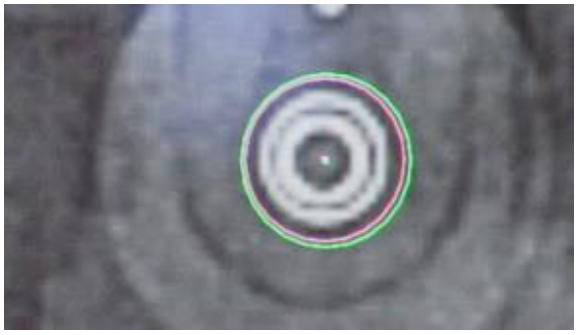
Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016





Finally the alignment has to be optimized by moving the RPU in positioning and angulation mode as shown below. For easy fine positioning the speed level can be set to slow by pushing the MINUS button on the HCU several times unless you hear a beep signal. The speed level is indicated on the display too.





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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

In case the alignment is done under fluoroscopy, a maximum zoom of the fluoro-image, adjustment of the diameters of the ring (in needle entry view, that represents the preplanned path) to the diameter of the marker and the resolution of the x-ray image (be careful: higher dose!) may increase the accuracy.

As this is not in the responsibility of iSYS, please contact the manufacturer of the imaging device for further information.

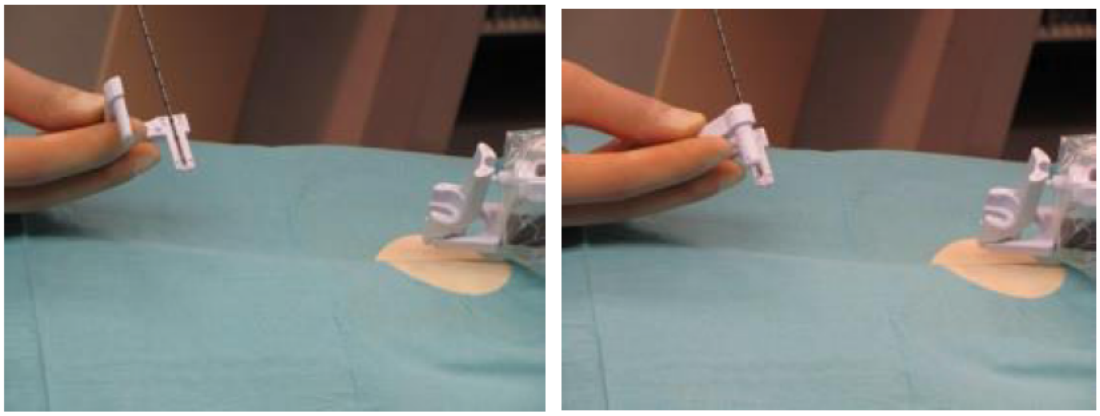
After alignment of the NG, remove the NGMI from the NGA.

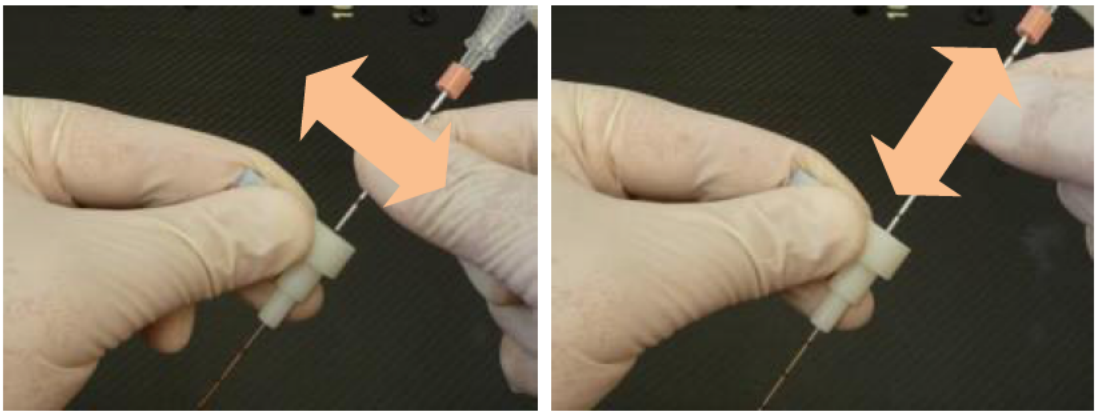
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

4.2.9. Attachment of the Needle Guide Insert and Needle Placement

The NGI has a very important function for needle guidance and quick release. Before attaching the sterile NGI to the NGA, check if the diameter of the needle fits to the NGI and check with the following manual test if the needle has a play-free and friction free guidance in the needle insert:





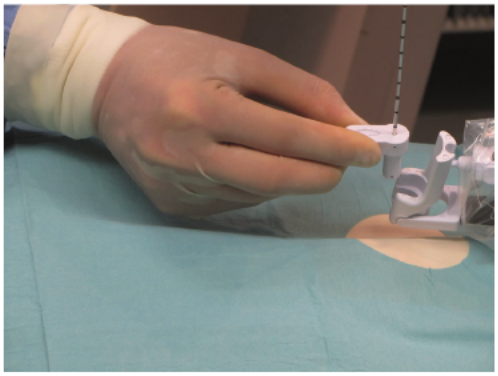
This check takes place in two steps. First insert the needle to the opened NGI, hold the NGI tightly with one hand (pressing the two halves of the NGI together) and try to move the needle in radial direction with the other hand. There should be no detectable play between NGI and needle. For the second step, try to move the needle in axial direction. The needle should move easily – there should be no blocking of the needle during such axial movement.

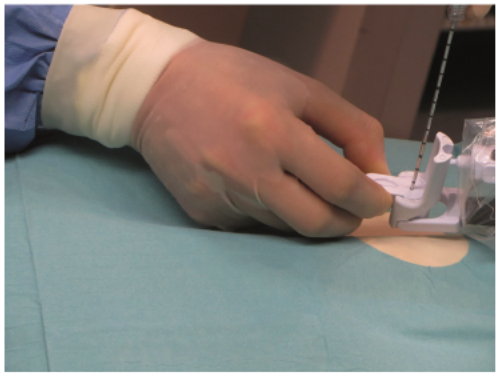
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

WARNING
Check the free and easy movement of the needle in the Needle Guide Insert. Be aware that the needle is not clamped.

After you have checked the functionality of the insert, insert the (sterile) Needle Guide Insert into the Needle Guide Adapter.





WARNING
Make sure and double check that the NGI is in the right endposition and that there is no play between NGA and NGI.

WARNING
Precise needle guidance is essential for the accuracy of the needle placement.
Precise needle guidance is only possible, if the needle diameter is in a certain tolerance over the whole length of the needle.
Always check the tolerances of the needle with your needle supplier before using it with the iSYS system!

After attachment of the NGI to the NGA, the needle can be introduced manually in z-axis into the patient. This step must be under full control of the surgeon!

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Depending on the used imaging device, the depth of the needle placement usually is being calculated by the planning software and is measured between the defined insertion point and the target point. For realization of the correct inserting depth the following procedure is being recommended:

- During planning, define the insertion point exactly on the skin surface of the patient.
- Before insertion of the needle, mark the calculated insertion depth (calculated by the planning system) with a sterile ruler and a sterile pen at the needle.
- Insert the needle until the marked insertion depth is reaching the skin surface
- It is highly recommended to check the needle insertion before reaching the final position by means of an intermediate scan (cf also sub-chapter "Verification and quality assurance" below).

Please note that iSYS is not taking any responsibility for realization of the correct inserting depth!

WARNING
Opening the MFA during the needle being inserted and connected to the RPU can lead to serious injuries at the patient.

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

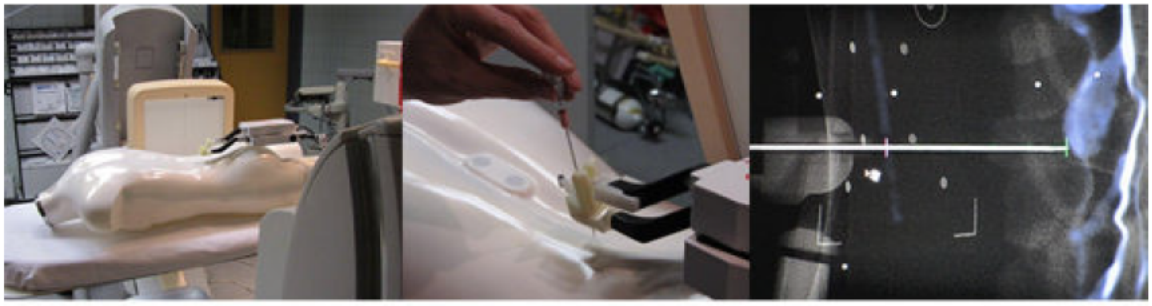
Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

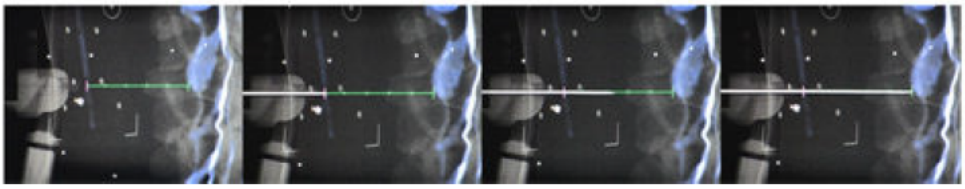
WARNING
The iSYS 1 system acts as a guidance system. It is not designed to compensate high forces from the needle or the user.

Forces on the mechanical components of iSYS 1 may lead to inaccuracy of the needle placement!

Verification and quality assurance:

As the NGE is radiolucent, the correct needle position can be verified with lateral scans ("needle progress view", "angulated needle guide view", optional: "needle entry view") before, during and after treatment.





It is in the responsibility of the surgeon to decide how often verification scans are necessary (this may depend on the region of interest, planned accuracy, critical/surrounding tissue, etc).

WARNING
In case of multiple needle procedures, be aware that the needles do not collide with each other or with iSYS 1 compontents! This can seriously harm the patient.

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

WARNING
Be aware that the setup of iSYS 1 does not influence the imaging in the area of interest. In case of doubts repeat the imaging procedure to avoid mistreatment of the patient.

WARNING
In case of an error (emergency stop): the error condition has to be resolved and the system has to be in the ready state to go on. The needle position and angulation has to be verified with the imaging device before inserting the needle/tool.

WARNING
The RPU must not be use as a (arm) rest at any time, not even as a support of the surgeons hand while inserting the needle.

WARNING
When inserting the needle avoid forces on the needle except for forces along the needle axis. Otherwise it leads to inaccuracies an may lead to mistreatment or injury of the patient.

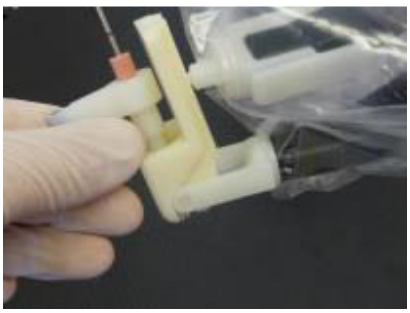
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

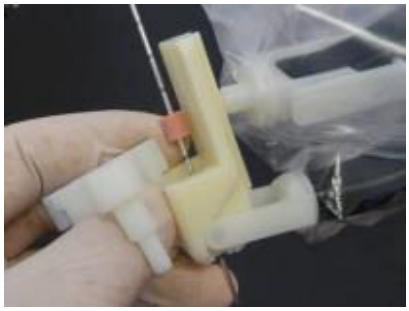
Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

4.2.10. Removing the NGI and Quick-Release

After needle introduction and/or whenever the surgeon steps apart from the patient and/or when the diagnosis/treatment with the needle starts, the NGI has to be removed (i.e. the needle gets decoupled from the robot).

Such decoupling can be easily performed by simply lifting the NGI (along the needle axis) until the NGI is no longer connected to the NGA. In this position the NGI can be opened and the needle is no longer attached to the needle guide.





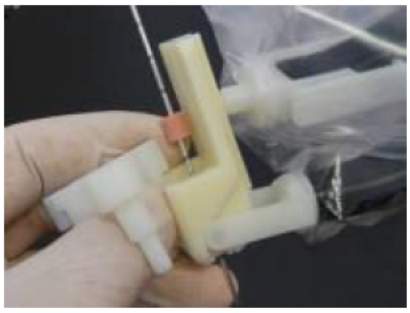
The decoupling also allows free “swinging” of the needle inside the needle guide and a removal of the iSYS 1 system in case of emergency.

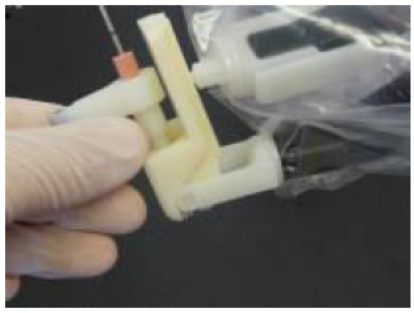
In case of multiple needle placements in larger distance to each other (bigger than the range of the robot), the decoupling also allows the removal of the RPU from the treatment area and a subsequent gross-positioning of the RPU for placement of the next needles.

If decoupling of the needle is only done temporarily (e.g. because the surgeon had to leave the patient for some time), the re-connection between needle and NGA can be done easily in the reverse order. The open NGI is being placed around the needle and being closed afterwards. Then the NGI is moved inside the NGA along the needle axis. Please be sure that the needle is fixed with the other hand during this step in order to avoid unintended needle insertion. For such re-connection the robot must not be moved between decoupling of the needle and re-connection.

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016





WARNING
During manipulation of the NGI for decoupling/coupling the needle from/to the NGA, please be sure that the needle is keeping in place (e.g. fixation with the other hand) in order to avoid unintended needle movement.

WARNING
In case of multiple needle procedures, be aware the needles do not collide with each other or with iSYS 1 compontents! This can seriously harm the patient.

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

WARNING

The MFA has progressive locking of the joints to allow precise positioning while locking and to avoid sudden movements when opening.

Always be aware that opening the MFA too fast can lead to uncontrolled movements of the arm itself or attached components (the robotic positioning unit).

Always open the MFA slowly and carefully with one hand and hold the arm or the attached device (robotic positioning unit) carefully with the other hand!

Although the RPU has an ergonomic design, always keep in mind that the steril cover may decrease the friction forces: Always hold and handle the MFA and the RPU carefully and safely!

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

4.3. Emergency Release/ Removing the system in case of emergency

In case of an emergency (e.g. patient panics), open the MFA, remove the RPU from the patient and bring it into parking position. Before manipulation of the RPU, please make sure to remove the needle from the NGI by either pulling out the needle or de-coupling the needle from the NGI (cf chapter 4.2.10).

WARNING
Before removing the system, always check that the NGI (or the needle) has been removed!
In case the needle insert has not been removed, friction forces can pull and/or push the needle and this can seriously harm the patient.

4.4. Dismounting

Before dismounting the system, bring the RPU into the "parking position" and remove the patient from the treatment table.

Remove the disposable parts first and dispose them according to the clinic guidelines.

Unplug the system, remove the cables, clean the components and dismount the mechanical parts.

For unplugging of the HCU connection cable please grab the circular connector at the grooved part and simply pull out the plug. For the flat connectors connecting the RPU with the CU please push the two locking rockers of the connector and then pull out the connector.

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Store the components carefully in the iSYS storage boxes.

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

4.5. User Interface

4.5.1. Alarms

This chapter describes the iSYS 1 alarms and what you should do if an alarm occurs.

The device provides only one alarm level, i.e. a technical alarm with low priority. Such a low priority alarm/alert warns you about a condition that prevents the system from operating normally. If, for example, the HCU is not connected to the CU, a runtime error is being detected and reported by triggering a dedicated low priority alarm/alert.

These alarms require your awareness. The alarm signal consists of a yellow LED and a sound that repeats a pattern of two beeps. The display has the message ***EMERGENCY STOP*** and an explanation of the alarm. The tables in Section 4.5.4 explain the alarm conditions and messages in more detail.

LCD Display

Error LED indicator

Alarm beeper

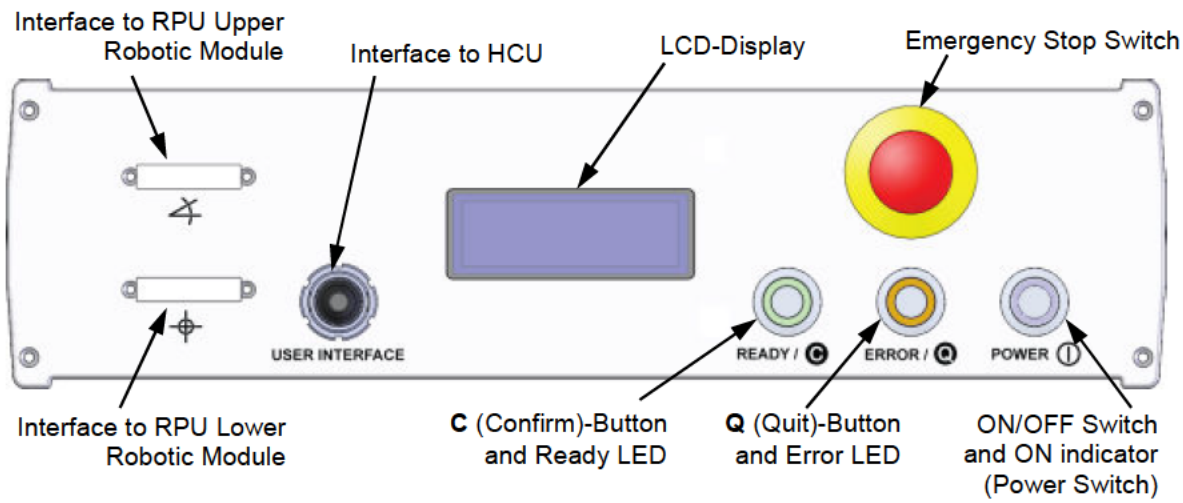
During a low priority alarm/alert:

- Look at the display for text.
- Look up the alarm in the alarm tables in Section 4.5.4 and perform the action specified.
- If the alarm can be cleared: Verify the position and angulation of the tool before you proceed.
- If the alarm persists: Stop the procedure or continue without using iSYS 1. Contact the manufacturer.

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

4.5.2. Front-Panel of the Control Unit



The front panel of the iSYS 1 Control Unit contains the following elements:

Buttons:

- ON/OFF Switch — Used to power the system (not accessible via software)
- **C** (Confirm) Button — Used to confirm triggered actions
- **Q** (Quit) Button — Used for controlled error recovering
- Emergency Stop Switch — Used for user initiated emergency stops

Indicators:

- Ready LED (green) — Indicates the system ready state (lighting) or prompts for confirmation input (flashing)
- Error LED (yellow) — Indicates error situations
- ON Indicator (blue) — Indicates if system is powered (not accessible via software)

LCD Display (4rows x 20 ASCII characters)

The LCD Display shows different states of the system.

Interface socket for Handheld Control Unit

The USER INTERFACE socket provides an electrical interface to control elements on the Handheld Control Unit.

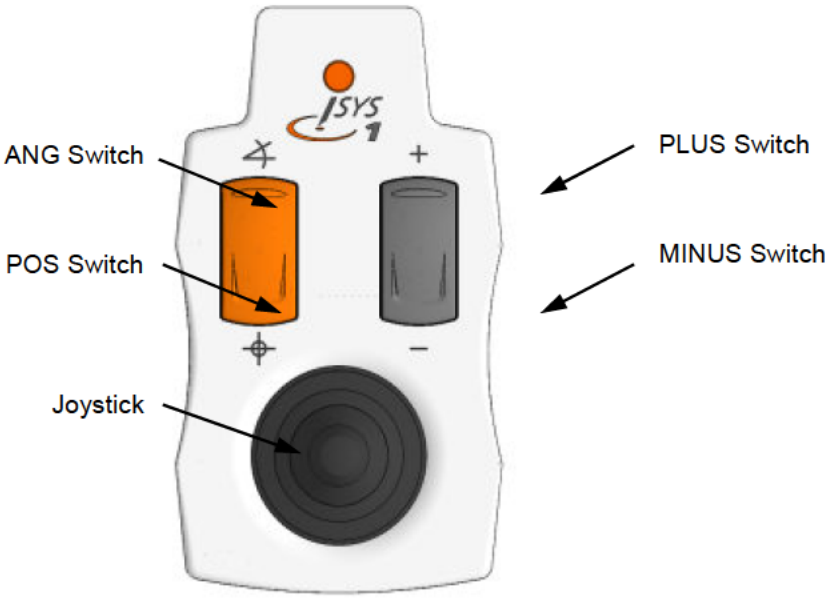
Interface sockets for angulation and positioning module.

..... These sockets provide an electrical interface to the robotic unit.

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

4.5.3. Handheld Control Unit



Left Rocker switch:

- ANG Switch — To activate angulation mode of the RPU
- POS Switch — To activate positioning mode of the RPU

Right Rocker switch:

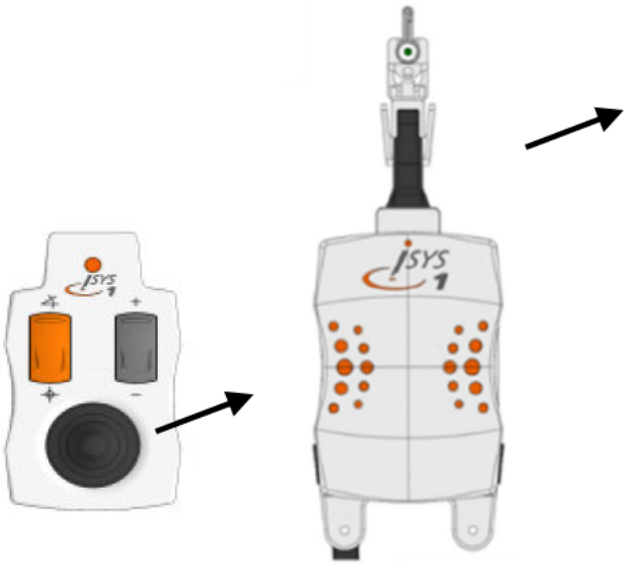
- PLUS Switch (+) — Used to increase the speed limit
- MINUS Switch (-) — Used to decrease the speed limit

Using the PLUS and MINUS button the overall speed level can be switched between 3 levels (100%, 60%, 20%), and thus scales the speed according to the joystick displacement to 100%, 60% or 20%.

Joystick:
The joystick initiates movement of the RPU according to the activated mode (POS or ANG). The shape of the HCU is based on the design of the RPU so that the desired direction of movement can be easily identified.

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016



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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

4.5.4. Display Messages

Boot-up screen

```
 iSYS1 - Needle
Guidance Platform
-------------------
System Bootup....
```

Operation Screen

```
### iSYS1 C-ARM  ###

Speedlevel: fast   *
Joystick Mode  [POS]
```

… Header
… Current Actions (Info Messages)
… Speedlevel and MotionInfo
… Joystickinfo

Message text	Description
Joystickinfo	
Joystick Mode [POS]	The positioning mode is active. Any joystick motion leads to an appropriate motion of the positioning module (lower RM).
Joystick Mode [ANG]	The angulation mode is active. Any joystick motion leads to an appropriate motion of the angulation module (upper RM).
Joystick Mode [ ]	The system is not enabled to perform motions. This steady state is supervised by an electronic circuit.
Speed level+Motion Info	
Speedlevel: {slow|medium|fast} [*] Example: Speedlevel: fast *	The currently active speed level is shown (slow| medium| fast). The asterisk "*" appears if the robotic unit is actually moving. It indicates that the elongation of the joystick is big enough to effectively move the robotic unit.
Info Messages	
Enable System...	The system is activated
Init System	The system is initialized
Starting APP	iSYS 1 application is starting
Rev2 C1.1/M1.6/W1.5	Version info
* Running SELFTEST *	The self-test is running now
Selftest PASSED	The self-test has been completed successfully
Selftest FAILED	Error during self-test

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Error Messages / Emergency Stop Screen

```
### iSYS1 C-ARM  ###
***Emergency Stop***
Stationary Error
Press Q to reset  ->
```

… Header
… ***Emergency Stop***
… Error in Detail (see table below)
… What to do? (e.g. press the Q-button to reset)

Emergency Stop Reasons:

Error Message	Description	Fault correction
Error Init Axis	The axis controller cannot be initialized.	Press Q to recover the system. If the error still arises, please contact the manufacturer.
Error Detect UI	There is no, or a wrong user interface (HCU) connected to the control unit.	Connect the right user interface to the control unit. Check the connection if already connected. Then press Q to recover the system.
Runtime Err Axis	A runtime error in an axis controller was detected.	Press Q to recover the system (if this error arises frequently, please contact the manufacturer).
Runtime Err Ctrl	A runtime error in the master controller was detected.	Press Q to recover the system (if this error arises frequently, please contact the manufacturer).
Prog Abort Axis	The axis controller program was aborted.	Press Q to recover the system (if this error arises frequently, please contact the manufacturer).
Watchdog Error	The watchdog reports a bad response behavior of the master controller.	Press Q to recover the system (if this error arises frequently, please contact the manufacturer).
Wrong App Config	There are wrong or invalid configuration data detected.	Press Q to recover the system (if this error arises frequently, please contact the manufacturer).
Check HW(5V,Mod)	The modules are not connected properly or the cable for angulation and positioning are switched. There is a problem with the internal power supply.	Check the connection of the module - cables. Press Q to recover the system. If the error still arises, please contact the manufacturer.
Emerg-Stop	No special emergency reason was detected by the system. Probably the Emergency Stop	Check the emergency stop switch (release). Press Q to recover the

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Error Message	Description	Fault correction
	Switch was pressed.	system.
Encoder SigError	An encoder signal error occurred.	Press Q to recover the system. If the error still arises, please contact the manufacturer.
Encoder CmpError	An encoder compare error occurred.	Press Q to recover the system. If the error still arises, please contact the manufacturer.
Axis Param Error	The parameters of an axis controller are invalid.	Press Q to recover the system. If the error still arises, please contact the manufacturer.
APP Config Error	The system parameter configuration is invalid.	Press Q to recover the system. If the error still arises, please contact the manufacturer.
Stationary Error	A motion was detected while the enable button (rocker POS/ANG) was not pressed.	Press Q to recover the system. If the error still arises, please contact the manufacturer.
Motor Fault	A motor fault was detected.	Press Q to recover the system. If the error still arises, please contact the manufacturer.
Overload	The applied load on the robotic unit is beyond the defined threshold.	Check the reason for the overload. Press Q to recover the system. If the error still arises, please contact the manufacturer.
Check HCU Center	The joystick of the HCU is not in its center position (is checked during startup). The change of the HCU can also be the reason for this message.	Ensure that the joystick of the HCU is in its center position during startup. Press Q to recover the system. If the error still arises, please contact the manufacturer.

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

5. Maintenance

The product life of the iSYS 1 Unit is **10 years** including a regular service on the device. The service is intended to be performed every year, starting from the 3rd year of use of the device (e.g. device was sold in June 2008; the first service is performed in June 2011). The service includes:

- Detecting wear on the main components
- Detecting failures in the system
- Ensuring the accuracy of the device
- Checking the functionality of the safety relevant components

During the complete lifetime of iSYS 1, all parts and components can be supplied. This means, starting from the end of sale of iSYS 1, the spare parts are available for another ten years.

The lifetime, and thus the end of sales and end of service, might be subject to changes due to growing experience with the product.

For service purposes, iSYS 1 will be sent to iSYS where the service is organized. During that time, the customer will receive a substitute iSYS 1.

WARNING
Changes, additions or maintenance to the equipment carried out by persons without appropriate qualifications and training and/or using unapproved spare parts may lead to fatal or serious personal injury and/or damage to the equipment as well as making the warranty void.

WARNING
Obey the maintenance and service times as given in this section. Disobeying maintanance and service causes loss of warranty and may cause damage of the system and harm of the patient.

WARNING
The housings of the different components may only be opened by an authorized qualified electrician. Before opening a housing, disconnect the iSYS 1 from the main supply.

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

5.1. Safety-relevant inspections

Recurrent testing of safety relevant parameters of the iSYS 1 system as given below has to be done every 24 month. When national laws or regulations prescribe further and/or more frequent inspections or maintenance these rules have to be followed. If the iSYS 1 system fails any step of the inspection/testing the iSYS 1 system must not be used and the manufacturer must be contacted.

WARNING
Measurements are only to be performed by a qualified electrician or under supervision of a qualified electrician.

The mentioned inspections are minimum requirements:

Test/Inspection	Item	Inspection
Functional testing	Emergency stop	When the emergency stop button is activated, no motions of the RPU should be possible
	Drive motors	Smooth operation, abnormal noise development
	Strain relief of RPU Cable Set	Secure hold
	CU and HCU	Side rail: safe locking / secure hold / safe unlocking
	TTAA and TTAB	Table top mounting: safe locking / secure hold / safe unlocking
	CU	Check indicators, beeper and display
Visual inspection	Housing enclosure	Look for damage, cracks etc.
	Contamination	Look for obstruction of moving parts, connector pins etc.
	Cabling	Look for cuts etc.
	Fuse rating	Check correct values after replacement
	Markings and Labeling	Check the integrity of safety markings
	Integrity of mechanical parts	Check for any obstructions

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Protective earth testing	Protective earth connection	According IEC 62353
Insulation resistance test	Insulation between mains parts, accessible parts and earth	According IEC 62353
Leakage measurements	Leakage current	According IEC 62353

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

6. Cleaning and Disinfection

It is important that any part of the equipment which may come into direct contact with patients is cleaned and disinfected on a regular basis. Cleaning is an important requirement for a successful chemical disinfection.

WARNING
Only persons instructed in the use of this medical device are allowed to clean the iSYS 1 system.

WARNING
Always clean and disinfect the reusable components of iSYS 1 according to this manual. Never use equipment that is contaminated or uncleaned as this can lead to serious infections.

WARNING
Do not sterilize the re-usable components of the iSYS 1. Sterilizing of any components of iSYS 1 causes loss of warranty and may cause damage of the system and harm to the patient. If components of iSYS 1 are sterilized by mistake contact the manufacturer.

The system must be cleaned and disinfected prior and after to each use. For cleaning and disinfection use appropriate agents which are proofed for compatibility. iSYS has proofed the following agents as compatible:

Approved disinfection agents:	Active agent
Incidin® Liquid	2-Propanol, 1-Propanol
Mikrozid® AF Liquid	94% Ethanol, 1-Propanol

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

CAUTION
Before beginning cleaning and disinfection, please note:

- **Unplug the power cable**
- **Make sure all other plugs are properly connected.**
- **None of the (electrical) components must show any visible damage; otherwise water or cleaning/disinfection solution could penetrate. This could lead to malfunction or damage to the electrical components.**
- **Before operating the system again, make sure that there is no residual moisture on the electrical contacts.**
- **All iSYS 1 components must not be cleaned with a water jet, a high pressure cleaner or other similar device! Do not use dipping method for cleaning and disinfection!**
- **Clean/disinfect all iSYS 1 components only with a moist towel!**
- **If you suspect that water or any other form of moisture has penetrated the electrical components, disconnect the power plug immediately. If already disconnected from the power supply, make sure it is not plugged in again. Clearly mark the device as "Defective" and take it immediately out of service. Report this to the operator promptly.**
- **Failure to follow these directions could lead to major damage of the system!**

WARNING
After cleaning and disinfection iSYS 1 has to be dried sufficiently. Follow the specific instructions for use and recommended contact times of the used cleaning and disinfection agents.

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

iSYS Medizintechnik GmbH
Bergwerksweg 21
6370 Kitzbühel
Austria
www.isys.co.at

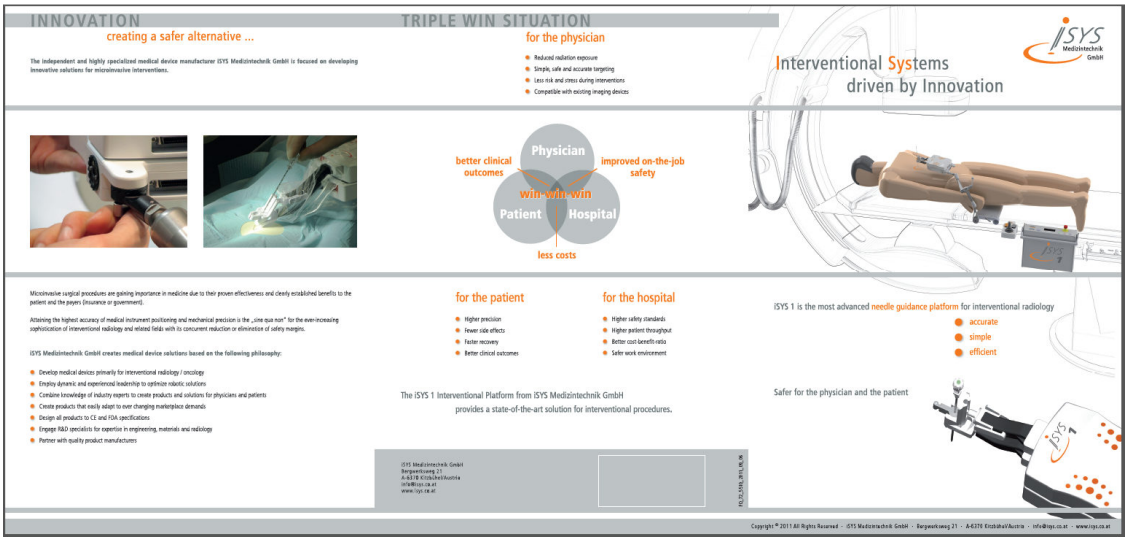
Order Nr.: 9567

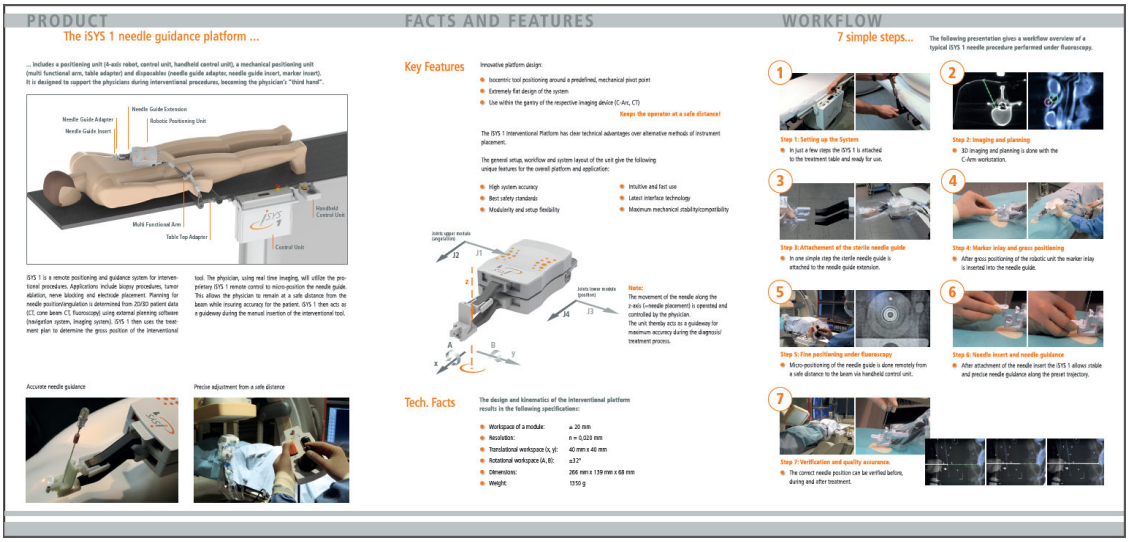
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Marketing Material

Flyer (6 pages):





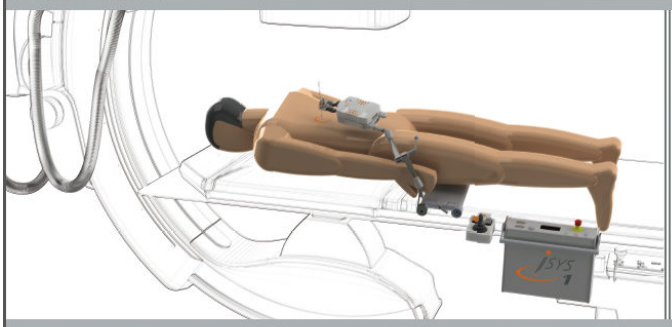
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

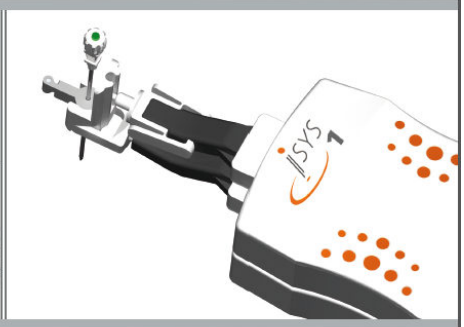
Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Product Flyer (2 pages):

Interventional Systems
driven by Innovation

iSYS Medizintechnik GmbH





iSYS 1 is the most advanced needle guidance platform for interventional radiology

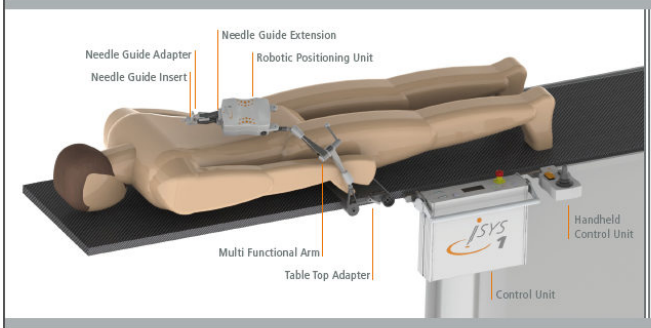
- accurate
- simple
- efficient

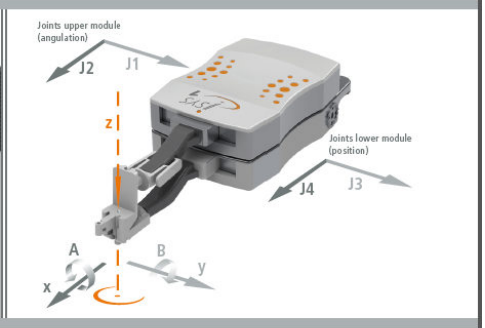
Safer for the physician and the patient

Copyright © 2011 All Rights Reserved · iSYS Medizintechnik GmbH · Bergwerksweg 21 · A-6370 Kitzbühel/Austria · info@isys.co.at · www.isys.co.at

On target from a safe distance.

iSYS Medizintechnik GmbH





System description:

The intended use of the iSYS 1 device is to function as a remote-operated positioning and guidance system during interventional procedures.

Core component is a robotic-positioning unit with 4 degrees of freedom which allows submillimetric needle positioning in x, y (range +/- 20mm) and angulation in A, B (range +/- 35°) around a fixed pivot point.

The passive gross positioning unit and variety of table adaptors allow for different system configurations of the system around the patient in the region of interest while providing maximum rigidity.
Planning of the desired position/angulation is done based on 2D/3D patient data (CT, cone-beam CT, fluoroscopy).

Fine positioning/angulation is done remotely from a safe distance.

After adjustment of the needle guide, the iSYS 1 acts as a guideway during the manual insertion of the interventional tool.

System benefits:

- High system accuracy — better clinical outcomes
- Small and lightweight robot — high safety standards
- Modularity and compatibility — maximum setup flexibility
- Intuitive use — easy and fast handling
- Latest technology — good cost-benefit ratio
- Extremely flat design — use inside the gantry

Keeps the operator at a safe distance!

FO_72_2051 Form 16.03.2011

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Form FDA 3654

Form Approved: OMB No. 0910-0120; Expiration Date: 12/31/13

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

ISO 15223-1 Second Edition 2012-07-01, Medical devices - Symbols to be used with medical device labels, labelling, and informati

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	#5-73	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☐	☒
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☒
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☒	☐
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☒	☐
If yes, was the guidance document followed in preparation of this 510k?	☒	☐

Title of guidance: Guidance for the Content of Premarket Submissions, Guidance for Off-the-Shelf Software, et. al.

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

[5] The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[6] The online search for CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html

FORM FDA 3654 (12/10) Page 1

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE
ISO 15223-1 Second Edition 2012-07-01, Medical devices - Symbols to be used with medical device labels, labelling, and informati

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
5	Symbols	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *
Symbol 5.2.8. is used although not recognized (see SIS)

DESCRIPTION

JUSTIFICATION
Symbol is common and used in the U.S. Use of it does not bear any risk. The meaning is described in the User Manual.

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

* Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

Paperwork Reduction Act Statement

Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and 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:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
1350 Piccard Drive, Room 400
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 number.

FORM FDA 3654 (12/10) Page 2

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Sterilization and Shelf Life

Table of Content

	Page
In General	2
Proposed Labeling	3
Validation Report (Packaging)	7
Summary Report Bioseal	17
Summary Report Preferred Medical	23
Bioburden Routine Report	25
Validation of Bioburden Determination	39
Data Sheets	50
Certificates	75

Following documents can be found on the appendix CD respectively in the Misc.-Files of the eCopy:

Document	Filename
Bioseal Sterilization Report (Gamma VDmax)	008_Bioseal VDMax Final Report.zip
Preferred Medical Hygiene Monitoring Plan 2011	009_PM_Hygiene Monitoring plan_RDP 0500_2011
Preferred Medical Clean room Monitoring Results2012	010_PM_Clean room Monitoring_Results2012
Gamma validation test plan	011_PM_Gamma validation Prüfplan_PRD0400_2010
Preferred Medical Bioburden Report 2012	012_PM_Bioburden_SC-80_report904377_2012

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

1. Drapes:

The drapes for iSYS 1 are no longer part of this submission but will be supplied and manufactured by Preferred Medical Products and packaged and sterilized by (b)(4) under their own responsibility.

The drapes are supplied by (b)(4) under 510(k) K863853 and packaged and sterilized by (b)(4) under 510(k) K893814.

For a comparison of the iSYS devices with the existing products from Bioseal and Preferred Medical see below (Summary Reports).

2. Needle Guide Adapter and Needle Guide Inserts:

The Needle Guide Adapters and Inserts are part of the robotic system manufactured by iSYS. (b)(4) performs packaging and sterilization.

Sterilization method:

(b)(4)

Description of packaging:

All components are double packed and sealed. For details of packaging material see below (Data Sheets).

The packaging is performed with the Colimatic Thera 450 at (b)(4) For validation see report below.

Validation Method: ANSI/AAMI/ISO 11607-2:2006, ASTM F1886:1998, ASTM F1929-98:2004, ASTM F88, ASTM F2096-11

Shelf-Life:

Shelf-life for all sterile components and validation method:

Lifetime/Shelf-life: 3 years

Validation Method: ASTM F 1980:2011

Device Description

Details see above (page 55 and following).

For technical data sheets see below.

Flammability:

See TDS below: according to UL 94, IEC 60695-2-12 and FMVSS 302.

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Proposed Labeling

The labeling is performed with the Colimatic Thera 450 at Bioseal. For retails see validation report below.

Safety Symbols:

STERILE EO	Symbol for STERILIZED USING ETHYLENE OXIDE
STERILE R	Symbol for STERILIZED USING RADIATION
	Symbol for DO NOT USE IF PACKAGE IS DAMAGED
	Symbol for DO NOT REUSE
MR	Symbol for NOT MRI SAFE
	Symbol for CAUTION, CONSULT ACCOMPANYING DOCUMENTS
	Symbol for STORAGE TEMPERATURE
	Symbol for DO NOT LITTER IN DOMESTIC WASTE

Product Identification:

SN	Symbol for SERIAL NUMBER
REF	Symbol for ORDER NUMBER

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

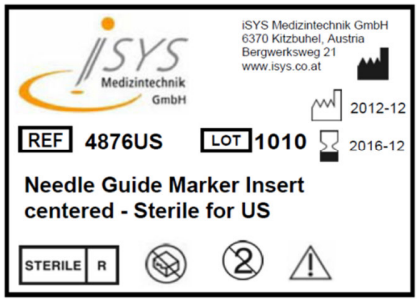
LOT	Symbol for BATCH NUMBER

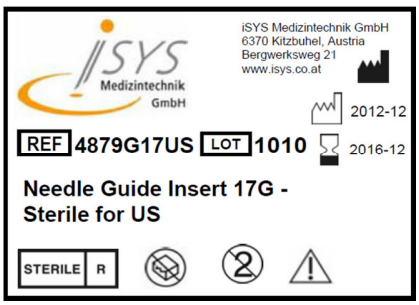
Additional Information

CE	Symbol for CE-conformity
	Symbol for MANUFACTURER
	Symbol for DATE OF MANUFACTURE
	Symbol for USE BY

Samples of Labels:

The presented labels are examples for the final product and packaging labels. Lot numbers and dates on these examples are placeholders only. They do not define any format of lot numbers, production or expiry dates.





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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

iSYS Medizintechnik GmbH
6370 Kitzbuhel, Austria
Bergwerksweg 21
www.isys.co.at

2012-12

REF 4881G20US LOT 1010 2016-12

Needle Guide Insert 20G - Sterile for US

STERILE R

iSYS Medizintechnik GmbH
6370 Kitzbuhel, Austria
Bergwerksweg 21
www.isys.co.at

2012-12

REF 4882G21US LOT 1010 2016-12

Needle Guide Insert 21G - Sterile for US

STERILE R

iSYS Medizintechnik GmbH
6370 Kitzbuhel, Austria
Bergwerksweg 21
www.isys.co.at

2012-12

REF 4880G18US LOT 1010 2016-12

Needle Guide Insert 18G - Sterile for US

STERILE R

iSYS Medizintechnik GmbH
6370 Kitzbuhel, Austria
Bergwerksweg 21
www.isys.co.at

2012-12

REF 5989G19US LOT 1010 2016-12

Needle Guide Insert 19G - Sterile for US

STERILE R

iSYS Medizintechnik GmbH
6370 Kitzbuhel, Austria
Bergwerksweg 21
www.isys.co.at

2012-12

REF 4878G16US LOT 1010 2016-12

Needle Guide Insert 16G - Sterile for US

STERILE R

iSYS Medizintechnik GmbH
6370 Kitzbuhel, Austria
Bergwerksweg 21
www.isys.co.at

2012-12

REF 5992G13US LOT 1010 2016-12

Needle Guide Insert 13G - Sterile for US

STERILE R

iSYS Medizintechnik GmbH
6370 Kitzbuhel, Austria
Bergwerksweg 21
www.isys.co.at

2012-12

REF 6289G10US LOT 1010 2016-12

Needle Guide Insert 10G - Sterile for US

STERILE R

iSYS Medizintechnik GmbH
6370 Kitzbuhel, Austria
Bergwerksweg 21
www.isys.co.at

2012-12

REF 5990G11US LOT 1010 2016-12

Needle Guide Insert 11G - Sterile for US

STERILE R

iSYS Medizintechnik GmbH
6370 Kitzbuhel, Austria
Bergwerksweg 21
www.isys.co.at

2012-12

REF 5993G14US LOT 1010 2016-12

Needle Guide Insert 14G - Sterile for US

STERILE R

iSYS Medizintechnik GmbH
6370 Kitzbuhel, Austria
Bergwerksweg 21
www.isys.co.at

2012-12

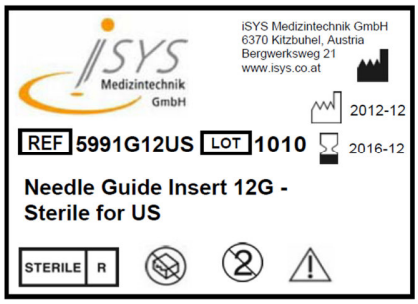
REF 4877G15US LOT 1010 2016-12

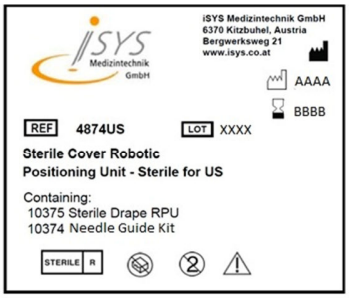
Needle Guide Insert 15G - Sterile for US

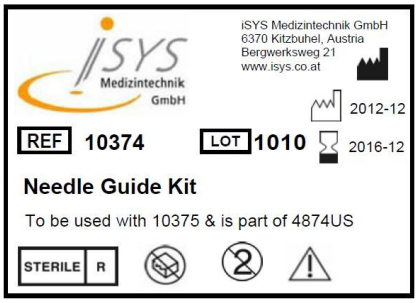
STERILE R

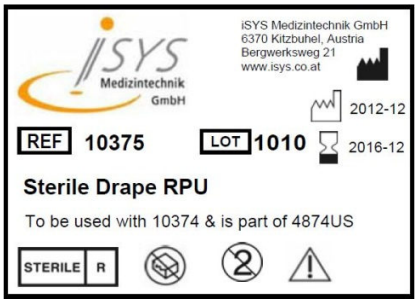
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016









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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

(b)(4)Third Party Test Data

[redacted]

Que

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4)Test Report

[redacted]

(b)(4)Test Report

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

(b)(4) Third Party Test Data

[redacted]

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

K131433/S002

Section 003	510k Cover Letter 510(k) Number: K131433	iSYS Medizintechnik GmbH

Name *Dr. Michael Vogele*

mobil *+43 (0) 664 2411140*
email *michael.vogele@isys.co.at*
web *www.isys.co.at*

iSYS Medizintechnik GmbH, Bergwerksweg 21, 6370 Kitzbühel, Austria

FDA CDRH DMC
JUN 27 2013
Received

iSYS Medizintechnik GmbH

Food and Drug Administration
Center for Device and Radiological Health
Document Mail Center WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Subject: 510(k) Notification K131433/S001

This is additional information to notify you of the intention of iSYS Medizintechnik GmbH, Bergwerksweg 21, A-6370 Kitzbuehel, Austria to market the following device:

1.	**Proprietary Name:**	iSYS 1 (U.S.)		
2.	**Common/Usual Name:**	Robotic Positioning Unit		
3.	**Establishment Registration Number:**	pending		
4.	**Address of manufacturing and packaging facility:**	Bergwerksweg 21, A-6370 Kitzbuehel, Austria		
5.	**Classification Name:**	Neurological stereotaxic instrument		
6.	**Classification:**	Device Class: Classification Panel: Product Code: CFR Section:	Class II Neurology HAW 882.4560	
7.	**Reason for Submission:**	New device		
8.	**Substantial Equivalence:**	***510(k) Number***	***Model name***	***Manufacturer***
		K101791	ROSA	Medtech
		K991081	Neuromate	Integrated Surgical Systems

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

38

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

9.	**Performance Standards:**	ÖNORM EN ISO 60601, ÖNORM EN ISO 62304, ANSI/AAMI/ISO 11737, AAMI TIR33, AAMI TIR35, AAMI ST67, ANSI/AAMI/ISO 11607-2, ISO 11137
10.	**Sterile Accessory**	Drapes supplied by (b)(4) [redacted] (b)(4) Third Party [redacted] under 510(k) **K863853** and packaged and sterilized by (b)(4) Third Party [redacted] (b)(4) [redacted] under 510(k) **K893814**.

The files coming with this 510k submission file are our response to the Acceptance Checklist of 21/06/2013 and contain the required changes. The following addresses the individual items of the Acceptance Checklist.

Organizational Elements:
Item 3: We will change the header and add the section number in the left corner for future submissions.

Elements of a Complete Submission (RTA Items)

A. Administrative
Item 4a:

- Okay, changed. See Section 005, page 1, No. 7
- Okay, added a summary for the bench testing on Section 005, page 7

B. Device Description
Item 11c, 12 and 13c: Correct.

C. SE-Discussion
Item 16:

- Added column titled "equivalence" (also to section 005)
- Added statement on differences. Please see section 012, page 5, number 4 – 7.

E. Sterilization
Item 22a: See Device Description Section 011, page 57 and Labeling Section 013, page 34: the title says "Accessory, sterile"; the products are listed under this heading.
Item 22b: We added to Section 014, page 2 that no components of the iSYS 1 are to be user sterilized.
Item 22c and text below: We added to Section 014, page 2 that only the hardware modules of the iSYS 1 are to be cleaned and disinfected.

F. Shelf Life
Item 26 and 27: Please refer to Section14 page 2 and 3 of 89.

Item 28: Added Bioseal's registration and 510k number on page 2 of Section 014.

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

H. Software

Item 32:

Please refer to additional information via Telko, classification and level of concern are clarified now.

Item 33:

Device Hazard Analysis: We can understand that the Risk Management File might appear incomplete as some of the fields in the table are not filled. That derives from the FMEA on which it is based. When performing an FMEA for a risk analysis there is a certain level in fragmentation when no additional risks are caused by the subdivision. For example the "Harm due to mistreatment" in Section 009, page 64 and following. According to the FMEA it doesn't make any difference why the patient is mistreated; severity and probability remain the same when subdividing the different causes. Thus, it doesn't lead to any further risk and the fields in the table remain unfilled. Different for the mechanical harms (see Section 009, page 58 ff.): it does make a difference if the device is falling on the patient when the RPU gets loose or when the MFA gets loose. This leads to different risks with different mitigation, and thus the fields are filled. This procedure is according to ISO 14971.

Traceability in general: we trace requirements from the design input to specifications, V&V-plan, tests and V&V-report. This can be seen in Section 018. The traceability of risks and mitigations from the Risk Management Process is provided by chapter 9 of Section 009 (page 86 ff.) and an additional document for the fulfillment of mitigations. We have added this document to Section 009 (see page 93 ff.).

We have also have included the information, that is required from the Guidance Document to Section 016, page 4 ff.

For traceability of software risks, we added the Software Risk Management File to Section 016, page 32 ff.

For Verification and Validation we have copied the respective tables from Section 009 to Section 016. Please see pages 37 ff. of Section 016. As mentioned above, the traceability of risk measures is provided in the system hazard analysis.

In case of any questions concerning this application, please contact either Dr. Michael Vogele, CEO at +43 (0) 664 2411140 (michael.vogele@isys.co.at) or Oliver Spitz (Regulatory Consultant) at +49 (0) 173 5904978 (oliver.spitz@isys.co.at).

The eCopy is an exact duplicate of the paper copy.

Sincerely,

Dr. Michael Vogele

CEO

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

iSYS Medizintechnik GmbH

510(k) Premarket Notification

(Basing on "Guidance for Industry and FDA Staff: Format for Traditional and Abbreviated 510(k)s"

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Table of Content

Section	Name	Number of Pages	Appendix/Misc
001	Medical Device User Fee Cover Sheet (Form FDA 3601)	4	No
002	CDRH Premarket Review Submission Cover Sheet	27	Yes
003	510(k) Cover Letter	3	No
004	Indications for Use Statement	1	No
005	510(k) Summary	8	No
006	Premarket Notification Truthful and Accurate Statement	1	No
007	Premarket Notification Class III Certification and Summary	1	No
008	Financial Certification or Disclosure Statement	1	No
009	Declarations of Conformity and Summary Reports (including Risk Management File)	104	No
010	Executive Summary	4	No
011	Device Description	57	No
012	Substantial Equivalence Discussion	6	No
013	Proposed Labeling	116	No
014	Sterilization and Shelf Life	89	Yes
015	Biocompatibility	1	No
016	Software	40	No
017	Electromagnetic Compatibility and Electrical Safety	24	No
018	Performance Testing – Bench	22	No
019	Performance Testing – Animal	1	No
020	Performance Testing – Clinical	40	Yes

* Highlighted sections are subject to changes due to FDA Acceptance Checklist of 06/21/2013.

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Section 001	Medical Device User Fee Cover Sheet (Form FDA 3601) 510(k) Number: K131433	iSYS Medizintechnik GmbH

Following files are on the Appendix CD for the paper version of this submission respectively in the Miscellaneous Files for the eCopy:

Filename	Document	Applies to Section
001_HamlynSymposium_iSYS Workflow_final	Workflow presented on the Hamlyn Symposium	020
002_Clinical cases	Summary of Clinical Cases	020
003_Dissertation-Schamberger	Dissertation Dr. Schamberger	020
004_ECR2013_C-2559	Presentation of Clinical Case	020
005_iSys robot iGuide	Phantom Study on Accuracy	020
006_Multi Center Study	Multi-Center Study	020
007_Zeego Schulz Zangos	Report Radiation Exposure	020
008_(b)(4) DMax Final Report.zip	(b)(4) terilization Report (b)(4)	014
009_PM_Hygiene Monitoring plan_RDP 0500_2011	(b)(4) Hygiene Monitoring Plan 2011	014
010_PM_Clean room Monitoring_Results2012	(b)(4) Clean room Monitoring Results2012	014
011_PM_Gamma validation Prüfplan_PRD0400_2010	Gamma validation test plan	014
012_PM_Bioburden_SC-80_report904377_2012	(b)(4) Bioburden Report 2012	014
013_FDA K113495	Correspondence of former submission	002

* Highlighted sections are subject to changes due to FDA Acceptance Checklist of 06/21/2013.

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Section 001	Medical Device User Fee Cover Sheet (Form FDA 3601) 510(k) Number: K131433	ISYS Medizintechnik GmbH

Form Approved: OMB No. 0910-511 Expiration Date: February 28, 2013. 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)
Write the Payment Identification number on your check.

A completed cover sheet must accompany each original application or supplement subject to fees. If payment is sent by U.S. mail or courier, please include a copy of this completed form with payment. Payment and mailing instructions can be found at: http://www.fda.gov/oc/mdufma/coversheet.html

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

ISYS MEDIZINTECHNIK GMBH
Bergwerksweg 21

KITZBUEHEL
6370
AT

1.1 EMPLOYER IDENTIFICATION NUMBER (EIN)

2. CONTACT NAME
Oliver Spitz
2.1 E-MAIL ADDRESS
oliver.spitz@isys.co.at
2.2 TELEPHONE NUMBER (include Area code)
0049 173 5904978
2.3 FACSIMILE (FAX) NUMBER (Include Area code)

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/oc/mdufma

Select an application type:
[X] Premarket notification(510(k)); except for third party
[ ] 513(g) Request for Information
[ ] Biologics License Application (BLA)
[ ] Premarket Approval Application (PMA)
[ ] Modular PMA
[ ] Product Development Protocol (PDP)
[ ] Premarket Report (PMR)
[ ] Annual Fee for Periodic Reporting (APR)
[ ] 30-Day Notice

3.1 Select a center
[X] CDRH
[ ] CBER
3.2 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)
[X] YES, I meet the small business criteria and have submitted the required qualifying documents to FDA
NO, I am not a small business
4.1 If Yes, please enter your Small Business Decision Number: SBD135332

5. FDA WILL NOT ACCEPT YOUR SUBMISSION IF YOUR COMPANY HAS NOT PAID AN ESTABLISHMENT REGISTRATION FEE THAT IS DUE TO FDA. HAS YOUR COMPANY PAID ALL ESTABLISHMENT REGISTRATION FEES THAT ARE DUE TO FDA?
[X] YES (All of our establishments have registered and paid the fee, or this is our first device, and we will register and pay the fee within 30 days of FDA's approval/clearance of this device.)
[ ] NO (If "NO," FDA will not accept your submission until you have paid all fees due to FDA. This submission will not be processed; see http://www.fda.gov/cdrh/mdufma for additional information)

6. 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
[ ] This biologics application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only
[ ] The sole purpose of the application is to support conditions of use for a pediatric population
[ ] The application is submitted by a state or federal government entity for a device that is not to be distributed commercially

7. 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

PAPERWORK REDUCTION ACT STATEMENT
Public reporting burden for this collection of information is estimated to average 18 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and 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 the address below.

Department of Health and Human Services, Food and Drug Administration, Office of Chief Information Officer, 1350 Piccard Drive, 4th Floor Rockville, MD 20850
[Please do NOT return this form to the above address, except as it pertains to comments on the burden estimate.]

8. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION
(b)(4) 03-May-2013

Form FDA 3601 (01/2007)

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Name ***Dr. Michael Vogele***

mobil ***+43 (0) 664 2411140***
email *michael.vogele@isys.co.at*
web *www.isys.co.at*

iSYS Medizintechnik GmbH, Bergwerksweg 21, 6370 Kitzbühel, Austria

Food and Drug Administration
Center for Device and Radiological Health
Document Mail Center WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Subject: 510(k) Notification K131433/S001

This is additional information to notify you of the intention of iSYS Medizintechnik GmbH, Bergwerksweg 21, A-6370 Kitzbuehel, Austria to market the following device:

1.	**Proprietary Name:**	iSYS 1 (U.S.)
2.	**Common/Usual Name:**	Robotic Positioning Unit
3.	**Establishment Registration Number:**	pending
4.	**Address of manufacturing and packaging facility:**	Bergwerksweg 21, A-6370 Kitzbuehel, Austria
5.	**Classification Name:**	Neurological stereotaxic instrument
6.	**Classification:**	Device Class: Class II Classification Panel: Neurology Product Code: HAW CFR Section: 882.4560
7.	**Reason for Submission:**	New device
8.	**Substantial Equivalence:**	

510(k) Number	***Model name***	***Manufacturer***
K101791	ROSA	Medtech
K991081	Neuromate	Integrated Surgical Systems

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

9.	**Performance Standards:**	ÖNORM EN ISO 60601, ÖNORM EN ISO 62304, ANSI/AAMI/ISO 11737, AAMI TIR33, AAMI TIR35, AAMI ST67, ANSI/AAMI/ISO 11607-2, ISO 11137
10.	**Sterile Accessory**	Drapes supplied by (b)(4) [redacted] (b)(4) [redacted] under 510(k) **K863853** and packaged and sterilized by (b)(4) [redacted] (b)(4) [redacted] under 510(k) **K893814**.

The files coming with this 510k submission file are our response to the Acceptance Checklist of 21/06/2013 and contain the required changes. The following addresses the individual items of the Acceptance Checklist.

Organizational Elements:
Item 3: We will change the header and add the section number in the left corner for future submissions.

Elements of a Complete Submission (RTA Items)

A. Administrative
Item 4a:

- Okay, changed. See Section 005, page 1, No. 7
- Okay, added a summary for the bench testing on Section 005, page 7

B. Device Description
Item 11c, 12 and 13c: Correct.

C. SE-Discussion
Item 16:

- Added column titled “equivalence” (also to section 005)
- Added statement on differences. Please see section 012, page 5, number 4 – 7.

E. Sterilization
Item 22a: See Device Description Section 011, page 57 and Labeling Section 013, page 34: the title says “Accessory, sterile”; the products are listed under this heading.
Item 22b: We added to Section 014, page 2 that no components of the iSYS 1 are to be user sterilized.
Item 22c and text below: We added to Section 014, page 2 that only the hardware modules of the iSYS 1 are to be cleaned and disinfected.

F. Shelf Life
Item 26 and 27: Please refer to Section14 page 2 and 3 of 89.

Item 28: Added (b)(4) [redacted] registration and 510k number on page 2 of Section 014.

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

H. Software

Item 32:

Please refer to additional information via Telko, classification and level of concern are clarified now.

Item 33:

Device Hazard Analysis: We can understand that the Risk Management File might appear incomplete as some of the fields in the table are not filled. That derives from the FMEA on which it is based. When performing an FMEA for a risk analysis there is a certain level in fragmentation when no additional risks are caused by the subdivision. For example the "Harm due to mistreatment" in Section 009, page 64 and following. According to the FMEA it doesn't make any difference why the patient is mistreated; severity and probability remain the same when subdividing the different causes. Thus, it doesn't lead to any further risk and the fields in the table remain unfilled. Different for the mechanical harms (see Section 009, page 58 ff.): it does make a difference if the device is falling on the patient when the RPU gets loose or when the MFA gets loose. This leads to different risks with different mitigation, and thus the fields are filled. This procedure is according to ISO 14971.

Traceability in general: we trace requirements from the design input to specifications, V&V-plan, tests and V&V-report. This can be seen in Section 018. The traceability of risks and mitigations from the Risk Management Process is provided by chapter 9 of Section 009 (page 86 ff.) and an additional document for the fulfillment of mitigations. We have added this document to Section 009 (see page 93 ff.).

We have also have included the information, that is required from the Guidance Document to Section 016, page 4 ff.

For traceability of software risks, we added the Software Risk Management File to Section 016, page 32 ff.

For Verification and Validation we have copied the respective tables from Section 009 to Section 016. Please see pages 37 ff. of Section 016. As mentioned above, the traceability of risk measures is provided in the system hazard analysis.

In case of any questions concerning this application, please contact either Dr. Michael Vogele, CEO at +43 (0) 664 2411140 (michael.vogele@isys.co.at) or Oliver Spitz (Regulatory Consultant) at +49 (0) 173 5904978 (oliver.spitz@isys.co.at).

The eCopy is an exact duplicate of the paper copy.

Sincerely,

Dr. Michael Vogele

CEO

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

510(k) SUMMARY

1.	Applicant:	iSYS Medizintechnik GmbH
2.	Address:	Bergwerksweg 21 6370 Kitzbühel / Austria
3.	Contact Person:	Dr. Michael Vogele Tel. +43 (0) 664 2411140
4.	Preparation Date:	June 26, 2013
5.	Device Submitted:	iSYS 1 (U.S.)
6.	Proprietary Name:	iSYS 1 (U.S.)
7.	Common Name:	Stereotaxic Instrument
8.	Classification Name:	Neurological Stereotaxic Instrument Product Code HAW, Reg.No. 882.4560
9.	Substantial Equivalence:	The iSYS 1 is substantially equivalent to the following legally marketed devices: Rosa Surgical Device manufactured by Medtech Surgical Inc. and Frameless Neuromate manufactured by Integrated Surgical Systems. The characteristics of this device are similar to those of the predicate devices identified on the comparison chart, which follows. It is our opinion that the iSYS 1 does not have technological characteristics that raise additional types of questions related to terms of safety and effectiveness.
10.	Device Description:	The iSYS 1 is a modular needle guidance platform for interventional radiology and related fields. Core components are a 4 DOF micro positioning unit which allows the submillimetric needle positioning from simple needle angulations up to positioning and angulations with adjustable pivot point and a control unit which is directed by a cable connected control panel. The passive macro positioning unit and different table adapters allow different setups of the system around the patient in the region of interest. The needle-guide-kit (manufactured by(b)(4) [redacted] provides disposable components that ensure precise and sterile needle guidance. Planning of the tool position/orientation as well as validation of the correctness of the tool position must be performed with an external planning and measurement system which is not part of the iSYS-1 Interventional Platform. The position of iSYS 1 is

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

visible for most imaging systems due to the used markers. During treatment the tool is controlled by the user.

11. Intended Use:

The intended use of the iSYS1 device is to function as a remote-operated positioning and guidance system during interventional procedures. Positioning is done in remote control manner; planning of the position/angulation is done based on 2D/3D patient data (CT, cone-beam CT, fluoroscopy) by external planning software – for example using an external navigation system, or planning software coming with the used imaging device. Also verification of the correct position and orientation of the tool prior to/during/after the intervention is done by means of these external devices. The iSYS1-System is then acting as a guideway during the manual insertion of the interventional tool – usually a needle type device, and the like. Applications include, but are not limited to, interventions like biopsy procedures, tumor ablation, nerve blocking, electrode placement, etc.

The iSYS 1 System is indicated for any medical condition in which the use of a stable and precise needle/tool guidance system may be appropriate, and where external navigation technology and/or imaging technology (e.g. CB-CT, CT, X-Ray) can be used for exact planning and tracking of the needle/tool.

12. Clinical Use

The Side Rail Adapter is attached to the side rail for the setup; the Table Top Adapter is attached directly onto the CT table. Both Adapters are equipped with a “starburst” connector, to which the Multifunctional Arm can be attached. The MFA is equipped with one “starburst” connector at the bottom and one “spoon” connector at the top. The “spoon” connector has its counterpart on the Robotic Positioning Unit for the setup. The Control Unit is attached directly to the side rail. The Robotic Positioning Unit is connected by a cable to the Control Unit, which has cable connections to both the electric power supply and to a Handheld Control Unit. The Needle Guide Extensions are screw-fixed onto the Robotic Positioning Modules. The Sterile Cover is directly fixed onto the Needle Guide Joints and can be drawn over the robotic parts. The Needle Insert is placed into the appropriate connector of the Needle Guide, to prepare needle usage. The Handheld Control Unit can be clamped onto the side rail and covered with a drape. Planning of the tool position/orientation as well as validation of the correctness of the tool position must be performed with

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

an external planning and measurement system (imaging or navigation software).

13. Biocompatibility: The iSYS 1 is not in contact with patient. At any time when in use a sterile cover sheet is to be placed between the patient and the system. Additionally there are no new materials introduced in the manufacture of the iSYS 1. Therefore, no biocompatibility studies were performed for this device.

14. Performance Data: Operating temperature/humidity range: 15 to 30°C; 30 to 70% relative humidity with no condensation

Storage temperature/humidity range: 10 to 50°C; 30 to 70% relative humidity with no condensation

Power Supply: 50W; 115VAC/230VAC; 50-60Hz; cable: C14 according to IEC/EN 60320-1, US498, CSA C22.2 no. 42;

Sterilization of the sterile accessories has been validated by Bioseal, the company responsible for packaging and sterilizing the iSYS accessories.

The accuracy of the intervention depends on the resolution and capabilities of the imaging device or software. The mechanical accuracy of iSYS1 is below 1 mm, but that gives no accuracy value for treatments.

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Device Comparison Summary:

Reference	Frameless Neuromate	ROSA Surgical Device	iSYS 1 (for new submission)	Equivalence ?
510k-Number	K991081	K101791	K131433	
Manufacturer	INTEGRATED SURGICAL SYSTEMS, INC. 1850 Research Park Dr. Davis, CA 95616 USA	Medtech Surgical Inc. 211 Warren Street Suite 306 Newark, NJ 07103 USA	Submitter	
Design				
General device description	Computer controlled electromechanical multi-joined arm indicated for use as a stereotactic instrument	Computer controlled electromechanical multi-joined arm indicated for use as a stereotactic instrument	Computer controlled electromechanical multi-joined arm indicated for invasive procedures	Yes
Localization means	Robot arm absolute encoders	Robot arm absolute encoders	Fiducial markers on tool holder.	*)5
Image-guided	Yes	Yes	Yes	Yes
Planning software	No (third party)	Yes	No (third party)	*1)
Registration method	Bone-mounted ultrasound device	Fiducial markers Optical registration device	Fiducial markers	*6)
Instrumen-tation	Laser pointer Tool Holder	Navigation probe Laser pointer Tool Holder	Marker Tool Holder Sterile Covers (third party)	Yes
Instrument fixation	Instruments are mounted onto robot arm	Instruments are mounted onto robot arm	Special tool holders for several applications mounted to the Robot	Yes
Instrument	Factory Calibration	Factory Calibration	Intra operative	*2)

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Reference	Frameless Neuromate	ROSA Surgical Device	iSYS 1 (for new submission)	Equivalence ?
calibration				
System immobilization between patient and device	Yes	Yes	Yes	Yes
Planning and Navigation Software				
N/A.				
System Operation				
Fiducial markers registration with pointer probe	No.	Yes.	No.	*3)
Optical registration	No.	Yes.	No.	*3)
Ultrasound Registration	Yes.	No.	No.	*3)
Accuracy verification	Yes, laser pointer.	Yes, navigation probe, laser beam.	Yes, performed by user	Yes
Provide mechanical guidance for tools	Yes.	Yes.	Yes.	Yes
Instrument guide position adjustment	Automatic.	Automatic.	Manual.	*7)
Surgeon carries out final gesture through tool guide	Yes.	Yes.	Yes.	Yes
Indications for Use				
Indication for use	Stereotactic spatial positioning and orientation of an instrument	Intended to be used in the operating room for the spatial positioning and	The intended use of the iSYS1 device is to function as a remote-operated	*4)

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Reference	Frameless Neuromate	ROSA Surgical Device	iSYS 1 (for new submission)	Equivalence ?
	holder or tool guide to be used by a surgeon to manually guide standard neurosurgical instruments (biopsy needle, stimulation or recording electrode, endoscope).	orientation of an instrument holder or tool guide, The system is intended to be used by neurosurgeons to guide standard neurosurgical instruments (biopsy needle, stimulation or recording electrode, endoscope). Indicated for any neurosurgical condition in which the use of stereotactic surgery may be appropriate.	positioning and guidance system during interventional procedures. Positioning is done in remote control manner; planning of the position/angulation is done based on 2D/3D patient data (CT, cone-beam CT, fluoroscopy) by external planning software – for example using an external navigation system, or planning software coming with the used imaging device. Also verification of the correct position and orientation of the tool prior to/during/after the intervention is done by means of these external devices. The iSYS1-System is then acting as a guideway during the manual insertion of the interventional tool – usually a needle type device, and the like. Applications include, but are not limited to, interventions like	

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Reference	Frameless Neuromate	ROSA Surgical Device	iSYS 1 (for new submission)	Equivalence ?
			biopsy procedures, tumor ablation, nerve blocking, electrode placement, etc.	
Anatomical site	Head	Head	total body	*4)
User	Neurosurgeon	Neurosurgeon	Surgeon	*4)
Accessory	Sterile drapes	Sterile drapes Fiducial markers Head Holder Light source	Sterile Covers Table Adapters Cable Sets	Yes
Real-time instrument position	Yes	Yes	Yes	Yes
Mechanical Guidance of instruments	Yes	Yes	Yes	Yes
Technology				
Powered	Yes	Yes	Yes	Yes
CE-Conformity	Yes	Yes	Yes	Yes
Computer-controlled	Yes	Yes	Yes	Yes
Materials	Metal, electronics and plastics	Metal, electronics and plastics	Metal, electronics Polyamide Polyethylene Bralen	Yes

Non-clinical testing has been performed to prove electrical and mechanical safety of the devices. Similar to the predicate devices, iSYS 1 was tested according to EN ISO 60601-1 2nd edition:

- EN 60601-1:1990 + A1:1993 + A2:1995
- EN 60601-1-8:2004 + A1:2006

The Electromagnetic Compatibility of the iSYS1 System has been tested according to FCC Part15 (Edition 1st October 2010) and ISO 60601-1-2:2007 and meets the acceptance criteria of both.

Performance tests have been performed to prove:

- the accuracy of the needle placement under clinical conditions,

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

- the compatibility with the imaging modality,
- the tendency to produce artifacts,
- the mechanical stability of the system despite external payload under worst conditions
- the mechanical stability of the table adapters despite external payload,
- the accuracy in remote-control mode
- the accuracy of needle guidance
- functionality of hardware modules
- effectiveness of hardware safety measures for the software,
- and the effectiveness of the alarm systems

The results of these performance tests support that the predicate devices and iSYS 1 are substantially equivalent.

Statement of safety and effectiveness:

It is our opinion that the iSYS 1 System (U.S.) does not have technological characteristics that raise additional types of safety or effectiveness questions, and we consider them to be an enhancement to the existing devices.

To validate the accuracy of the iSYS 1 an external reference system has to be used. We have used and tested the iSYS 1 System (U.S.) with the Philips Allura Xper Guide FD 20 X-ray system.

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Declarations of Conformity and Summary Reports

Table of Content: Page

Declarations of Conformity (iSYS)	2
Declaration of Conformity (Bioseal)	6
Summary Report Sterility	8
Summary Report Software	10
Summary Report Electricity	13
Risk Management File	15
System Hazards Traceability Matrix	93

Remark to Risk Management File:

The risk management file was established before iSYS Medizintechnik GmbH decided to apply for the US-American market. Thus, (b)(4) [redacted] the supplier for sterile components for the US-American market, does not appear in the file, but the European supplier (b)(4) [redacted] does.

The abbreviations “NAK” and “AK” in the risk management file are standard in Austria and stand for “not acceptable” and “acceptable”. The abbreviation “DIMDI” refers to the medical vigilance system in Germany.

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Declarations of Conformity iSYS

PD/B16	iSYS 1	iSYS Medizintechnik GmbH
Declaration of Conformity		

Konformitätserklärung / Declaration of Conformity / Declaration de Conformité

Wir,	We,	Nous,
iSYS Medizintechnik GmbH, **Bergwerksweg 21, 6370 Kitzbühel, Austria**		
erklären in alleiniger Verantwortung, dass das Medizinprodukt	declare on our own responsibility that the medical device	déclarons sous notre propre responsabilité que le dispositif médical
iSYS 1 (Art. Nr. 4268) **iSYS 1 (U.S.) (Art. Nr. 6224)** **Seriennummern 003 bis 030 (Revision 1)** **HCU Cable Extension (Art. Nr. 6162)**		
allen Anforderungen der Richtlinie 93/42/EWG ergänzt durch die Richtlinie 2007/47/EG entspricht	meets all the provisions of the Directives **93/42/EEC and 2007/47/EC**	remplit toutes les exigences de les directives sur les dispositifs médicaux **93/42/CEE et 2007/47/CE**
Angewandte harmonisierte Normen:	**Applied harmonized standards:**	**Normes harmonisées appliquées:**
OENORM EN 980:2008, EN 1041:2008, OENORM EN 60601-1:2007, OENORM EN 60601-1-2+A1:2006, OENORM EN 60601-1-6:2008, OENORM EN 60601-1-8:2008		
Klassifizierung basiert auf den Anforderungen der **Regel**	**Classification** is based on the requirements of **Rule**	**Classification** La classification est fondée sur les exigences de la **Règle**
12		
des **Anhang IX** der Richtlinie über Medizinprodukte	of **annex IX** of the Medical Device Directive	de **l'annexe IX** de la directive sur les dispositifs médicaux
Medizinprodukt der **Klasse**	Medical device **Class**	les dispositifs médicaux **Classe**
I		
Konformitätsbewertungsverfahren gemäß der Richtlinie 93/42 EWG, **Anhang**	**Conformity assessment procedure** according to Directive 93/42 EEC, **Annex**	**Procédure d'évaluation de la conformité** en application de la directive 93/42/CEE **Appendice**
VII		
Benannte Stelle (falls zutreffend)	**Notified body** (if applicable)	**Organisme notifié** (le cas échéant)
TÜV Austria Services GmbH (CE 0408)		
Diese Konformitätserklärung gilt für obige Serien-/ Lotnummern ab dem Produktionsdatum	**This declaration of conformity is effective for above Serial/ Lot numbers as of the production date**	**Cette déclaration de conformité est valable pour les numéros de série/ du lot dès la date de production**
29. November 2012		
Geschäftsführer		Kitzbühel, 29.11.12

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

CE-SetDescription	iSYS Medizintechnik GmbH

iSYS Medizintechnik GmbH
Bergwerksweg 21
6370 Kitzbühel
Austria
Tel. +43 (0) 664 / 2411140
Fax. +49 (0) 8232 / 969222
www.isys.co.at

EC Declaration of Conformity

We iSYS Medizintechnik GmbH declare under sole responsibility that the set to which this declaration relates, as an accessory to the **iSYS 1**, meets the essential health and safety requirements and is in conformance with the EC directives 93/42/EC and 2007/47/EC (MDD).

Set description:

iSYS 1 – class I product

Accessory sterile – class Is product

Accessory non-sterile – class I product

The set is classified as Is according to rules 1 and 12.

iSYS Medizintechnik GmbH meets the requirements of EN ISO 13485:2003 as indicated on certificate registration # TÜV-A-MT-1/11/E148.
The registration has been granted by TÜV Austria Services GmbH, Austria (# 0408).

The CE mark is applied with respect to annex II of the MDD. This CE marking has been affixed on the device according to article 17 of the MDD.

This declaration is effective from: see date of sign off

General Manager

Kitzbühel, 29.11.12
Place / date

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

PD/B16	iSYS 1
Declaration of Conformity	

Konformitätserklärung / Declaration of Conformity / Declaration de Conformité

Wir,	We,	Nous,
iSYS Medizintechnik GmbH, **Bergwerksweg 21, 6370 Kitzbühel, Austria**		
erklären in alleiniger Verantwortung, dass das Medizinprodukt	declare on our own responsibility that the medical device	déclarons sous notre propre responsabilité que le dispositif médical
Zubehör iSYS 1 **Side Rail Adapter (Art.Nr. 4095)** **Multi Functional Arm (Art. Nr. 4271)** **Table Top Adapter Version A (Art.Nr. 4117)** **Table Top Adapter Version B (Art.Nr. 4120)**		
allen Anforderungen der Richtlinie 93/42/EWG ergänzt durch die Richtlinie 2007/47/EG entspricht	meets all the provisions of the Directives **93/42/EEC and 2007/47/EC**	remplit toutes les exigences de les directives sur les dispositifs médicaux **93/42/CEE et 2007/47/CE**
Angewandte harmonisierte Normen:	**Applied harmonized standards:**	**Normes harmonisées appliquées:**
OENORM EN 980:2008, EN 1041:2008, OENORM EN 60601-1:2007, OENORM EN 60601-1-2+A1:2006, OENORM EN 60601-1-6:2008, OENORM EN 60601-1-8:2008		
Klassifizierung basiert auf den Anforderungen der **Regel**	**Classification** is based on the requirements of **Rule**	**Classification** La classification est fondée sur les exigences de la **Règle**
1		
des **Anhang IX** der Richtlinie über Medizinprodukte	of **annex IX** of the Medical Device Directive	de **l'annexe IX** de la directive sur les dispositifs médicaux
Medizinprodukt der **Klasse**	Medical device **Class**	les dispositifs médicaux **Classe**
I		
Konformitätsbewertungsverfahren gemäß der Richtlinie 93/42 EWG, **Anhang**	**Conformity assessment procedure** according to Directive 93/42 EEC, **Annex**	**Procédure d'évaluation de la conformité** en application de la directive 93/42/CEE **Appendice**
VII		
Benannte Stelle (falls zutreffend)	**Notified body** (if applicable)	**Organisme notifié** (le cas échéant)
TÜV Austria Services GmbH (CE 0408)		
Diese Konformitätserklärung gilt für obige Serien-/ Lotnummern ab dem Produktionsdatum	**This declaration of conformity is effective for above Serial/ Lot numbers as of the production date**	**Cette déclaration de conformité est valable pour les numéros de série/ du lot dès la date de production**
29. November 2012		
..... Geschäftsführer	Kitzbühel, 29.11.12	

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

PD/B16	Accessory, sterile
Declaration of Conformity	

Konformitätserklärung / Declaration of Conformity / Declaration de Conformité

Wir,	We,	Nous,
iSYS Medizintechnik GmbH, Bergwerksweg 21, 6370 Kitzbühel, Austria		
erklären in alleiniger Verantwortung, dass die Medizinprodukte	declare on our own responsibility that the medical devices	déclarons sous notre propre responsabilité que les dispositifs médicaux
6289G10US Needle Guide Insert 10G – sterile for US 5990G11US Needle Guide Insert 11G – sterile for US 5991G12US Needle Guide Insert 12G – sterile for US 5992G13US Needle Guide Insert 13G – sterile for US 5993G14US Needle Guide Insert 14G – sterile for US 4877G15US Needle Guide Insert 15G – sterile for US 4878G16US Needle Guide Insert 16G – sterile for US 4874US Sterile Cover Robotic Positioning Unit – sterile for US 4883US Sterile Cover Handheld Control Unit – sterile for US 4879G17US Needle Guide Insert 17G – sterile for US 4880G18US Needle Guide Insert 18G – sterile for US 5989G19US Needle Guide Insert 19G – sterile for US 4881G20US Needle Guide Insert 20G – sterile for US 4882G21US Needle Guide Insert 21G – sterile for US 4875US Needle Guide Marker Insert – sterile for US 4876US Needle Guide Marker Insert centered – sterile for US		
allen Anforderungen der Richtlinie 93/42/EWG ergänzt durch die Richtlinie 2007/47/EG entspricht	meets all the provisions of the Directives **93/42/EEC and 2007/47/EC**	remplit toutes les exigences de les directives sur les dispositifs médicaux **93/42/CEE et 2007/47/CE**
Angewandte harmonisierte Normen:	**Applied harmonized standards:**	**Normes harmonisées appliquées:**
OENORM EN 980:2008, DIN EN 1041:2008, ÖNORM EN ISO 11607-1:2007, ÖNORM EN ISO 11607-2:2006		
Klassifizierung basiert auf den Anforderungen der **Regel**	**Classification** is based on the requirements of **Rule**	**Classification** La classification est fondée sur les exigences de la **Règle**
1		
des **Anhang IX** der Richtlinie über Medizinprodukte	of **annex IX** of the Medical Device Directive	de **l'annexe IX** de la directive sur les dispositifs médicaux
Medizinprodukte der **Klasse**	Medical devices **Class**	les dispositifs médicaux **Classe**
IIa		
Konformitätsbewertungsverfahren gemäß der Richtlinie 93/42 EWG, **Anhang**	**Conformity assessment procedure** according to Directive 93/42 EEC, **Annex**	**Procédure d'évaluation de la conformité** en application de la directive 93/42/CEE **Appendice**
II		
Benannte Stelle (falls zutreffend)	**Notified body** (if applicable)	**Organisme notifié** (le cas échéant)
TÜV Austria Services GmbH (CE 0408)		
Diese Konformitätserklärung gilt für alle Serien-/ Lotnummern ab dem Produktionsdatum	**This declaration of conformity is effective of all Serial/ Lot numbers as of the production date**	**Cette déclaration de conformité est valable pour toutes les numéros de série/ du lot dès la date de production**
12. Dezember 2012		
Geschäftsführer	Kitzbühel, 29.11.12	

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

PD/B18	Declarations of Conformity and Summary Reports 510(k) Number:	iSYS Medizintechnik GmbH

(b)(4) Third Party Test Data

[redacted]

Qu

(b)(4) Third Party Test Data

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

PD/B18	Declarations of Conformity and Summary Reports 510(k) Number:	iSYS Medizintechnik GmbH

Summary Report Sterility

(b)(4) Third Party Test Data

[redacted]

(b)(4) Third Party Test Data

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

PD/B18	Declarations of Conformity and Summary Reports 510(k) Number:	iSYS Medizintechnik GmbH

Summary Report Software

(b)(4)

[redacted]

Qu

(b)(4)

(b)(4)

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

PD/B18	Declarations of Conformity and Summary Reports 510(k) Number:	iSYS Medizintechnik GmbH

Summary Report Electricity

(b)(4)

[redacted]

Q

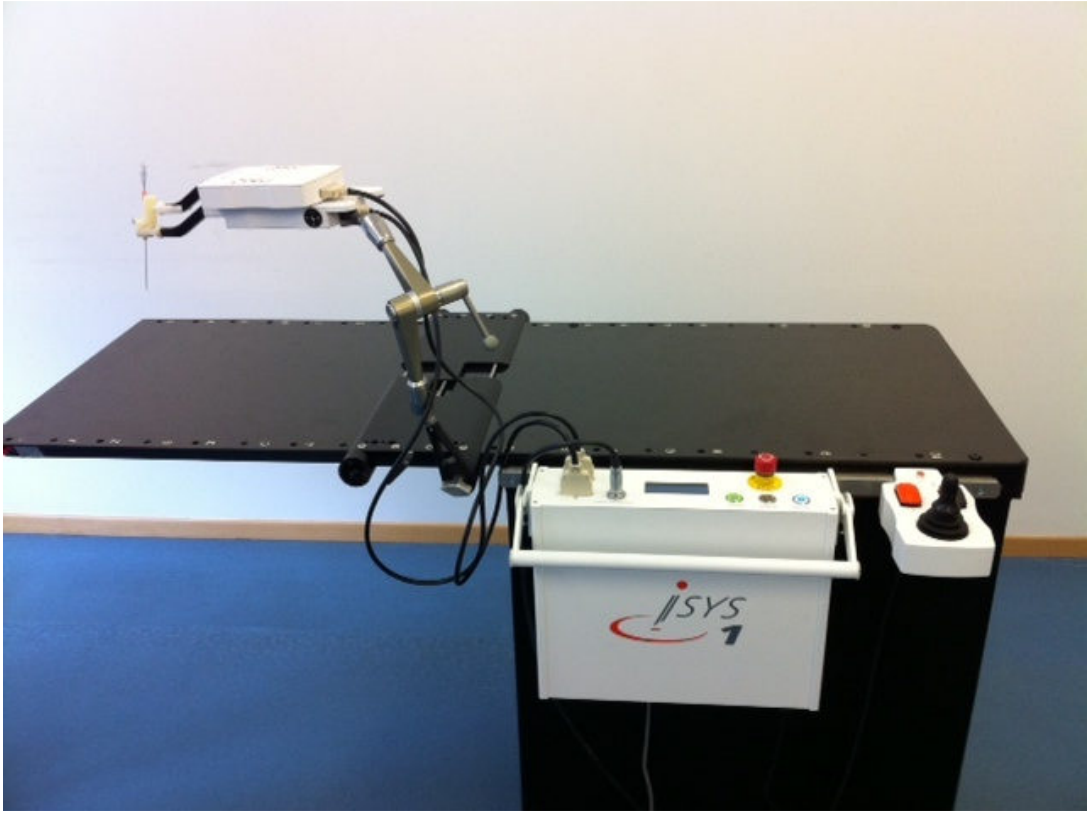
(b)(4)

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Risk Management File

Risk Management

for iSYS 1



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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Revision-History:

Reference	Effective Date	Description of changes
Rev 01	2010-12-13	Start of Risk Analysis Process: Chapter 1, 2, 3, 4 Risk Management Plan
Rev 02	2011-04-08	Risk Analysis
Rev 03	2011-05-12	Risk Evaluation
Rev 04	2011-05-13	Summary
Rev05	2012-08-21	Product Lifetime

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

TABLE OF CONTENTS

1 Scope / Description of iSYS 1 18
1.1 Lifecycle of iSYS 1 20
2 Related Documentation 22
2.1 Specification / Design Documents 22
2.2 Guidance Documents 22
2.3 Abbreviations and Acronyms 22
3 The Risk Analysis Team 23
4 Identification of Applicable Hazards 24
4.1 Fault Assumptions 24
4.2 Method 24
4.3 Usability 25
4.4 Classification of the Severity of each Risk 25
4.5 Estimation of Probability of Occurrence of each Cause 26
4.6 Determination of the Potential Causes of each Hazard 26
4.7 Definition of Risk Mitigation Measures 27
5 Summary 28
6 Identification of the Qualitative and Quantitative Characteristics 30
7 Checklist for Identification of Possible Hazards 40
8 Risk Management Table 46
9 Summary of Mitigations 86
10 Overview Risk Management Plan 92

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

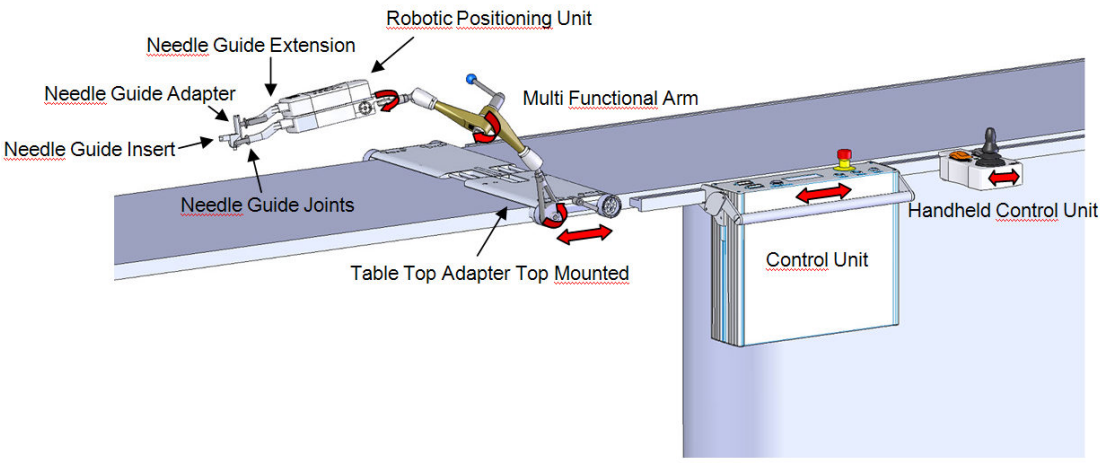
1 Scope / Description of iSYS 1

iSYS 1 is a modular equipment for the following intended use:

The intended use of iSYS 1 device is to function as a remote-operated positioning and guidance system during interventional procedures. Positioning is done in remote control manner; planning of the position/angulation is done based on 2D/3D patient data (CT, cone-beam CT, fluoroscopy) by external planning software – for example using an external navigation system, or planning software coming with the used imaging device. Also verification of the correct position and orientation of the tool prior to/during/after the intervention is done by means of these external devices. The iSYS1-System is then acting as a guideway during the manual insertion of the interventional tool – usually a needle type device, and the like. Applications include, but are not limited to, interventions like biopsy procedures, tumor ablation, nerve blocking, electrode placement, etc.

It is typically configured by the physician or the nurse to a system which includes components from various manufacturers. The iSYS 1 risk analysis cannot cover all of these components because not all are under control of the manufacturer of iSYS 1. This section defines which components are covered by this risk analysis and which are not.

The Basic Hardware Elements of iSYS 1 are elucidated in the following schematic picture:



iSYS 1 will be shipped in a basic configuration which consists of the following:

- one Control Unit
- one Handheld Control Unit with a Sterile Cover (not reusable) if required
- one Table Top or Side Rail Adapter

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

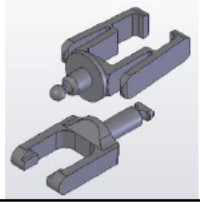
Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

- one Multi Functional Arm
- one Robotic Positioning Device consisting of two Robot Modules
- two Needle Guide Extensions
- two Needle Guide Joints coupled with the Sterile Cover (not reusable)
- one Needle Guide Adapter (not reusable)
- one Needle Guide Insert (not reusable)
- one Needle Guide Marker Inlay for the setup (not reusable)

See "QA_73_2200_PD-B01_CoreProdDef" for further information.

The following components are integrated into the system but are optional:
On purchasing accessories, the user might expand the standard setup to achieve different variations. These accessories include: a Side Rail Adapter, a Table Top Adapter – Version B - Bottom Mounted, and a Cable Set 3m (from Robotic Positioning Unit to Control Unit) as well as a User Interface Cable Extension 5m (from Control Unit to HCU).

The following third party components are attachable to the system via interfaces provided by iSYS 1. This risk analysis does also cover the hazards created or mitigated by these components, except risks deriving from the sterility of the components:

	iSYS 1	**Needle Guide Set (disposable parts)**
	Component	**Needle Guide Joints and Sterile Cover (sterile)**
	Description	The Needle Guide Joints allow a quick and reversible connection of the Needle Guide Adapter to the Needle Guide Extension. The sterile cover is fixed onto the joints to one unit building the sterile bridge for the iSYS1.
	Component	**Needle Guide Adapter (sterile)**
	Description	The Needle Guide connects both Needle Guide Joints and allows accurate and safe needle guidance with 4 degrees of freedom.

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

	Component	Needle Guide Inserts (sterile)
	Description	During the intervention the tool is inserted and guided by the (sterile) Needle Guide Insert. It is available for needle diameters in the range between 9 and 22 gauge (= from 3.7mm to 0.7mm needle diameter); for the iSYS1.
	Component	**Needle Guide Marker Inlay (sterile)**
	Description	The Needle Guide Marker Inlay allows precise and remote-controlled alignment of the Needle Guide based on real-time imaging data;

1.1 Lifecycle of iSYS 1

The product life of the iSYS 1 Unit is **10 years*** including a regular service on the device. The service is intended to be performed every year, starting from the 3rd year of use of the device (e.g. device was sold in June 2008; the first service is performed in June 2011). The service includes:

- Detecting wear on the main components
- Detecting failures in the system
- Ensuring the accuracy of the device
- Checking the functionality of the safety relevant components

During the complete lifetime of iSYS 1, all parts and components must be supplied. This means, starting from the last sale of iSYS 1, the spare parts must be available for another five years.

The lifetime, and thus the end of sales and end of service, might be subject to changes due to growing experience with the product.

For service purposes, iSYS 1 will be sent to iSYS where the service is organized. During that time, the customer will receive a spare iSYS 1 to continue the interventions.

Upgrades to iSYS 1 are planned already and will be performed during 2011. The Needle Guide Extensions will receive markers to reduce the time for the intervention. This will lead to iSYS 1.1. In the coming years, the iSYS 2 will be presented, which allows an automatic positioning of the needle. Both upgrades will be offered to the customers of iSYS 1. Thus, the upgrade must be compatible in hard- and software.

Additionally, further inserts for needles with different diameters and other instruments will be developed. They are covered by this risk analysis.

The lifecycle of iSYS 1 covers the following phases:

- Development
- Production
- Sales
- Use
- Disposal

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

* The lifetime has been changed from 5 years to 10 years. In the beginning, the lifetime was defined basing on the use of the device by the physician 16 hours per day and 365 days per year. Then, an analysis of the lifetime of the single components has led to a lifetime of 5 years.

After two years of clinical experience with the iSYS 1 we can now say, that a use of the device 10 hours a day at 280 days are year is much more reasonable.

Therefore, the lifetime of the iSYS 1 is changed to 10 years.

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

2 Related Documentation

2.1 Specification / Design Documents

Core Product Definition	V 1.0 of 2010-09-16
Accessories	V 1.0 of 2010-09-17
Variations of the Product	V 2.0 of 2011-02-15

2.2 Guidance Documents

The methodology used in sections 6 and 7 was influenced by the following guidelines: ÖNORM EN ISO 14971: 2009 Medical Devices – Application of risk management to medical devices.

No	Standard	Title
1	ISO 62304	Medizingeräte-Software – Software-Lebenszyklus-Prozesse
2	ISO 60601-1	Medizinische elektrische Geräte
3	ISO 60601-1-6	Gebrauchstauglichkeit
4		
5		

2.3 Abbreviations and Acronyms

AC	Alternating Current
ALARP	As Low as Reasonably Practicable
CEO	Chief Executive Officer
CT	Computer Tomography
DIN	German Institute of Standards (Deutsches Institut für Normung)
EN	Europäische Norm
FDA	Food and Drug Administration
FMEA	Failure Mode and Effect Analysis
ISO	International Organization for Standardization
MOF	Main Operating Function (dt.: Hauptbedienfunktion)
ÖNORM	Österreichische Norm
PD	Product Documentation

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

3 The Risk Analysis Team

The iSYS 1 Risk Analysis Team evaluated the risks associated with the iSYS 1 system. The members of this team are:

Name	Position in the company	Function within the risk analysis
Dr. Gernot Kronreif	ACMIT	expert for the operation and functions of the device
(b)(6) [redacted]	ACMIT	expert for the manufacturing of the mechanical parts
	-	expert for the manufacturing of the electronics
Dr. Michael Vogele	CEO	expert for the use of the device
Oliver Spitz	Manager Regulatory Affairs	expert for the risk analysis process
(b)(6) [redacted]	ACMIT	expert for the electrical hardware design
	ACMIT	expert for the software design
	ACMIT	project manager
Dr. Michael Vogele	CEO	expert for evaluation of hazard severity
(b)(6) [redacted]	ACMIT	documentation
Dr. Michael Vogele	CEO	product manager
Dr. Michael Vogele	CEO	clinical expert

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

4 Identification of Applicable Hazards

4.1 Fault Assumptions

The "single fault philosophy" of the IEC 60601 series was used in this risk analysis. It means that within a limited period of time only single points of failure are considered. This first failure shall not lead to a hazard. If it is not a hazard and not detected (a 'passive failure'), an additional failure has to be assumed after a certain time (device specific) has elapsed. Also this second failure shall not lead to a hazard. Three independent failures are usually not assumed during the life time of a medical device. The time after which an independent second failure has to be assumed depends on the type of device and is usually defined by a standard. The currently applicable standards for a medical robotic system do not include this definition. Therefore this time is defined as 'one treatment'. This means that all passive failures have to be detected before the next use of the device.
Operator errors have been assumed as far as foreseeable, given the trained and instructed physician as the only operator.

4.2 Method

A list of potential hazards was established, at first separately for patient, operators, bystanders, and technical devices which could be affected. This includes hazards deriving from the usability of the product.

Note: A hazardous situation is always the result of a causal chain which starts from subtle, often barely noticeable technical or psychological causes and results in damage to the human body. In this risk analysis a "hazard" is understood as that link of the causal chain where the human body is affected for the first time.

Where necessary, the generic hazards have been divided in more specific hazards. Hazards are identified in the risk management table with an identifier of the form "H_…".

Sources of Information:
For finding the applicable hazards the following sources have been used:

- experience of the design engineers with similar products
- brainstorming in the team
- analysis of FDA Medical Device Reports and the DIMDI

List of the Applicable Potential Hazards
This is the list of applicable potential hazards found by the iSYS 1 risk analysis team:

Hazards to the patient:
- H_P1 Electrical Shock
- H_P2 Infection
- H_P3 Burning
- H_P4 Mechanical Injury
- H_P5 Mistreatment

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Hazards to the operator and other persons, e.g. service technician
- H_O1 Electrical shock
- H_O2 Infection
- H_O3 Burning
- H_O4 Mechanical Injury
- H_O5 Ergonomics

Generic hazards
- H_X1 Interference with other medical devices
- H_X2 Malfunction of other devices
- H_X3 Environmental hazards

The list of potential hazards and contributing factors given in ISO 14971 annex A was used for a check of completeness of the device hazard list. The result of this check is documented in the checklist in annex A of this hazard analysis.

4.3 Usability

The usability of the medical device is examined during the risk analysis. The basic for the evaluation are the main operating functions and, according to the type of the device, either ISO 62304 or ISO 60601-1-6. Parts of the usability are also evaluated in the Essential Requirements (see PD-B08).

Main Operating Functions (MOF):

- MOF1: Usage of the HCU in combination with the sterile cover (foil)
- MOF2: Applying the Needle Insert to the Robot Unit
- MOF3: Using the table adapters, cables and the MFA for the set-up
- MOF4: Cleaning and disinfecting the devices
- MOF5: Receiving status information at the display of the control unit

4.4 Classification of the Severity of each Risk

For each applicable hazard the severity was estimated under responsibility of a medical expert. The severity was assigned in a semi-quantitative way by means of categories. As given by the risk management plan, the following four severity levels were defined:

Severity	Value	Effect on Patient	Examples
Negligible	1	little or no potential of injury	1. black marks 2. minor infections
Marginal	2	potential of injury	1. mechanical injury by sharp edge 2. minor electrical shock 3. infection 4. elongation of treatment
Critical	3	potential of death or serious injury	1. serious infection 2. harming of healthy tissue

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

			3. electrical shock with mains voltage
Catastrophic	4	potential of multiple deaths or serious injuries	1. repeated death of several patients due to systematic malfunction

4.5 Estimation of Probability of Occurrence of each Cause

For each of the causes of the applicable hazards (see section 4.2 of this report) the probability of occurrence was estimated. The following sources of information were used:

- experience with similar products
- agreed rules of technology
- life tests
- if nothing else was available, the best engineering guess of the team

Note: if an individual probability cannot be estimated, it must be set to probability level 5 (100%) and, thus must be mitigated.

The result of the probability estimation was assigned as semi-quantitative categories as given by the risk management plan. Six categories were defined:

Category	Value	Frequency	Examples
Incredible	1	Very unlikely to occur during lifetime of all instruments of this type	simultaneous random hardware failures in two independent microcontroller systems within the same treatment
Improbable	2	May occur once in the life time of a device	random hardware failure of a component on a microcontroller system (e.g. failure of RAM, EPROM, crystal oscillator, etc.)
Remote	3	May occur once in 100 treatments	mains power failure
Occasional	4	May occur once in 10 treatments	operator error
Probable	5	May occur once in a treatment	systematic failure while positioning of the device
Frequent	6	May occur several times in a treatment	unintended movements (bounce) of the iSYS 1 (loose mechanical connection)

4.6 Determination of the Potential Causes of each Hazard

For each of the hazards given in sections 4.2 of this report the potential causes were determined. The search was done first intuitively according to the expertise of each of the team members. Additional hazards were found later by an FMEA of the preliminary design.

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

The applicable causes for each hazard are documented in the risk management file in column "Causes and sub causes". They are identified with an identifier of the form

Cxx_IN	Integration cause
Cxx_HU	Human cause
Cxx_HW	Hardware cause
Cxx_SW	Software cause

4.7 Definition of Risk Mitigation Measures

If the risk region was not already "broadly acceptable", risk mitigation measures were defined for each hazard/cause pair. Where more than one measure was defined, the combined effect of all countermeasures was considered to be necessary.
The risk mitigation measures are documented in column "Mitigation Measures" in the risk management table. They are identified with an identifier of the form "M…".

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

5 Summary

As shown in the risk management table, the residual risk of each individual hazard/cause pair is either reduced to the broadly acceptable level or it is in the ALARP region, and for each ALARP case a rationale is provided why a further reduction is not practicable.
The following tables provide an overview for the status pre and post mitigation. They show how many of the applicable hazard/cause pairs are assigned to each of the fields of the tables. As can be seen, pre mitigation **62** cases were not acceptable and **5** cases were ALARP. Post mitigation there aren't any more cases which are not acceptable and the remaining **48** ALARP cases are in the lower ALARP area.

pre mitigation

		Severity			
		1	2	3	4
Proba-bility	6				
	5				1
	4	19	3	27	
	3		2	9	
	2	7	8	23	
	1	2	3	3	

post mitigation

	Severity			
	1	2	3	4
6				
5				
4				
3				
2	6	3		
1	32	18	48	

Following hazards have been mitigated to an acceptable risk level:

- H_P3 Burning
- H_P4 Mechanical Injury
- H_O2 Infection
- H_O3 Burning
- H_O4 Mechanical Injury
- H_O5 Ergonomics
- H_X1 Interference with other medical devices
- H_X2 Malfunction of other devices
- H_X3 Environmental hazards

The following hazards have been mitigated to the ALARP region:

- H_P1 Electrical Shock
- H_P2 Infection
- H_P5 Mistreatment
- H_O1 Electrical shock

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

The remaining hazards concerning the **electrical shock** derive from the general danger of electrical components. Any measure that is reasonable has been taken and the system is tested according to the IEC 60601-1 for electrical safety. Nevertheless, an electric system in an operation theatre bears a remaining risk.
The danger of **infecting a patient** derives from the foreseeable misuse of reusing the single use (sterilized) components, which can especially for poor countries never been excluded. All measures including a summary of risks in case of misuse in the user manual are taken and the components are labeled accordingly. Further measures are not applicable.
The remaining hazard of **mistreatment** derives from the invention itself. Independent from using a robotic unit or performing the treatment freehand, any shifting of the target after imaging and before treatment has the probability of a mistreatment. Although the use of a robot unit reduces the risk of a mistreatment, a certain amount of risk remains.

Therefore also the overall risk can be considered as acceptable.
Since robotic units are used in operation theatres since many years, the medical benefit of such a machine is beyond any doubt. Therefore the risk benefit ratio can be considered as positive.
The additional information from the Post Marketing Surveillance must be added to this risk file according to the VA_73_2544 (Post Marketing).

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

6 Identification of the Qualitative and Quantitative Characteristics

This section describes the risk-related characteristics of iSYS 1. In the early phase of the project, when the preliminary risk analysis was performed, not yet all of these characteristics have been finally decided. For the unknown data preliminary estimations have been used, and during the further development final data have been added when available.
The following list contained in ISO 14971 annex C was used as a tool for determination of the risk-related characteristics of the product. In the following the questions are given and the answers to each question.
The list cannot be complete for each product. Thus, any relevant information (risk-related characteristic) that could affect the risk management process must be added at the end of this list. Questions that are not applicable, should be marked with a “N/A”.

a) What is the intended use and how is the medical device to be used?

Factors that should be considered include:

- what is the medical device's role relative to
  - diagnosis, prevention, monitoring, treatment or alleviation of disease,
  - compensation for injury or handicap or
  - replacement or modification of anatomy, or control of conception?
- what are the indications for use (e.g. patient population)?
- does the medical device sustain or support life?
- is special intervention necessary in the case of failure of the medical device?

The intended use of the iSYS1 device is to function as a remote-operated positioning and guidance system during interventional procedures. Positioning is done in remote control manner; planning of the position/angulation is done based on 2D/3D patient data (CT, cone-beam CT, fluoroscopy) by external planning software – for example using an external navigation system, or planning software coming with the used imaging device. Also verification of the correct position and orientation of the tool prior to/during/after the intervention is done by means of these external devices. The iSYS1-System is then acting as a guideway during the manual insertion of the interventional tool – usually a needle type device, and the like. Applications include, but are not limited to, interventions like biopsy procedures, tumor ablation, nerve blocking, electrode placement, etc.

- **diagnosis (tissue harvesting), treatment, alleviation**
- **no compensation**
- **no replacement or modification, control of conception**
- **no restrictions of patient population (in case of uncontrolled movements of the patient)**
- **no life support**
- **the system provides an emergency-stop system**

b) Is the medical device intended to be implanted?

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Factors that should be considered include the location of implantation, the characteristics of the patient population, age, weight, physical activity, the effect of ageing on implant performance, the expected lifetime of the implant, the reversibility of the implantation.

N/A

c) Is the device intended to contact the patient or other persons?

Factors that should be considered include intended contact, surface contact, invasive contact, implantation and, respectively, period and frequency of contact.

- **no intended direct contact**
- **but connection to the patient via the needle**
- **unintended contact is possible, but only short-time**

d) What materials and/or components are incorporated in the device or are used with, or are in contact with, the medical device?

Factors that should be considered include:
- compatibility with relevant substances;
- compatibility with tissues or body fluids;
- whether characteristics relevant to safety are known;
- is the device manufactured utilizing materials of animal origin?

- **materials: electronic components, PA6 , PA6 GF30, stainless steel, paint, aluminum, copper, cabling, rubber, (see data sheets for details) → Compatibility to cleaning and disinfection will be tested**
- **for the hardware components of iSYS 1 no biocompatibility is necessary as no intended contact to patient**
- **material is selected due to the mechanical stability of the system**
- **the sterile cover has contact to the patient, but this is not a medical product produced by iSYS, but by Websinger, and is not covered with this risk analysis**
- **No materials of animal origin**
- **REACH, RoHS and WEEE compatible**

e) Is energy delivered to and/or extracted from the patient?

Factors that should be considered include:
- the type of energy transferred;
- its control, quality, quantity, intensity and duration;
- whether energy levels are higher than those currently used for similar devices.

N/A

f) Are substances delivered to and/or extracted from the patient?

Factors that should be considered include:
- whether the substance is delivered or extracted;
- whether it is a single substance or range of substances;

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

– the maximum and minimum transfer rates and control thereof.

N/A

g) Are biological materials processed by the device for subsequent re-use, transfusion or transplantation?

Factors that should be considered include the type of process and substance(s) processed (e.g. autotransfusion, dialysis, blood component or cell therapy processing).

N/A

h) Is the device supplied sterile or intended to be sterilized by the user, or are other microbiological controls applicable?

Factors that should be considered include
- whether the medical device is intended for single use or re-use packaging;
- shelf-life issues;
- limitation on the number of re-use cycles
- method of product sterilization;
- the impact of other sterilization methods not intended by the manufacturer.

N/A. Websinger (see above)

i) Is the medical device intended to be routinely cleaned and disinfected by the user?

Factors that should be considered include the types of cleaning or disinfecting agents to be used and any limitations on the number of cleaning cycles. The design of the medical device can influence the effectiveness of routine cleaning and disinfection. In addition, consideration should be given to the effect of cleaning and disinfecting agents on the safety or performance of the device.

Yes, cleaning and disinfection must be performed prior to each use. Compatibility to the agents will be tested.

j) Is the medical device intended to modify the patient environment?

Factors that should be considered include:
- temperature;
- humidity;
- atmospheric gas composition;
- pressure;
- light

N/A

k) Are measurements taken?

Factors that should be considered include the variables measured and the accuracy and the precision of the measurement results.

N/A

l) Is the medical device interpretative?

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Factors that should be considered include whether conclusions are presented by the medical device from input or acquired data, the algorithms used, and confidence limits. Special attention should be given to unintended applications of the data or algorithm.

Yes, the marker inlay is visible in the imaging device and is used for the positioning of the needle.

Additionally, information is displayed on the control unit (display, status LEDs).

m) Is the medical device intended for use in conjunction with other medical devices, medicines or other medical technologies?

Factors that should be considered include identifying any other medical devices, medicines or other medical technologies that can be involved and the potential problems associated with such interactions, as well as patient compliance with the therapy.

Yes, the iSYS1 is used with the interventional device (needle, etc.), the tabletop of the treatment couch, the siderail of the treatment couch, the imaging device (C-Arm, etc.) and the planning software.

To be considered are also the use and installation of the iSYS1 with clinical gloves and the use of defibrillator, life-support measures and syringe pumps or similar (infusion, etc.).

n) Are there unwanted outputs of energy or substances?

Energy-related factors that should be considered include noise and vibration, heat, radiation (including ionizing, non-ionizing, and ultraviolet/visible/infrared radiation), contact temperatures, leakage currents, and electric or magnetic fields.
Substance-related factors that should be considered include substances used in manufacturing, cleaning or testing having unwanted physiological effects if they remain in the product.
Other substance-related factors that should be considered include discharge of chemicals, waste products, and body fluids.

Yes, these are noise and vibration, heat, radiation (non-ionizing), contact temperatures, leakage currents, and electric or magnetic fields.

o) Is the medical device susceptible to environmental influences?

Factors that should be considered include the operational, transport and storage environments. These include light, temperature, humidity, vibrations, spillage, and susceptibility to variations in power and cooling supplies, and electromagnetic interference.

Yes, the environmental conditions must be defined according to the data sheets (use, transport and storage). The visibility of the display depends on the surrounding light. The device depends on the power supply and the electromagnetic fields.

p) Does the medical device influence the environment?

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Factors that should be considered include:
- the effects on power and cooling supplies;
- emission of toxic materials;
- the generation of electromagnetic disturbance.

The iSYS1 is connected to the power supply and can produce electromagnetic fields.

q) Are there essential consumables or accessories associated with the medical device?

Factors that should be considered include specifications for such consumables or accessories and any restrictions placed upon users in their selection of these.

Yes, the needle guide kits are for single use. Only consumables supplied by iSYS are allowed.

r) Is maintenance or calibration necessary?

Factors that should be considered include:
- whether maintenance or calibration are to be carried out by the operator or user or by a specialist;
- are special substances or equipment necessary for proper maintenance or calibration?

Yes, the iSYS1 will receive regular maintenance after three years of use and any two years (see lifecycle in chapter 1.1).

s) Does the medical device contain software?

Factors that should be considered include whether software is intended to be installed, verified, modified or exchanged by the operator or user or by a specialist.

Yes, in case (upgrade) new software will be installed on the iSYS1 by a specialist.

t) Does the medical device have a restricted shelf-life?

Factors that should be considered include labeling or indicators and the disposal of such medical devices when the expiration date is reached.

Yes, the shelf-life of the iSYS1 is restricted to five years. Experiences with former prototypes show no problems within 7.5 years.

u) Are there any delayed or long-term use effects?

Factors that should be considered include ergonomic and cumulative effects. Examples could include pumps for saline that corrode over time, mechanical fatigue, loosening of straps and attachments, vibration effects, labels that wear or fall off, long term material degradation.

Yes, see r)

v) To what mechanical forces will the medical device be subjected?

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Factors that should be considered include whether the forces to which the medical device will be subjected are under the control of the user or controlled by interaction with other persons.

Yes, the mechanical arm and the table adapters are tightened by the user and might be overtightened.

Misuse: the cables could be hauled by the user.

w) What determines the lifetime of the medical device?

Factors that should be considered include ageing and battery depletion.

The data sheets of the single components give the lifetime of these components. Aging of single components (plastics, electronic components) might occur.

x) Is the medical device intended for single use?

Factors that should be considered include: does the medical device self-destruct after use? Is it obvious that the device has been used?

Yes, the needle guide kits are for single use. Only consumables supplied by iSYS are allowed.

y) Is safe decommissioning or disposal of the medical device necessary?

Factors that should be considered include the waste products that are generated during the disposal of the medical device itself. For example, does it contain toxic or hazardous material, or is the material recyclable?

Yes, RoHS and WEEE are complied with. National regulations must be followed.

z) Does installation or use of the medical device require special training or special skills?

Factors that should be considered include the novelty of the medical device and the likely skill and training of the person installing the device.

Yes, installation and use require special training.

aa) How will information for safe use be provided?

Factors that should be considered include:

- whether information will be provided directly to the end user by the manufacturer or will it involve the participation of third parties such as installers, care providers, health care professionals or pharmacists and whether this will have implications for training;
- commissioning and handing over to the end user and whether it is likely/possible that installation can be carried out by people without the necessary skills;
- based on the expected life of the device, whether re-training or re-certification of operators or service personnel would be required.

User Manual and User Trainings are provided by iSYS.

ab) Will new manufacturing processes need to be established or introduced?

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Factors that should be considered include new technology or a new scale of production.

No, iSYS will not produce the iSYS1, but specialized companies.

ac) Is successful application of the medical device critically dependent on human factors such as the user interface?

ac.1) Can the user interface design features contribute to use error?

Factors that should be considered are user interface design features that can contribute to use error. Examples of interface design features include: control and indicators, symbols used, ergonomic features, physical design and layout, hierarchy of operation, menus for software driven devices, visibility of warnings, audibility of alarms, standardization of colour coding. See IEC 60601-1-6[25] for additional guidance on usability and IEC 60601-1-8[26] for guidance on alarms.

The use of the marker inlay is critical for the correct positioning of the invasive device. The information on the display, acoustic alarms and status LEDs have influence on a safe use as they have to be considered (needle placement).

ac.2) Is the medical device used in an environment where distractions can cause use error?

Factors that should be considered include:

- the consequence of use error;
- whether the distractions are commonplace;
- whether the user can be disturbed by an infrequent distraction.

The visual alarms can be overlooked and lead to mistreatment.

Under normal circumstances the user cannot be distracted during the use of iSYS1.

The patient is partly visually covered by iSYS1. The robot unit is visible in the imaging device and might partly overlap the patient's image. The image might contain a marker-like structure which can be mistaken in the positioning process.

ac.3) Does the medical device have connecting parts or accessories?

Factors that should be considered include the possibility of wrong connections, similarity to other products' connections, connection force, feedback on connection integrity, and over- and under-tightening.

Table top adapter: the table adapter is connected to the treatment couch and might be over- or undertightened. Overtightening might lead to damage of the components. Undertightening cannot be detected easily.

Mechanical Arm: the mechanical arm is connected to the table top adapter and might be over- or undertightened. Overtightening might lead to damage of the components. Undertightening cannot be detected easily.

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Robot unit: the robot unit is connected to the mechanical arm and might be over- or undertightened. Overtightening might lead to damage of the components. Undertightening cannot be detected easily.

Needle Guide Kit: the needle guide kit is connected to the robot unit by the means of a twist lock and a snap fit. Improper connection is possible and might lead to mistreatment.

Needle: the needle inserted in the needle insert. Use of an insert with a too big size leads to an improper guidance of the needle, use of a too small insert might lead to a sticking needle.

Cabling: the cables are connected to the several components. The cables can be mixed and connected to the wrong devices.

ac.4) Does the medical device have a control interface?

Factors that should be considered include spacing, coding, grouping, mapping, modes of feedback, blunders, slips, control differentiation, visibility, direction of activation or change, whether the controls are continuous or discrete, and the reversibility of settings or actions.

Handheld Control Unit: the HCU offers a joystick for movement control, a rocker switch for selection of angulation or positioning and a rocker switch for speed level. All setting and actions are fully reversible.

ac.5) Does the medical device display information?

Factors that should be considered include visibility in various environments, orientation, the visual capabilities of the user, populations and perspectives, clarity of the presented information, units, colour coding, and the accessibility of critical information.

The control unit has a display for information regarding speed level, alarms, mode of movement, and status of the iSYS1.

At the control unit are three light indicators for status information (green, red, and blue), green for “ready for use”, red for “error” and blue for “power”.

Color coding is performed according to 60601-1, chapter 7.8.1.

The display is back-lighted and, thus, also visible in the dark.

ac.6) Is the medical device controlled by a menu?

Factors that should be considered include complexity and number of layers, awareness of state, location of settings, navigation method, number of steps per action, sequence clarity and memorization problems, and importance of control function relative to its accessibility and the impact of deviating from specified operating procedures.

The display contains no menu, but the HCU offers the possibility to change the speed and the mode of movement.

ac.7) Will the medical device be used by persons with special needs?

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Factors that should be considered include the user, their mental and physical abilities, skill and training, ergonomic aspects, the use environment, installation requirements, and the patient's capability to control or influence the use of the medical device. Special attention should be paid to users with special needs, such as handicapped persons, the elderly and children. Their special needs might include assistance by another person to enable the use of a medical device. Is the medical device intended to be used by individuals with various skill levels and cultural backgrounds?

The iSYS1 is only operated and installed by trained clinical personnel. The personnel might be of different cultural and linguistic background.

ac.8) Can the user interface be used to initiate user actions?

Factors that should be considered include the possibility of initiating a deliberate action for the user to enter a controlled operation mode, which enlarges the risks for the patient and which creates awareness for the user for this condition.

N/A

ad) Does the medical device use an alarm system?

Factors that should be considered are the risk of false alarms, missing alarms, disconnected alarm systems, unreliable remote alarm systems, and the medical staff's possibility of understanding how the alarm system works. Guidance for alarm systems is given in IEC 60601-1-8.

Yes, the iSYS1 uses acoustic and optical alarms to inform the user about errors. The acoustic alarms are designed according to the respective standards. <u>The optical alarms are subject to review.</u>

ae) In what way(s) might the medical device be deliberately misused?

Factors that should be considered are incorrect use of connectors, disabling safety features or alarms, neglect of manufacturer's recommended maintenance.

Incorrect use of connectors, neglect cleaning and disinfection procedures, re-use of single use components, neglect of manufacturer's recommended maintenance, use of not released accessories, neglect disposal recommendations, mounting siderail adapter on loose siderail, positioning robot unit on patient's skin, using the iSYS1 as a rest or placement area, use the iSYS1 in combination with unsuitable imaging devices, use outside the intended use (other interventions), neglect the recommendation for the sterile cover, neglect the specified lifetime, neglect specified workflow.

af) Does the medical device hold data critical to patient care?

Factors that should be considered include the consequence of the data being modified or corrupted.

N/A

ag) Is the medical device intended to be mobile or portable?

Factors that should be considered are the necessary grips, handles, wheels, brakes, mechanical stability and durability.

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Yes, but only for setup.

ah) Does the use of the medical device depend on essential performance?

Factors that should be considered are, for example, the characteristics of the output of life-supporting devices or the operation of an alarm.

N/A

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

7 Checklist for Identification of Possible Hazards

The following lists contained in ISO14971 annex E were used as a tool for identification of possible hazards. Since some of the items of this list are hazards in the sense of this risk analysis, and some are causes of hazards, they have been considered either in the hazard or in the causes determination.
For each point it is explained if it is relevant for iSYS 1 and - if relevant - which hazard or which cause reflects it.
Be aware, that the following lists are only an example, and the hazards and causes for the product might differ. Add additional points to the list, where applicable and set “N/A”, if a hazard is not relevant for the product.

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Energy hazards

Item from ISO 14971	applicability to iSYS 1	Ref.
Electromagnetic energy		
Line voltage	Yes, electrical safety acc. to EN 60601-1 has to be tested.	
Leakage current (enclosure, earth or patient)	Yes, electrical safety acc. to EN 60601-1 has to be tested.	
Electric fields	Yes, tested at Seibersdorf Laboratory GmbH acc. to EN 60601-1-2.	
Magnetic fields (e.g., MRI)	n/a.	
Radiation energy		
Ionizing radiation	n/a.	
Non-ionizing radiation	see above, electric fields.	
Thermal energy		
High temperature	Yes, iSYS1 can overheat. Test at ACMIT will be performed.	
Low temperature	n/a.	
Mechanical energy		
Gravity (falling, suspended masses)	Yes, the device can be badly fixed and fall on the user or patient. Ergonomics will be tested.	
Vibration	Yes, if components (e.g. fan) break. In case of vibrations, the device must not be used.	UM
Stored energy	Only at the HCU, but not hazardous.	
Moving parts	Yes, but the movements are so slow and limited in force that no hazardous situation can occur.	
Torsion, shear and tensile force	In case of bad fixation of the device, it can fall down and harm user or patient.	
Moving and positioning of patient	n/a.	
Acoustic energy (ultrasonic, infrasound, sound)	The acoustic alarms are acc. to EN 60601-1-8 and thus not hazardous. Movements in the robot units can lead to unintended noise (e.g. wrong control settings). In this case, the device must not be used.	UM Goods Inspections Service Manual

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Item from ISO 14971	applicability to iSYS 1	Ref.
High pressure fluid injection	n/a.	

Biological and chemical hazards

Item from ISO 14971	applicability to iSYS 1	Ref.
Biological		
Bacteria	Yes, if cleaning and disinfection procedures are neglected or the sterile cover is not used.	UM
Viruses	Yes, if cleaning and disinfection procedures are neglected or the sterile cover is not used.	UM
Other agents (e.g. prions)	Yes, if cleaning and disinfection procedures are neglected or the sterile cover is not used.	UM
Re- or cross-infection	Yes, if cleaning and disinfection procedures are neglected or the sterile cover is not used.	UM
Chemical (exposure of airway, tissues, environment or property to:)		
Acids or alkalis	n/a.	
Residues	Yes, if the cleaning agents remain on the iSYS1 and the cleaning and disinfection procedure is shortened.	UM
Contaminates	Yes, if cleaning and disinfection procedures are neglected or the sterile cover is not used.	
Additives or processing aids	Yes, if the grease from the drive chain gets in contact with patient or user. Yes, if glue or other liquids from the manufacturing process remain on the iSYS1.	Goods Inspections
Cleaning, disinfection or testing agents	Yes, if the cleaning agents remain on the iSYS1 and the cleaning and disinfection procedure is shortened.	UM
Degradation products	n/a.	
Medical gasses	n/a.	

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

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Item from ISO 14971	applicability to iSYS 1	Ref.
Anaesthetic products	n/a.	
Biocompatibility		
Allergenicity	n/a, no intended contact to patient.	
Mutagenicity	n/a, no intended contact to patient.	
Oncogenicity	n/a, no intended contact to patient.	
Teratogenicity	n/a, no intended contact to patient.	
Carcinogenicity	n/a, no intended contact to patient.	
Pyrogenicity	n/a, no intended contact to patient.	

Operational hazards

Item from ISO 14971	applicability to iSYS 1	Ref.
Function		
Incorrect or inappropriate output or functionality	Yes, each individual device will be tested before delivered to the user.	Goods Inspections
Incorrect measurement	n/a.	
Erroneous data transfer	Yes, each individual device will be tested before delivered to the user.	Goods Inspections
Loss or deterioration of function	Not within the specified lifetime. Use after the lifetime is covered by intended misuse.	UM
Use error		
Attentional failure	Yes, but only when placing the instrument, not during the use of the iSYS1.	UM
Memory failure	Yes, but only when placing the instrument, not during the use of the iSYS1.	UM
Rule-based failure	Yes, e.g. shortening or neglecting the cleaning and disinfection procedures. Yes, shortening or neglecting the workflow.	UM

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Item from ISO 14971	applicability to iSYS 1	Ref.
Knowledge-based failure	Yes, but training on the iSYS1 will be provided.	
Routine violation	see above (rule-based failure).	UM

Environmental hazards (deriving from the former version of the standard)

Item from ISO 14971	applicability to iSYS 1	Ref.
Electromagnetic fields	Yes, see above.	
Susceptibility to electromagnetic interference	Yes, see above.	
Emissions of electromagnetic interference	Yes, see above.	
Inadequate supply of power	Yes, but the iSYS1 will have a power-supply unit with universal input. Different fuses required for different voltages (e.g. US market).	
Inadequate supply of coolant	n/a.	
Storage or operation outside prescribed environmental conditions	Yes, storage and transport is possible. Operation is in clinical environment.	
Incompatibility with other devices with which it is intended to be used	Yes, collision with imaging device is possible. It also might happen that imaging quality is being influenced by the iSYS system, especially if the robot is placed in the imaging beam.	UM
Accidental mechanical damage	Yes, collision with imaging device is possible. Damage due to falling down of a component leading to malfunction.	UM
Contamination due to waste products and /or medical device disposal	Yes, national regulations must be applied.	UM

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Information hazards

Item from ISO 14971	applicability to iSYS 1	Ref.
Labeling		
Incomplete instructions for use	Yes, a validation of the UM will be performed.	
Inadequate description of performance characteristics	Yes, a validation of the performance data will be performed (accuracy, compatibility to agents, power supply, movement ranges, compatibility to imaging devices, fixing devices like MFA etc., environmental conditions, weight and dimensions)	
Inadequate specification of intended use	Yes, the intended use has to be validated. Any information in the intended use has to be tested.	
Inadequate disclosure of limitations	Yes, the limitations have to be defined by the risk analysis team and clinical experts.	
Operating instructions		
Inadequate specification of accessories	No, the accessories are limited and defined in the UM. The use of any other accessory is restricted or forbidden.	
Inadequate specification of pre-use checks	Yes, the pre-use checks have to be defined and validated.	
Overcomplicated operating instructions	Yes, a validation of the UM will be performed.	
Warnings		
Insufficient warning of side effects	n/a.	
Inadequate warning of hazards likely with re-use of single use medical devices	Yes, the warnings have to be in the UM.	
Specification of service and maintenance	Yes, the service and maintenance procedures have to be defined acc. to specifications of the single components.	

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

8 Risk Management Table

Severity (Se)

1 = Negligible
2 = Marginal
3 = Critical
4 = Catastrophic

Probability (Pr)

1 = Incredible
2 = Improbable
3 = Remote
4 = Occasional
5 = Probable
6 = Frequent

Risk

P\S	1	2	3	4
6		NAK	NAK	NAK
5		NAK	NAK	NAK
4	AK	NAK	NAK	NAK
3	AK		NAK	NAK
2	AK	AK	NAK	NAK
1	AK	AK		NAK

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Hazards to the patient

H_P1 Harm due to Electrical Shock

	Pre Mitigation				Post Mitigation		
Potential causes and sub causes	**Se**	**Pr**	**Risk**	**Mitigation Measures**	**Se**	**Pr**	**Risk**
C1 Due to cabling							
C1.1 due to EMC problems (FMEA line 70)	2	4	NAK	M1 Test according to IEC 60601-1-2 M2 construction: defined length of cables	2	1	AK
C1.2 due to missing grounding (FMEA line 71)	3	2	NAK	M3 periodically inspection in the clinic (user / service manual) M4 safe connection to housing M5 contact surfaces on each component	3	1	ALARP
C1.3 due to damages caused by mechanical or chemical influences (power supply)	3	2	NAK	M6 Reinforced and/or double insulation and/or class I housing (see technical drawings for details) M7 Warning in UM	3	1	ALARP
C1.4 due to damages caused by mechanical or chemical influences (data cable, HCU cable)	1	3	AK	M6 Reinforced and/or double insulation and/or class I housing (see technical drawings for details) M7 Warning in UM	1	1	AK
C1.5 due to damages by X-Ray radiation of the imaging device (power supply)	3	1	AK	M8 Literature / Data Sheets	3	1	ALARP
C1.6 due to damages by X-Ray radiation of the imaging device (data cable, HCU cable)	1	1	AK	M8 Literature / Data Sheets	1	1	AK
C2 Due to wrong power supply of components (FMEA lines 91-94, 96-98), (MOF3)	3	4	NAK	M9 Test according to IEC 60601-1 M10 Usage of wide range power supply unit M11 Fuses for high current M12 Alarm due to voltage watchdog	2	1	AK

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

	Pre Mitigation				Post Mitigation		
Potential causes and sub causes	**Se**	**Pr**	**Risk**	**Mitigation Measures**	**Se**	**Pr**	**Risk**
				M13 LED “ready-to-use” ceases			
C3 Failure in the power supply unit	3	4	NAK	M11 Fuses for high current M6 class 1 housing for the control unit M14 Overvoltage protection in the power supply (schematics should be provided to TÜV by Traco)	2	1	AK
C4 Housing of control unit not sufficiently grounded and voltage on touchable parts (230V)	3	4	NAK	M15 Grounding pins on every part M5 contact surfaces on each component	3	1	ALARP
C5 Power supply cable of the control unit gets damaged and touches the secondary circuit							
C5.1 on the 24V cabling	3	1	NAK	M16 usage of varistor and Schottky Zener diode (30V)	2	1	AK
C5.2 on the Power Led cable	3	2	NAK	M17 direct connection of the Power LED to the output of the Power Supply M16 usage of varistor and Schottky Zener diode (30V)	2	1	AK
C5.3 on the PEC	3	2	NAK	M18 Construction with dividing plate M2 defined length of cabling preventing M6 class 1 housing for the control unit M11 Fuses for high current	3	1	ALARP
C6 Due to condensed water in the devices	3	2	NAK	M19 Definition of operating, storage and transport conditions M6 Class1 housing of control unit M9 air clearance and creepage distance acc. to IEC 60601-1 M20 User Manual: if transported outside the	2	1	AK

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

	Pre Mitigation				Post Mitigation		
Potential causes and sub causes	**Se**	**Pr**	**Risk**	**Mitigation Measures**	**Se**	**Pr**	**Risk**
				specification, time for drying defined.			
C7 Due to spilling on the device	3	3	NAK	M9 Test acc. to IEC 60601-1 M6 Class1 housing of control unit M21 Construction: openings on the bottom side M22 UM/Workflow: covering by sterile cover	2	1	AK
C8 Due to rests of disinfection liquids (MOF4)	3	4	NAK	M23 UM/Workflow: drying after disinfection and cleaning M6 Class1 housing of control unit M9 Test acc. to IEC 60601-1 M21 Construction: openings on the bottom side	2	1	AK
C9 Due to fluids getting into the housing (MOF4)							
C9.1 of the control unit	3	4	NAK	M9 Test acc. to IEC 60601-1 M6 Class1 housing of control unit M21 Construction: openings on the bottom side	2	1	AK
C9.2 of the robot unit	1	3	AK	M9 Test acc. to IEC 60601-1 M24 Low voltage power supply (6,5V) M22 UM/Workflow: covering by sterile cover	1	1	AK
C9.3 of the HCU	1	3	AK	M9 Test acc. to IEC 60601-1 M25 Low voltage power supply (24V)	1	1	AK
C10 Due to overheating of components and, thus, malfunction of components	1	2	AK	M9 Test for overheating (IEC 60601-1)	2	1	AK
C11 Due to overvoltage in the mains supply	3	2	NAK	M1 Test according to IEC 60601-1-2 M14 Overvoltage protection in the power supply (schematics should be provided to TÜV by Traco)	1	1	AK

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

	Pre Mitigation				Post Mitigation		
Potential causes and sub causes	**Se**	**Pr**	**Risk**	**Mitigation Measures**	**Se**	**Pr**	**Risk**
C12 loose cabling in the Robot Unit	1	3	AK	M26 insulated housing	1	1	AK
C13 breaking of the housing	3	1	ALARP	M9 Test according to IEC 60601-1	1	1	AK
C14 loose connector of Cable (MOF3)							
C14.1 between Control Unit and Robot Unit	1	3	NAK	M27 construction of plugs, pins not reachable M28 Warning in the UM: check connections between components M29 Workflow/UM: first all components connected to each other, then main power supply	1	1	AK
C14.2 between Control Unit and HCU	1	3	NAK	M27 construction of plugs, pins not reachable M28 Warning in the UM: check connections between components M29 Workflow/UM: first all components connected to each other, then main power supply	1	1	AK
C14.3 Mains cable	3	2	NAK	M27 construction of plugs, pins not reachable M28 Warning in the UM: check connections between components M29 Workflow/UM: first all components connected to each other, then main power supply	3	1	AK
C15 Due to electrostatic discharge of the operator	1	2	NAK	M30 insulation of the patient connection	1	1	AK
C16 touching the circuits in the Robot Unit, due to loose/broken covering band	1	2	NAK	M9 distance to circuits acc. IEC 60601-1 M31 User Manual: never touch inside components	1	1	AK
C17 touching a metallic part inside the Robot Unit, due to loose/broken covering band and single fault condition in the insulation of the circuits of the Robot Unit	1	2	NAK	M31 User Manual: never touch inside components M32 construction: covering (warning color) the front side of the robot unit	1	1	AK

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

	Pre Mitigation				Post Mitigation		
Potential causes and sub causes	**Se**	**Pr**	**Risk**	**Mitigation Measures**	**Se**	**Pr**	**Risk**
C18 due to wrong re-assembling after service (MOF3)	1	2	NAK	M33 Service Manual: provide checklist after service (Technical Safety Check)	1	1	AK
C19 due to aging of components	3	2	NAK	M149 User Manual: define times for service and maintenance acc. to chapter 1	3	1	AK

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

H_P2 Harm due to Infection

	Pre Mitigation				Post Mitigation		
Potential causes and sub causes	**Se**	**Pr**	**Risk**	**Mitigation Measures**	**Se**	**Pr**	**Risk**
C1 by re-use of single use, sterile parts (FMEA line 6), (MOF2)	4	5	NAK	M34 Combining the sterile cover with the Needle Guide Adapter M35 Labelling: single use, sterile M36 Warning in the UM: single use, sterile, misuse	3	1	ALARP
C2 by loosening of the sterile cover (connection to needle guide joints)							
C2.1 due to application of patient disinfection and/or mechanical forces (MOF2)	3	2	NAK	M37 Chemical and mechanical Tests (websinger) M38 Redundant fixation of the sterile cover to the joints (glue and mechanical shim)	3	1	ALARP
C2.2 due to bad manufacturing (FMEA line 26)	3	2	NAK	M39 Qualified supplier for manufacturing M40 Special assembling tool + Sampling inspection of components	3	1	ALARP
C3 by touching the non-sterile robot components and then touching the sterile area (FMEA line 28), (MOF2)	3	4	NAK	M41 Using a sterile cover for the robot unit M42 Warning in the UM: never touch non-sterile components and the sterile area M43 Disinfection of the robot unit prior to its use	3	1	ALARP
C4 by touching the not sterile MFA and then touching the sterile area (MOF2)	3	4	NAK	M44 Using a sterile cover for the MFA M42 Warning in the UM M45 Disinfection of the MFA prior to its use	3	1	ALARP
C5 by touching the not sterile HCU and then touching the sterile area (MOF2)	3	4	NAK	M46 Disinfection of the HCU prior to its use M 42Warning in the UM M47 Using a sterile cover for the HCC	3	1	ALARP
C6 Damaging the sterile covers							
C6.1 by using the lever at the MFA	3	4	NA	M48 Test for opening of the MFA with attached	3	1	ALA

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

	Pre Mitigation				Post Mitigation		
Potential causes and sub causes	**Se**	**Pr**	**Risk**	**Mitigation Measures**	**Se**	**Pr**	**Risk**
			K	sterile cover M49 Warning in the UM: Do not continue procedure if cover is damaged M50 Use of robust material for the sterile cover			RP
C6.2 by sharp edges	3	4	NAK	M51 Avoid sharp edges in the design of outside surfaces M49 Warning in the UM: Do not continue procedure if cover is damaged M50 Use of robust material for the sterile cover	3	1	ALARP
C6.3 by opening the packaging of the sterile cover (MOF2)	3	4	NAK	M52 Design of packaging (easy opening) M49 Warning in the UM: Do not continue procedure if cover is damaged M50 Use of robust material for the sterile cover	3	1	ALARP
C6.4 by using the tape at the sterile cover (MOF2)	3	4	NAK	M53 Selection of compatible of tapes at the sterile cover M54 Test of tapes at the sterile cover M49 Warning in the UM: Do not continue procedure if cover is damaged M50 Use of robust material for the sterile cover	3	1	ALARP
C6.5 with the needle/instrument (FMEA line 27), (MOF2)	3	4	NAK	M55 Components inside the cover are disinfected M49 Warning in the UM: Do not continue procedure if cover is damaged M50 Use of robust material for the sterile cover	3	1	ALARP
C6.6 by tearing open the sterile cover due to movements of the robot unit	3	4	NAK	M56 Design of the cover (wide enough) M57 Test for moving the robot unit with sterile cover M49 Warning in the UM: Do not continue procedure	3	1	ALARP

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

	Pre Mitigation				Post Mitigation		
Potential causes and sub causes	**Se**	**Pr**	**Risk**	**Mitigation Measures**	**Se**	**Pr**	**Risk**
				if cover is damaged M50 Use of robust material for the sterile cover			
C6.7 while mounting the needle guide joints (MOF2)	3	4	NAK	M58 Appropriate packing of the cover M59 Test for mounting the needle guide joints M49 Warning in the UM: Do not continue procedure if cover is damaged M50 Use of robust material for the sterile cover	3	1	ALARP
C6.8 by movements of the patient	3	4	NAK	M50 Use of robust material for the sterile cover	3	1	ALARP
C7 Incorrect usage of the sterile cover and, thus, not separating the sterile area from the non-sterile area	3	4	NAK	M60 UM: Description of the right use and the workflow of the sterile cover	3	1	ALARP
C8 Use of inappropriate accessories (sterile, single-use parts)	3	4	NAK	M61 UM: Defining of allowed accessories M62 Warning in the UM: The use of any other accessory is restricted or forbidden.	3	1	ALARP
C9 Touching sterile area with non-sterile components (MOF2)			NAK				
C9.1 robot unit cabling	3	4	NAK	M2 Appropriate length and running of cables	3	1	ALARP
C9.1 HCU cabling	3	4	NAK	M2 Appropriate running of cables M63 Warning in the UM: Do not touch sterile cover with the HCU cabling.	3	1	ALARP
C9.1 patient touches sterile components	3	4	NAK	M64 Warning in the UM: The patient must not touch sterile cover.	3	1	ALARP
C10 Touching non-sterile components and then touching the sterile area (user and patient), (MOF2)	3	4	NAK	C10.1 to C10.10: M65 Workflow/UM (sterile / non-sterile area)	3	1	ALARP

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

	Pre Mitigation				Post Mitigation		
Potential causes and sub causes	**Se**	**Pr**	**Risk**	**Mitigation Measures**	**Se**	**Pr**	**Risk**
				M42 Warning in the UM			
C10.1 control unit							
C10.2 HCU including cabling							
C10.3 robot unit including cabling							
C10.4 cabling (power supply)							
C10.5 MFA							
C10.6 Table/Side Rail Adapter							
C10.7 Needle Guide Extensions							
C11 Putting sterile components in the non-sterile area	3	4	NAK	M65 Workflow/UM M42 Warning in the UM	3	1	ALARP
C12 Infecting the patient by fluids and additives flowing out of the device (MOF4)	3	2	NAK	M19 Definition of operating, storage and transport conditions M20 User Manual: if transported outside the specification, time for drying defined. M9 Test for overheating M66 Construction: Minimal use/disuse of fluids and additives M22 UM/Workflow: covering by sterile cover M23 UM/Workflow: drying after disinfection and cleaning	3	1	ALARP
C13 Infecting the patient during the set-up of the iSYS1 while the patient is on the treatment couch (MOF2)	3	2	NAK	M23 Workflow/UM M67 User Manual: Disinfection and cleaning of components prior to use	3	1	ALARP
C14 Fan blowing non sterile air to the sterile area	3	2	NAK	M68 Mounting of control unit thus no direct airflow to the patient occurs	3	1	ALARP

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

	Pre Mitigation				Post Mitigation		
Potential causes and sub causes	**Se**	**Pr**	**Risk**	**Mitigation Measures**	**Se**	**Pr**	**Risk**
				M21 Construction: openings on the bottom side M69 Small fan			
C15 Improper cleaning and disinfection of the device (MOF4)	2	1	AK	M70 Use of standardized disinfection and cleaning procedures M23 Description in the UM	1	1	AK
C16 Improper dismantling of the system (MOF2, 3)	3	2	NAK	M71 Description in the UM: setup and demounting	3	1	ALARP
C17 Mechanical injury of the user leading to infections	2	1	AK	M51 Construction: no sharp edges	1	1	AK
C18 Device is strongly contaminated during manufacturing and, thus, cannot be disinfected properly	2	1	AK	M72 Incoming inspection of supplied parts M73 Clean manufacturing rooms	1	1	AK

- Since the use of the iSYS1 requires installation by the operator, and since human errors cannot be excluded completely, some residual risks remain in case of human error. However, this reflects the current state of the art and further mitigation is not practicable.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

H_P3 Harm due to Burning

	Pre Mitigation				Post Mitigation		
Potential causes and sub causes	**Se**	**Pr**	**Risk**	**Mitigation Measures**	**Se**	**Pr**	**Risk**
C1 by touching the hot surface of the:	2	2	AK	C1.1 to C1.4: M11 Fuses for high current M9 Test according to IEC 60601-1	1	1	AK
C1.1 Robot Unit							
C1.2 Control Unit							
C1.3 HCU							
C1.4 Cables							
C2 by burning of the device (flames)	2	2	AK	C2.1 to C2.5: M11 Fuses for high current	1	1	AK
C2.1 Robot Unit due to electrical overheating							
C2.2 Control Unit due to electrical overheating							
C2.3 Control Unit, when standing on the bottom surface and thus blocking the air convention				M74 Mounting the CU if there is no siderail available			
C2.4 HCU due to electrical overheating							
C2.5 Cables due to electrical overheating							
C3 by hot liquids running out of the robot unit	2	2	AK	M11 Fuses for high current M9 Test according to IEC 60601-1	1	1	AK
C4 by residuals of disinfection and cleaning agents inflamed by a spark	2	2	AK	M23 UM/Workflow: drying after disinfection and cleaning	1	1	AK

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

H_P4 Harm due to Mechanical injury

	Pre Mitigation				Post Mitigation		
Potential causes and sub causes	**Se**	**Pr**	**Risk**	**Mitigation Measures**	**Se**	**Pr**	**Risk**
C1 Falling of the device on the patient due to lose mechanical connection							
C1.1 Robot Unit	1	3	AK	M75 Lightweight design M76 UM/Workflow: correct setup and checks	1	2	AK
C1.2 MFA	1	3	AK	M75 Lightweight design M76 UM/Workflow: correct setup and checks	1	2	AK
C1.3 Control Unit if siderail is not used	1	3	AK	M77 Warning in the UM	1	1	AK
C2 Falling of the device (robot unit) on the patient due to pulling at the cable	1	3	AK	M2 Appropriate length of cables M78 Test for mechanical stability of MFA M79 Strain relief for cables M80 Warning in the UM	1	1	AK
C3 Falling of the device (robot unit + MFA) on the patient due to pushing of the device with the moving imaging device	2	4	NAK	M76 UM/Workflow: correct setup and checks M81 Warning in the UM: be aware the imaging device does not hit the iSYS 1	2	2	AK
C4 Unintended movement of the inserted needle due to:							
C4.1 unintended movement of the Robot Unit	3	4	NAK		3	1	ALARP
C4.1.1 by using the HCU while the needle is being inserted				M82 Enable switch M83 Warning in the UM: do not move the robot, when needle is inserted			
C4.1.2 by malfunction of control components/electronic components				M84 Stationary check M85 Encoder check			

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

	Pre Mitigation				Post Mitigation		
Potential causes and sub causes	**Se**	**Pr**	**Risk**	**Mitigation Measures**	**Se**	**Pr**	**Risk**
				M86 Emergency stop			
C4.1.3 by software error				M84 Stationary check M87 Error handling within software M88 Watchdog M86 Emergency stop			
C4.1.4 by breaking of mechanical components (FMEA line 19)				M9 Design according EN 60601-1 M78 Test of mechanical stability			
C4.1.5 by electromagnetic interference of other devices				M1 Test according EN 60601-1-2			
C4.1.6 environmental conditions (short circuit due to humidity)				M9 Test according EN 60601-1 M19 Definition of operating, storage and transport conditions M20 User Manual: if transported outside the specification, time for drying defined. M84 Stationary check M86 Emergency stop			
C4.1.6 by bad fixation at the table (FMEA line 43), (MOF3)				M76 UM/Workflow: Test of fixation during setup			
C4.1.7 due to unintended loosing of the fixation at the table (FMEA line 44), (MOF3)				M87 Design: self-locking lead screw M76 UM/Workflow: Test of fixation at the table			
C4.1.8 due to malfunction of electronic components due to X-Ray radiation of the imaging device				M88 Literature and datasheet analysis			
C4.1.9 due to bad fixation/loose mechanical fixation during setup (MOF3)				M76 UM/Workflow: Test of fixation at the table			
C4.2 unintended movement of the table	3	4	NA	M89 Mechanical Design: Robot + Adapter + Table is	3	1	ALA

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

	Pre Mitigation				Post Mitigation		
Potential causes and sub causes	**Se**	**Pr**	**Risk**	**Mitigation Measures**	**Se**	**Pr**	**Risk**
			K	one Unit M90 Warning User Manual: table must be fixed and not move			RP
C4.3 movement of the patient	3	4	NAK	M91 Warning in the UM (“Adequate compliance and immobilization of the patient is necessary and in the responsibility of the physician”)	3	1	ALARP
C4.4 movement of the mechanical setup cause of interference with the user (“Physician uses the setup as an arm rest”, misuse)	3	4	NAK	M78 Test of mechanical stability M92 Warning in the UM: do not misuse the iSYS 1 as an armrest or tablet	1	1	AK
C4.5 accidental pushing of the device	3	2	NAK	M78 Test of mechanical stability M93 Warning in the UM: do not accidental push the device, in case repeat imaging	1	1	AK
C4.6 falling of the control unit and thus pulling on the cables (FMEA lines 36-40)	3	2	NAK	M94 Secure locking mechanism of control unit M78 Test of mechanical stability M79 Strain relief for cables	3	1	ALARP
C4.7 loose or to tight mechanical connection (MOF3)	3	3	NAK	M76 UM/Workflow: correct setup and checks M94 Design of the needle insert (User can check the needle guidance over the whole needle length by testing the needle insert) M95 Warning in Manual: check the needle guidance over the whole needle length by testing the needle insert	3	1	ALARP
C4.7.1 due to inaccuracies in the diameter of the needle/instrument (FMEA line 5)				M96 Warning in the Manual: use correct diameter of needle guide insert			
C4.7.2 inaccurate production of the needle guide insert (FMEA line 3)				M72 incoming good inspections			
C4.7.3 usage of wrong needle guide insert				M97 inscription of diameter on the needle guide			

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

	Pre Mitigation				Post Mitigation		
Potential causes and sub causes	**Se**	**Pr**	**Risk**	**Mitigation Measures**	**Se**	**Pr**	**Risk**
(FMEA line 4)				insert M95 Warning in Manual: check the needle guidance over the whole needle length by testing the needle insert			
C4.8 wear of the components (neglect maintenance)	3	2	NAK	M98 Warning in the UM: obey maintenance and lifecycle times	3	1	ALARP
C4.9 falling of the HCU on the Joystick	3	3	NAK	M82 Enable switch M86 Emergency Stop	2	1	AK
C4.10 collision of the device with the imaging device (FMEA line 42)	3	3	NAK	M83 Warning in the UM: do not move the robot, when needle is inserted	2	1	AK
C4.11 breaking of the needle guide extensions	1	3	AK	M78 Test of mechanical stability	1	1	AK
C4.12 moving the needle with the insert when releasing it (FMEA line 15)	1	3	AK	M99 Warning in the UM: do not move the inserted needle when releasing the needle	1	2	AK
C4.13 Unintended opening of the MFA	3	2	NAK	M100 Warning in the UM: unintended opening of the MFA can lead to serious injuries.	3	1	ALARP
C5 Misuse of the device	3	3	NAK		3	1	ALARP
C5.1 use in MRI environment				M101 Warning in the UM: do not use in MRI environment M102 Labelling: not MRI-compatible			
C5.2 incorrect use of connectors				M103 Module detection M104 Labeling the connectors			
C5.3 mounting to loosened siderail				M76 UM/Workflow: correct setup and checks			
C5.4 touching the patients skin with the Robot							

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

	Pre Mitigation				Post Mitigation		
Potential causes and sub causes	**Se**	**Pr**	**Risk**	**Mitigation Measures**	**Se**	**Pr**	**Risk**
Unit							
C5.4.1 during setup				M75 Lightweight design M51 No sharp edges			
C5.4.2 while moving the Robot Unit				M105 Limited range of motion and forces M51 No sharp edges			
C5.5 neglect specified lifetime or maintenance				M98 Warning in the UM: obey maintenance and lifecycle times			
C5.6 applying a sterilization procedure				M106 Warning in the UM: do not sterilize the components of the iSYS 1			
C6 Sharp edges	2	3	ALARP	M75 Design: no sharp edges	2	1	AK
C7 Overhanging parts	1	3	AK	M75 Design: no sharp edges	1	2	AK
C8 Pinching of the patient while moving of the Robot Unit	1	3	AK	M105 Limited range of motion and forces	1	1	AK
C9 Covering the head with the sterile cover (MOF3)	1	2	AK		1	1	AK
C9.1 during setup				M107 Warning in the UM: do not cover the patient's face with the sterile cover			
C9.2 while moving the Robot Unit				M105 Limited range of motion of the robot unit			
C10 Strangulation with the cables (MOF3)	1	2	AK		1	1	AK
C10.1 standing on the cable				M108 Warning in the UM: do not stand on the cables M79 Streng relief			
C10.2 while moving the Robot Unit				M105 Limited range of motion and forces			
C11 Improper dismantling of the system (MOF3)	1	3	AK		1	1	AK

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

	Pre Mitigation				Post Mitigation		
Potential causes and sub causes	**Se**	**Pr**	**Risk**	**Mitigation Measures**	**Se**	**Pr**	**Risk**
C11.1 patient is standing up while Robot Unit is not completely dismantled				M76 UM/Workflow: correct setup and checks			
C11.2 Robot Unit or MFA is falling on the patient while dismantling				M75 Lightweight Design M76 UM/Workflow: correct setup and checks			
C12 Harming the patient with the moving Table Top Adapter	1	3	AK	M109 Design of the table adapters	1	1	AK
C13 Small plastic parts fall in the open wound of the patient	2	2	AK	M110 incoming goods inspection: needle insert free of burrs M111 Design of the needle insert	2	1	AK
C14 Due to collision of needles in case of multiple planning (pre-inserted needles)	2	4	NAK	M112 Warning in the UM: in case of multiple needle procedures, be aware the needles to not collide with another	2	2	AK
C15 Due to needle getting stuck in the quick release (FMEA line 34, 35)	2	2	AK	M113 Design: Possibility of either removing the needle or the needle guide insert M114 User Manual: check the free and easy movement of the needle in the insert	2	1	AK
C16 due to aging of components	3	2	NAK	M149 User Manual: define times for service and maintenance acc. to chapter 1	3	1	AK

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

H_P5 Harm due to Mistreatment

	Pre Mitigation				Post Mitigation		
Potential causes and sub causes	**Se**	**Pr**	**Risk**	**Mitigation Measures**	**Se**	**Pr**	**Risk**
Harming of healthy tissue due to wrong position of the needle leading to damaging healthy tissue or wrong diagnosis	3	3	NAK		3	1	ALARP
C1 Needle Guidance Insert gets loose							
C1.1 due to mechanical failure (breaking of components, FMEA line 19)				M115 Safety relevant components are tested and traced in the device history			
C2 Needle Guide Adapter gets loose due to mechanical failure							
C2.1 due to mechanical failure (breaking of components, FMEA line 19, 68, 69)				M115 Safety relevant components are tested traced in the device history			
C2.2 due to bad adoption by the user (FMEA 64-66) (MOF3)				M76UM/Workflow: correct setup and checks			
C3 Needle Guide Extension gets loose due to mechanical failure (FMEA line 59-63)				M116 Design: use of multiple screws			
C4 Parts in the robot unit are instable (FMEA line 46 – 50)				M115 Safety relevant components are tested traced in the device history			
C5 Due to movements of the patient (FMEA line 33)				M91Warning in the UM (“Adequate compliance and immobilization of the patient is necessary and in the responsibility of the physician”)			
C6 Due to movements of the target				M91Warning in the UM (“Planning, targeting and intervention in the same breathing phase, it is in the responsibility of the physician”)			
C7 Due to wrong movements of the robot unit (FMEA line 51)							
C7.1 mixing the cables				M103 Module detection M104 Labeling the connectors			

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

	Pre Mitigation				Post Mitigation		
Potential causes and sub causes	**Se**	**Pr**	**Risk**	**Mitigation Measures**	**Se**	**Pr**	**Risk**
C7.2 due to mechanical failure (breaking of components) in the robot unit				M85 Encoder comparison			
C7.3 due to failure in the electronic or software (FMEA line 107)				M82 Enable switch M84 Stationary check M85 Encoder check M87 Error handling within software M88 Watchdog			
C7.4 due to bad fixation at the table (FMEA line 43), (MOF3)				M76 UM/Workflow: correct setup and checks			
C7.5 due to unintended loosing of the fixation at the table (FMEA line 44)				M117 Design: self-locking lead screw M76 UM/Workflow: correct setup and checks			
C7.6 due to unintended movements by the user (FMEA line 105)							
C7.7 due to damage of the Control Unit by shortening the Outputs to the Robot Unit				M118 Test of shortening the Outputs to the Robot Unit			
C7.8 due to unintended movement of one Robotic Module while moving (intended) the other Robotic Module				M119 Design: Both - position and angulation - can be seen with the imaging device when verifying the correct targeting.			
C8 Due to artifacts of the robot unit (FMEA line 16, 29, 32)				M120 Test for artefacts			
C9 Due to electromagnetic interference				M1 Test according EN 60601-1-2			
C10 Due to badly manufactured parts (FMEA lines 20-23)				M115 Safety relevant components are tested and traced in the device history M121 Assembling instructions			
C10.1 due to inaccuracies at the markers on the marker inlay (FMEA line 17, 18)							
C10.2 due to inaccuracies in the clearance of the							

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

	Pre Mitigation				Post Mitigation		
Potential causes and sub causes	**Se**	**Pr**	**Risk**	**Mitigation Measures**	**Se**	**Pr**	**Risk**
parts (FMEA line 3)							
C10.3 due to inaccuracies in the diameter of the needle/instrument (FMEA line 5)							
C10.4 other parts							
C11 Due to bad inserting of the marker inlay or the needle guide insert in the needle guide adapter (FMEA lines 10, 18, 109), (MOF2)				M76 UM/Workflow: correct setup and checks			
C12 Due to bad connecting of the needle guide joints to the needle guide extensions and needle guide adapter (FMEA line 24), (MOF2)				M76 UM/Workflow: correct setup and checks			
C13 Due to wrong inserting of the needle guide marker inlay in the needle guide adapter				M122 Usability Test M123 User Training M76 UM/Workflow: correct setup and checks			
C14 Due to wrong alignment of the imaging device (entry point view)				M122 Usability Test M123 User Training M76 UM/Workflow: correct setup and checks			
C15 Due to bad/inaccurate planning of the trajectory				M123 User Training M76 UM/Workflow: correct setup and checks			
C16 Due to bad fine positioning of the marker when using the imaging device				M122 Usability Test M123 User Training M76 UM/Workflow: correct setup and checks			
C16.1 due to instabilities of the complete setup (FMEA line 41)				M122 Usability Test M123 User Training M76 UM/Workflow: correct setup and checks			
C17 Due to movements of the robot unit after fine positioning with the marker or while inserting the							

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

	Pre Mitigation				Post Mitigation		
Potential causes and sub causes	**Se**	**Pr**	**Risk**	**Mitigation Measures**	**Se**	**Pr**	**Risk**
needle							
C17.1 due to intended moving the robot unit after fine positioning				M83 Warning in the UM: do not move the robot, when needle is inserted			
C17.2 due to unintended moving the robot unit after fine positioning (FMEA line 53) with the HCU				M82 Enable switch M83 Warning in the UM: do not move the robot, when needle is inserted			
C17.3 due to bad/loose mechanical connections (FMEA lines 20-25, 55-58), (MOF2, 3)				M78 Test of mechanical stability M122 Usability Test M76 UM/Workflow: correct setup and checks			
C17.4 due to bad electrical signals (FMEA lines 102-104)				M85 Encoder check M124 Use of line drivers M84 Stationary check			
C17.5 due to bad software signals				M84 Stationary check M87 Error handling within software M88 Watchdog			
C18 Due to a stick-slip-effect on components				M125 Selection of appropriate materials / Data Sheets M126 Test of stick-slip effect			
C19 Due to bad communication in the intervention team (e.g. moving the robot unit while inserting the needle)				M122 Usability Test M123 User Training M76 UM/Workflow: correct setup and checks			
C20 Due to partially covering areas of interest on the patient with the robot unit (e.g. catheter)				M127 Warning in the UM: setup must not cover area of interest			
C21 Due to wrong/bad use of the needle while inserting in the patient (MOF2)				M122 Usability Test M123 User Training			

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

	Pre Mitigation				Post Mitigation		
Potential causes and sub causes	**Se**	**Pr**	**Risk**	**Mitigation Measures**	**Se**	**Pr**	**Risk**
				M76 UM/Workflow: correct setup and checks			
C21.1 due to radial forces on the needle when penetrating the skin							
C21.2 due to collision with harder tissue/substances (artificial or natural) inside the patient							
C21.3 due to sticking of the needle in the insert (FMEA line 13)							
C21.4 touching the needle with the insert when releasing it (FMEA line 15)							
C22 Due to positioning the robot unit in a way, that the needle does not reach the point of interest (MOF1)				M122 Usability Test M123 User Training M76 UM/Workflow: correct setup and checks			
C22.1 due to positioning the robot to far from the patient's skin							
C22.2 due to misinterpretation of the inserting depth of the needle							
C23 Due to covering the signal LEDs on the control unit and thus not realizing the alarm (MOF5)				M128 Acoustic alarm M129 Activation of emergency stop state in case of a serious error M130 Warning in the UM: do not cover the display or the front panel of the control unit			
C24 Due to misinterpretation of the signal LEDs on the control unit and thus not realizing the alarm (MOF5)				M131 Colors according EN 60601-1-8 M128 Acoustic alarm M129 Activation of emergency stop state in case of a serious error			
C25 Unintended movement after fine positioning and							

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

	Pre Mitigation				Post Mitigation		
Potential causes and sub causes	**Se**	**Pr**	**Risk**	**Mitigation Measures**	**Se**	**Pr**	**Risk**
before inserting the needle							
C25.1 unintended movement of the Robot Unit							
C25.1.1 by using the HCU (FMEA line 101), (MOF1)				M82 Enable switch M132 Warning in the UM: do not move the robot after positioning			
C25.1.2 by malfunction of control components/electronic components				M133 All safety relevant systems are redundant systems			
C25.1.3 by software error				M84 Stationary check M87 Error handling within software M88 Watchdog			
C25.1.4 by breaking of mechanical components (FMEA line 19)				M78 Test of mechanical stability			
C25.1.5 by electromagnetic interference of other devices (FMEA line 103)				M1 the device is designed to comply with the relevant standards (IEC 60601-1-2)			
C25.1.6 environmental conditions (short circuit due to humidity)				M1 the device is designed to comply with the relevant standards (IEC 60601-1-2)			
C25.1.7 due to malfunction of electronic components due to X-Ray radiation of the imaging device				M85 safety circuit “encoder comparison” M84 safety circuit “stationary check” M134 software positioning check M8 Literature			
C25.2 unintended movement of the table				M89 Mechanical Design: Robot + Adapter + Table is one Unit M90 Warning User Manual: table must be fixed and not move			
C25.3 movement of the patient (e.g. breathing)				M91 Warning in the UM (“Adequate compliance and immobilization of the patient is necessary and			

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

	Pre Mitigation				Post Mitigation		
Potential causes and sub causes	**Se**	**Pr**	**Risk**	**Mitigation Measures**	**Se**	**Pr**	**Risk**
				in the responsibility of the physician”)			
C25.4 using the device as an arm rest				M78 Test of mechanical stability M92 Warning in the UM: do not misuse the iSYS 1 as an armrest or tablet			
C25.5 accidental pushing of the device				M78 Test of mechanical stability M93 Warning in the UM: do not accidental push the device, in case repeat imaging			
C25.6 falling of the control unit and thus pulling on the cables				M94 Secure locking mechanism of control unit M78 Test of mechanical stability M79 Strain relief for cables			
C25.7 loose mechanical connection (FMEA lines 20-25, 30, 31), (MOF3)				M76 UM/Workflow: correct setup and checks M94 Design of the needle insert (User can check the needle guidance over the whole needle length by testing the needle insert) M95 Warning in Manual: check the needle guidance over the whole needle length by testing the needle insert			
C25.8 wear of the components (neglect maintenance)				M98 Warning in the UM: obey maintenance and lifecycle times			
C25.9 falling of the HCU on the Joystick (MOF1)				M82 Enable switch M86 Emergency Stop			
C25.10 collision of the device with the imaging device (FMEA line 42)				M81 Do not move the imaging device while the needle is inserted			
C25.11 breaking of the needle guide extensions (FMEA line 19)				M78 Test of mechanical stability			
C26 Using a needle/instrument not appropriate to the				M97 inscription of diameter on the needle guide			

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

	Pre Mitigation				Post Mitigation		
Potential causes and sub causes	**Se**	**Pr**	**Risk**	**Mitigation Measures**	**Se**	**Pr**	**Risk**
needle guide insert (FMEA line 4)				insert M96 Warning in the Manual: use correct diameter of needle guide insert			
Harm due to additional imaging procedures (additional radiation)	2	3	ALARP	M122 Usability Test M123 User Training M76 UM/Workflow: correct setup and checks	2	2	AK
C27 Fine positioning or imaging takes too long/longer or must be repeated							
C27.1 due to untrained personnel							
C27.2 due to wrong speed level (FMEA line 72-74)							
C27.3 due to wrong mode of movement							
C27.4 due to misinterpretation of the direction of movement (MOF5)							
C27.5 due to wrong pre-positioning of the robot unit and thus not reaching the point of interest (MOF3)							
C27.6 due to technical failure (FMEA lines 75, 99, 100)							
C27.7 due to emergency stop or reboot of the iSYS1 (FMEA lines 83-91)							
C27.7.1 due to misinterpretation of an alarm (MOF5)							
C27.7.2 due to unintended switching off (FMEA lines 76-78)							
C27.7.3 due to unintended plugging off (FMEA lines 95, 108)							
C27.8 due to not reaching the region of interest							

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

	Pre Mitigation				Post Mitigation		
Potential causes and sub causes	**Se**	**Pr**	**Risk**	**Mitigation Measures**	**Se**	**Pr**	**Risk**
with the robot (gross positioning)							
C27.9 due to patient movement and thus restarting the procedure							
C27.10 due to overcomplicated workflow or wrong workflow (e.g. sterilization during planning)							
C27.11 due to missing of the right accessories (e.g. wrong needle guide insert)							
C27.12 due to short power cord/cable and additional setup							
C27.13 due to failures in the display (FMEA lines 79-82), (MOF5)							
C28 due to aging of components	3	2	NAK	M149 User Manual: define times for service and maintenance acc. to chapter 1	3	1	AK

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Hazards to the operator

H_O1 Harm due to Electrical Shock

	Pre Mitigation				Post Mitigation		
Potential causes and sub causes	**Se**	**Pr**	**Risk**	**Mitigation Measures**	**Se**	**Pr**	**Risk**
C1 Due to cabling							
C1.1 due to EMC problems (FMEA line 70)	2	4	NAK	M1 Test according to IEC 60601-1-2 M2 construction: defined length of cables	2	1	AK
C1.2 due to missing grounding (FMEA line 71)	3	2	NAK	M3 periodically inspection in the clinic (user / service manual) M4 safe connection to housing M5 contact surfaces on each component	3	1	ALARP
C1.3 due to damages caused by mechanical or chemical influences (power supply)	3	2	NAK	M6 Reinforced and/or double insulation and/or class I housing (see technical drawings for details) M7 Warning in UM	3	1	ALARP
C1.4 due to damages caused by mechanical or chemical influences (data cable, HCU cable)	1	3	AK	M6 Reinforced and/or double insulation and/or class I housing (see technical drawings for details) M7 Warning in UM	1	1	AK
C1.5 due to damages by X-Ray radiation of the imaging device (power supply)	3	1	AK	M8 Literature / Data Sheets	3	1	ALARP
C1.6 due to damages by X-Ray radiation of the imaging device (data cable, HCU cable)	1	1	AK	M8 Literature / Data Sheets	1	1	AK
C2 Due to wrong power supply of components (FMEA lines 91-94, 96-98)	3	4	NAK	M9 Test according to IEC 60601-1 M10 Usage of wide range power supply unit M11 Fuses for high current M12 Alarm due to voltage watchdog	2	1	NAK

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

	Pre Mitigation				Post Mitigation		
Potential causes and sub causes	**Se**	**Pr**	**Risk**	**Mitigation Measures**	**Se**	**Pr**	**Risk**
				M13 LED “ready-to-use” ceases			
C3 Failure in the power supply unit	3	4	NAK	M11 Fuses for high current M6 class 1 housing for the control unit M14 Overvoltage protection in the power supply (schematics should be provided to TÜV by Traco)	2	1	NAK
C4 Housing of control unit not sufficiently grounded and voltage on touchable parts (230V)	3	4	NAK	M15 Grounding pins on every part M5 contact surfaces on each component	3	1	ALARP
C5 Power supply cable of the control unit gets damaged and touches the secondary circuit							
C5.1 on the 24V cabling	3	1	NAK	M16 usage of varistor and Schottky Zener diode (30V)	2	1	AK
C5.2 on the Power Led cable	3	2	NAK	M17 direct connection of the Power LED to the output of the Power Supply M16 usage of varistor and Schottky Zener diode (30V)	2	1	AK
C5.3 on the PEC	3	2	NAK	M18 Construction with dividing plate M2 defined length of cabling preventing M6 class 1 housing for the control unit M11 Fuses for high current	3	1	ALARP
C6 Due to condensed water in the devices	3	2	NAK	M19 Definition of operating, storage and transport conditions M6 Class1 housing of control unit M9 air clearance and creepage distance acc. to IEC 60601-1 M20 User Manual: if transported outside the	2	1	ALARP

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

	Pre Mitigation				Post Mitigation		
Potential causes and sub causes	**Se**	**Pr**	**Risk**	**Mitigation Measures**	**Se**	**Pr**	**Risk**
				specification, time for drying defined.			
C7 Due to spilling on the device	3	3	NAK	M9 Test acc. to IEC 60601-1 M6 Class1 housing of control unit M21 Construction: openings on the bottom side M22 UM/Workflow: covering by sterile cover	2	1	AK
C8 Due to rests of disinfection liquids (MOF4)	3	4	NAK	M23 UM/Workflow: drying after disinfection and cleaning M6 Class1 housing of control unit M9 Test acc. to IEC 60601-1 M21 Construction: openings on the bottom side	2	1	AK
C9 Due to fluids getting into the housing							
C9.1 of the control unit	3	4	NAK	M9 Test acc. to IEC 60601-1 M6 Class1 housing of control unit M21 Construction: openings on the bottom side	2	1	AK
C9.2 of the robot unit	1	3	AK	M9 Test acc. to IEC 60601-1 M24 Low voltage power supply (6,5V) M22 UM/Workflow: covering by sterile cover	1	1	AK
C9.3 of the HCU	1	3	AK	M9 Test acc. to IEC 60601-1 M25 Low voltage power supply (24V)	1	1	AK
C10 Due to overheating of components and, thus, malfunction of components	1	2	AK	M9 Test for overheating (IEC 60601-1)	2	1	AK
C11 Due to overvoltage in the mains supply	3	2	NAK	M1 Test according to IEC 60601-1-2 M14 Overvoltage protection in the power supply (schematics should be provided to TÜV by Traco)	1	1	AK

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

	Pre Mitigation				Post Mitigation		
Potential causes and sub causes	**Se**	**Pr**	**Risk**	**Mitigation Measures**	**Se**	**Pr**	**Risk**
C12 loose cabling in the Robot Unit	1	3	AK	M26 insulated housing	1	1	AK
C13 breaking of the housing	3	1	ALARP	M9 Test according to IEC 60601-1	1	1	AK
C14 loose connector of Cable (MOF3)							
C14.1 between Control Unit and Robot Unit	1	3	NAK	M27 construction of plugs, pins not reachable M28 Warning in the UM: check connections between components M29 Workflow/UM: first all components connected to each other, then main power supply	1	1	AK
C14.2 between Control Unit and HCU	1	3	NAK	M27 construction of plugs, pins not reachable M28 Warning in the UM: check connections between components M29 Workflow/UM: first all components connected to each other, then main power supply	1	1	AK
C14.3 Mains cable	3	2	NAK	M27 construction of plugs, pins not reachable M28 Warning in the UM: check connections between components M29 Workflow/UM: first all components connected to each other, then main power supply	3	1	AK
C16 touching the circuits in the Robot Unit, due to loose/broken covering band	1	2	NAK	M9 distance to circuits acc. IEC 60601-1 M31 User Manual: never touch inside components	1	1	AK
C17 touching a metallic part inside the Robot Unit, due to loose/broken covering band and single fault condition in the insulation of the circuits of the Robot Unit	1	2	NAK	M31 User Manual: never touch inside components M32 construction: covering (warning color) the front side of the robot unit	1	1	AK
C18 use of wrong power supply cable				M135 Warning in User Manual: only use provided components, never use accessories that are			

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

	Pre Mitigation				Post Mitigation		
Potential causes and sub causes	**Se**	**Pr**	**Risk**	**Mitigation Measures**	**Se**	**Pr**	**Risk**
				not cleared by iSYS			
C20 use of damaged components				M136 User Manual: Warning, never operate damaged components			
C21 due to wrong re-assembling after service	1	2	NAK	M33 Service Manual: provide checklist after service (Technical Safety Check)	1	1	AK
C22 due to aging of components	3	2	NAK	M149 User Manual: define times for service and maintenance acc. to chapter 1	3	1	AK

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

H_O2 Harm due to Infection

Statement: **There is no increased risk due to infection by the use of iSYS 1 for the operator compared with not using this system.**	**Pre Mitigation**				**Post Mitigation**		
Potential causes and sub causes	**Se**	**Pr**	**Risk**	**Mitigation Measures**	**Se**	**Pr**	**Risk**
C1 by re-use of single use, sterile parts (FMEA line 6)			n.a.				
C2 Use of inappropriate accessories (sterile, single-use parts)			n.a.				
C3 Improper cleaning and disinfection of the device			n.a.				
C4 Improper dismantling of the system			n.a.				
C5 Mechanical injury of the user leading to infections			n.a.				
C6 Device is strongly contaminated during manufacturing and, thus, cannot be disinfected properly			n.a.				

- Since the use of the iSYS1 requires installation by the operator, and since human errors cannot be excluded completely, some residual risks remain in case of human error. However, this reflects the current state of the art and further mitigation is not practicable.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

H_O3 Harm due to Burning

	Pre Mitigation				Post Mitigation		
Potential causes and sub causes	**Se**	**Pr**	**Risk**	**Mitigation Measures**	**Se**	**Pr**	**Risk**
C1 by touching the hot surface of the:	2	2	AK	C1.1 to C1.4: M11 Fuses for high current M9 Test according to IEC 60601-1	1	1	AK
C1.1 Robot Unit							
C1.2 Control Unit							
C1.3 HCU							
C1.4 Cables							
C2 by burning of the device (flames)	2	2	AK	C2.1 to C2.5: M11 Fuses for high current	1	1	AK
C2.1 Robot Unit due to electrical overheating							
C2.2 Control Unit due to electrical overheating							
C2.3 Control Unit, when standing on the bottom surface and thus blocking the air convention				M74 Mounting the CU if there is no siderail available			
C2.4 HCU due to electrical overheating							
C2.5 Cables due to electrical overheating							
C3 by hot liquids running out of the robot unit	2	2	AK	M11 Fuses for high current M9 Test according to IEC 60601-1	1	1	AK
C4 by residuals of disinfection and cleaning agents inflamed by a spark	2	2	AK	M23 UM/Workflow: drying after disinfection and cleaning	1	1	AK

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

H_O4 Harm due to Mechanical Injury

	Pre Mitigation				Post Mitigation		
Potential causes and sub causes	**Se**	**Pr**	**Risk**	**Mitigation Measures**	**Se**	**Pr**	**Risk**
C1 falling of the control unit (MOF3)							
C1.1 due to bad fixing at the siderail (FMEA line 36)	2	3	ALARP	M94 Secure locking mechanism of control unit M78 Test of mechanical stability M79 Strain relief for cables	2	2	AK
C1.2 due to unintended loosing (FMEA line 37)	2	3	ALARP	M94 Secure locking mechanism of control unit M78 Test of mechanical stability M79 Strain relief for cables	2	2	AK
C1.3 due to instable siderail (FMEA line 39, 40)	2	2	AK	M140 User Manual: siderail must be safe and rigid	2	2	AK
C1.4 due to persons tripping over power cable/ HCC cable	2	3	ALARP	M78 Test of mechanical stability	2	2	AK
C2 Falling of the robot unit on the user due to pulling at the cable	1	3	AK	M78 Test of mechanical stability M79 Strain relief for cables	1	1	AK
C3 Falling of the device on the user due to pushing of the device with the moving imaging device	2	3	ALARP	M81 Warning in the UM: be aware the imaging device does not hit the iSYS 1	2	2	AK
C4 Misuse of the device							
C4.1 neglect specified lifetime or maintenance	1	2	AK	M98 Warning in the UM: obey maintenance and lifecycle times	1	1	AK
C4.2 applying a sterilization procedure	1	2	AK	M106 Warning in the UM: do not sterilize the components of the iSYS 1	1	1	AK
C5 Sharp edges	2	3	ALARP	M75 Design: no sharp edges	2	1	AK
C6 Overhanging parts	1	3	AK	M75 Design: no sharp edges	1	2	AK
C7 Improper dismantling of the system, components	1	3	AK	M122 Usability Test	1	2	AK

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

	Pre Mitigation				Post Mitigation		
Potential causes and sub causes	**Se**	**Pr**	**Risk**	**Mitigation Measures**	**Se**	**Pr**	**Risk**
are falling on the user (MOF3)				M123 User Training M76 UM/Workflow: correct setup and checks			
C8 Harming the operator with the moving Table Top Adapter	1	3	AK	M122 Usability Test M123 User Training M76 UM/Workflow: correct setup and checks	1	2	AK
C9 Harm to user due to getting exposed to radiation	2	3	ALARP	M122 Usability Test M123 User Training M76 UM/Workflow: correct setup and checks	2	1	AK
C10 due to aging of components	3	2	NAK	M149 User Manual: define times for service and maintenance acc. to chapter 1	3	1	AK

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

H_O5 Harm due to Ergonomics

	Pre Mitigation				Post Mitigation		
Potential causes and sub causes	**Se**	**Pr**	**Risk**	**Mitigation Measures**	**Se**	**Pr**	**Risk**
C1 falling of the control unit (MOF3)	2	2	AK		2	1	AK
C1.1 due to bad fixing at the siderail (FMEA line 36)				M94 Secure locking mechanism of control unit M78 Test of mechanical stability M79 Strain relief for cables			
C1.2 due to unintended loosing (FMEA line 37)				M94 Secure locking mechanism of control unit M78 Test of mechanical stability M79 Strain relief for cables			
C1.3 due to instable siderail (FMEA line 39, 40)				M140 User Manual: siderail must be safe and rigid			
C2 due to weight of the complete system including packaging (transport case)	2	2	AK	M141 Warning in the UM (“Do not lift alone”) M142 Label of weight on packaging	2	1	AK

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Hazards to other persons, e.g. service technician

H_O1 Harm due to Electrical Shock

Additional risks for other persons

	Pre Mitigation				Post Mitigation		
Potential causes and sub causes	**Se**	**Pr**	**Risk**	**Mitigation Measures**	**Se**	**Pr**	**Risk**
C1 due to opening the housings when still connected to the main supply	3	3	NAK	M137 Warning in Service Manual: first step, disconnect from main supply M138 Labeling: label on the components: disconnect from main supply before opening	3	1	ALARP
C2 due to service measures that are done while the components are connected to the main supply	3	3	NAK	M139 Service Manual: measures are only to be performed by an electrically qualified person	3	1	ALARP

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Generic hazards

H_X1 Interference with other medical devices

	Pre Mitigation				Post Mitigation		
Potential causes and sub causes	**Se**	**Pr**	**Risk**	**Mitigation Measures**	**Se**	**Pr**	**Risk**
C1 Unpredictable malfunction of the device due to electromagnetic irradiation or disturbances on power line	3	3	NAK	M1 the device is designed to comply with the relevant standards (IEC 60601-1-2)	2	1	ALARP
C2 due to aging of components	3	2	NAK	M149 User Manual: define times for service and maintenance acc. to chapter 1	3	1	AK

H_X2 Malfunction of other devices

	Pre Mitigation				Post Mitigation		
Potential causes and sub causes	**Se**	**Pr**	**Risk**	**Mitigation Measures**	**Se**	**Pr**	**Risk**
C1 markings on the needle get rubbed off when guided through the needle insert	1	1	AK	n.a.	1	1	AK
C2 Blocking the movement of the patient table	1	3	AK	M143 User Manual: be aware that the setup does not block intended movements of the table	1	2	AK
C3 Collision of the system with the imaging device	1	3	AK	M91	1	2	AK
C4 Blunting of the needle tip while inserting into the NG Insert	1	3	AK	M144 Design: use appropriate material that does not cause wear on the needle	1	1	AK

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

H_X3 Environmental hazards

	Pre Mitigation				Post Mitigation		
Potential causes and sub causes	**Se**	**Pr**	**Risk**	**Mitigation Measures**	**Se**	**Pr**	**Risk**
C1 Toxic materials used in construction could be hazardous waste when disposed	*	*	*	M145 Avoidance of highly toxic materials M146 User Manual: do not litter in domestic waste M147 User Manual: apply to local and national regulations according to disposal of electronic waste M148 Labeling: use label for “do not litter in domestic waste”	*	*	*

* For environmental hazards the quantification in terms of hazard severity and probability is not practicable.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

9 Summary of Mitigations

The Summary of Mitigations summarizes all mitigations of the risk analysis and evaluation including the dates when they have been added. This summary is forwarded to “FO_73_2553_PD-B06_RiskContr” where the mitigations are traced to hazards and causes mapped or applicable product specification/requirements.

Mitigation Measure in RA	Added (Date)
M1 Test according to IEC 60601-1-2	2011-05-12
M2 construction: defined length of cables	2011-05-12
M3 periodically inspection in the clinic (user / service manual)	2011-05-12
M4 safe connection to housing	2011-05-12
M5 contact surfaces on each component	2011-05-12
M6 Reinforced and/or double insulation and/or class I housing	2011-05-12
M7 Warning in UM	2011-05-12
M8 Literature / Data Sheets	2011-05-12
M9 Test according to IEC 60601-1	2011-05-12
M10 Usage of wide range power supply unit	2011-05-12
M11 Fuses for high current	2011-05-12
M12 Alarm due to voltage watchdog	2011-05-12
M13 LED “ready-to-use” ceases	2011-05-12
M14 Overvoltage protection in the power supply	2011-05-12
M15 Grounding pins on every part	2011-05-12
M16 usage of varistor and Schottky Zener diode (30V)	2011-05-12
M17 direct connection of the Power LED to the output of the Power Supply	2011-05-12
M18 Construction with dividing plate	2011-05-12
M19 Definition of operating, storage and transport conditions	2011-05-12
M20 User Manual: if transported outside the specification, time for drying defined.	2011-05-12
M21 Construction: openings on the bottom side	2011-05-12
M22 UM/Workflow: covering by sterile cover	2011-05-12
M23 UM/Workflow: drying after disinfection and cleaning	2011-05-12
M24 Low voltage power supply (6,5V)	2011-05-12
M25 Low voltage power supply (24V)	2011-05-12

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

M26 insulated housing	2011-05-12
M27 construction of plugs, pins not reachable	2011-05-12
M28 Warning in the UM: check connections between components	2011-05-12
M29 Workflow/UM: first all components connected to each other, then main power supply	2011-05-12
M30 insulation of the patient connection	2011-05-12
M31 User Manual: never touch inside components	2011-05-12
M32 construction: covering (warning color) the front side of the robot unit	2011-05-12
M33 Service Manual: provide checklist after service (Technical Safety Check)	2011-05-12
M34 Combining the sterile cover with the Needle Guide Adapter	2011-05-12
M35 Labelling: single use, sterile	2011-05-12
M36 Warning in the UM: single use, sterile, misuse	2011-05-12
M37 Chemical and mechanical Tests (websinger)	2011-05-12
M38 Redundant fixation of the sterile cover to the joints (glue and mechanical shim)	2011-05-12
M39 Qualified supplier for manufacturing	2011-05-12
M40 Special assembling tool + Sampling inspection of components	2011-05-12
M41 Using a sterile cover for the robot unit	2011-05-12
M42 Warning in the UM: never touch non-sterile components and the sterile area	2011-05-12
M43 Disinfection of the robot unit prior to its use	2011-05-12
M44 Using a sterile cover for the MFA	2011-05-12
M45 Disinfection of the MFA prior to its use	2011-05-12
M46 Disinfection of the HCU prior to its use	2011-05-12
M47 Using a sterile cover for the HCC	2011-05-12
M48 Test for opening of the MFA with attached sterile cover	2011-05-12
M49 Warning in the UM: Do not continue procedure if cover is damaged	2011-05-12
M50 Use of robust material for the sterile cover	2011-05-12
M51 Avoid sharp edges in the design of outside surfaces	2011-05-12
M52 Design of packaging (easy opening)	2011-05-12

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

M53 Selection of compatible of tapes at the sterile cover	2011-05-12
M54 Test of tapes at the sterile cover	2011-05-12
M55 Components inside the cover are disinfected	2011-05-12
M56 Design of the cover (wide enough)	2011-05-12
M57 Test for moving the robot unit with sterile cover	2011-05-12
M58 Appropriate packing of the cover	2011-05-12
M59 Test for mounting the needle guide joints	2011-05-12
M60 UM: Description of the right use and the workflow of the sterile cover	2011-05-12
M61 UM: Defining of allowed accessories	2011-05-12
M62 Warning in the UM: The use of any other accessory is restricted or forbidden	2011-05-12
M63 Warning in the UM: Do not touch sterile cover with the HCU cabling.	2011-05-12
M64 Warning in the UM: The patient must not touch sterile cover	2011-05-12
M65 Workflow/UM (sterile / non-sterile area)	2011-05-12
M66 Construction: Minimal use/disuse of fluids and additives	2011-05-12
M67 User Manual: Disinfection and cleaning of components prior to use	2011-05-12
M68 Mounting of control unit thus no direct airflow to the patient occurs	2011-05-12
M69 Small fan	2011-05-12
M70 Use of standardized disinfection and cleaning procedures	2011-05-12
M71 Description in the UM: setup and demounting	2011-05-12
M72 Incoming inspection of supplied parts	2011-05-12
M73 Clean manufacturing rooms	2011-05-12
M74 Mounting the CU if there is no siderail available	2011-05-12
M75 Lightweight design	2011-05-12
M76 UM/Workflow: correct setup and checks	2011-05-12
M76 UM/Workflow: Test of fixation during setup	
M76 UM/Workflow: Test of fixation at the table	
M77 Warning in the UM	2011-05-12
M78 Test for mechanical stability of MFA	2011-05-12
M79 Strain relief for cables	2011-05-12

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

M80 Warning in the UM	2011-05-12
M81 Warning in the UM: be aware the imaging device does not hit the iSYS 1	2011-05-12
M82 Enable switch	2011-05-12
M83 Warning in the UM: do not move the robot, when needle is inserted	2011-05-12
M84 Stationary check	2011-05-12
M85 Encoder check	2011-05-12
M86 Emergency stop	2011-05-12
M87 Error handling within software	2011-05-12
M88 Watchdog	2011-05-12
M89 Mechanical Design: Robot + Adapter + Table is one Unit	2011-05-12
M90 Warning User Manual: table must be fixed and not move	2011-05-12
M91 Warning in the UM (“Adequate compliance and immobilization of the patient is necessary and in the responsibility of the physician”)	2011-05-12
M92 Warning in the UM: do not misuse the iSYS 1 as an armrest or tablet	2011-05-12
M93 Warning in the UM: do not accidental push the device, in case repeat imaging	2011-05-12
M94 Secure locking mechanism of control unit	2011-05-12
M95 Warning in Manual: check the needle guidance over the whole needle length by testing the needle insert	2011-05-12
M96 Warning in the Manual: use correct diameter of needle guide insert	2011-05-12
M97 inscription of diameter on the needle guide insert	2011-05-12
M98 Warning in the UM: obey maintenance and lifecycle times	2011-05-12
M99 Warning in the UM: do not move the inserted needle when releasing the needle	2011-05-12
M100 Warning in the UM: unintended opening of the MFA can lead to serious injuries.	2011-05-12
M101 Warning in the UM: do not use in MRI environment	2011-05-12
M102 Labelling: not MRI-compatible	2011-05-12
M103 Module detection	2011-05-12
M104 Labeling the connectors	2011-05-12
M105 Limited range of motion and forces	2011-05-12

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

M106 Warning in the UM: do not sterilize the components of the iSYS 1	2011-05-12
M107 Warning in the UM: do not cover the patient's face with the sterile cover	2011-05-12
M108 Warning in the UM: do not stand on the cables	2011-05-12
M109 Design of the table adapters	2011-05-12
M110 incoming goods inspection: needle insert free of burrs	2011-05-12
M111 Design of the needle insert	2011-05-12
M112 Warning in the UM: in case of multiple needle procedures, be aware the needles to not collide with another	2011-05-12
M113 Design: Possibility of either removing the needle or the needle guide insert	2011-05-12
M114 User Manual: check the free and easy movement of the needle in the insert	2011-05-12
M115 Safety relevant components are tested and traced in the device history	2011-05-12
M116 Design: use of multiple screws	2011-05-12
M117 Design: self-locking lead screw	2011-05-12
M118 Test of shortening the Outputs to the Robot Unit	2011-05-12
M119 Design: Both - position and angulation - can be seen with the imaging device when verifying the correct targeting	2011-05-12
M120 Test for artefacts	2011-05-12
M121 Assembling instructions	2011-05-12
M122 Usability Test	2011-05-12
M123 User Training	2011-05-12
M124 Use of line drivers	2011-05-12
M125 Selection of appropriate materials / Data Sheets	2011-05-12
M126 Test of stick-slip effect	2011-05-12
M127 Warning in the UM: setup must not cover area of interest	2011-05-12
M128 Acoustic alarm	2011-05-12
M129 Activation of emergency stop state in case of a serious error	2011-05-12
M130 Warning in the UM: do not cover the display or the front panel of the control unit	2011-05-12
M131 Colors according EN 60601-1-8	2011-05-12
M132 Warning in the UM: do not move the robot after positioning	2011-05-12

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

M133 All safety relevant systems are redundant systems	2011-05-12
M134 software positioning check	2011-05-12
M135 Warning in User Manual: only use provided components, never use accessories that are not cleared by iSYS	2011-05-12
M136 User Manual: Warning, never operate damaged components	2011-05-12
M137 Warning in Service Manual: first step, disconnect from main supply	2011-05-12
M138 Labeling: label on the components: disconnect from main supply before opening	2011-05-12
M139 Service Manual: measures are only to be performed by an electrically qualified person	2011-05-12
M140 User Manual: siderail must be safe and rigid	2011-05-12
M141 Warning in the UM (“Do not lift alone”)	2011-05-12
M142 Label of weight on packaging	2011-05-12
M143 User Manual: be aware that the setup does not block intended movements of the table	2011-05-12
M144 Design: use appropriate material that does not cause wear on the needle	2011-05-12
M145 Avoidance of highly toxic materials	2011-05-12
M146 User Manual: do not litter in domestic waste	2011-05-12
M147 User Manual: apply to local and national regulations according to disposal of electronic waste	2011-05-12
M148 Labeling: use label for “do not litter in domestic waste”	2011-05-12
M149 User Manual: define times for service and maintenance acc. to chapter 1	2012-08-21

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Substantial Equivalence Discussion

Device Comparison Table:

Reference	Frameless Neuromate	ROSA Surgical Device	iSYS 1 (for new submission)	Equivalence ?
510k-Number	K991081	K101791	K131433	
Manufacturer	INTEGRATED SURGICAL SYSTEMS, INC. 1850 Research Park Dr. Davis, CA 95616 USA	Medtech Surgical Inc. 211 Warren Street Suite 306 Newark, NJ 07103 USA	Submitter	
Design				
General device description	Computer controlled electromechanical multi-joined arm indicated for use as a stereotactic instrument	Computer controlled electromechanical multi-joined arm indicated for use as a stereotactic instrument	Computer controlled electromechanical multi-joined arm indicated for invasive procedures	Yes
Localization means	Robot arm absolute encoders	Robot arm absolute encoders	Fiducial markers on tool holder.	*)5
Image-guided	Yes	Yes	Yes	Yes
Planning software	No (third party)	Yes	No (third party)	*1)
Registration method	Bone-mounted ultrasound device	Fiducial markers Optical registration device	Fiducial markers	*6)
Instrumen-tation	Laser pointer Tool Holder	Navigation probe Laser pointer Tool Holder	Marker Tool Holder Sterile Covers (third party)	Yes
Instrument fixation	Instruments are mounted onto robot arm	Instruments are mounted onto robot arm	Special tool holders for several applications mounted to the Robot	Yes

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Reference	Frameless Neuromate	ROSA Surgical Device	iSYS 1 (for new submission)	Equivalence ?
Instrument calibration	Factory Calibration	Factory Calibration	Intra operative	*2)
System immobilization between patient and device	Yes	Yes	Yes	Yes
Planning and Navigation Software				
N/A.				
System Operation				
Fiducial markers registration with pointer probe	No.	Yes.	No.	*3)
Optical registration	No.	Yes.	No.	*3)
Ultrasound Registration	Yes.	No.	No.	*3)
Accuracy verification	Yes, laser pointer.	Yes, navigation probe, laser beam.	Yes, performed by user	Yes
Provide mechanical guidance for tools	Yes.	Yes.	Yes.	Yes
Instrument guide position adjustment	Automatic.	Automatic.	Manual.	*7)
Surgeon carries out final gesture through tool guide	Yes.	Yes.	Yes.	Yes
Indications for Use				
Indication for use	Stereotactic spatial positioning and orientation of an	Intended to be used in the operating room for the spatial	The intended use of the iSYS1 device is to function as a	*4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Reference	Frameless Neuromate	ROSA Surgical Device	iSYS 1 (for new submission)	Equivalence ?
	instrument holder or tool guide to be used by a surgeon to manually guide standard neurosurgical instruments (biopsy needle, stimulation or recording electrode, endoscope).	positioning and orientation of an instrument holder or tool guide, The system is intended to be used by neurosurgeons to guide standard neurosurgical instruments (biopsy needle, stimulation or recording electrode, endoscope). Indicated for any neurosurgical condition in which the use of stereotactic surgery may be appropriate.	remote-operated positioning and guidance system during interventional procedures. Positioning is done in remote control manner; planning of the position/angulation is done based on 2D/3D patient data (CT, cone-beam CT, fluoroscopy) by external planning software – for example using an external navigation system, or planning software coming with the used imaging device. Also verification of the correct position and orientation of the tool prior to/during/after the intervention is done by means of these external devices. The iSYS1-System is then acting as a guideway during the manual insertion of the interventional tool – usually a needle type device, and the like. Applications include, but are not limited to,	

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Reference	Frameless Neuromate	ROSA Surgical Device	iSYS 1 (for new submission)	Equivalence ?
			interventions like biopsy procedures, tumor ablation, nerve blocking, electrode placement, etc.	
Anatomical site	Head	Head	total body	*4)
User	Neurosurgeon	Neurosurgeon	Surgeon	*4)
Accessory	Sterile drapes	Sterile drapes Fiducial markers Head Holder Light source	Sterile Covers Table Adapters Cable Sets	Yes
Real-time instrument position	Yes	Yes	Yes	Yes
Mechanical Guidance of instruments	Yes	Yes	Yes	Yes
Technology				
Powered	Yes	Yes	Yes	Yes
CE-Conformity	Yes	Yes	Yes	Yes
Computer-controlled	Yes	Yes	Yes	Yes
Materials	Metal, electronics and plastics	Metal, electronics and plastics	Metal, electronics Polyamide Polyethylene Bralen	Yes

Similarities and Differences:

All three devices are intraoperative instruments used by surgeons for assisting the spatial positioning and orientation of a surgical tool.

iSYS 1 is equivalent to:

- Frameless Neuromate and ROSA Surgical Device for assisting the spatial positioning and orientation of a surgical tool.
- Frameless Neuromate and ROSA Surgical Device for being localized by the navigation or imaging software.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

- Frameless Neuromate and ROSA Surgical Device for being guided by an imaging device
- Frameless Neuromate and ROSA Surgical Device for providing a registration method for the imaging device.
- Frameless Neuromate and ROSA Surgical Device for instrumentation and instrument fixation.
- Frameless Neuromate and ROSA Surgical Device for being immobilized in relation to the patient.
- Frameless Neuromate and ROSA Surgical Device for providing accuracy verification, tool guidance and position adjustment.
- Frameless Neuromate and ROSA Surgical Device for the physician making the final gesture.
- Frameless Neuromate and ROSA Surgical Device for having the same indications for use, but on a wider field of application for the iSYS 1 (ROI).
- Frameless Neuromate and ROSA Surgical Device for having similar technology.

Non-clinical testing has mainly been performed to prove electrical and mechanical safety of the devices. Similar to the predicate devices, iSYS 1 was tested according to EN ISO 60601-1 2nd edition:

- EN 60601-1:1990 + A1:1993 + A2:1995
- EN 60601-1-8:2004 + A1:2006

The Electromagnetic Compatibility of the iSYS1 System has been tested according to FCC Part15 (Edition 1st October 2010) and ISO 60601-1-2:2007 and meets the acceptance criteria of both.

Performance tests have been performed to prove:

- the accuracy of the needle placement under clinical conditions,
- the compatibility with the imaging modality,
- the tendency to produce artifacts,
- the mechanical stability of the system despite external payload under worst conditions
- the mechanical stability of the table adapters despite external payload,
- the accuracy in remote-control mode
- the accuracy of needle guidance
- functionality of hardware modules
- effectiveness of hardware safety measures for the software,
- and the effectiveness of the alarm systems

The results of these performance tests support that the predicate devices and iSYS 1 are substantially equivalent.

Differences:

*1) Frameless Neuromate and iSYS 1 do not contain planning software as ROSA Surgical Device does. Position and orientation of the iSYS 1 are given by external planning software. This has no effect on safety or effectiveness.

*2) Frameless Neuromate and ROSA Surgical Device provide a factory instrument calibration of the encoders during intervention. During intervention the surgeon using the iSYS1 verifies the position of the needle or needle-type instrument (tool). Verification of

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

the tool position requires greater physician effort but provides for exact (depending on the imaging system) tool localization. The localization of the tool is not required for the iSYS 1 and, thus, this has no effect on safety or effectiveness.

*3) ROSA Surgical Device provides registration with pointer probe whereas the Frameless Neuromate provides ultra sound registration. This step is not necessary for the workflow of the iSYS 1, because the iSYS marker and the needle are real time imaged during the whole procedure, which, thus, reduces time and effort for intervention. This is as safe and effective as a probe registration.

*4) As stated by Dr. Doucet's letter of October 4, 2012, both he and Dr. Nandkumar agree with ISYS interpretation that Indications for Use is broadly indicated.

*5) Frameless Neuromate and ROSA Surgical Device provide encoders for localization, whereas iSYS uses fudicial markers on the tool. Using fudicial markers provides greater localization safety.

*6) Frameless Neuromate uses ultrasound for navigation and therefore fudicial markers are not visible. iSYS and ROSA Surgical Device provide fudicial markers. Both methods are equivalent and only represent different imaging systems.

*7) Frameless Neuromate and ROSA Surgical Device provide for automatic instrument adjustment, whereas the iSYS is adjusted manually using the Handheld Control Unit. Since all three receive their information from the imaging software, the accuracy of instrument adjustment is the same. They are all safe and effective.

Statement of safety and effectiveness:

It is our opinion that the iSYS 1 System (U.S.) does not have technological characteristics that raise additional types of safety or effectiveness questions, and we consider them to be an enhancement to the existing devices.

To validate the accuracy of the iSYS 1 an external reference system has to be used. We have used and tested the iSYS 1 System (U.S.) with the Philips Allura Xper Guide FD 20 X-ray system.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Sterilization and Shelf Life

Table of Content

	Page
In General	2
Proposed Labeling	4
Validation Report (Packaging)	8
Summary Report Bioseal	18
Summary Report Preferred Medical	24
Bioburden Routine Report	26
Validation of Bioburden Determination	40
Data Sheets	51
Certificates	76

Following documents can be found on the appendix CD respectively in the Misc.-Files of the eCopy:

Document	Filename
(b)(4) [redacted] eport ([redacted] (b)(4) [redacted]	008_[redacted]VDMax Final Report.zip
(b)(4) [redacted]Hygiene Monitoring Plan 2011	009_PM_Hygiene Monitoring plan_RDP 0500_2011
(b)(4) [redacted] Clean room Monitoring Results2012	010_PM_Clean room Monitoring_Results2012
Gamma validation test plan	011_PM_Gamma validation Prüfplan_PRD0400_2010
(b)(4) [redacted]Bioburden Report 2012	012_PM_Bioburden_SC-80_report904377_2012

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

In General

With the iSYS 1 system several sterile components are supplied. They are not meant to be reused or user sterilized, but are for single use only.

Cleaning and disinfection procedures according to regular clinical standards are recommended in the user manual and should be applied to the hardware modules only, as they are reusable.

1. Drapes:

The drapes for iSYS 1 are no longer part of this submission but will be supplie manufactured by (b)(4) [redacted] and packaged and sterilized by (b)(4) [redacted] under their own responsibility.

The drapes are supplied b (b)(4) [redacted] nder 510(k) K863853 and packaged and sterilized by (b)(4) [redacted] under 510(k) K893814.

For a comparison of the iSYS devices with the existing products from Bioseal and Preferred Medical see below (Summary Reports).

2. Needle Guide Adapter and Needle Guide Inserts:

The Needle Guide Adapters and Inserts are part of the robotic system manufactured by iSYS. (b)(4) [redacted] performs packaging and sterilization under 510(k) K893814.

Sterilization method:

(b)(4) [redacted]

Description of packaging:

All components are double packed and sealed. For details of packaging material see below (Data Sheets).

The packaging is performed with the (b)(4) [redacted] For validation see report below.

Validation Method: ANSI/AAMI/ISO 11607-2:2006, ASTM F1886:1998, ASTM F1929-98:2004, ASTM F88, ASTM F2096-11

Shelf-Life:

Shelf-life for all sterile components and validation method:

Lifetime/Shelf-life: 3 years

Validation Method: ASTM F 1980:2011

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Device Description

Details see Section 011, pages 26 – 36 and 56 – 57, for technical data sheets see below.

Flammability:

See TDS below: according to UL 94, IEC 60695-2-12 and FMVSS 302.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Proposed Labeling

The labeling is performed with the Colimatic Thera 450 at Bioseal. For retails see validation report below.

Safety Symbols:

STERILE EO	Symbol for STERILIZED USING ETHYLENE OXIDE
STERILE R	Symbol for STERILIZED USING RADIATION
	Symbol for DO NOT USE IF PACKAGE IS DAMAGED
	Symbol for DO NOT REUSE
MR	Symbol for NOT MRI SAFE
	Symbol for CAUTION, CONSULT ACCOMPANYING DOCUMENTS
	Symbol for STORAGE TEMPERATURE
	Symbol for DO NOT LITTER IN DOMESTIC WASTE

Product Identification:

SN	Symbol for SERIAL NUMBER
REF	Symbol for ORDER NUMBER

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

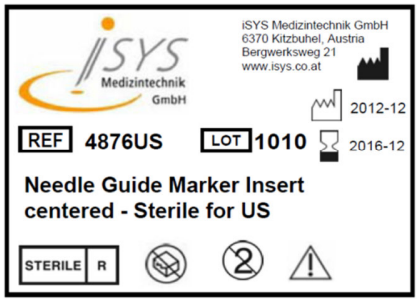
LOT	Symbol for BATCH NUMBER

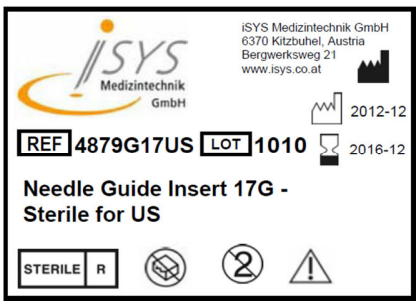
Additional Information

CE	Symbol for CE-conformity
	Symbol for MANUFACTURER
	Symbol for DATE OF MANUFACTURE
	Symbol for USE BY

Samples of Labels:

The presented labels are examples for the final product and packaging labels. Lot numbers and dates on these examples are placeholders only. They do not define any format of lot numbers, production or expiry dates.





Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

iSYS Medizintechnik GmbH
6370 Kitzbuhel, Austria
Bergwerksweg 21
www.isys.co.at

2012-12

REF 4881G20US LOT 1010 2016-12

Needle Guide Insert 20G - Sterile for US

STERILE R

iSYS Medizintechnik GmbH
6370 Kitzbuhel, Austria
Bergwerksweg 21
www.isys.co.at

2012-12

REF 4882G21US LOT 1010 2016-12

Needle Guide Insert 21G - Sterile for US

STERILE R

iSYS Medizintechnik GmbH
6370 Kitzbuhel, Austria
Bergwerksweg 21
www.isys.co.at

2012-12

REF 4880G18US LOT 1010 2016-12

Needle Guide Insert 18G - Sterile for US

STERILE R

iSYS Medizintechnik GmbH
6370 Kitzbuhel, Austria
Bergwerksweg 21
www.isys.co.at

2012-12

REF 5989G19US LOT 1010 2016-12

Needle Guide Insert 19G - Sterile for US

STERILE R

iSYS Medizintechnik GmbH
6370 Kitzbuhel, Austria
Bergwerksweg 21
www.isys.co.at

2012-12

REF 4878G16US LOT 1010 2016-12

Needle Guide Insert 16G - Sterile for US

STERILE R

iSYS Medizintechnik GmbH
6370 Kitzbuhel, Austria
Bergwerksweg 21
www.isys.co.at

2012-12

REF 5992G13US LOT 1010 2016-12

Needle Guide Insert 13G - Sterile for US

STERILE R

iSYS Medizintechnik GmbH
6370 Kitzbuhel, Austria
Bergwerksweg 21
www.isys.co.at

2012-12

REF 6289G10US LOT 1010 2016-12

Needle Guide Insert 10G - Sterile for US

STERILE R

iSYS Medizintechnik GmbH
6370 Kitzbuhel, Austria
Bergwerksweg 21
www.isys.co.at

2012-12

REF 5990G11US LOT 1010 2016-12

Needle Guide Insert 11G - Sterile for US

STERILE R

iSYS Medizintechnik GmbH
6370 Kitzbuhel, Austria
Bergwerksweg 21
www.isys.co.at

2012-12

REF 5993G14US LOT 1010 2016-12

Needle Guide Insert 14G - Sterile for US

STERILE R

iSYS Medizintechnik GmbH
6370 Kitzbuhel, Austria
Bergwerksweg 21
www.isys.co.at

2012-12

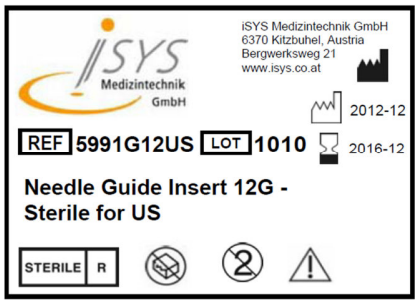
REF 4877G15US LOT 1010 2016-12

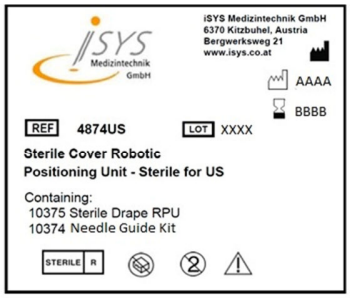
Needle Guide Insert 15G - Sterile for US

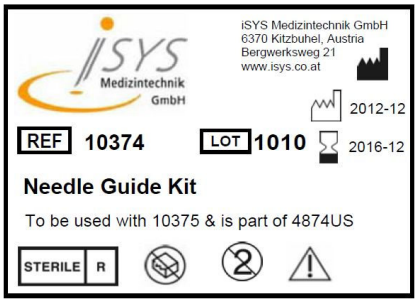
STERILE R

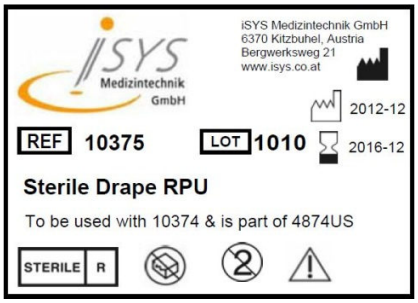
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016









Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Section 014	Sterilization and Shelf Life 510(k) Number: K131433	iSYS Medizintechnik GmbH

(b)(4) Third Party Test Data

[redacted]

Q

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

(b)(4) Third Party Test Data

[redacted]

Qu

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Software

Table of Content

	Page
In General	2
Software Description	5
Software Risk List	32
Verification and Validation	37
Standards Data Reports	39

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

In General

The iSYS 1 (U.S.) is controlled by software, used with the help of a Handheld Control Unit (HCU) and user relevant information is displayed on the Control Unit.

The *Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices*, published on May 11, 2005 by *Center for Devices and Radiological Health (CDRH) – Office of Device Evaluation* complements the *guidance documents General Principals of Software Validation and Guidance for Off-the-Shelf Software Use in Medical Devices. ISYS shall utilize these guidance documents* for the purpose of validating the software associated with the ISYS 1.

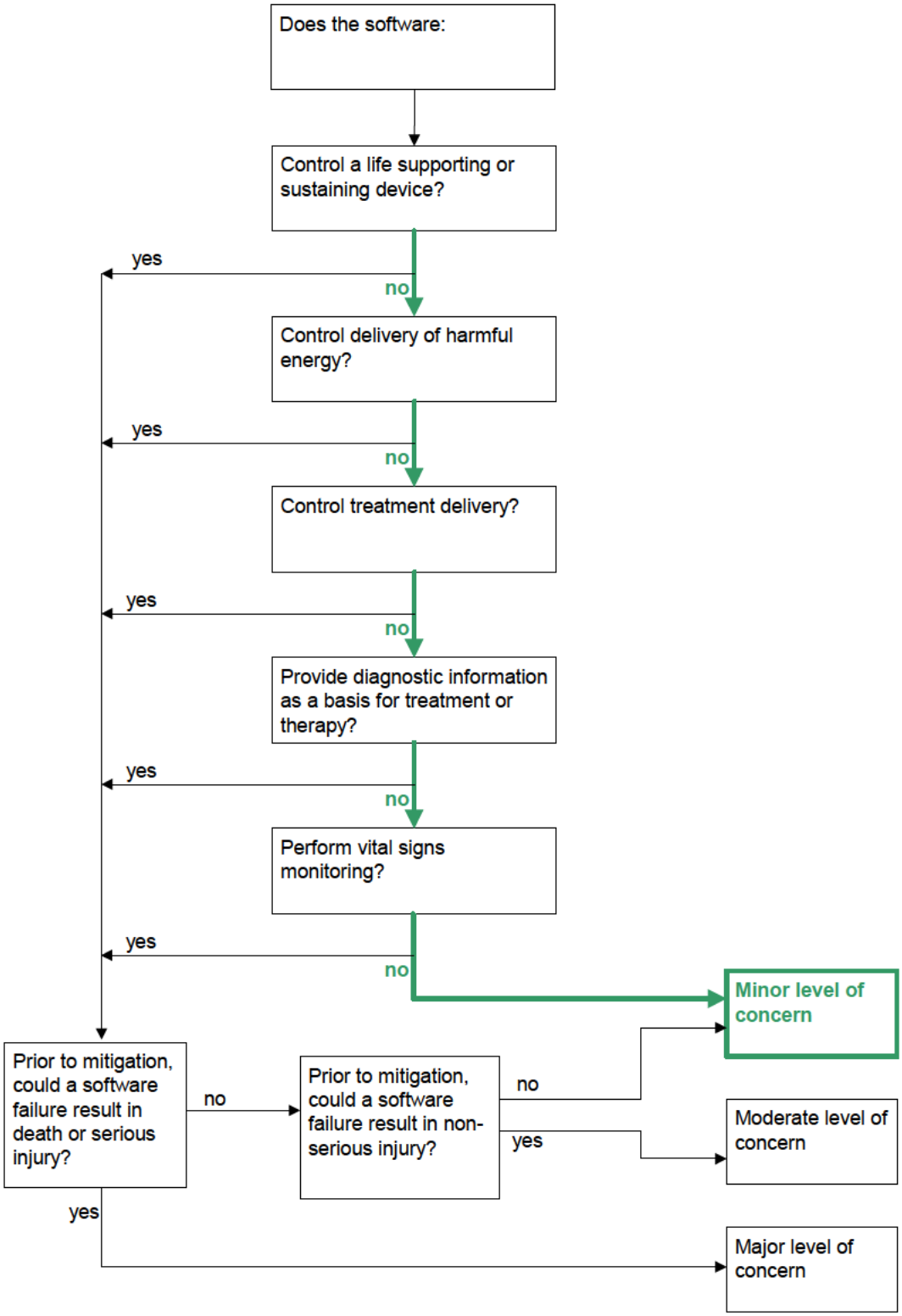
The standard report forms can be found at the end of the document (pages 39 and 40). The documentation of the design process for usability is part of the risk management and can be found in section “009 Declarations of Conformity and Summary Reports”.

Level of concern:

According to the figure below the determination of the Level of Concern for the iSYS1 software results in a “**Minor level of concern**”.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

According to Chapter 3 of the *Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices* and the *Level of Concern* of this product, the following documentation will provide the following content:

SOFTWARE DOCUMENTATION	MINOR CONCERN	MODERATE CONCERN	MAJOR CONCERN
Level of Concern	A statement indicating the Level of Concern and a description of the rationale for that level.		
Software Description	A summary overview of the features and software operating environment.		
Device Hazard Analysis	Tabular description of identified hardware and software hazards, including severity assessment and mitigations.		
Software Requirements Specification (SRS)	Summary of functional requirements from SRS.	The complete SRS document.	
Architecture Design Chart	No documentation is necessary in the submission.	Detailed depiction of functional units and software modules. May include state diagrams as well as flow charts.	
Software Design Specification (SDS)	No documentation is necessary in the submission.	Software design specification document.	
Traceability Analysis	Traceability among requirements, specifications, identified hazards and mitigations, and Verification and Validation testing.		
Software Development Environment Description	No documentation is necessary in the submission.	Summary of software life cycle development plan, including a summary of the configuration management and maintenance activities.	Summary of software life cycle development plan. Annotated list of control documents generated during development process. Include the configuration management and maintenance plan documents.
Verification and Validation Documentation	Software functional test plan, pass / fail criteria, and results.	Description of V&V activities at the unit, integration, and system level. System level test protocol, including pass/fail criteria, and tests results.	Description of V&V activities at the unit, integration, and system level. Unit, integration and system level test protocols, including pass/fail criteria, test report, summary, and tests results.
Revision Level History	Revision history log, including release version number and date.		
Unresolved Anomalies (Bugs or Defects)	No documentation is necessary in the	List of remaining software anomalies, annotated with an explanation of the	

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

	submission.	impact on safety or effectiveness, including operator usage and human factors.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Standards Data Reports

Form Approved: OMB No. 0910-0120; Expiration Date: 12/31/13

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

IEC 62366, Medical devices - Application of usability engineering to medical devices

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	#5-50	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☐	☒
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☒
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☒	☐
If yes, was the guidance document followed in preparation of this 510k?	☒	☐

Title of guidance: Medical Device Use-Safety: Incorporating Human Factors into Risk Management

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

[5] The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[6] The online search for CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html

FORM FDA 3654 (12/10) Page 1

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Form Approved: OMB No. 0910-0120; Expiration Date: 12/31/13

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

IEC 62304 First edition 2006-05, Medical device software - Software life cycle processes

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	#13-8	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☐	☒
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☒
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☒	☐
If yes, was the guidance document followed in preparation of this 510k?	☒	☐

Title of guidance: Guidance for the Content of Premarket Submissions, Guidance for Off-the-Shelf Software, et. al.

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

[5] The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[6] The online search for CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html

FORM FDA 3654 (12/10) Page 1

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

K131433/S3

Section 003	510k Cover Letter 510(k) Number: K131433	iSYS Medizintechnik GmbH

Name *Dr. Michael Vogele*

mobil *+43 (0) 664 2411140*
email *michael.vogele@isys.co.at*
web *www.isys.co.at*

iSYS Medizintechnik GmbH

iSYS Medizintechnik GmbH, Bergwerksweg 21, 6370 Kitzbühel, Austria

FDA CDRH DMC
FEB 11 2014
Received

Food and Drug Administration
Center for Device and Radiological Health
Document Mail Center WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Subject: 510(k) Notification K131433/S002

This is additional information to notify you of the intention of iSYS Medizintechnik GmbH, Bergwerksweg 21, A-6370 Kitzbuehel, Austria to market the following device:

1.	**Proprietary Name:**	iSYS 1 (U.S.)
2.	**Common/Usual Name:**	Robotic Positioning Unit
3.	**Establishment Registration Number:**	pending
4.	**Address of manufacturing and packaging facility:**	Bergwerksweg 21, A-6370 Kitzbuehel, Austria
5.	**Classification Name:**	System, X-ray, Tomography, computed
6.	**Classification:**	Device Class: Class II Classification Panel: Radiology Product Code: JAK, HAW CFR Section: 892.1750
7.	**Reason for Submission:**	New device
8.	**Substantial Equivalence:**	***510(k) Number*** ***Model name*** ***Manufacturer*** K974513 PinPoint Philips Medical
9.	**Performance Standards:**	ÖNORM EN ISO 60601, ÖNORM EN ISO 62304, ANSI/AAMI/ISO 11737, AAMI TIR33, AAMI TIR35, AAMI ST67, ANSI/AAMI/ISO 11607-2, ISO 11137
10.	**Sterile Accessory**	Drapes produced, packaged and sterilized by (b)(4) [redacted] under 510(k) **K863853**. Injection molded components packaged and sterilized by (b)(4) [redacted] (b)(4) [redacted] under 510(k) **K893814**.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

30

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

The files coming with this 510k submission file are our response to the Additional Information Request dated 26/08/2013 and contain the required changes. The following addresses the individual items of the request.

Indications for Use

1. **In your submission, you provide an Indications for Use (IFU) statement along with two predicates (Frameless Neuromate and ROSA Surgical Device). However, your IFU diverges significantly from the predicate IFUs. While the predicate IFUs are specific to neurosurgical procedures performed by neurosurgeons, your IFU is expanded to procedures throughout the body done by any physician. Given the predicates that you have provided, we recommend an IFU that similar to the following:**

   The predicate device has been changed to PinPoint (K974513). We have removed all references to the prior predicated devices (ROSA and Neuromate) from the file.

Bench Testing

(b)(4)

[redacted]

3. **The description of your performance testing is incomplete. Please reference Section 18 of the guidance document "Guidance for Industry and FDA Staff: Format for Traditional and Abbreviated 510(k)s," located at: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm084365.htm, and provide the information specified in this guidance document.**

   Section 018 has been revised according to the guidance document.

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

(b)(4)

[redacted]

5. **In some of your provided test reports, which indicate that your device failed your prespecified pass criteria, you state that you provide additional warning to the device operator. For example, in Document PD/B12 (page 2 of 8) you state:**

   "*Additional warning in user manual that external force to needle guide must be avoided during needle inserting.*"

   However, these statements could not be located in your labeling. Therefore, please revise your labeling to include all of these warnings to the operator. Please also provide a listing of all of these warnings in your response, along with the page number that they appear.

   The warnings are in the user manual, pages 55, 57, 85, 91, 93, and 94.

Packaging/Shelf-life for Sterile Device Accessories

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

7. **We cannot identify the sterile packaging configurations you plan to distribute. Please provide a table in which you identify the sterile components in each packaging configuration you plan to distribute.**

   On pages 4-6 of section 014 the sterile packaging configurations are identified.

(b)(4)

[redacted]

Consensus Standards

9. **We could not locate FDA form 3654 for the consensus standards referenced in your validation of the gamma radiation sterilization process and for establishing packaging integrity and shelf-life for your sterilized device accessories. Please provide FDA form 3654 – Standards Data Report for 510(K)s for each referenced consensus standard.**

   All FDA forms 3654 can be found in Section 002 (Cover Letter), starting from page 8. The forms for the sterile components can be found starting from page 15.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Cleaning and Disinfecting Instructions for Non-patient Contacting iSYS 1 System Components

10. **Users in the U.S. will not understand terminology such as proofed for compatibility. Please revise the following labeling instructions:**
    From:

    "The system must be cleaned and disinfected prior and after to each use. For cleaning and disinfection use appropriate agents which are proofed for compatibility. iSYS has proofed the following agents as compatible:…"

    To:
    "The system must be cleaned and disinfected prior and after to each use. iSYS System components are validated for cleaning and disinfection using the following agents:…"

    The wording has been changed accordingly. Please refer to page 110 in Section 013.

11. **The reprocessing instructions should only include equipment and products that are legally marketed in the U.S. Please document that the disinfecting products recommended in you**

    The product names have been removed. Please refer to page 117 in Section 013.

Electromagnetic Compatibility (EMC)

12. **Please clarify if wireless technology is incorporated in the device. If wireless technology is part of the device system you should address the safety and effectiveness concerns involving the wireless technology, which are largely outside the scope of the IEC 60601-1-2 standard for EMC. For wireless medical devices please address the following areas with testing and information that describes the device wireless specifications and characteristics, the device functions and associated risks, testing results, and acceptable tolerances for: data integrity, data latency, coexistence with other radiofrequency wireless, EMC of the wireless signals, and data security. The labeling for each device system component incorporating wireless technology should contain a summary of this information as well.**

    No wireless technology is used.

13. **The information in the submission is not clear about what was done to address the EMC of the iSYS-1 device. Please address the following:**
    a. **While the information provided in Electromagnetic Compatibility and Electrical Safety" section of the original submission indicates the device complies with IEC 60601-1-2 standard, EMC testing information to support the claimed compliance appears to be absent in the submissions. Therefore, please provide a summary of all EMC testing (emissions and immunity) of this iSYS-1 device with the test**

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

results and data to support your claims for immunity to electromagnetic interference (EMI). Please note, while the information for compliance to FCC is helpful, the information does not adequately address safety and effectiveness of the iSYS-1 device.

We have added the EMC test report. Please refer to Section 017, pages 8 to 33. Additionally, the device was tested according to FCC 47 CFR Part 15. Please refer to Section 017, pages 34 to 48. For testing against influences of RFID or similar devices please see below issue 13f.

b. **Please provide a statement of the essential performance of the device as called out in the IEC 60601-1-2 standard referenced in the submission.**

The statements on the essential performance characteristics are part of the EMC test report. Please refer to Section 017, page 19.

c. **Please provide a brief explanation of how each EMC test was performed and how the testing for each mode addresses the risks for EMI and demonstrates EMC to the claimed levels. This should include a brief explanation of how the testing addresses connections to the patient, alarms, and the time for the device to perform its function.**

Detailed description of the tests can be found in Section 017, pages 14 to 18 and in the annex of the test report (pages 21 to 33). The main performance characteristics (this includes alarm systems and function) were not influenced during the EMC testing and all actions of the device were still within the given requirements.

d. **Please provide the pass/fail criteria for each of the EMC tests, how these were quantified and measured, and justifications for these criteria.**

The pass/fail criteria for each of the EMC tests are documented in the EMC test report. Please refer to Section 017, pages 11 to 13. For quantification and measurement details please refer to Section 017, page 14 to 18.

e. **If there were any modifications to the device in order to pass any of the EMC tests then you should provide brief summary explanations of the modification and a statement that all modifications will be incorporated into all production units.**

There were no modifications.

f. **Information provided in Proposed Labeling of the previous Supplement 1 submission (page 25) contains a warning against the device exposure to "radiotransmitting devices (such as mobile phones, diathermy units, etc.)" In addition, please specifically address other common RF emitters such as RFID. It is foreseeable that the device**

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

will be exposed to such RF sources. Therefore, you should perform adequate testing to assure safety and effectiveness of your device. In general, the present published consensus standards do not adequately address these potential threats.

We have added a test report addressing the influences of RFID and WLAN devices on the iSYS 1. Please refer to Section 017, pages 49 and following.

14. **Information provided in the Proposed Labeling of the Supplement 1 submission (page 21 through 25) contains EMC related labeling information as called out in the IEC 60601-1-2 standard. However, the EMC testing information to support the claimed compliance level appears to be absent in this and previous submissions. Therefore, please provide EMC testing information to support the claimed compliance level (see point 13c, above). The EMC labeling information should provide clear and consistent summary information about what was done to address the safety and effectiveness of the iSYS-1 device.**

    We have added the required information. Please refer to Section 017, pages 8 to 48 and issue 13 above.

Labeling

15. **In your proposed User's Manual (page 11 of 116), you provide a description of the iSYS 1 system that states,**

    "The iSYS 1 Interventional Platform is a modular needle guidance platform for interventional radiology and related fields"

    Additionally, you state in your included marketing material (beginning on page 113 of 116) that,

    "iSYS 1 is the most advanced needle guidance platform for interventional radiology"

    However, as discussed in Deficiency #1 above, the predicate devices are directed towards neurosurgical uses. Therefore, please remove or revise these documents to be consistent with your Indications for Use statement.

    The predicate device has been changed to PinPoint. Please see issue #1.

16. **In the marketing material (proposed labeling section beginning on page 113 of 116), there are statements that claim or imply superiority over existing devices and are unsubstantiated by the submission. Please remove the following claims from the promotional material or provide data to support them:**
    - **Reduced radiation exposure**
    - **Less risk and stress during interventions**
    - **Higher precision**
    - **Fewer side effects**
    - **Faster recovery**
    - **Better clinical outcomes**

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

- **Higher safety standards**
- **Higher patient throughput**
- **Better cost-benefit ratio**
- **Safer work environment**
- **iSYS 1 is the most advanced needle guidance platform for interventional radiology**
- **Safer for the physician and the patient**
- **Best safety standards**
- **Intuitive and fast use**
- **Maximum mechanical stability/compatibility**

We have added the definition of marketing information including the analysis of marketing phrases to Section 013 of our submission (pages 120 to 126). The analysis contains the required data that supports our statements.

Software

17. **You state that the Level of Concern for the software which controls your device is MINOR. However, your listed predicate devices have software Level of Concern of MODERATE. Further, since prior to the mitigation of hazards, failure of the software could result in injury to the patient we believe the software Level of Concern should be MODERATE. Therefore, please revise your Level of Concern to MODERATE and provide the additional required software documentation for software with a MODERATE Level of Concern. The required documentation may be found in "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices," listed above.**

    As agreed on in the Telko with Dr. Jordan, we have changed the level of concern to "moderate" and added the comment on remaining software anomalies. Please refer to Section 016, pages 2 and 3.
    The development environment can be found on page 5 in Section 016.

Literature

18. **You include a dissertation by Dr. Werner Jaschke in your submission. However, the document is in German and you do not provide an English translation. Therefore, please provide an English translation of the document if you wish for the information to be used to support your claims of substantial equivalence to a legally marketed predicate device. Please also include your summary of the information in the article and a discussion of how that information supports the substantial equivalence of your device to its predicate.**

    The dissertation is not used for proofing substantially equivalency, or to validate any performance criteria.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

19. **You include various literature articles in your submission. However, you do not provide a discussion of how each article is applicable to support the substantial equivalence of your device to a legally marketed predicate device. Therefore, for each article, please summarize the article and provide a discussion of how the article supports the substantial equivalence of your device to its predicate.**

    The literature articles are not used for proofing substantially equivalency, or to validate any performance criteria.

Administrative

20. **In your proposed 510(k) Summary, you do not provide an IFU statement. Instead, you provide an "Intended Use." Please revise your 510(k) Summary to provide your Indications for Use statement. Please also ensure that your IFU statement is consistent throughout all documents in your submission (e.g., Indications for Use, 510(k) Summary, Labeling and User Manual, etc.)**

    We have added the Indications for Use in Section 005, page 2.

(b)(4)

[redacted]

In case of any questions concerning this application, please contact either Dr. Michael Vogele, CEO at +43 (0) 664 2411140 (michael.vogele@isys.co.at) or Oliver Spitz (Regulatory Consultant) at +49 (0) 173 5904978 (oliver.spitz@isys.co.at).

The eCopy is an exact duplicate of the paper copy.

Sincerely,

Dr. Michael Vogele

CEO

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

K131433/S003

Section 003	510k Cover Letter 510(k) Number: K131433	iSYS Medizintechnik GmbH

FDA CDRH DMC
FEB 04 2014
Received

Name *Dr. Michael Vogele*

mobil *+43 (0) 664 2411140*
email *michael.vogele@isys.co.at*
web *www.isys.co.at*

iSYS Medizintechnik GmbH, Bergwerksweg 21, 6370 Kitzbühel, Austria

Food and Drug Administration
Center for Device and Radiological Health
Document Mail Center WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Subject: 510(k) Notification K131433/S002

This is additional information to notify you of the intention of iSYS Medizintechnik GmbH, Bergwerksweg 21, A-6370 Kitzbuehel, Austria to market the following device:

1.	**Proprietary Name:**	iSYS 1 (U.S.)
2.	**Common/Usual Name:**	Robotic Positioning Unit
3.	**Establishment Registration Number:**	pending
4.	**Address of manufacturing and packaging facility:**	Bergwerksweg 21, A-6370 Kitzbuehel, Austria
5.	**Classification Name:**	System, X-ray, Tomography, computed
6.	**Classification:**	Device Class: Class II Classification Panel: Radiology Product Code: JAK, HAW CFR Section: 892.1750
7.	**Reason for Submission:**	New device
8.	**Substantial Equivalence:**	***510(k) Number*** / ***Model name*** / ***Manufacturer*** K974513 / PinPoint / Philips Medical
9.	**Performance Standards:**	ÖNORM EN ISO 60601, ÖNORM EN ISO 62304, ANSI/AAMI/ISO 11737, AAMI TIR33, AAMI TIR35, AAMI ST67, ANSI/AAMI/ISO 11607-2, ISO 11137
10.	**Sterile Accessory**	Drapes produced, packaged and sterilized by (b)(4) [redacted] under 510(k) **K863853**. Injection molded components packaged and sterilized by (b)(4) [redacted] (b)(4) [redacted] under 510(k) **K893814**.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

23

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

The files coming with this 510k submission file are our response to the Additional Information Request dated 26/08/2013 and contain the required changes. The following addresses the individual items of the request.

Indications for Use

1. **In your submission, you provide an Indications for Use (IFU) statement along with two predicates (Frameless Neuromate and ROSA Surgical Device). However, your IFU diverges significantly from the predicate IFUs. While the predicate IFUs are specific to neurosurgical procedures performed by neurosurgeons, your IFU is expanded to procedures throughout the body done by any physician. Given the predicates that you have provided, we recommend an IFU that similar to the following:**

   The predicate device has been changed to PinPoint (K974513). We have removed all references to the prior predicated devices (ROSA and Neuromate) from the file.

Bench Testing

(b)(4)

[redacted]

3. **The description of your performance testing is incomplete. Please reference Section 18 of the guidance document "Guidance for Industry and FDA Staff: Format for Traditional and Abbreviated 510(k)s," located at: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm084365.htm, and provide the information specified in this guidance document.**

   Section 018 has been revised according to the guidance document.

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

(b)(4)

[redacted]

5. **In some of your provided test reports, which indicate that your device failed your prespecified pass criteria, you state that you provide additional warning to the device operator. For example, in Document PD/B12 (page 2 of 8) you state:**

   "Additional warning in user manual that external force to needle guide must be avoided during needle inserting."

   However, these statements could not be located in your labeling. Therefore, please revise your labeling to include all of these warnings to the operator. Please also provide a listing of all of these warnings in your response, along with the page number that they appear.

   The warnings are in the user manual, pages 55, 57, 85, 91, 93, and 94.

Packaging/Shelf-life for Sterile Device Accessories

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

7. **We cannot identify the sterile packaging configurations you plan to distribute. Please provide a table in which you identify the sterile components in each packaging configuration you plan to distribute.**

   On pages 4-6 of section 014 the sterile packaging configurations are identified.

(b)(4)

[redacted]

Consensus Standards

9. **We could not locate FDA form 3654 for the consensus standards referenced in your validation of the gamma radiation sterilization process and for establishing packaging integrity and shelf-life for your sterilized device accessories. Please provide FDA form 3654 – Standards Data Report for 510(K)s for each referenced consensus standard.**

   All FDA forms 3654 can be found in Section 002 (Cover Letter), starting from page 8. The forms for the sterile components can be found starting from page 15.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Cleaning and Disinfecting Instructions for Non-patient Contacting iSYS 1 System Components

10. **Users in the U.S. will not understand terminology such as proofed for compatibility. Please revise the following labeling instructions:**
    From:

    "The system must be cleaned and disinfected prior and after to each use. For cleaning and disinfection use appropriate agents which are proofed for compatibility. iSYS has proofed the following agents as compatible:..."

    To:
    "The system must be cleaned and disinfected prior and after to each use. iSYS System components are validated for cleaning and disinfection using the following agents:..."

    The wording has been changed accordingly. Please refer to page 110 in Section 013.

11. **The reprocessing instructions should only include equipment and products that are legally marketed in the U.S. Please document that the disinfecting products recommended in you**

    The product names have been removed. Please refer to page 117 in Section 013.

Electromagnetic Compatibility (EMC)

12. **Please clarify if wireless technology is incorporated in the device. If wireless technology is part of the device system you should address the safety and effectiveness concerns involving the wireless technology, which are largely outside the scope of the IEC 60601-1-2 standard for EMC. For wireless medical devices please address the following areas with testing and information that describes the device wireless specifications and characteristics, the device functions and associated risks, testing results, and acceptable tolerances for: data integrity, data latency, coexistence with other radiofrequency wireless, EMC of the wireless signals, and data security. The labeling for each device system component incorporating wireless technology should contain a summary of this information as well.**

    No wireless technology is used.

13. **The information in the submission is not clear about what was done to address the EMC of the iSYS-1 device. Please address the following:**
    a. **While the information provided in Electromagnetic Compatibility and Electrical Safety" section of the original submission indicates the device complies with IEC 60601-1-2 standard, EMC testing information to support the claimed compliance appears to be absent in the submissions. Therefore, please provide a summary of all EMC testing (emissions and immunity) of this iSYS-1 device with the test**

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

results and data to support your claims for immunity to electromagnetic interference (EMI). Please note, while the information for compliance to FCC is helpful, the information does not adequately address safety and effectiveness of the iSYS-1 device.

We have added the EMC test report. Please refer to Section 017, pages 8 to 33. Additionally, the device was tested according to FCC 47 CFR Part 15. Please refer to Section 017, pages 34 to 48. For testing against influences of RFID or similar devices please see below issue 13f.

b. **Please provide a statement of the essential performance of the device as called out in the IEC 60601-1-2 standard referenced in the submission.**

The statements on the essential performance characteristics are part of the EMC test report. Please refer to Section 017, page 19.

c. **Please provide a brief explanation of how each EMC test was performed and how the testing for each mode addresses the risks for EMI and demonstrates EMC to the claimed levels. This should include a brief explanation of how the testing addresses connections to the patient, alarms, and the time for the device to perform its function.**

Detailed description of the tests can be found in Section 017, pages 14 to 18 and in the annex of the test report (pages 21 to 33). The main performance characteristics (this includes alarm systems and function) were not influenced during the EMC testing and all actions of the device were still within the given requirements.

d. **Please provide the pass/fail criteria for each of the EMC tests, how these were quantified and measured, and justifications for these criteria.**

The pass/fail criteria for each of the EMC tests are documented in the EMC test report. Please refer to Section 017, pages 11 to 13. For quantification and measurement details please refer to Section 017, page 14 to 18.

e. **If there were any modifications to the device in order to pass any of the EMC tests then you should provide brief summary explanations of the modification and a statement that all modifications will be incorporated into all production units.**

There were no modifications.

f. **Information provided in Proposed Labeling of the previous Supplement 1 submission (page 25) contains a warning against the device exposure to "radiotransmitting devices (such as mobile phones, diathermy units, etc.)" In addition, please specifically address other common RF emitters such as RFID. It is foreseeable that the device**

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

- **Higher safety standards**
- **Higher patient throughput**
- **Better cost-benefit ratio**
- **Safer work environment**
- **iSYS 1 is the most advanced needle guidance platform for interventional radiology**
- **Safer for the physician and the patient**
- **Best safety standards**
- **Intuitive and fast use**
- **Maximum mechanical stability/compatibility**

We have added the definition of marketing information including the analysis of marketing phrases to Section 013 of our submission (pages 120 to 126). The analysis contains the required data that supports our statements.

Software

17. **You state that the Level of Concern for the software which controls your device is MINOR. However, your listed predicate devices have software Level of Concern of MODERATE. Further, since prior to the mitigation of hazards, failure of the software could result in injury to the patient we believe the software Level of Concern should be MODERATE. Therefore, please revise your Level of Concern to MODERATE and provide the additional required software documentation for software with a MODERATE Level of Concern. The required documentation may be found in "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices," listed above.**

    As agreed on in the Telko with Dr. Jordan, we have changed the level of concern to "moderate" and added the comment on remaining software anomalies. Please refer to Section 016, pages 2 and 3.
    The development environment can be found on page 5 in Section 016.

Literature

18. **You include a dissertation by Dr. Werner Jaschke in your submission. However, the document is in German and you do not provide an English translation. Therefore, please provide an English translation of the document if you wish for the information to be used to support your claims of substantial equivalence to a legally marketed predicate device. Please also include your summary of the information in the article and a discussion of how that information supports the substantial equivalence of your device to its predicate.**

    The dissertation is not used for proofing substantially equivalency, or to validate any performance criteria.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

19. You include various literature articles in your submission. However, you do not provide a discussion of how each article is applicable to support the substantial equivalence of your device to a legally marketed predicate device. Therefore, for each article, please summarize the article and provide a discussion of how the article supports the substantial equivalence of your device to its predicate.

The literature articles are not used for proofing substantially equivalency, or to validate any performance criteria.

Administrative

20. In your proposed 510(k) Summary, you do not provide an IFU statement. Instead, you provide an "Intended Use." Please revise your 510(k) Summary to provide your Indications for Use statement. Please also ensure that your IFU statement is consistent throughout all documents in your submission (e.g., Indications for Use, 510(k) Summary, Labeling and User Manual, etc.)

We have added the Indications for Use in Section 005, page 2.

(b)(4)

[redacted]

In case of any questions concerning this application, please contact either Dr. Michael Vogele, CEO at +43 (0) 664 2411140 (michael.vogele@isys.co.at) or Oliver Spitz (Regulatory Consultant) at +49 (0) 173 5904978 (oliver.spitz@isys.co.at).

The eCopy is an exact duplicate of the paper copy.

Sincerely,

Dr. Michael Vogele

CEO

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

iSYS Medizintechnik GmbH

510(k) Premarket Notification

(Basing on "Guidance for Industry and FDA Staff: Format for Traditional and Abbreviated 510(k)s"

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Table of Content

Section	Name	Number of Pages	Appendix/Misc
001	Medical Device User Fee Cover Sheet (Form FDA 3601)	3	No
002	CDRH Premarket Review Submission Cover Sheet	27	Yes
003	510(k) Cover Letter	9	No
004	Indications for Use Statement	1	No
005	510(k) Summary	9	No
006	Premarket Notification Truthful and Accurate Statement	1	No
007	Premarket Notification Class III Certification and Summary	1	No
008	Financial Certification or Disclosure Statement	1	No
009	Declarations of Conformity and Summary Reports (including Risk Management File)	104	No
010	Executive Summary	4	No
011	Device Description	57	No
012	Substantial Equivalence Discussion	7	No
013	Proposed Labeling	135	No
014	Sterilization and Shelf Life	159	No
015	Biocompatibility	1	No
016	Software	38	No
017	Electromagnetic Compatibility and Electrical Safety	66	No
018	Performance Testing – Bench	103	No
019	Performance Testing – Animal	1	No
020	Performance Testing – Clinical	40	Yes

* Highlighted sections are subject to changes due to FDA's Request for additional Information dated 08/26/2013.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Section 001	Medical Device User Fee Cover Sheet (Form FDA 3601) 510(k) Number: K131433	ISYS Medizintechnik GmbH

Form Approved: OMB No. 0910-511 Expiration Date: February 28, 2013. 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) [redacted] Write the Payment Identification number on your check.

A completed cover sheet must accompany each original application or supplement subject to fees. If payment is sent by U.S. mail or courier, please include a copy of this completed form with payment. Payment and mailing instructions can be found at: http://www.fda.gov/oc/mdufma/coversheet.html

1. COMPANY NAME AND ADDRESS (include name, street address, city state, country, and post office code)	2. CONTACT NAME
ISYS MEDIZINTECHNIK GMBH Bergwerksweg 21 KITZBUEHEL 6370 AT	Oliver Spitz 2.1 E-MAIL ADDRESS oliver.spitz@isys.co.at 2.2 TELEPHONE NUMBER (include Area code) 0049 173 5904978 2.3 FACSIMILE (FAX) NUMBER (Include Area code)
1.1 EMPLOYER IDENTIFICATION NUMBER (EIN)	

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/oc/mdufma

Select an application type:	3.1 Select a center
[X] Premarket notification(510(k)); except for third party	[X] CDRH
[ ] 513(g) Request for Information	[ ] CBER
[ ] Biologics License Application (BLA)	3.2 Select one of the types below
[ ] Premarket Approval Application (PMA)	[X] Original Application
[ ] Modular PMA	Supplement Types:
[ ] Product Development Protocol (PDP)	[ ] Efficacy (BLA)
[ ] Premarket Report (PMR)	[ ] Panel Track (PMA, PMR, PDP)
[ ] Annual Fee for Periodic Reporting (APR)	[ ] Real-Time (PMA, PMR, PDP)
[ ] 30-Day Notice	[ ] 180-day (PMA, PMR, PDP)

4. ARE YOU A SMALL BUSINESS? (See the instructions for more information on determining this status)

[X] YES, I meet the small business criteria and have submitted the required qualifying documents to FDA

NO, I am not a small business

4.1 If Yes, please enter your Small Business Decision Number: SBD135332

5. FDA WILL NOT ACCEPT YOUR SUBMISSION IF YOUR COMPANY HAS NOT PAID AN ESTABLISHMENT REGISTRATION FEE THAT IS DUE TO FDA. HAS YOUR COMPANY PAID ALL ESTABLISHMENT REGISTRATION FEES THAT ARE DUE TO FDA?

[X] YES (All of our establishments have registered and paid the fee, or this is our first device, and we will register and pay the fee within 30 days of FDA's approval/clearance of this device.)

[ ] NO (If "NO," FDA will not accept your submission until you have paid all fees due to FDA. This submission will not be processed; see http://www.fda.gov/cdrh/mdufma for additional information)

6. 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

[ ] This biologics application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only

[ ] The sole purpose of the application is to support conditions of use for a pediatric population

[ ] The application is submitted by a state or federal government entity for a device that is not to be distributed commercially

7. 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

PAPERWORK REDUCTION ACT STATEMENT

Public reporting burden for this collection of information is estimated to average 18 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and 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 the address below.

Department of Health and Human Services, Food and Drug Administration, Office of Chief Information Officer, 1350 Piccard Drive, 4th Floor Rockville, MD 20850

[Please do NOT return this form to the above address, except as it pertains to comments on the burden estimate.]

8. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION

(b)(4) [redacted]

03-May-2013

Form FDA 3601 (01/2007)

Doc No: PD_75_11531	Revision 04 from: 21.01.2014			3/3
Created by:	Approved by:	Invalid since:	Source:	Approval Date:
Oliver Spitz	Dr. Michael Vogele		FO_42_1996	06.06.2011

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Name ***Dr. Michael Vogele***

mobil ***+43 (0) 664 2411140***
email *michael.vogele@isys.co.at*
web *www.isys.co.at*

iSYS Medizintechnik GmbH, Bergwerksweg 21, 6370 Kitzbühel, Austria

Food and Drug Administration
Center for Device and Radiological Health
Document Mail Center WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Subject: 510(k) Notification K131433/S002

This is additional information to notify you of the intention of iSYS Medizintechnik GmbH, Bergwerksweg 21, A-6370 Kitzbuehel, Austria to market the following device:

1.	**Proprietary Name:**	iSYS 1 (U.S.)
2.	**Common/Usual Name:**	Robotic Positioning Unit
3.	**Establishment Registration Number:**	pending
4.	**Address of manufacturing and packaging facility:**	Bergwerksweg 21, A-6370 Kitzbuehel, Austria
5.	**Classification Name:**	System, X-ray, Tomography, computed
6.	**Classification:**	Device Class: Class II Classification Panel: Radiology Product Code: JAK, HAW CFR Section: 892.1750
7.	**Reason for Submission:**	New device
8.	**Substantial Equivalence:**	***510(k) Number*** / ***Model name*** / ***Manufacturer*** K974513 / PinPoint / Philips Medical
9.	**Performance Standards:**	ÖNORM EN ISO 60601, ÖNORM EN ISO 62304, ANSI/AAMI/ISO 11737, AAMI TIR33, AAMI TIR35, AAMI ST67, ANSI/AAMI/ISO 11607-2, ISO 11137
10.	**Sterile Accessory**	Drapes produced, packaged and sterilized by (b)(4) [redacted] under 510(k) **K863853**. Injection molded components packaged and sterilized by (b)(4) [redacted] (b)(4) [redacted] under 510(k) **K893814**.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

The files coming with this 510k submission file are our response to the Additional Information Request dated 26/08/2013 and contain the required changes. The following addresses the individual items of the request.

Indications for Use

1. **In your submission, you provide an Indications for Use (IFU) statement along with two predicates (Frameless Neuromate and ROSA Surgical Device). However, your IFU diverges significantly from the predicate IFUs. While the predicate IFUs are specific to neurosurgical procedures performed by neurosurgeons, your IFU is expanded to procedures throughout the body done by any physician. Given the predicates that you have provided, we recommend an IFU that similar to the following:**

   The predicate device has been changed to PinPoint (K974513). We have removed all references to the prior predicated devices (ROSA and Neuromate) from the file.

Bench Testing

(b)(4)

[redacted]

3. **The description of your performance testing is incomplete. Please reference Section 18 of the guidance document "Guidance for Industry and FDA Staff: Format for Traditional and Abbreviated 510(k)s," located at: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm084365.htm, and provide the information specified in this guidance document.**

   Section 018 has been revised according to the guidance document.

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

(b)(4)

[redacted]

5. **In some of your provided test reports, which indicate that your device failed your prespecified pass criteria, you state that you provide additional warning to the device operator. For example, in Document PD/B12 (page 2 of 8) you state:**

   "*Additional warning in user manual that external force to needle guide must be avoided during needle inserting.*"

   However, these statements could not be located in your labeling. Therefore, please revise your labeling to include all of these warnings to the operator. Please also provide a listing of all of these warnings in your response, along with the page number that they appear.

   The warnings are in the user manual, pages 55, 57, 85, 91, 93, and 94.

Packaging/Shelf-life for Sterile Device Accessories

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

7. **We cannot identify the sterile packaging configurations you plan to distribute. Please provide a table in which you identify the sterile components in each packaging configuration you plan to distribute.**

   On pages 4-6 of section 014 the sterile packaging configurations are identified.

(b)(4)

[redacted]

Consensus Standards

9. **We could not locate FDA form 3654 for the consensus standards referenced in your validation of the gamma radiation sterilization process and for establishing packaging integrity and shelf-life for your sterilized device accessories. Please provide FDA form 3654 – Standards Data Report for 510(K)s for each referenced consensus standard.**

   All FDA forms 3654 can be found in Section 002 (Cover Letter), starting from page 8. The forms for the sterile components can be found starting from page 15.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Cleaning and Disinfecting Instructions for Non-patient Contacting iSYS 1 System Components

10. **Users in the U.S. will not understand terminology such as proofed for compatibility. Please revise the following labeling instructions:**
    From:

    "The system must be cleaned and disinfected prior and after to each use. For cleaning and disinfection use appropriate agents which are proofed for compatibility. iSYS has proofed the following agents as compatible:…"

    To:
    "The system must be cleaned and disinfected prior and after to each use. iSYS System components are validated for cleaning and disinfection using the following agents:…"

    The wording has been changed accordingly. Please refer to page 110 in Section 013.

11. **The reprocessing instructions should only include equipment and products that are legally marketed in the U.S. Please document that the disinfecting products recommended in you**

    The product names have been removed. Please refer to page 117 in Section 013.

Electromagnetic Compatibility (EMC)

12. **Please clarify if wireless technology is incorporated in the device. If wireless technology is part of the device system you should address the safety and effectiveness concerns involving the wireless technology, which are largely outside the scope of the IEC 60601-1-2 standard for EMC. For wireless medical devices please address the following areas with testing and information that describes the device wireless specifications and characteristics, the device functions and associated risks, testing results, and acceptable tolerances for: data integrity, data latency, coexistence with other radiofrequency wireless, EMC of the wireless signals, and data security. The labeling for each device system component incorporating wireless technology should contain a summary of this information as well.**

    No wireless technology is used.

13. **The information in the submission is not clear about what was done to address the EMC of the iSYS-1 device. Please address the following:**
    a. **While the information provided in Electromagnetic Compatibility and Electrical Safety" section of the original submission indicates the device complies with IEC 60601-1-2 standard, EMC testing information to support the claimed compliance appears to be absent in the submissions. Therefore, please provide a summary of all EMC testing (emissions and immunity) of this iSYS-1 device with the test**

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

results and data to support your claims for immunity to electromagnetic interference (EMI). Please note, while the information for compliance to FCC is helpful, the information does not adequately address safety and effectiveness of the iSYS-1 device.

We have added the EMC test report. Please refer to Section 017, pages 8 to 33. Additionally, the device was tested according to FCC 47 CFR Part 15. Please refer to Section 017, pages 34 to 48. For testing against influences of RFID or similar devices please see below issue 13f.

b. Please provide a statement of the essential performance of the device as called out in the IEC 60601-1-2 standard referenced in the submission.

The statements on the essential performance characteristics are part of the EMC test report. Please refer to Section 017, page 19.

c. Please provide a brief explanation of how each EMC test was performed and how the testing for each mode addresses the risks for EMI and demonstrates EMC to the claimed levels. This should include a brief explanation of how the testing addresses connections to the patient, alarms, and the time for the device to perform its function.

Detailed description of the tests can be found in Section 017, pages 14 to 18 and in the annex of the test report (pages 21 to 33). The main performance characteristics (this includes alarm systems and function) were not influenced during the EMC testing and all actions of the device were still within the given requirements.

d. Please provide the pass/fail criteria for each of the EMC tests, how these were quantified and measured, and justifications for these criteria.

The pass/fail criteria for each of the EMC tests are documented in the EMC test report. Please refer to Section 017, pages 11 to 13. For quantification and measurement details please refer to Section 017, page 14 to 18.

e. If there were any modifications to the device in order to pass any of the EMC tests then you should provide brief summary explanations of the modification and a statement that all modifications will be incorporated into all production units.

There were no modifications.

f. Information provided in Proposed Labeling of the previous Supplement 1 submission (page 25) contains a warning against the device exposure to "radiotransmitting devices (such as mobile phones, diathermy units, etc.)" In addition, please specifically address other common RF emitters such as RFID. It is foreseeable that the device

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

will be exposed to such RF sources. Therefore, you should perform adequate testing to assure safety and effectiveness of your device. In general, the present published consensus standards do not adequately address these potential threats.

We have added a test report addressing the influences of RFID and WLAN devices on the iSYS 1. Please refer to Section 017, pages 49 and following.

14. **Information provided in the Proposed Labeling of the Supplement 1 submission (page 21 through 25) contains EMC related labeling information as called out in the IEC 60601-1-2 standard. However, the EMC testing information to support the claimed compliance level appears to be absent in this and previous submissions. Therefore, please provide EMC testing information to support the claimed compliance level (see point 13c, above). The EMC labeling information should provide clear and consistent summary information about what was done to address the safety and effectiveness of the iSYS-1 device.**

    We have added the required information. Please refer to Section 017, pages 8 to 48 and issue 13 above.

<u>Labeling</u>

15. **In your proposed User's Manual (page 11 of 116), you provide a description of the iSYS 1 system that states,**

    "*The iSYS 1 Interventional Platform is a modular needle guidance platform for interventional radiology and related fields*"

    Additionally, you state in your included marketing material (beginning on page 113 of 116) that,

    "*iSYS 1 is the most advanced needle guidance platform for interventional radiology*"

    However, as discussed in Deficiency #1 above, the predicate devices are directed towards neurosurgical uses. Therefore, please remove or revise these documents to be consistent with your Indications for Use statement.

    The predicate device has been changed to PinPoint. Please see issue #1.

16. **In the marketing material (proposed labeling section beginning on page 113 of 116), there are statements that claim or imply superiority over existing devices and are unsubstantiated by the submission. Please remove the following claims from the promotional material or provide data to support them:**
    - **Reduced radiation exposure**
    - **Less risk and stress during interventions**
    - **Higher precision**
    - **Fewer side effects**
    - **Faster recovery**
    - **Better clinical outcomes**

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

- **Higher safety standards**
- **Higher patient throughput**
- **Better cost-benefit ratio**
- **Safer work environment**
- **iSYS 1 is the most advanced needle guidance platform for interventional radiology**
- **Safer for the physician and the patient**
- **Best safety standards**
- **Intuitive and fast use**
- **Maximum mechanical stability/compatibility**

We have added the definition of marketing information including the analysis of marketing phrases to Section 013 of our submission (pages 120 to 126). The analysis contains the required data that supports our statements.

Software

17. **You state that the Level of Concern for the software which controls your device is MINOR. However, your listed predicate devices have software Level of Concern of MODERATE. Further, since prior to the mitigation of hazards, failure of the software could result in injury to the patient we believe the software Level of Concern should be MODERATE. Therefore, please revise your Level of Concern to MODERATE and provide the additional required software documentation for software with a MODERATE Level of Concern. The required documentation may be found in "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices," listed above.**

    As agreed on in the Telko with Dr. Jordan, we have changed the level of concern to "moderate" and added the comment on remaining software anomalies. Please refer to Section 016, pages 2 and 3.
    The development environment can be found on page 5 in Section 016.

Literature

18. **You include a dissertation by Dr. Werner Jaschke in your submission. However, the document is in German and you do not provide an English translation. Therefore, please provide an English translation of the document if you wish for the information to be used to support your claims of substantial equivalence to a legally marketed predicate device. Please also include your summary of the information in the article and a discussion of how that information supports the substantial equivalence of your device to its predicate.**

    The dissertation is not used for proofing substantially equivalency, or to validate any performance criteria.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

19. **You include various literature articles in your submission. However, you do not provide a discussion of how each article is applicable to support the substantial equivalence of your device to a legally marketed predicate device. Therefore, for each article, please summarize the article and provide a discussion of how the article supports the substantial equivalence of your device to its predicate.**

    The literature articles are not used for proofing substantially equivalency, or to validate any performance criteria.

Administrative

20. **In your proposed 510(k) Summary, you do not provide an IFU statement. Instead, you provide an "Intended Use." Please revise your 510(k) Summary to provide your Indications for Use statement. Please also ensure that your IFU statement is consistent throughout all documents in your submission (e.g., Indications for Use, 510(k) Summary, Labeling and User Manual, etc.)**

    We have added the Indications for Use in Section 005, page 2.

(b)(4)

[redacted]

In case of any questions concerning this application, please contact either Dr. Michael Vogele, CEO at +43 (0) 664 2411140 (michael.vogele@isys.co.at) or Oliver Spitz (Regulatory Consultant) at +49 (0) 173 5904978 (oliver.spitz@isys.co.at).

The eCopy is an exact duplicate of the paper copy.

Sincerely,

Dr. Michael Vogele

CEO

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Indications for Use Statement

510(k) Number (if known): K131433

Device Name: **iSYS 1 (U.S.)**

Intended Use: The intended use of the iSYS1 device is to function as a remote-operated positioning and guidance system during interventional procedures. Positioning is done in remote control manner; planning of the position/angulation is done based on 2D/3D patient data (CT, cone-beam CT, fluoroscopy) by external planning software – for example using an external navigation system, or planning software coming with the used imaging device. Also verification of the correct position and orientation of the tool prior to/during/after the intervention is done by means of these external devices. The iSYS1-System is then acting as a guideway during the manual insertion of the interventional tool – usually a needle type device, and the like

Indicated User: Physician

Indicated Environment: Operating room

Indicated Surgical Procedures: Applications include, but are not limited to, interventions like biopsy procedures, tumor ablation, nerve blocking, electrode placement, etc.

Indications for Use The iSYS 1 device is a user-controlled electromechanical arm with a needle guide. It is intended to assist the surgeon in the positioning of a needle or electrode where both computed tomography (CT) and fluoroscopic imaging can be used for target trajectory planning and intraoperative tracking. The needle or electrode is then manually advanced by the surgeon. Trajectory planning is made with software that is not part of the iSYS device

Indicated parts of the body: Total body

Prescription Use _YES___ AND/OR Over-The-Counter Use ___NO__
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE 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 2015-10247; Released by CDRH on 07/08/2016

510(k) SUMMARY

1.	Applicant:	iSYS Medizintechnik GmbH
2.	Address:	Bergwerksweg 21 6370 Kitzbühel / Austria
3.	Contact Person:	Dr. Michael Vogele Tel. +43 (0) 664 2411140
4.	Preparation Date:	January 20, 2014
5.	Device Submitted:	iSYS 1 (U.S.)
6.	Proprietary Name:	iSYS 1 (U.S.)
7.	Common Name:	Robotic Positioning Unit
8.	Classification Name:	System, X-ray, Tomography, computed Product Code JAK, HAW, Reg.No. 892.1750
9.	Substantial Equivalence:	The iSYS 1 is substantially equivalent to the following legally marketed devices: PinPoint manufactured by Philips Medical. The characteristics of this device are similar to those of the predicate devices identified on the comparison chart, which follows. It is our opinion that the iSYS 1 does not have technological characteristics that raise additional types of questions related to terms of safety and effectiveness.
10.	Device Description:	The iSYS 1 is a modular needle guidance platform for interventional radiology and related fields. Core components are a 4 DOF micro positioning unit which allows the submillimetric needle positioning from simple needle angulations up to positioning and angulations with adjustable pivot point and a control unit which is directed by a cable connected control panel. The passive macro positioning unit and different table adapters allow different setups of the system around the patient in the region of interest. The needle-guide-kit (manufactured by ECOLAB) provides disposable components that ensure precise and sterile needle guidance. Planning of the tool position/orientation as well as validation of the correctness of the tool position must be performed with an external planning and measurement system which is not part of the iSYS-1 Interventional Platform. The position of iSYS 1 is visible for most imaging systems due to the used markers. During treatment the tool is controlled by the

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

user.

11. Intended Use:

The intended use of the iSYS1 device is to function as a remote-operated positioning and guidance system during interventional procedures. Positioning is done in remote control manner; planning of the position/angulation is done based on 2D/3D patient data (CT, cone-beam CT, fluoroscopy) by external planning software – for example using an external navigation system, or planning software coming with the used imaging device. Also verification of the correct position and orientation of the tool prior to/during/after the intervention is done by means of these external devices. The iSYS1-System is then acting as a guideway during the manual insertion of the interventional tool – usually a needle type device, and the like. Applications include, but are not limited to, interventions like biopsy procedures, tumor ablation, nerve blocking, electrode placement, etc.

12. Indications for Use

The iSYS 1 device is a user-controlled electromechanical arm with a needle guide. It is intended to assist the surgeon in the positioning of a needle or electrode where both computed tomography (CT) and fluoroscopic imaging can be used for target trajectory planning and intraoperative tracking. The needle or electrode is then manually advanced by the surgeon. Trajectory planning is made with software that is not part of the iSYS device

13. Clinical Use

The Side Rail Adapter is attached to the side rail for the setup; the Table Top Adapter is attached directly onto the CT table. Both Adapters are equipped with a “starburst” connector, to which the Multifunctional Arm can be attached. The MFA is equipped with one “starburst” connector at the bottom and one “spoon” connector at the top. The “spoon” connector has its counterpart on the Robotic Positioning Unit for the setup. The Control Unit is attached directly to the side rail. The Robotic Positioning Unit is connected by a cable to the Control Unit, which has cable connections to both the electric power supply and to a Handheld Control Unit. The Needle Guide Extensions are screw-fixed onto the Robotic Positioning Modules. The Sterile Cover is directly fixed onto the Needle Guide Joints and can be drawn over the robotic parts. The Needle Insert is placed into the appropriate connector of the Needle Guide, to prepare needle usage. The Handheld Control Unit can be clamped onto the side rail and covered with a drape. Planning of the tool position/orientation as well as validation of the

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

correctness of the tool position must be performed with an external planning and measurement system (imaging or navigation software).

14. Biocompatibility: The iSYS 1 is not in contact with patient. At any time when in use a sterile cover sheet is to be placed between the patient and the system. Additionally there are no new materials introduced in the manufacture of the iSYS 1. Therefore, no biocompatibility studies were performed for this device.

15. Performance Data: Operating temperature/humidity range: 15 to 30°C; 30 to 70% relative humidity with no condensation

Storage temperature/humidity range: 10 to 50°C; 30 to 70% relative humidity with no condensation

Power Supply: 50W; 115VAC/230VAC; 50-60Hz; cable: C14 according to IEC/EN 60320-1, US498, CSA C22.2 no. 42;

Sterilization of the sterile accessories has been validated by Bioseal and Preferred Medical, the companies responsible for packaging and sterilizing the iSYS accessories.

The accuracy of the intervention depends on the resolution and capabilities of the imaging device or software. The mechanical accuracy of iSYS1 is below 1 mm, but that gives no accuracy value for treatments.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Device Comparison Summary:

Reference	PinPoint	iSYS 1 (for new submission)	Equivalence ?
510k-Number	K974513	K131433	
Manufacturer	PHILIPS MEDICAL SYSTEMS (CLEVELAND), INC. 595 Miner rd. Cleveland, OH 44143 USA	iSYS Medizintechnik GmbH Bergwerksweg 21 A-6370 Kitzbuehel Austria	
Design			
General device description	Five jointed, position-sensing stereotactic arm, mounted on the CT gantry, and indicated for invasive procedures	Computer controlled electromechanical multi-joined arm indicated for invasive procedures	Yes
Localization means	Robot arm absolute encoders	Fiducial markers on tool holder.	*3)
Image-guided	Yes	Yes	Yes
Planning software	No, not cleared under this 510k (K955268)	No (third party)	Yes
Registration method	During installation	Fiducial markers	*4)
Instrumentation	Cannula Laser needle guide	Marker Tool Holder Sterile Covers (third party)	Yes
Instrument fixation	Cannula attached to the arm (optional: laser needle guidance)	Special tool holders for several applications mounted to the Robot	Yes
Instrument calibration	Factory Calibration Optional: intra operative	Intra operative	*1)
System immobilization between patient and device	Yes	Yes	Yes
Planning and Navigation Software			
N/A.			
System Operation			
Fiducial markers registration with	No	No	Yes

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Reference	PinPoint	iSYS 1 (for new submission)	Equivalence ?
pointer probe			
Optical registration	No	No	Yes
Ultrasound Registration	No	No	Yes
Accuracy verification	Yes, external anatomical verification	Yes, performed by user	Yes
Provide mechanical guidance for tools	Yes	Yes	Yes
Instrument guide position adjustment	Manual	Manual	Yes
Physician carries out final gesture through tool guide	Yes	Yes	Yes
Indications for Use			
Indication for use	The PinPoint is an accessory to a CT system intended to provide the radiologist with a means of simulating and initiating interventional procedures by interactively relating the patient´s CT image volume to the actual target field. This accessory includes mounting the stereotactic arm on a CT-Gantry, a flat panel TV monitor, cabling, biopsy phantom and software. In addition the CT is intended to produce cross-sectional images of the body by computer reconstruction of X-ray transmission data from	The iSYS 1 device is a user-controlled electromechanical arm with a needle guide. It is intended to assist the surgeon in the positioning of a needle or electrode where both computed tomography (CT) and fluoroscopic imaging can be used for target trajectory planning and intraoperative tracking. The needle or electrode is then manually advanced by the surgeon. Trajectory planning is made with software that is not part of the iSYS device.	Yes

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Reference	PinPoint	iSYS 1 (for new submission)	Equivalence ?
	the same axial plane taken at different angels. This device may include signal analysis and display equipment, patient and equipment supports, components and accessories. PinPoint is not limited to any particular region of the body. It is equally viable for planning head and spine interventions as it is in the abdomen. It is expected that its major use will be in the planning of biopsies of abdominal organs and drainage of fluid collections in the abdomen. However, more complicated procedures such as Brachy therapy and bone pinnings will be planned using the PinPoint.		
Intended Use	The PinPoint is an accessory to a CT system intended to provide the radiologist with a means of simulating and initiating interventional procedures by interactively relating the patient´s CT image volume to the actual target field. The system produces cross sectional images by computer reconstruction of x-ray transmission data from the same axial plane taken at different angles. A stereotactic arm on a	The intended use of the iSYS1 device is to function as a remote-operated positioning and guidance system during interventional procedures. Positioning is done in remote control manner; planning of the position/angulation is done based on 2D/3D patient data (CT, cone-beam CT, fluoroscopy) by external planning software – for example using an external navigation system, or planning software coming with the used imaging device. Also	Yes

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Reference	PinPoint	iSYS 1 (for new submission)	Equivalence ?
	CT Gantry, a flat panel TV monitor, and biopsy phantom are used as accessories to produce these images. The primary intend of the system is to provide guidance for biopsies in the abdomen, spine and head.	verification of the correct position and orientation of the tool prior to/during/after the intervention is done by means of these external devices. The iSYS1-System is then acting as a guideway during the manual insertion of the interventional tool – usually a needle type device, and the like. Applications include, but are not limited to, interventions like biopsy procedures, tumor ablation, nerve blocking, electrode placement, etc.	
Anatomical site	Total Body	Total body	Yes
User	Radiologist	Physician	*2)
Accessory	V-Channel Cannula Cylindrical Cannula	Sterile Covers Table Adapters Cable Sets	Yes
Real-time instrument position	Yes	Yes	Yes
Mechanical Guidance of instruments	Yes	Yes	Yes
Technology			
Powered	Yes	Yes	Yes
CE-Conformity	No	Yes	Yes
Computer-controlled	Yes	Yes	Yes
Materials	Metal, electronics and plastics	Metal, electronics Polyamide Polyethylene Bralen	Yes

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Similarities and Differences:

All three devices are intraoperative instruments used by physician for assisting the spatial positioning and orientation of a surgical tool.

iSYS 1 is equivalent to:

- PinPoint for assisting the spatial positioning and orientation of a surgical tool.
- PinPoint for being localized by the navigation or imaging software.
- PinPoint for being guided by an imaging device
- PinPoint for providing a registration method for the imaging device.
- PinPoint for instrumentation and instrument fixation.
- PinPoint for being immobilized in relation to the patient.
- PinPoint for providing accuracy verification, tool guidance and position adjustment.
- PinPoint for the physician making the final gesture.
- PinPoint for having the same indications for use and region of interest.

Non-clinical testing has mainly been performed to prove electrical and mechanical safety of the devices. Similar to the predicate devices, iSYS 1 was tested according to EN ISO 60601-1 2nd edition:

- EN 60601-1:1990 + A1:1993 + A2:1995
- EN 60601-1-8:2004 + A1:2006

The Electromagnetic Compatibility of the iSYS1 System has been tested according to FCC Part15 (Edition 1st October 2010) and ISO 60601-1-2:2007 and meets the acceptance criteria of both.

Performance tests have been performed to prove:

- the accuracy of the needle placement under clinical conditions,
- the compatibility with the imaging modality,
- the tendency to produce artifacts,
- the mechanical stability of the system despite external payload under worst conditions
- the mechanical stability of the table adapters despite external payload,
- the accuracy in remote-control mode
- the accuracy of needle guidance
- functionality of hardware modules
- effectiveness of hardware safety measures for the software,
- and the effectiveness of the alarm systems

The results of these performance tests support that the predicate devices and iSYS 1 are substantially equivalent.

Differences:

*1) PinPoint provides a factory instrument calibration of the encoders. During intervention the physician using iSYS1 and PinPoint verifies the position of the needle or needle-type instrument (tool). Verification of the tool position requires greater physical effort but provides for exact (depending on the imaging system) tool localization. The localization of the tool is not required for the iSYS 1 and, thus, this has no effect on safety or effectiveness.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

*2) While the PinPoint is indicated to be used by radiologists only, the iSYS 1 is indicated to be used by any trained physician. This has no effects on safety and effectiveness.

*3) PinPoint provides encoders for localization, whereas iSYS uses fudicial markers on the tool. Using fiducial markers provides better localization safety.

*4) While the Pinpoint is registered during installation, the iSYS 1 uses fiducial markers for registration. Again, using fiducial markers provides better localization safety.

Statement of safety and effectiveness:

It is our opinion that the iSYS 1 System (U.S.) does not have technological characteristics that raise additional types of safety or effectiveness questions, and we consider them to be an enhancement to the existing devices.

To validate the accuracy of the iSYS 1 an external reference system has to be used. We have used and validated the accuracy of the iSYS 1 System (U.S.) with the Philips Allura Xper Guide FD 20 X-ray system and the Axiom Artis Zeego from Siemens Healthcare, and passed all tests.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Substantial Equivalence Discussion

Device Comparison Table:

Reference	PinPoint	iSYS 1 (for new submission)	Equivalence?
510k-Number	K974513	K131433	
Manufacturer	PHILIPS MEDICAL SYSTEMS (CLEVELAND), INC. 595 Miner rd. Cleveland, OH 44143 USA	iSYS Medizintechnik GmbH Bergwerksweg 21 A-6370 Kitzbuehel Austria	
Design			
General device description	Five jointed, position-sensing stereotactic arm, mounted on the CT gantry, and indicated for invasive procedures	Computer controlled electromechanical multi-joined arm indicated for invasive procedures	Yes
Localization means	Robot arm absolute encoders	Fiducial markers on tool holder.	*3)
Image-guided	Yes	Yes	Yes
Planning software	No, not cleared under this 510k (K955268)	No (third party)	Yes
Registration method	During installation	Fiducial markers	*4)
Instrumentation	Cannula Laser needle guide	Marker Tool Holder Sterile Covers (third party)	Yes
Instrument fixation	Cannula attached to the arm (optional: laser needle guidance)	Special tool holders for several applications mounted to the Robot	Yes
Instrument calibration	Factory Calibration Optional: intra operative	Intra operative	*1)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Reference	PinPoint	iSYS 1 (for new submission)	Equivalence?
System immobilization between patient and device	Yes	Yes	Yes
Planning and Navigation Software			
N/A.			
System Operation			
Fiducial markers registration with pointer probe	No	No	Yes
Optical registration	No	No	Yes
Ultrasound Registration	No	No	Yes
Accuracy verification	Yes, external anatomical verification	Yes, performed by user	Yes
Provide mechanical guidance for tools	Yes	Yes	Yes
Instrument guide position adjustment	Manual	Manual	Yes
Physician carries out final gesture through tool guide	Yes	Yes	Yes
Indications for Use			
Indication for use	The PinPoint is an accessory to a CT system intended to provide the radiologist with a means of simulating and initiating interventional procedures by interactively relating the patient´s CT image volume to the actual target field. This accessory includes mounting the	The iSYS 1 device is a user-controlled electromechanical arm with a needle guide. It is intended to assist the surgeon in the positioning of a needle or electrode where both computed tomography (CT) and fluoroscopic imaging can be used for target trajectory planning and	Yes

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Reference	PinPoint	iSYS 1 (for new submission)	Equivalence?
	stereotactic arm on a CT-Gantry, a flat panel TV monitor, cabling, biopsy phantom and software. In addition the CT is intended to produce cross-sectional images of the body by computer reconstruction of X-ray transmission data from the same axial plane taken at different angels. This device may include signal analysis and display equipment, patient and equipment supports, components and accessories. PinPoint is not limited to any particular region of the body. It is equally viable for planning head and spine interventions as it is in the abdomen. It is expected that its major use will be in the planning of biopsies of abdominal organs and drainage of fluid collections in the abdomen. However, more complicated procedures such as Brachy therapy and bone pinnings will be planned using the PinPoint.	intraoperative tracking. The needle or electrode is then manually advanced by the surgeon. Trajectory planning is made with software that is not part of the iSYS device.	
Intended Use	The PinPoint is an accessory to a CT system intended to provide the radiologist with a means of simulating and initiating interventional procedures by interactively relating the patient´s CT image volume to the actual target field. The system produces cross sectional images by computer reconstruction of x-	The intended use of the iSYS1 device is to function as a remote-operated positioning and guidance system during interventional procedures. Positioning is done in remote control manner; planning of the position/angulation is done based on 2D/3D patient data (CT, cone-beam CT, fluoroscopy) by external planning	

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Reference	PinPoint	iSYS 1 (for new submission)	Equivalence?
	ray transmission data from the same axial plane taken at different angles. A stereotactic arm on a CT Gantry, a flat panel TV monitor, and biopsy phantom are used as accessories to produce these images. The primary intend of the system is to provide guidance for biopsies in the abdomen, spine and head.	software – for example using an external navigation system, or planning software coming with the used imaging device. Also verification of the correct position and orientation of the tool prior to/during/after the intervention is done by means of these external devices. The iSYS1-System is then acting as a guideway during the manual insertion of the interventional tool – usually a needle type device, and the like. Applications include, but are not limited to, interventions like biopsy procedures, tumor ablation, nerve blocking, electrode placement, etc.	
Anatomical site	Total Body	Total body	Yes
User	Radiologist	Physician	*2)
Accessory	V-Channel Cannula Cylindrical Cannula	Sterile Covers Table Adapters Cable Sets	Yes
Real-time instrument position	Yes	Yes	Yes
Mechanical Guidance of instruments	Yes	Yes	Yes
Technology			
Powered	Yes	Yes	Yes
CE-Conformity	No	Yes	Yes

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Reference	PinPoint	iSYS 1 (for new submission)	Equivalence?
Computer-controlled	Yes	Yes	Yes
Materials	Metal, electronics and plastics	Metal, electronics Polyamide Polyethylene Bralen	Yes

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Similarities and Differences:

All three devices are intraoperative instruments used by physician for assisting the spatial positioning and orientation of a surgical tool.

iSYS 1 is equivalent to:

- PinPoint for assisting the spatial positioning and orientation of a surgical tool.
- PinPoint for being localized by the navigation or imaging software.
- PinPoint for being guided by an imaging device
- PinPoint for providing a registration method for the imaging device.
- PinPoint for instrumentation and instrument fixation.
- PinPoint for being immobilized in relation to the patient.
- PinPoint for providing accuracy verification, tool guidance and position adjustment.
- PinPoint for the physician making the final gesture.
- PinPoint for having the same indications for use and region of interest.

Non-clinical testing has mainly been performed to prove electrical and mechanical safety of the devices. Similar to the predicate devices, iSYS 1 was tested according to EN ISO 60601-1 2nd edition:

- EN 60601-1:1990 + A1:1993 + A2:1995
- EN 60601-1-8:2004 + A1:2006

The Electromagnetic Compatibility of the iSYS1 System has been tested according to FCC Part15 (Edition 1st October 2010) and ISO 60601-1-2:2007 and meets the acceptance criteria of both.

Performance tests have been performed to prove:

- the accuracy of the needle placement under clinical conditions,
- the compatibility with the imaging modality,
- the tendency to produce artifacts,
- the mechanical stability of the system despite external payload under worst conditions
- the mechanical stability of the table adapters despite external payload,
- the accuracy in remote-control mode
- the accuracy of needle guidance
- functionality of hardware modules
- effectiveness of hardware safety measures for the software,
- and the effectiveness of the alarm systems

The results of these performance tests support that the predicate devices and iSYS 1 are substantially equivalent.

Differences:

*1) PinPoint provides a factory instrument calibration of the encoders. During intervention the physician using iSYS1 and PinPoint verifies the position of the needle or needle-type instrument (tool). Verification of the tool position requires greater physical effort but provides for exact (depending on the imaging system) tool localization. The localization of the tool is not required for the iSYS 1 and, thus, this has no effect on safety or effectiveness.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

*2) While the PinPoint is indicated to be used by radiologists only, the iSYS 1 is indicated to be used by any trained physician. This has no effects on safety and effectiveness.

*3) PinPoint provides encoders for localization, whereas iSYS uses fudicial markers on the tool. Using fiducial markers provides better localization safety.

*4) While the Pinpoint is registered during installation, the iSYS 1 uses fiducial markers for registration. Again, using fiducial markers provides better localization safety.

Statement of safety and effectiveness:

It is our opinion that the iSYS 1 System (U.S.) does not have technological characteristics that raise additional types of safety or effectiveness questions, and we consider them to be an enhancement to the existing devices.

To validate the accuracy of the iSYS 1 an external reference system has to be used. We have used and validated the accuracy of the iSYS 1 System (U.S.) with the Philips Allura Xper Guide FD 20 X-ray system and the Axiom Artis Zeego from Siemens Healthcare, and passed all tests.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Proposed Labeling

Content | Page

Product and Packaging Labels	2
User Manual	7
Marketing Material	120
Form FDA 3654	133

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Product and Packaging Labels

Safety Symbols:

STERILE R	Symbol for STERILIZED USING RADIATION
	Symbol for DO NOT USE IF PACKAGE IS DAMAGED
	Symbol for DO NOT REUSE
MR	Symbol for NOT MRI SAFE
	Symbol for ALTERNATING CURRENT
	Symbol for CAUTION, CONSULT ACCOMPANYING DOCUMENTS
	Symbol for TYBE B APPLIED PART
	Symbol for ON/OFF SWITCH (PUSH-PUSH)
	Symbol for PROTECTIVE EARTH
	Symbol for STORAGE TEMPERATURE
	Symbol for DO NOT LITTER IN DOMESTIC WASTE

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Product identification Symbols:

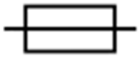
SN	Symbol for SERIAL NUMBER
REF	Symbol for ORDER NUMBER
LOT	Symbol for BATCH NUMBER

Additional Symbols:

CE	Symbol for CE-conformity
+	Symbol for PLUS (increase speed level)
–	Symbol for MINUS (decrease speed level)
	Symbol for POSITIONING
	Symbol for ANGULATION
READY	Label for the ready indicator light
ERROR	Label for the error indicator light
POWER	Label for the power indicator light
USER INTERFACE	Label for the user interface connector
C	Symbol for the confirm push button
Q	Symbol for the quit push button

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

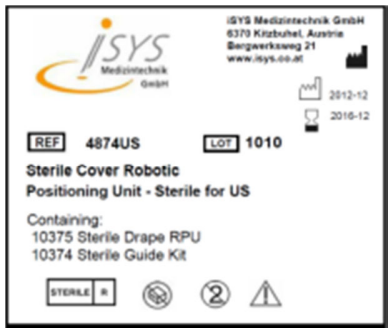
	Symbol for MANUFACTURER
	Symbol for DATE OF MANUFACTURE
	Symbol for USE BY
	Symbol for FUSE
	Symbol for KEEP DRY
	Symbol for THIS SIDE UP
	Label for the Weight
iSYS Medizintechnik GmbH	Company Label

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Examples for Product Labels:

The presented labels are examples for the final product and packaging labels. Lot numbers and dates on these examples are placeholders only. They do not define any format of lot numbers, production or expiry dates.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

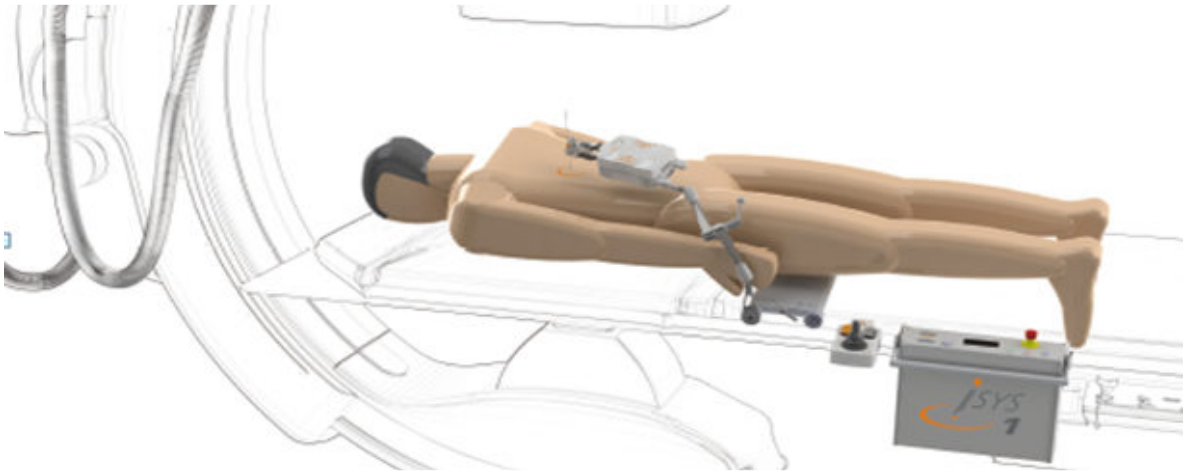
Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

User Manual

USER MANUAL US



iSYS Medizintechnik GmbH
Bergwerksweg 21
6370 Kitzbühel
Austria
www.isys.co.at

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Copyright Statement

© 2011 iSYS Medizintechnik GmbH.

All rights reserved. No part of this document may be reproduced in any form without written permission from the copyright holder.

Use of the information contained herein in any form and/or by any means whatsoever is strictly reserved for iSYS and its licensees.

Trademarks

iSYS, iSYS 1 and iSYS Medizintechnik GmbH or its subsidiaries are subject to filed trademark applications.

All rights reserved.

Acknowledgement of Other Trademarks

Other manufacturer's registered trademarks and trade names that appear in this document are hereby acknowledged.

Referenced Documents

Not all documents referred to in this document are part of the scope of delivery for the equipment.

iSYS reserves the right to determine which documents are delivered with a product.

Contact Information

Manufacturer

iSYS Medizintechnik GmbH

Bergwerksweg 21

6370 Kitzbühel

Österreich

Tel +43 (664) 2411140

www.isys.co.at

Representative USA

Cornelia Damsky

56 Westcott Road
Stamford, CT 06902
USA
Phone: +1 (203) 323- 7535
Email: cdamsky@att.net

CE 0408

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

PD/B16	iSYS 1	iSYS Medizintechnik GmbH
Declaration of Conformity		

Konformitätserklärung / Declaration of Conformity / Declaration de Conformité

Wir,	We,	Nous,
iSYS Medizintechnik GmbH, **Bergwerksweg 21, 6370 Kitzbühel, Austria**		
erklären in alleiniger Verantwortung, dass das Medizinprodukt	declare on our own responsibility that the medical device	déclarons sous notre propre responsabilité que le dispositif médical
iSYS 1 (Art. Nr. 4268) **iSYS 1 (U.S.) (Art. Nr. 6224)** **Seriennummern 003 bis 030 (Revision 1)** **HCU Cable Extension (Art. Nr. 6162)**		
allen Anforderungen der Richtlinie **93/42/EWG** ergänzt durch die Richtlinie **2007/47/EG** entspricht	meets all the provisions of the Directives **93/42/EEC and 2007/47/EC**	remplit toutes les exigences de les directives sur les dispositifs médicaux **93/42/CEE et 2007/47/CE**
Angewandte harmonisierte Normen:	**Applied harmonized standards:**	**Normes harmonisées appliquées:**
OENORM EN 980:2008, EN 1041:2008, OENORM EN 60601-1:2007, OENORM EN 60601-1-2+A1:2006, OENORM EN 60601-1-6:2008, OENORM EN 60601-1-8:2008		
Klassifizierung basiert auf den Anforderungen der **Regel**	**Classification** is based on the requirements of **Rule**	**Classification** La classification est fondée sur les exigences de la **Règle**
12		
des **Anhang IX** der Richtlinie über Medizinprodukte	of **annex IX** of the Medical Device Directive	de **l'annexe IX** de la directive sur les dispositifs médicaux
Medizinprodukt der **Klasse**	Medical device **Class**	les dispositifs médicaux **Classe**
I		
Konformitätsbewertungsverfahren gemäß der Richtlinie 93/42 EWG, **Anhang**	**Conformity assessment procedure** according to Directive 93/42 EEC, **Annex**	**Procédure d'évaluation de la conformité** en application de la directive 93/42/CEE **Appendice**
VII		
Benannte Stelle (falls zutreffend)	**Notified body** (if applicable)	**Organisme notifié** (le cas échéant)
TÜV Austria Services GmbH (CE 0408)		
Diese Konformitätserklärung gilt für obige Serien-/ Lotnummern ab dem Produktionsdatum	**This declaration of conformity is effective for above Serial/ Lot numbers as of the production date**	**Cette déclaration de conformité est valable pour les numéros de série/ du lot dès la date de production**
29. November 2012		
..... Geschäftsführer		Kitzbühel, 29.11.12

Doc No: PD_73_4825	Revision 04 from: 29.11.2012			1/1
Created by:	Approved by:	Invalid since:	Source:	Approval Date:
Oliver Spitz	Thomas Pfeifer		FO_73_2565	07.06.2011

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

PD/B16	iSYS 1	iSYS Medizintechnik GmbH
Declaration of Conformity		

Konformitätserklärung / Declaration of Conformity / Declaration de Conformité

Wir,	We,	Nous,
iSYS Medizintechnik GmbH, **Bergwerksweg 21, 6370 Kitzbühel, Austria**		
erklären in alleiniger Verantwortung, dass das Medizinprodukt	declare on our own responsibility that the medical device	déclarons sous notre propre responsabilité que le dispositif médical
Zubehör iSYS 1 **Side Rail Adapter (Art.Nr. 4095)** **Multi Functional Arm (Art. Nr. 4271)** **Table Top Adapter Version A (Art.Nr. 4117)** **Table Top Adapter Version B (Art.Nr. 4120)**		
allen Anforderungen der Richtlinie **93/42/EWG** ergänzt durch die Richtlinie **2007/47/EG** entspricht	meets all the provisions of the Directives **93/42/EEC and 2007/47/EC**	remplit toutes les exigences de les directives sur les dispositifs médicaux **93/42/CEE et 2007/47/CE**
Angewandte harmonisierte Normen:	**Applied harmonized standards:**	**Normes harmonisées appliquées:**
OENORM EN 980:2008, EN 1041:2008, OENORM EN 60601-1:2007, OENORM EN 60601-1-2+A1:2006, OENORM EN 60601-1-6:2008, OENORM EN 60601-1-8:2008		
Klassifizierung basiert auf den Anforderungen der **Regel**	**Classification** is based on the requirements of **Rule**	**Classification** La classification est fondée sur les exigences de la **Règle**
1		
des **Anhang IX** der Richtlinie über Medizinprodukte	of **annex IX** of the Medical Device Directive	de **l'annexe IX** de la directive sur les dispositifs médicaux
Medizinprodukt der **Klasse**	Medical device **Class**	les dispositifs médicaux **Classe**
I		
Konformitätsbewertungsverfahren gemäß der Richtlinie 93/42 EWG, **Anhang**	**Conformity assessment procedure** according to Directive 93/42 EEC, **Annex**	**Procédure d'évaluation de la conformité** en application de la directive 93/42/CEE **Appendice**
VII		
Benannte Stelle (falls zutreffend)	**Notified body** (if applicable)	**Organisme notifié** (le cas échéant)
TÜV Austria Services GmbH (CE 0408)		
Diese Konformitätserklärung gilt für obige Serien-/ Lotnummern ab dem Produktionsdatum	**This declaration of conformity is effective for above Serial/ Lot numbers as of the production date**	**Cette déclaration de conformité est valable pour les numéros de série/ du lot dès la date de production**
29. November 2012		
Geschäftsführer	Kitzbühel, 29.11.12	

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

PD/B16	Accessory, sterile	iSYS Medizintechnik GmbH
Declaration of Conformity		

Konformitätserklärung / Declaration of Conformity / Declaration de Conformité

Wir,	We,	Nous,
iSYS Medizintechnik GmbH, Bergwerksweg 21, 6370 Kitzbühel, Austria		
erklären in alleiniger Verantwortung, dass die Medizinprodukte	declare on our own responsibility that the medical devices	déclarons sous notre propre responsabilité que les dispositifs médicaux
6289G10US Needle Guide Insert 10G – sterile for US **5990G11US Needle Guide Insert 11G – sterile for US** **5991G12US Needle Guide Insert 12G – sterile for US** **5992G13US Needle Guide Insert 13G – sterile for US** **5993G14US Needle Guide Insert 14G – sterile for US** **4877G15US Needle Guide Insert 15G – sterile for US** **4878G16US Needle Guide Insert 16G – sterile for US** **4879G17US Needle Guide Insert 17G – sterile for US** **4880G18US Needle Guide Insert 18G – sterile for US** **5989G19US Needle Guide Insert 19G – sterile for US** **4881G20US Needle Guide Insert 20G – sterile for US** **4882G21US Needle Guide Insert 21G – sterile for US** **4875US Needle Guide Marker Insert – sterile for US** **4876US Needle Guide Marker Insert centered – sterile for US** **4874US Sterile Cover Robotic Positioning Unit – sterile for US** **4883US Sterile Cover Handheld Control Unit – sterile for US**		
allen Anforderungen der Richtlinie **93/42/EWG** ergänzt durch die Richtlinie **2007/47/EG** entspricht	meets all the provisions of the Directives **93/42/EEC and 2007/47/EC**	remplit toutes les exigences de les directives sur les dispositifs médicaux **93/42/CEE et 2007/47/CE**
Angewandte harmonisierte Normen:	**Applied harmonized standards:**	**Normes harmonisées appliquées:**
OENORM EN 980:2008, DIN EN 1041:2008, ÖNORM EN ISO 11607-1:2007, ÖNORM EN ISO 11607-2:2006		
Klassifizierung basiert auf den Anforderungen der **Regel**	**Classification** is based on the requirements of **Rule**	**Classification** La classification est fondée sur les exigences de la **Règle**
1		
des **Anhang IX** der Richtlinie über Medizinprodukte	of **annex IX** of the Medical Device Directive	de **l'annexe IX** de la directive sur les dispositifs médicaux
Medizinprodukte der **Klasse**	Medical devices **Class**	les dispositifs médicaux **Classe**
Is		
Konformitätsbewertungsverfahren gemäß der Richtlinie 93/42 EWG, **Anhang**	**Conformity assessment procedure** according to Directive 93/42 EEC, **Annex**	**Procédure d'évaluation de la conformité** en application de la directive 93/42/CEE **Appendice**
II		
Benannte Stelle (falls zutreffend)	**Notified body** (if applicable)	**Organisme notifié** (le cas échéant)
TÜV Austria Services GmbH (CE 0408)		
Diese Konformitätserklärung gilt für alle Serien-/ Lotnummern ab dem Produktionsdatum	**This declaration of conformity is effective of all Serial/ Lot numbers as of the production date**	**Cette déclaration de conformité est valable pour toutes les numéros de série/ du lot dès la date de production**
12. Dezember 2012		
Geschäftsführer	Kitzbühel, 29.11.12	

Doc No: PD_73_09597	Revision 01 from: 29.11.2012			1/1
Created by:	Approved by:	Invalid since:	Source:	Approval Date:
Oliver Spitz	Thomas Pfeifer		FO_73_2565	07.06.2011

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

CE-SetDescription	iSYS Medizintechnik GmbH

iSYS Medizintechnik GmbH
Bergwerksweg 21
6370 Kitzbühel
Austria
Tel. +43 (0) 664 / 2411140
Fax. +49 (0) 8232 / 969222
www.isys.co.at

EC Declaration of Conformity

We iSYS Medizintechnik GmbH declare under sole responsibility that the set to which this declaration relates, as an accessory to the **iSYS 1**, meets the essential health and safety requirements and is in conformance with the EC directives 93/42/EC and 2007/47/EC (MDD).

Set description:

iSYS 1 – class I product

Accessory sterile – class Is product

Accessory non-sterile – class I product

The set is classified as Is according to rules 1 and 12.

iSYS Medizintechnik GmbH meets the requirements of EN ISO 13485:2003 as indicated on certificate registration # TÜV-A-MT-1/11/E148.
The registration has been granted by TÜV Austria Services GmbH, Austria (# 0408).

The CE mark is applied with respect to annex II of the MDD. This CE marking has been affixed on the device according to article 17 of the MDD.

This declaration is effective from: see date of sign off

General Manager

Kitzbühel, 29.11.12
Place / date

Dok-Nr: PD_73_6387	Revision 01 vom: 29.11.2012			Seite 1/1
Erstellt von:	Freigabe durch:	Ungültig ab:	Vorlage dazu:	Vom:
Oliver Spitz	Thomas Pfeifer		FO_42_1928	06.06.2011

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Table of Contents:

1. Introduction 16

1.1. About this Manual 16

1.2. Description of iSYS 1 16

1.3. Intended Use 17

1.4. Abbreviations 18

1.5. Glossary 19

1.6. Text Formats 20

2. Safety 21

2.1. Warnings, Cautions and Notes 21

2.2. Manual Handling Procedures 21

2.3. Warning Labels 22

2.3.1. Safety Symbols 22

2.3.2. Product Identification Symbols 23

2.3.3. Additional Symbols 23

2.4. Final Disposal 25

2.5. EMC and Mobile Telephones 26

2.6. Compatibility 31

2.7. Compliance 31

2.7.1. IEC Safety Standards 31

2.7.2. IEC Classification 31

2.8. Training 32

3. Specifications 34

3.1. Environmental Conditions 34

3.1.1. Environmental Conditions for Transport and Storage 34

3.1.2. Environmental Conditions for the Intended Use 34

3.2. Components 35

3.2.1. System iSYS 1 U.S. (Art.No. 6224) 36

3.2.2. Accessory – non sterile 39

3.2.3. Accessory - sterile: 40

3.3. Technical Specifications 41

3.3.1. Robotic Positioning Unit 41

3.3.2. Control Unit 41

3.3.3. RPU Cable Set 1500 41

3.3.4. RPU Cable Set 3000 41

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

3.3.5. Handheld Control Unit 41
3.3.6. HCU Cable Extension 41
3.3.7. Multi Functional Arm 41
3.3.8. Table Top Adapter Version B 42
3.3.9. Table Top Adapter Version A 42
3.3.10. Side Rail Adapter 42

4. Operating iSYS 1 43

4.1. Set-Up and Installation 44

4.1.1. Mounting of the (Radiolucent) Needle Guide Extension to the Robotic Positioning 45
4.1.2. Adaptation of the Table Adapters 47
4.1.3. Mounting of the Multi Functional Arm (MFA) 53
4.1.4. Mounting the Robotic Positioning Unit 55
4.1.5. Mounting the Control Unit to the Side Rail 56
4.1.6. Using the Control Unit without Side Rail 57
4.1.7. Adaptation of the Handheld Control Unit to the Side Rail 59
4.1.8. Connection of the Power and Data Cables 60
4.1.9. Bringing the RPU into the "Parking position" 64
4.1.10. Start-up Procedure of the iSYS 1 Robot 66

4.2. Use of iSYS 1 69

4.2.1. Checking the Mechanical Setup and the Range of iSYS 1 69
4.2.2. Setup and Preparing the Patient 70
4.2.3. Image Acquisition and Treatment Planning 72
4.2.4. Working with the sterile iSYS 1 Disposables 73
4.2.5. Attaching the Sterile Cover over the Robotic Positioning Unit 78
4.2.6. Attaching the Sterile Cover to the HCU 89
4.2.7. Gross-Positioning of the RPU and Insertion of the Sterile Needle Guide Marker Insert into the Needle Guide Adapter 90
4.2.8. Micro-Positioning and Accurate Alignment of the NGA under fluoroscopy 92
4.2.9. Ultra-fine-Positioning and Accurate Alignment of the Needle under fluoroscopy 96
4.2.10. Attachment of the Needle Guide Insert and Needle Placement 97
4.2.11. Removing the NGI and Quick-Release 102

4.3. Emergency Release/ Removing the system in case of emergency 105

4.4. Dismounting 105

4.5. User Interface 107

4.5.1. Alarms 107
4.5.2. Front-Panel of the Control Unit 108

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

4.5.3. Handheld Control Unit 109
4.5.4. Display Messages 111
5. Maintenance 114
5.1. Safety-relevant inspections 115
6. Cleaning and Disinfection 117

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

1. Introduction

1.1. About this Manual

This manual is intended to assist users in the safe and effective operation of the equipment described. The term 'user' is used throughout this manual for both the body that has the authority over the equipment and those persons, who actually handle the equipment.

a) The term clinical user means a qualified person who uses any part of the device and its accessories for the purpose of treating patients, and who has been specifically trained in the safe clinical use of the device. Such treatment is restricted to being therapeutic in nature.

b) The term service user means a qualified service engineer who has been trained in servicing the device, and who operates any part of the device for the purpose of performing tests, adjustments and/or repairs to the equipment without, in any manner, involving the presence or treatment of a patient, and personnel who are involved in site planning and installation of the device.

Before attempting to work with this equipment, you must read, understand, note and, where applicable, strictly observe all danger notices, warnings, cautions and safety markings on the equipment and in this manual paying particular attention to all:

- Warnings
- Cautions
- Notes

Please pay special attention to all the safety information provided, and safety procedures described (see section 2).

The use of this equipment by unauthorized persons is strictly prohibited.

1.2. Description of iSYS 1

The iSYS 1 Interventional Platform is a modular needle guidance platform for interventional radiology and related fields.

Core components are a 4 DOF Robotic Positioning Unit which allows submillimetric needle positioning as well as angulation and a Control Unit which is controlled by a cable connected Handheld Control Unit.

The passive macro positioning unit and different table adapters allow different setups of the system around the patient in the region of interest by still providing maximum rigidity.

The needle-guide-set provides disposable components that ensure precise and sterile needle guidance.

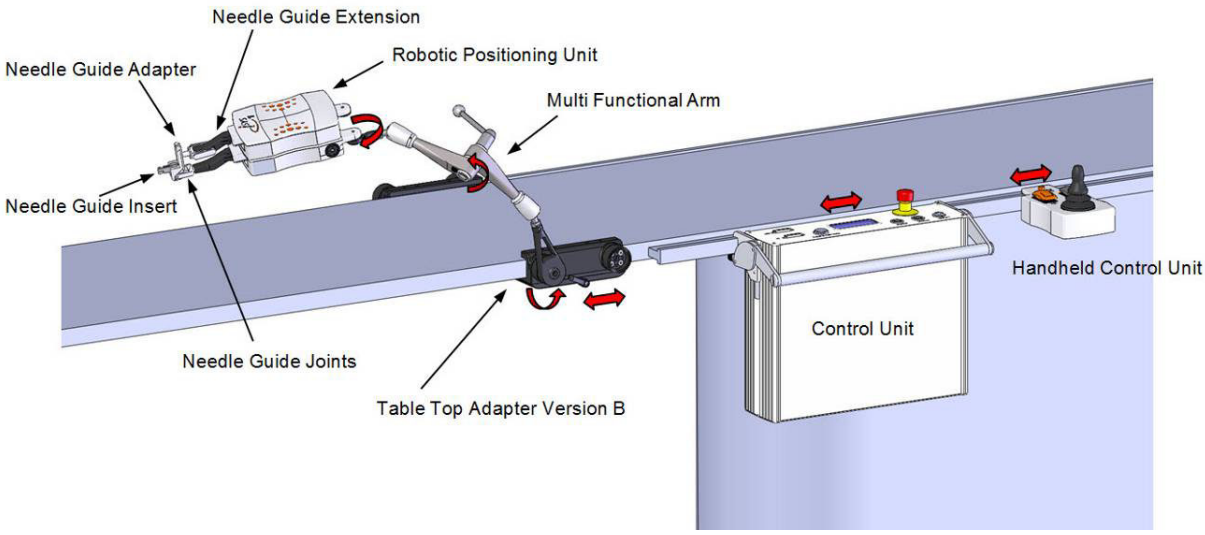
Planning of the intervention is based on digital image data acquired intra-operatively using different kinds of modalities, like CT or fluoroscopy (standard C-arms and/or cone-beam CT systems).

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Planning and verification of both the entry position of the needle-type tool as well as the angulation is performed with the aid of the used imaging device or by an external navigation system.

By using the iSYS 1 Handheld Control Unit the surgeon can remotely move the tool to the desired position and angulation in order to start the clinical procedure.



The system includes the following mechanical parts:

- one Control Unit
- one Table Top Adapter Version B (Bottom Mounted)
- optional: Side Rail Adapter or Table Top Adapter Version A (Top Mounted)
- one Multi Functional Arm
- one Robotic Positioning Unit
- two Needle Guide Extensions

The sterile disposables for each procedure are:

- Sterile Cover Robotic Positioning Unit (not reusable) including Needle Guide Joints and Needle Guide Adapter (not reusable)
- Sterile Cover Handheld Control Unit (not reusable)
- Needle Guide Insert (not reusable)
- Marker Insert (not reusable)

see description in chapter “3.2.4. Accessory – sterile”

1.3. Intended Use

The intended use of the iSYS 1 device is to function as a remote-operated positioning and guidance system during interventional procedures. Positioning is done in remote control manner; planning of the position/angulation is done based on 2D/3D patient data (CT,

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

cone-beam CT, fluoroscopy) by external planning software – for example using an external navigation system, or planning software coming with the used imaging device. Also verification of the correct position and orientation of the tool prior to/during/after the intervention is done by means of these external devices. The iSYS 1 system is then acting as a guideway during the manual insertion of the interventional tool – usually a needle type device, and the like. Applications include, but are not limited to, interventions like biopsy procedures, tumor ablation, nerve blocking, electrode placement, etc.

WARNING
in the USA, Federal law restricts this device to sale by or on the order of a physician.

1.4. Abbreviations

The following are abbreviations and acronyms which are used in this document. Their definition is explained below.

Abbreviation	Definition
AC	Alternating current
ASCII	American Standard Code for Information Interchange
AM	Amplitude modulation
CT	Computed tomography
CU	Control Unit
DOF	Degree of Freedom
EMC	Electromagnetic compatibility
FM	Frequency modulation
HCU	Handheld Control Unit
IEC	International Electrotechnical Commission
iSYS	iSYS Medizintechnik GmbH
LCD	Liquid crystal display
LED	Light emitting diode
MFA	Multi Functional Arm
MRI	Magnet resonance imaging
N/A	Not applicable

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Abbreviation	Definition
NGA	Needle Guide Adapter
NGE	Needle Guide Extension
NGI	Needle Guide Insert
NGMI	Needle Guide Marker Insert centered
OR	Operating room
ÖVE	Österreichischer Verband für Elektrotechnik (*Austrian* Electrotechnical Committee)
RF	Radio frequency
RM	Robotic Module
RPU	Robotic Positioning Unit
SRA	Side Rail Adapter
TTAA	Table Top Adapter Version A - Top Mounted
TTAB	Table Top Adapter Version B - Bottom Mounted
TV	Tele-vision
WxH	Width and height

Table 1-1: Abbreviations and Acronyms

1.5. Glossary

Throughout this manual, the following terms have the specific meaning listed below.

Term	Definition
Imaging device	(Medical) Imaging devices are devices used to create images of the human body (or parts and function thereof) for clinical purposes. Imaging modalities for iSYS 1 include CT or fluoroscopy (standard C-arms and/or cone-beam CT systems).
Gantry	In medical imaging, the Gantry is a circular assembly that allows sensors, and possibly energy sources, to rotate around a patient.
Treatment Table	Also called “Imaging Table” or “Treatment Couch”. Table system of the imaging device. Usually this table has a number of degrees of freedom (DOF) – e.g. for vertical and horizontal movement – in order to preposition the

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Term	Definition
	patient relatively to the imaging arm.
(Carbon fiber) Table Top	Upper part of the Treatment Table. This part of the table usually is made of radiolucent material – in most cases CFRP (carbon-fiber-reinforced plastic).
Side Rail	Most Treatment Tables have a (metal) on the rail left and right side along the table in order to fix components. Depending on the producer of the table these Side Rail setups may differ from each other, for most of the table systems the Side Rail has a rectangular cross section.
Treatment Planning	During Treatment Planning, the surgeon is using pre-operative or intra-operative imaging in order to select the target position for the tool (e.g. the tumor to be treated) as well as the tool trajectory from the skin entry point to the target position. Depending on the used Imaging device such Treatment Planning can be done using 2D or 3D images.

Table 1-2: Glossary

1.6. Text Formats

The following text formats may be found in this document. Their definitions are explained below.

Text Format	Definition
italic	notes
CAPS	symbol names
`courier`	text displayed on screens

Table 1-3: Text Formats

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

2. Safety

2.1. Warnings, Cautions and Notes

The following are examples of how warnings, cautions and notes will appear throughout this document. The text within the examples explains their purpose.

WARNING
Warnings are directions which, if not followed, could constitute a health hazard or cause injury, including fatal or serious injury, or could lead to clinical mistreatment.

CAUTION
Cautions are directions which, if not followed, could cause damage to the equipment described in this manual, and/or any other equipment or goods, and/or could cause environmental damage.

Note: *Notes provide advice and highlight unusual points. A note is not intended as an instruction.*

2.2. Manual Handling Procedures

WARNING
When lifting heavy components, it is important that the correct procedures are adhered to. Local regulations and procedures regarding manual handling must be observed at all times. Failure to do so may lead to fatal or serious personal injury.

WARNING
If any liquids are spilled over components of the iSYS 1, the component needs to be dried in a drying case for at least 24 hours.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

2.3. Warning Labels

2.3.1. Safety Symbols

STERILE R	Symbol for STERILIZED USING RADIATION
	Symbol for DO NOT USE IF PACKAGE IS DAMAGED
	Symbol for DO NOT REUSE
MR	Symbol for NOT MRI SAFE
	Symbol for ALTERNATING CURRENT
	Symbol for CAUTION, CONSULT ACCOMPANYING DOCUMENTS
	Symbol for TYBE B APPLIED PART
	Symbol for ON/OFF SWITCH (PUSH-PUSH) Power Switch
	Symbol for PROTECTIVE EARTH
	Symbol for STORAGE TEMPERATURE

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

	Symbol for DO NOT LITTER IN DOMESTIC WASTE

2.3.2. Product Identification Symbols

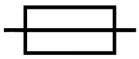
SN	Symbol for SERIAL NUMBER
REF	Symbol for ORDER NUMBER
LOT	Symbol for BATCH NUMBER

2.3.3. Additional Symbols

CE	Symbol for CE-conformity
+	Symbol for PLUS (increase speed level)
–	Symbol for MINUS (decrease speed level)
	Symbol for POSITIONING
	Symbol for ANGULATION
READY	Label for the ready indicator light
ERROR	Label for the error indicator light
POWER	Label for the power indicator light

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

USER INTERFACE	Label for the user interface connector
	Symbol for the confirm push button
	Symbol for the quit push button
	Symbol for MANUFACTURER
	Symbol for DATE OF MANUFACTURE
	Symbol for USE BY
	Symbol for FUSE
	Symbol for KEEP DRY
	Symbol for THIS SIDE UP
	Label for the Weight
iSYS Medizintechnik GmbH	Company Label

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

2.4. Final Disposal

Final disposal means the disposal of the equipment or any part of it in such a way that it can no longer be used for its intended use.

Disposal must always be executed in an environmentally sensitive manner that complies with all local and international regulations and laws. Materials hazardous to human health and the environment must be separately removed and disposed of by competent, licensed facilities. The remaining material may be recycled, where facilities and local regulations permit this.

Never dispose iSYS products in the domestic waste stream.

Prior to disposal, always contact iSYS Medizintechnik GmbH for advice and a list of the substances that require special attention.

WARNING
Incorrect handling or disposal of hazardous material may cause fatal or serious injury and environmental damage. Always disposit iSYS 1 and its components according to the regional regulations.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

2.5. EMC and Mobile Telephones

The iSYS 1 system is compliant with the requirements according EN 60601-1-2:2007 and FCC: 47 CFR Part 15:

Guidance and manufacturer's declaration – electromagnetic emissions		
iSYS 1 is intended for use in the electromagnetic environment specified below. The customer or the user of iSYS 1 should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions CISPR 11	Group 1	iSYS 1 uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	iSYS 1 is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Not applicable	

Guidance and manufacturer's declaration – electromagnetic immunity			
iSYS 1 is intended for use in the electromagnetic environment specified below. The customer or the user of iSYS 1 should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment –guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines ±2 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV line(s) to line(s)	±1 kV line(s) to line(s)	Mains power quality should be that of a typical commercial or hospital

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

	±2 kV line(s) to earth	±2 kV line(s) to earth	environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % U_T (>95 % dip in U_T) for 0,5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % UT (>95 % dip in U_T) for 5 sec	<5 % U_T (>95 % dip in U_T) for 0,5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % UT (>95 % dip in U_T) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of iSYS 1 requires continued operation during power mains interruptions, it is recommended that the iSYS 1 be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Note U_T is the AC mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration – electromagnetic immunity			
iSYS 1 is intended for use in the electromagnetic environment specified below. The customer or the user of iSYS 1 should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment –guidance**
Conducted RF	3 Vrms 150 kHz to 80	10 Vrms 150 kHz to 80	Portable and mobile RF communications equipment should be used no closer to any part of iSYS 1 including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d = 0{,}35\sqrt{P}$

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

IEC 61000-4-6 Radiated RF IEC 61000-4-3	MHz 3 V/m 80 MHz to 2,5 GHz	MHz 10 V/m 150 kHz to 80 MHz	$d = 0{,}35\sqrt{P}$ MHz 80 MHz to 800 $d = 0{,}70\sqrt{P}$ GHz 800 MHz to 2,5 where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[a], should be less than the compliance level in each frequency range[b]. Interference may occur in the vicinity of equipment marked with the following symbol:
Note 1	At 80 MHz and 800 MHz, the higher frequency range applies.		
Note 2	These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.		

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which iSYS 1 is used exceeds the applicable RF compliance level above, iSYS 1 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating iSYS 1.

[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 10 V/m.

Recommended separation distances between portable and mobile RF

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

communications equipment and iSYS 1

iSYS 1 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of iSYS 1 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and iSYS 1 as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	**Separation distance according to frequency of transmitter** m		
	150 kHz to 80 MHz $d = 0{,}35\sqrt{P}$	**80 MHz to 800 MHz** $d = 0{,}35\sqrt{P}$	**800 MHz to 2,5 GHz** $d = 0{,}70\sqrt{P}$
0,01	0,035	0,035	0,07
0,1	0,11	0,11	0,22
1	0,35	0,35	0,70
10	1,11	1,11	2,21
100	3,50	3,50	7,00

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

Note 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

Note 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

The iSYS 1 system requires special precautions regarding EMC and must be installed and put into service in accordance with the EMC information provided in the accompanying documents.

WARNING
The iSYS 1 system should not be used adjacent to or stacked with other equipment. If the iSYS 1 system is used while positioned adjacent to other equipment, it should be observed to verify normal operation in the configuration in which it will be used.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

CAUTION
Class A Equipment – iSYS 1 is not suitable for use in domestic establishments and establishments directly connected to a low voltage power supply network which supplies buildings used for domestic purposes.

WARNING
Portable and mobile RF communications equipment can affect medical electrical equipment.

WARNING
Do not allow any radio-transmitting devices (such as mobile phones, diathermy units, etc.) or devices exceeding the limits defined in the applicable EMC standards in the vicinity of the iSYS 1 system.
Such devices could exceed EMC standards and in unusual circumstances could interfere with the correct functioning of the iSYS 1 system. This could lead to fatal or serious injury, clinical mistreatment, or equipment damage.

CAUTION
The use of cables and other components not specified and/or not supplied by iSYS may adversely affect the EMC performance.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

2.6. Compatibility

Equipment described in this manual shall only be used in combination with other equipment or components, if these are expressly approved by iSYS as compatible. A list of such equipment and components is available from iSYS upon request.

Changes and/or additions to the equipment shall only be carried out by persons expressly authorized by iSYS to do so. Such changes shall comply with best engineering practice and all applicable laws and regulations that have the force of law within the jurisdiction the equipment will be used within.

WARNING
Changes, additions or maintenance to the equipment carried out by persons without appropriate qualifications and training and/or using unapproved spare parts may lead to fatal or serious personal injury and/or damage to the equipment as well as making the warranty void.

2.7. Compliance

Note:	*The iSYS 1 system has been designed and tested for compliance when used in the clinical environment only.*

The iSYS 1 system is designed to comply with internationally recognized standards for safety and performance.

2.7.1. IEC Safety Standards

The iSYS 1 system complies with the following IEC Safety Standards:

- IEC 60601-1 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2 Medical electrical equipment – Part 1-2: General requirements for safety – Collateral standard: Electromagnetic compatibility – Requirements and tests
- IEC 60601-1-6 Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral Standard: Usability
- IEC 60601-1-8 Medical electrical equipment – Part 1-8: General requirements for basic safety and essential performance – Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems

2.7.2. IEC Classification

According to the above listed IEC standards, the iSYS 1 system is classified as set out in

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

the table below:

Type of protection against electric shock	Class I
Degree of protection against electric shock	Type B (the RPU is rated as type B and the needle/tool guided by the system is seen as applied part according IEC 60601-1)
Degree of protection provided by enclosures	IP2X as defined in IEC 60529. (protection against ingress of solid objects with diameter larger than 12,5 mm, no protection against ingress of liquids).
Methods of disinfection recommended by the manufacturer	Disinfected equipment (or elements). See section 6 Cleaning and Disinfection for methods.
Degree of safety of application in the presence of flammable anesthetic mixture with air or with oxygen or with nitrous oxide	Equipment NOT suitable for use in the presence of a flammable anesthetic mixture with air or with oxygen, or nitrous oxide.
Mode of operation	Continuous

Table 2-2: IEC Classification

Explanation of the classification:

A “Class 1 electrical shock classification” means that the iSYS 1 system must be powered via a power cable connected to a protective earth ground.

2.8. Training

Before using the system at the patient, the user must feel confident with the system and therefore adequate training with the system is mandatory.

Training requirements may vary from country to country. Please make sure that you have received enough training without patient and that you are confident with the use of the system (in accordance with local laws or regulations that have the force of law). Information on training is available from the local iSYS representative.

Purpose of the training:

- Learn the safe use of the system.
- Guarantee a safe and fast workflow.
- Learn how to manipulate the NGA with the joystick in 3D. This step is crucial for precise needle alignment.
- The user has to learn the functionality of the joystick and to learn the intuitive use of the joystick.

Important note:

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

- The user needs to understand how she/he wants to integrate the use of iSYS 1 into the overall workflow of the treatment process: Therefore it is mandatory not just to understand how the system works as a standalone, but also how the system interferes with the overall workflow.
- To avoid complications (setup failures for the specific applications, time consuming breaks that lead to inaccuracy and/or additional radiation, etc.) in the overall workflow and overall setup, it is strongly recommended to train the overall workflow as well.

If problems occur or questions remain, please contact iSYS.

WARNING
The iSYS 1 system and its accessories may only be operated by qualified and authorised personnel. 'Qualified' personnel in this case mean personnel which have been approved to operate medical electrical devices by the responsible management of the clinical environment using the iSYS 1 system.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

3. Specifications

Electrical installations in the room where the iSYS 1 system is used must comply with the following regulations (in other countries the equivalent standards) where applicable:

- ÖVE EN7
- ÖVE EN1
- ÖVE ÖNORM E8007
- ÖVE ÖNORM E8001

3.1. Environmental Conditions

3.1.1. Environmental Conditions for Transport and Storage

CAUTION
Noncompliance with stated transport and storage conditions may result in damage to the iSYS 1 system. In this case it is essential to completely dry the components of the iSYS 1 system for at least 24 hours and check the functionality of the system before using.

The environmental conditions for transport and storage of the iSYS 1 system are specified in table 3-1.

Ambient temperature	+10°C to +50°C (50°F to 122°F)
Relative humidity	30% to 70%, non-condensing (no outdoor storage)
Atmospheric pressure	800 mbar to 1100 mbar

Table 3-1: Environmental conditions for transport and storage

3.1.2. Environmental Conditions for the Intended Use

The environmental conditions for the intended use of the iSYS 1 system are specified in table 3-2.

Ambient temperature	15°C to 30°C (59°F to 96°F)
Relative humidity	30% to 70%, non-condensing
Atmospheric pressure	800 mbar to 1100 mbar
Max. operating altitude	2000m (6560 ft)

Table 3-2: Environmental conditions for the intended use

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

3.2. Components

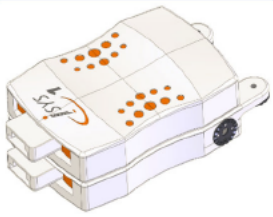
WARNING
iSYS 1 must only be used in combination with accessory described in this manual. Other equipment or components shall only be used, if these are expressly approved by iSYS as compatible. A list of such equipment and components is available from iSYS upon request.

The following tables show the single components of the iSYS 1 system, including optional components for variation of the system according to the user's particular requirements. For further details regarding these optional components please contact iSYS Medizintechnik GmbH.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

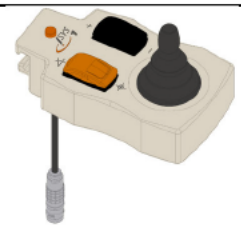
Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

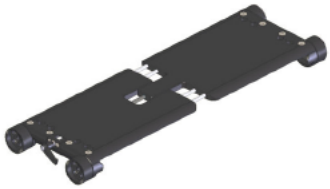
3.2.1. System iSYS 1 U.S. (Art.No. 6224)

Name	Picture	Article-No.:	Standard/Optional/	Description
Robotic Positioning Unit (RPU):		3908	Standard	Robotic Positioning Unit with two 2DOF modules which allows - in combination with the Needle Guide Set - tool angulation (± 30° for both pitch and yaw angle) and needle positioning (± 20 mm for both lateral and longitudinal direction).
Needle Guide Extension 20mm (NGE)		4965	Standard	The Needle Guide Extension comprises two cranked "fingers" which are connected to the Robotic Positioning Unit by screws. This standard version provides an offset of 20mm between the bottom edge of the RPU and the NGE. The "fingers" are made out of radiolucent plastic and thus do not cause imaging artifacts.
Control Unit (CU):		6254	Standard	The iSYS 1 Control Unit aims to control the iSYS 1 Robotic Positioning Unit. The CU is integrated into a metal rack and can be attached to the side rail of the treatment table by a simple locking mechanism. It is designed to interface with a standard OR siderail with the following dimensions: (WxH) 10 mm x 25 mm.
RPU Cable Set:		3926 5905	Standard Standard	Set of two cables to connect the CU and RPU. 3926 - RPU Cable Set 1500 mm 5905 - RPU Cable Set 3000 mm
Handheld Control Unit (HCU):		3901	Standard	The Handheld Control Unit comprises a 2-axis joystick as well as confirmation and control buttons for remote operation of the RPU from "safe" distance. A simple locking mechanism allows the

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

				attachment to the side rail. A sterile cover for the Handheld Control Unit is also available. It is designed to interface with a standard OR siderail with the following dimensions: (WxH) 10 mm x 25 mm.

Name	Picture	Article-No.:	Standard/ Optional/	Description
Multi Functional Arm (MFA):		4271	Standard	Single-lever passive multi-functional arm for flexible pre-positioning of the iSYS 1 Robotic Positioning Unit. There are two different connectors: the "Starburst"-adapter connects the MFA to the different table adapters; the "Spoon"-adapter connects the MFA to the RPU.
Table Top Adapter Version B - Bottom Mounted (TTAB):		4120	Standard	Mechanical adapter for safe and stable connection of the MFA directly to a standard C-Arm Couch Top; It is mounted from the bottom of the Couch Top. This adapter is designed to interface with a carbon fiber table top with the following dimensions: Width between 470 mm and 530 mm Maximal thickness of the table: 6 mm (at the border) and 38mm (in the middle of the table)
Table Top Adapter Version A - Top Mounted (TTAA):		4117	Optional	Mechanical adapter for safe and stable connection of the MFA directly to a standard C-Arm Couch Top; The Table Top Adapter Version A – Top Mounted is mounted from the top and provides maximum stability. This adapter is designed to interface with a carbon fiber table top with the following dimensions: Width between 470 mm and 530 mm Maximal thickness of the table: 6 mm (at the border)
Transport		6098	Standard	Transport box

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

box				
Power Cord:		6163	Standard	Power cord (U.S.) length 2500 mm

Table 3-3: iSYS 1 U.S. System

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

3.2.2. Accessory – non sterile

Name	Picture	Article-No.:	Standard/Optional/	Description
Table Top Adapter Version A - Top Mounted (TTAA):		4117	Optional	Mechanical adapter for safe and stable connection of the MFA directly to a standard C-Arm Couch Top; The Table Top Adapter Version A – Top Mounted is mounted from the top and provides maximum stability. This adapter is designed to interface with a carbon fiber table top with the following dimensions: Width between 470 mm and 530 mm Maximal thickness of the table: 6 mm (at the border)
Side Rail Adapter (SRA):		4095	Optional	Adapter to connect the MFA to a standard side rail. The extension with a metal rod is possible if needed. The rod is inserted and into the adapter and fixed with a screw. The Starburst connector is located at the end of the rod as well as on the adapter itself. This adapter is designed to interface with a standard OR side rail with the following dimensions: (WxH) 10 mm x 25 mm
HCU Cable Extension:		6162	Optional	HCU Cable Extension

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

3.2.3. Accessory - sterile:

Name	Picture	Article No.	Disposable	Description
Sterile Cover RPU - sterile for US:		4874US	Disposable	It is a disposable sterile component to cover the RPU and part of the MFA and RPU Cable Set. This assembly consists of a Sterile Drape (Nr. 10375) and the Needle Guide Kit (Nr. 10374) (including 2 Needle Guide Joints with Fixation Rings). Needle Guide Joints allow a quick and reversible connection of the Needle Guide Adapter to the Needle Guide Extension.
Sterile Cover HCU - sterile for US:		4883US	Disposable	It is a disposable sterile component to cover the HCU during operation.
Needle Guide Marker Insert centered - sterile for US:		4876US	Disposable	The Needle Guide Marker Insert (sterile) allows precise and remote-controlled alignment of the Needle Guide based on real-time imaging data.
Needle Guide Insert xxG - sterile for US:		6289G10US 5990G11US 5991G12US 5992G13US 5993G14US 4877G15US 4878G16US 4879G17US 4880G18US 5989G19US 4881G20US 4882G21US	Disposable	During the intervention the tool is inserted and guided by the sterile Needle Guide Insert. Needle Guide Insert – 10G Needle Guide Insert – 11G Needle Guide Insert – 12G Needle Guide Insert – 13G Needle Guide Insert – 14G Needle Guide Insert – 15G Needle Guide Insert – 16G Needle Guide Insert – 17G Needle Guide Insert – 18G Needle Guide Insert – 19G Needle Guide Insert – 20G Needle Guide Insert – 21G

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

3.3. Technical Specifications

3.3.1. Robotic Positioning Unit

Range of Motion: 40 mm x 40 mm (for each Robotic Module)
Max. Force: 35 N
Dimensions: 266 mm x 139 mm x 68,5 mm
Weight: 1,35 kg

3.3.2. Control Unit

Dimensions: 360 mm x 406 mm x 147 mm
Side rail dimensions: 10 mm x 25 mm
Weight: 5,8 kg
Power rating: 230 V ~
50-60 Hz
50 VA
Fuse rating: 2x T1AL 250 V
Alarm Beeper: approx. 55 dB (A) in a distance of 1 m
Power supply cord: 3x min. 1 mm²; max. length 5 m

3.3.3. RPU Cable Set 1500

Cable length: 1,5 m

3.3.4. RPU Cable Set 3000

Cable length: 3,0 m

3.3.5. Handheld Control Unit

Dimensions: 187 mm x 107 mm x 122 mm
Side rail dimensions: 10 mm x 25 mm
Weight: 0,85 kg
Cable length: 3 m

3.3.6. HCU Cable Extension

Cable length: 10 m

3.3.7. Multi Functional Arm

Dimensions: 500 mm x 105 mm x 145 mm
Weight: 1,36 kg

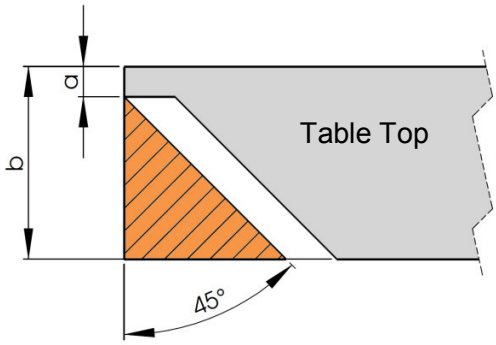
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

3.3.8. Table Top Adapter Version B

Dimensions: 614 mm x 190 mm x 59 mm
Weight: 2,98 kg

Table Top requirements:
Min. table top width: 466 mm
Max. table top width: 535 mm
Min. (a): 3,5 mm
Max. (a): 6 mm
Max. (b): 38 mm



(a) Thickness of the Table Top at the border
(b) Height of the Table Top
Table Top must not reach the orange marked area.

3.3.9. Table Top Adapter Version A

Dimensions: 614 mm x 190 mm x 45 mm
Weight: 2,39 kg

Table Top requirements:
Min. table top width: 466 mm
Max. table top width: 535 mm
Min. (a): 3,5 mm
Max. (a): 6 mm

3.3.10. Side Rail Adapter

Dimensions: 230 mm x 82 mm x 120 mm (without Extension Rod)
610 mm x 45 mm x 25 mm (with Extension Rod)
Side rail dimensions: 10 mm x 25 mm
Weight: 3,29 kg

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

4. Operating iSYS 1

This chapter describes the assembling and operation of the components of the iSYS 1 system. Please be aware that not every type of setup can be described in detail, but with the possibilities described (see below) you should be able to create your desired setup.

WARNING
Never use equipment that is damaged or appears to be working not properly.

WARNING
Never try to touch parts inside of components when operating iSYS 1. Never put your finger in openings. Danger of damage by mains voltage.

WARNING
Always make sure that all components of the hardware setup of iSYS 1 are not causing any collisions with moving parts and/or the gantry of the imaging device.
Therefore, move the gantry and all other moving parts of the imaging device carefully and manually in all desired positions and check for potential collisions before you start the treatment.
Repeat this whenever you have changed the hardware setup of iSYS 1.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

4.1. Set-Up and Installation

For correct system use and an efficient clinical workflow, please follow the Set-Up and Installation instructions below.

WARNING
Check the power supply cord and plug. Should the power supply cord or plug be damaged, the iSYS 1 system must not be used!

CAUTION
Check the mechanical stability of the setup while setting up the iSYS 1 system!

WARNING
Do not use the iSYS 1 setup in MRI environment.

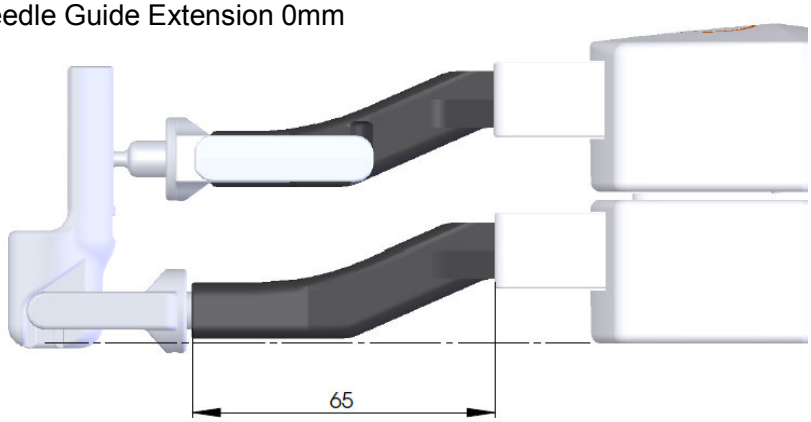
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

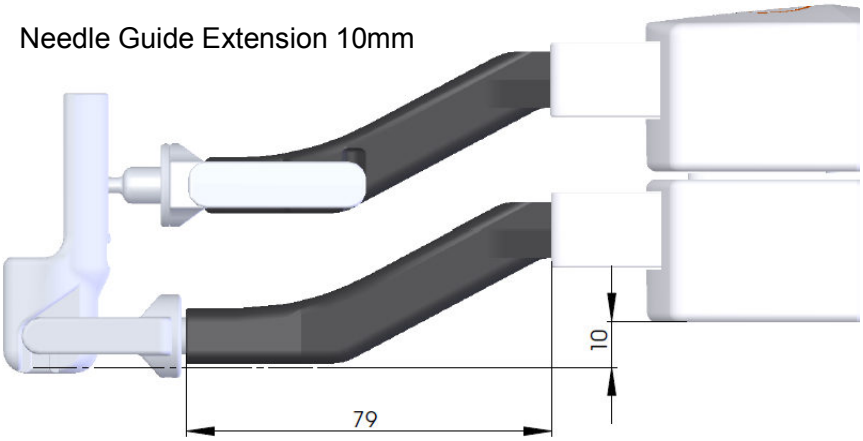
4.1.1. Mounting of the (Radiolucent) Needle Guide Extension to the Robotic Positioning

For the iSYS 1 system different types of Needle Guide Extension are available that differ in offset and length. The system is delivered ready for use with already mounted NGE.

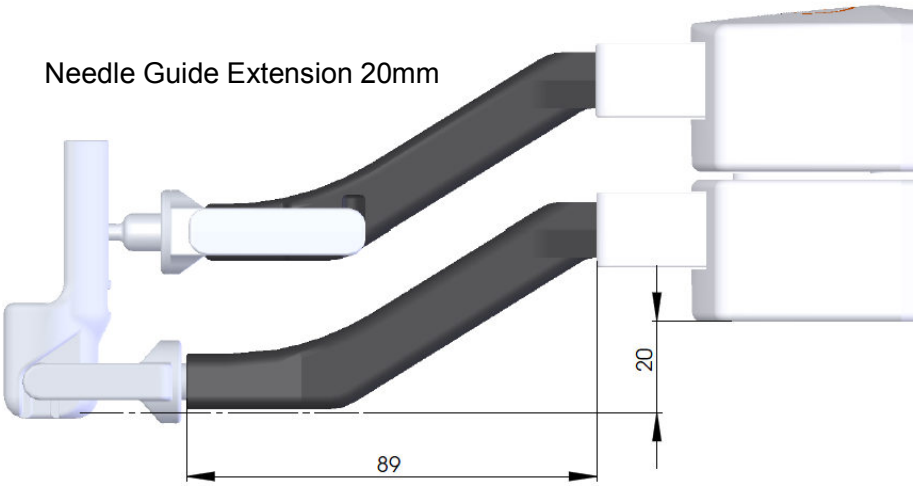
Needle Guide Extension 0mm



Needle Guide Extension 10mm



Needle Guide Extension 20mm



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Note:	*This setup step is only optional and needs to be done in case the user wants to use a different type of NGE (see descriptions of the NGE above).* *This procedure is performed with the robotic unit only, and can be done outside the treatment room.*

WARNING
The mounting of the (radiolucent) Needle Guide Extension to the Robotic Positioning Unit can only be done by a professional iSYS technician. There has to be done a SW-modification. If you want to change the needle NGE, please contact iSYS Medizintechnik GmbH.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

4.1.2. Adaptation of the Table Adapters

For attachment of the Robotic Positioning Unit to the imaging table, iSYS is offering three solutions (a, b and c).

Depending on the type of imaging table and the (carbon fiber) table top, one or more of the below described adapter solutions (a, b and c) can be used.

Note:	*Every table adapter offers different features and setup possibilities, depending on the region of interest and the type of intervention.*

CAUTION
Make sure that the treatment couch and/or the table top fulfills the interface requirements for the adapters!
- **Side rail payload: min. 20 kg**
- **Side rail size: 10 mm x 25 mm (WxH)**

In case you are not sure which adapter you can use (or the user manual of the treatment couch and/or the table top manufacturer does not give you the required information), please ask the service technician of the table/couch top manufacturer or contact iSYS for professional advice!

CAUTION
Be aware that the setup does not block intended movements of the table.

WARNING
All table adapters contain metal parts/material and thereof cause imaging artefacts if they are in the field of view of the X-ray beam. Make sure the adapters are outside the field of view of the imaging device!

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

WARNING
For all types of adapters, the following setup rules are essential:

- **Always make sure that the levers are locked properly and that the adapter provides a solid, clearance-free connection to the table!**
  This is not only essential for the accuracy of the final tool placement – any undesired movement of the mechanical setup also is a potential risk for mistreatment or may cause injuriy to the patient!

- **Always perform a manual stability-test (by pushing or pulling the adapter in different directions):**
  The adapter must maintain the position, must not slip and the setup must not wobble!

- **Make sure that the treatment couch and the adapter are permanently fixed to each other. In case you want to move the table with the patient on it, the adapter has to follow this movement!**
  This is not only essential for the accuracy of the tool placement. Failures in the mechanical setup are a potential risk for mistreatment and may cause injuriy to the patient!

- **Be aware that other devices mounted nearby the Table Adapter or the influence of persons may decrease the mechanical stability.**

- **Be aware, that by opening the locking-levers too far, the adapter may not be safely locked and the adapter/setup may drop and this can cause damage to the system or harm the patient!**

WARNING
Make sure that the table is properly fixed before attaching the components of the iSYS 1 system.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

WARNING
If the Side Rail Adapter is being used please make sure that the side rail is firmly connected to the treatment table before attaching any of the iSYS 1 components.

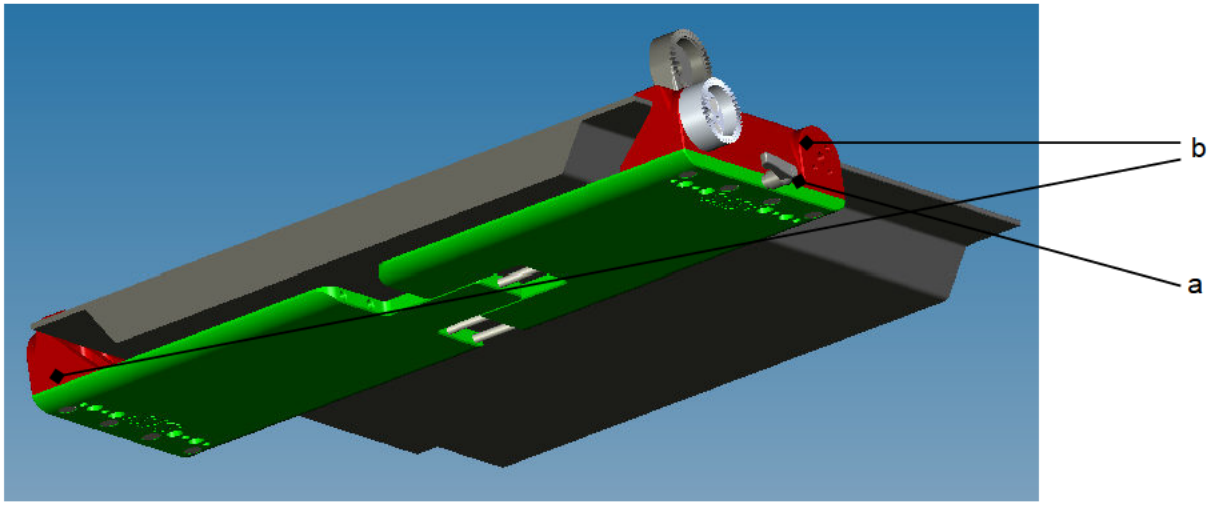
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

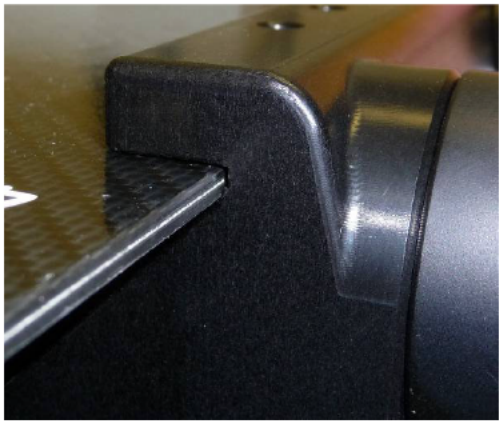
a. Mounting of the Table Top Adapter (Version B - Bottom Mounted)

Open the lever (a) of the Table Top Adapter as far that the clamping jaws (b) can grab the edges of the couch top of the treatment table as shown in the picture below.

By turning the lever clockwise, the clamping jaws (b) of the Table Top Adapter clutch the lateral edges of the table top and thus the adapter is fixed to the table.



The following picture shows the connection between the clamping jaw and the lateral edge of the (carbon) table top.



Once the adapter is locked to the table, it functions as a rigid adapter for the MFA.

If the adapter is not tightened, it can glide and be positioned easily in different positions on the table top.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

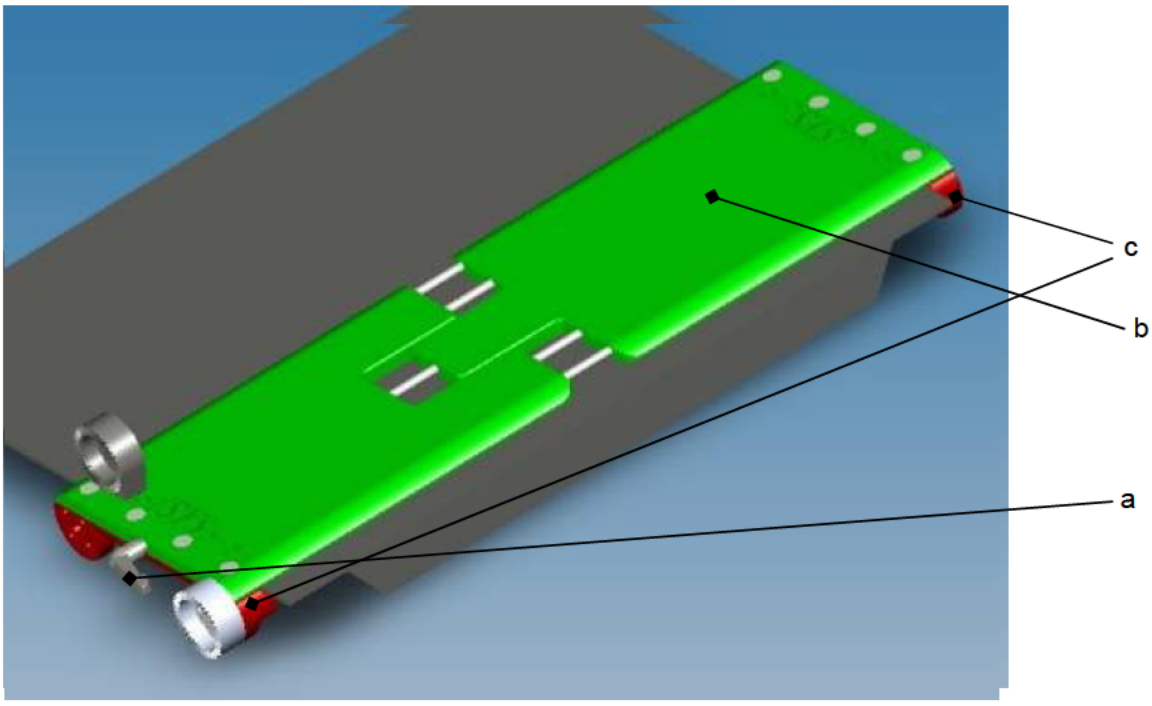
Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

WARNING
Never open the adapter so far that the adapter can fall down.

b. Mounting of the Table Top Adapter (Version A - Top Mounted)

Open the lever (a) of the Table Top Adapter so that the adapter plate (b) can be located on top of the couch top of the treatment table.

By turning the lever (a) clockwise, the clamping jaws (c) of the Table Top Adapter clench the lateral edges of the table top and the adapter is fixed to the table.



Once the adapter is locked to the table, it functions as a rigid adapter for the MFA.

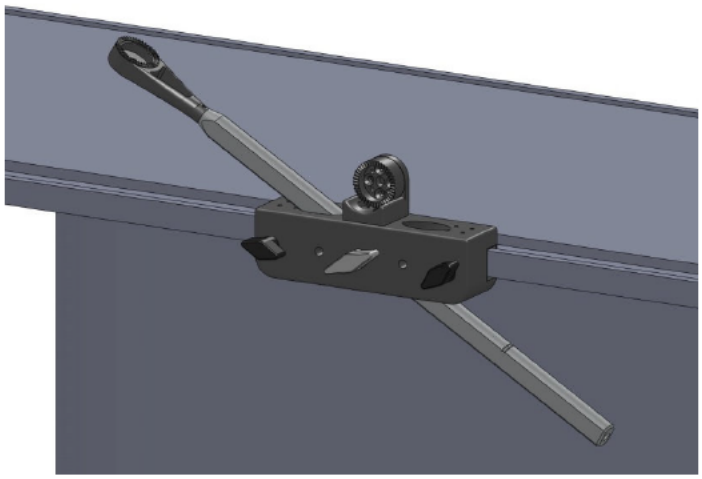
If the adapter is not tightened, it can glide and be positioned easily in different positions on the table

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

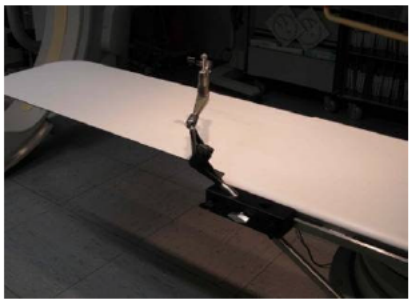
Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

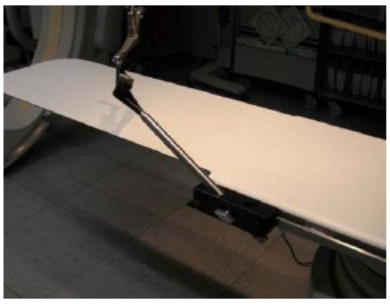
c. Mounting the Side Rail Adapter to the Side Rail of the Imaging Table

Attach the Side Rail Adapter to the side rail of the treatment table as shown below:



By turning the black levers clockwise, the adapter is rigidly attached to the side rail.



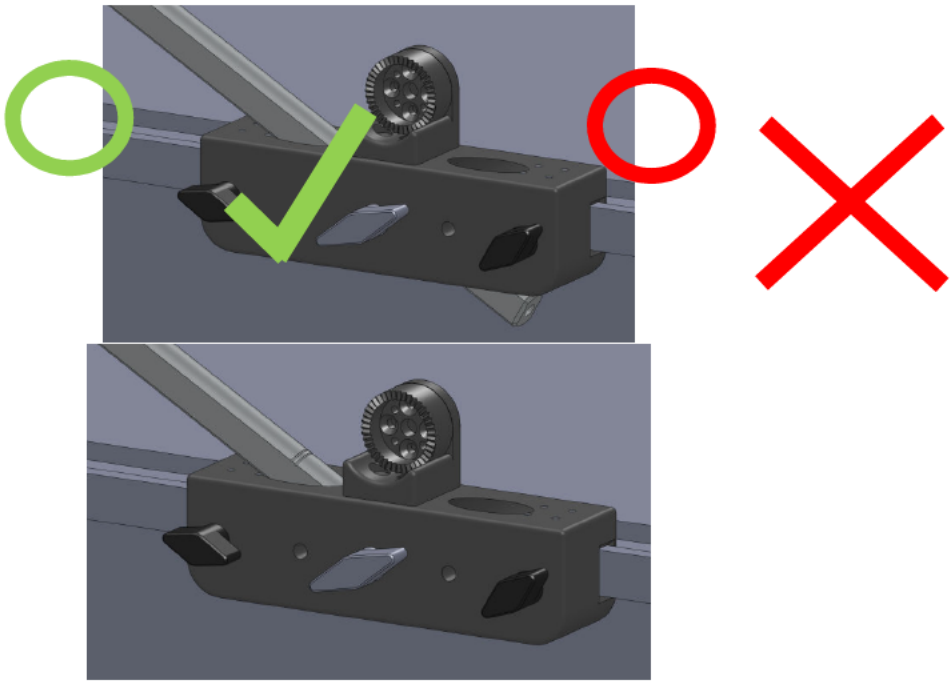


The height of the extension rod can be adjusted by opening and locking the middle lever.

WARNING
Make sure that the markings on the extension rod are not visible!

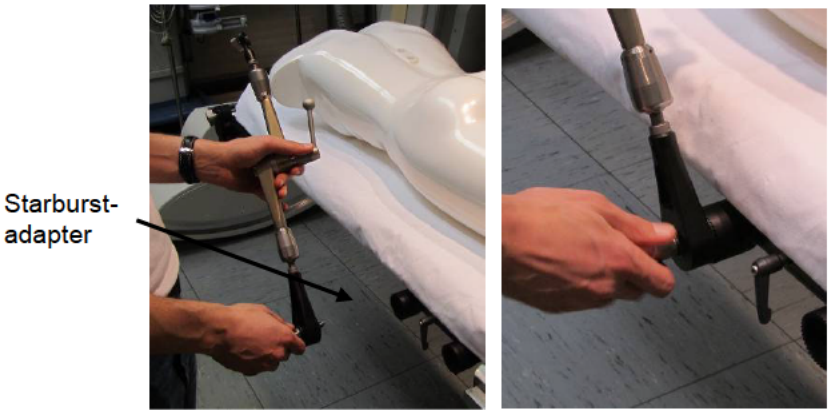
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016



4.1.3. Mounting of the Multi Functional Arm (MFA)

Attach the MFA to one of the Starburst-adapters available on the Table Top Adapter or Side Rail Adapter.



Turn the lever of the Starburst-adapter till the arm is tightly locked to the table adapter.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

WARNING
Whenever the MFA is mounted or the position of the MFA is being changed (opening and locking) the stability has to be verified with a simple test:
push/pull the Spoon of the MFA or the Robotic Unit gently and check if the MFA and the attached components remain in their position.
Always be aware that the stability of the setup depends on the tightening force of the lever at the MFA.

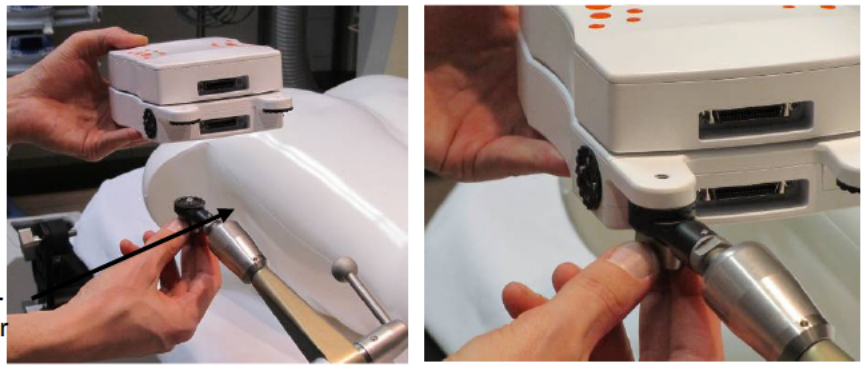
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

4.1.4. Mounting the Robotic Positioning Unit

Attach the Spoon-adapter at the Robot Positioning Unit to the MFA as shown below:

Spoon-adapter



Turn the lever of the Spoon-adapter till the Robot Positioning Unit is tightly locked to the MFA.

WARNING
Always make sure that the levers are locked strong enough and that the mechanical interfaces guarantee a solid, clearance-free connection to each other! This is essential for the treatment, because without high mechanical stability no high accuracies can be achieved with the Robot Positioning Unit!
With a simple manual stability test (by pushing or pulling the RPU carfully in different directions) the rigidity of the mechanical setup can be tested:
The RPU must maintain its position, must not slip and it must not wobble!

WARNING
Whenever the mechanical setup is changed, make sure that the components of iSYS 1 do not cause collisions with the gantry, with the treatment table or with any other part of the imaging device!

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

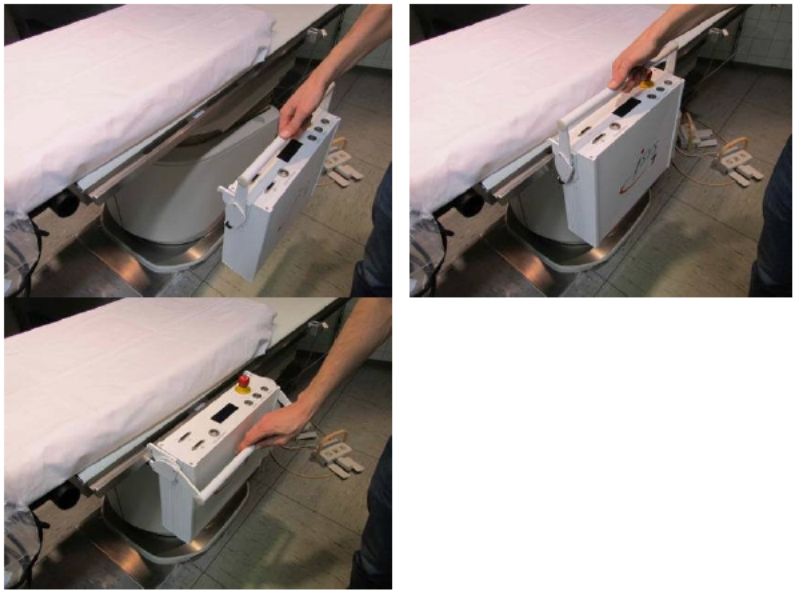
Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

4.1.5. Mounting the Control Unit to the Side Rail

CAUTION
If iSYS 1 or components are attached to the side rail of a table, ensure that the side rail is capable of carrying the weight. Refer to section 3 for technical data.
Please verify also if the connection of the side rail to the table is tight and does not wobble.

WARNING
Do not cover the front panel of the Control Unit or the display to make sure that any safety-relevant information can be recognized.

Move the CU to the side rail of the table with the handle in straight up position. Hang the unit on the side rail and close the locking mechanism by turning down the handle.



WARNING
Make sure the Control Unit is safely locked to the side rail of the treatment couch.

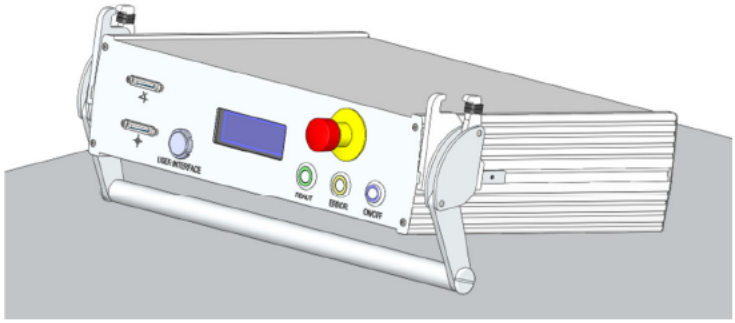
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

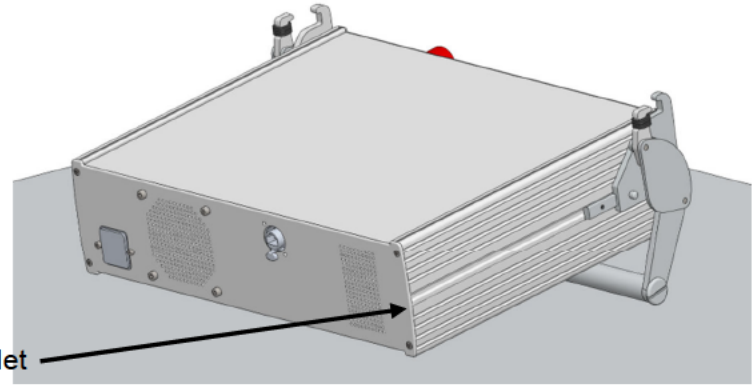
Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

4.1.6. Using the Control Unit without Side Rail

When there is no side rail available make sure the Control Unit is placed on a stable and flat surface which is capable of carrying its weight.

Use the handle as a support as shown in the picture below.





WARNING
Place the Control Unit so that no direct airflow to the patient or sterile areas occur. Otherwise the fan may blow non sterile air to the sterile area.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

WARNING
You must pay special attention to the stability of the placement of the Control Unit and the cable routing. Carelessness may lead to falling down of components and harm patient or user.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

4.1.7. Adaptation of the Handheld Control Unit to the Side Rail

CAUTION
If iSYS 1 or components are attached to the side rail of a table, ensure that the side rail is capable of carrying the weight. Refer to section 3 for technical data.
Please verify also if the connection of the side rail to the table is tight and does not wobble.

Hold the upper orange button pressed and attach the HCU to the side rail of the treatment couch as shown below.

After release of the upper orange button, the HCU is locked to the side rail.

Now the mechanical setup is finished.

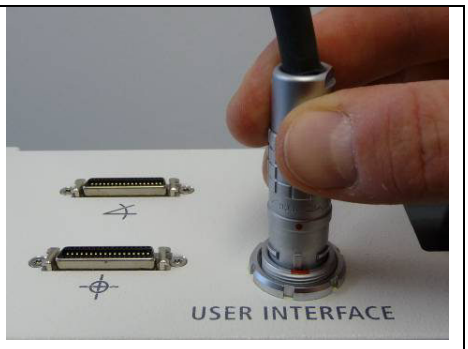
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

4.1.8. Connection of the Power and Data Cables

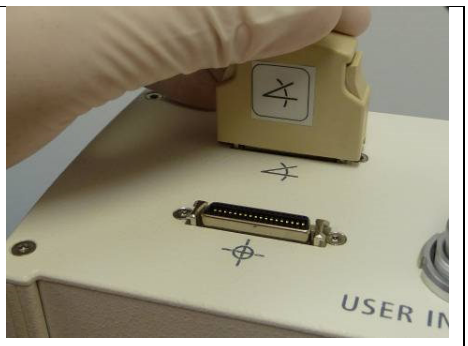
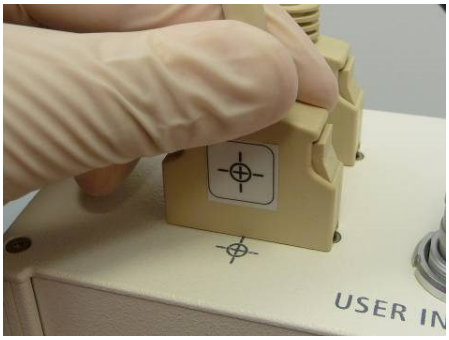
Overview:

Connect the power and data cables like shown in the following table:

Connection between HCU and CU	Connect the circular connector to the socket marked with “USER INTERFACE”. The correct position of the connector is marked with a red dot on both sides, connector and socket	

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

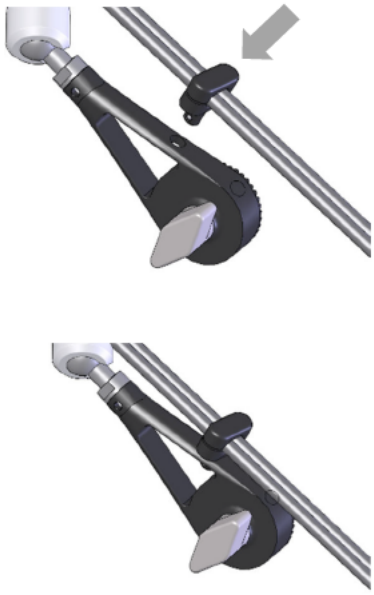
Connection of between RPU and CU	Connect the two flat connectors to the sockets on the CU marked with ⊿ and ⊕. The connectors are marked with the same symbols. Please check for the correct orientation of the connectors before inserting. There should be two “clicks” indicating that the connector is fixed firmly.	 
	Connect the two flat connectors to the sockets on the RPU. The connector marked with ⊕ is for the lower robot module (positioning module), whereas the connector marked with ⊿ is for the upper robot module (angulation module). Please check for the correct orientation of the connectors before inserting. There should be two “clicks” indicating that the connector is fixed firmly.	

In case of wrong connection between CU and RPU an error message will be displayed at the CU (“Check HW(5V,Mod)”, cf. “Error Messages”, chapter 0)

For the cabling between CU and RPU please attach the strain-relief connector to the recess at the MFA accordingly in order to avoid pulling forces to the RPU (see picture below).

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016



WARNING
Make sure that the cables do not cross the routes of the patient or the medical staff.
In case this is not avoidable (e.g. no electrical socket nearby), make sure that the cables are taped to the floor so that the patient/medical staff cannot fall over.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

WARNING
Attach the strain-relief connector to the recess at the MFA accordingly in order to avoid pulling forces to the RPU. If the strain relief is not connected properly this may cause damage to the RPU or may harm the patient.

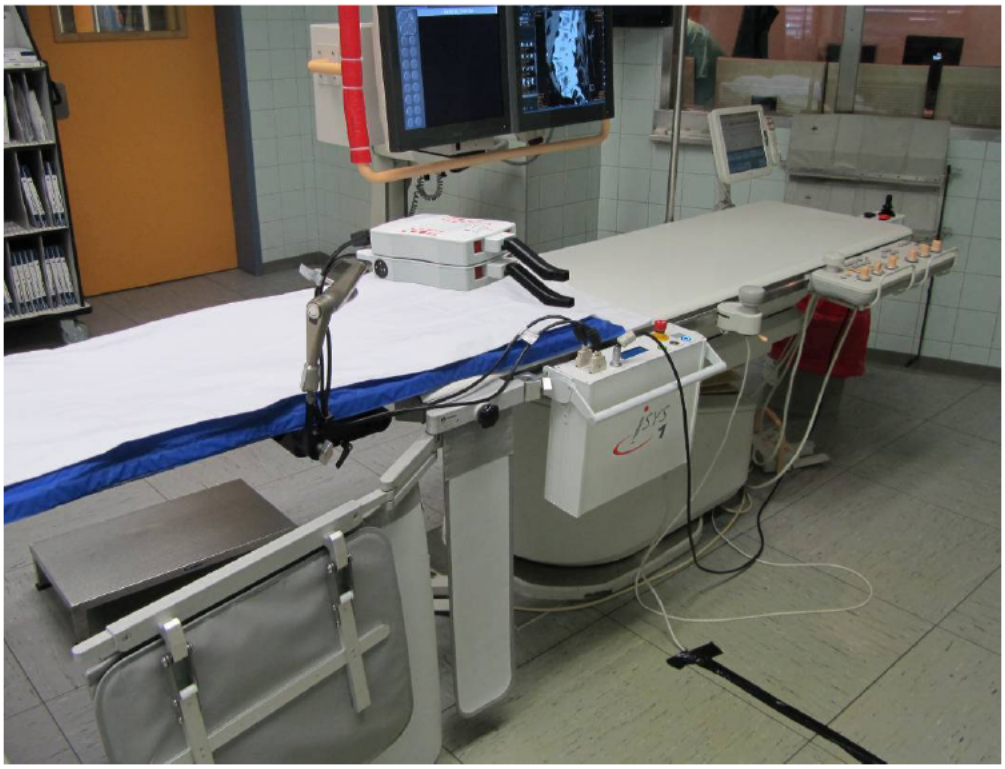
WARNING
Do not pull at the cables, especially when setting up the patient! This may lead to falling down of components, interference with the mechanical setup and potentially harm patient or user.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

4.1.9. Bringing the RPU into the "Parking position"

After the mechanical system setup, the RPU has to be parked in a safe parking position.



Reasons for the parking position:

- The parking position allows the easy attachment of the sterile cover.
- The parking position makes room for setting up the patient.
- The parking position allows access to the region of interest for preparing the surgical intervention (disinfection of the skin, sterile covering of the patient etc.)

WARNING
The MFA has progressive locking of the joints to allow precise positioning while locking and to avoid sudden movements when opening.
Always be aware that opening the MFA too fast can lead to uncontrolled movements of the arm itself or attached components (i.e. the Robotic Positioning Unit).
Always open the MFA slowly and carefully with one hand and hold the MFA or the attached device (Robotic Positioning Unit) carfully with the other hand!

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

WARNING
Do not misuse iSYS 1 as an armrest or tablet. This can lead to mechanical failures and serious injuries.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

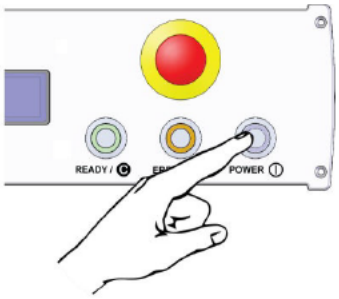
4.1.10. Start-up Procedure of the iSYS 1 Robot

1

Follow the Setup – Procedure (mounting of devices and establishing of cable connections) according to chapter 4.1.

2

Switch-on the system using the POWER switch.



Remark: Ensure that the joystick of the HCU is in its center position.

During boot-up the following message is shown.

```
iSYS1 – Needle
Guidance Platform
--------------------
System Bootup...
```

3

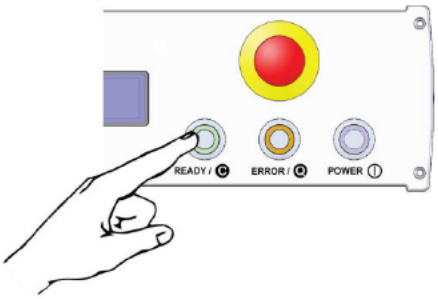
The system is now ready to perform the self-test.

```
### iSYS1 C-ARM  ###
* Running SELFTEST *
Rev1:C1.1/M1.6/W1.5
Press C to start  ->
```

4

Press the **C** (Confirm) button to start the self-test.

CAUTION: All axes of the robot will move approximately 1mm during self-test.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

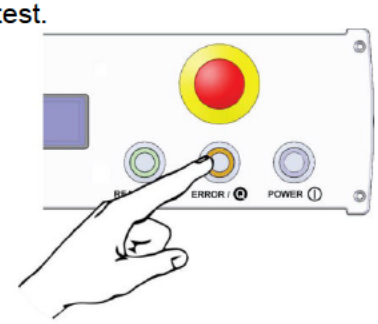
5

After the first step of the self-test you are asked to start the next step.

```
### iSYS1 C-ARM  ###
* Running SELFTEST *
Execute Step 2 of 5
Press Quit-Error  ->
```

6

Press the **Q** (Quit) button to start the next step of the self-test.



Repeat **step 6** until all steps are performed.

7

You will get the following message if the self-test was successfully executed.

```
### iSYS1 C-ARM  ###
Selftest PASSED
```

See instructions at **step 7A + 7B** if the self-test fails.

8

Once the self-test is passed you will get the operation screen.

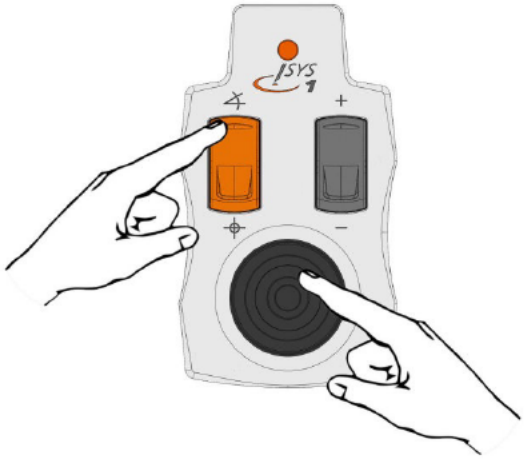
```
### iSYS1 C-ARM  ###

Speedlevel: fast
Joystick Mode  [  ]
```

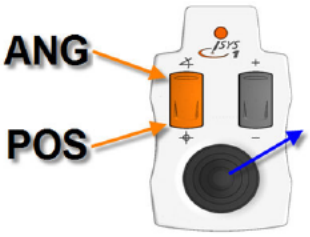

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

9

The system is now ready for operation. Use the Handheld Control Unit (HCU) to activate the desired mode (ANG or POS). During activation you can use the joystick to move the robot. The elongation of the joystick is proportional to the motion speed.
You can change the maximum speed using the +/- rocker-switch on the HCU.





7A

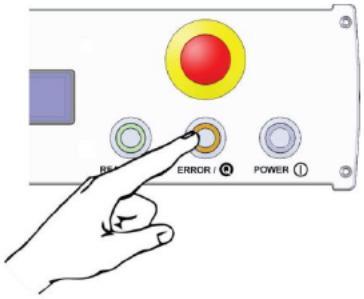
If the self-test fails you will get the following message.

```
### iSYS1 C-ARM  ###
* Running SELFTEST *
Selftest FAILED
Press Q to reset  ->
```

Remark: There are some possible reasons where the self-test fails, even tough no critical failure is present (e.g. a module is very close to its motion limit).

7B

Press the **Q** (Quit) button to restart the self-test and continue the procedure at step **3**.



If the self-test still fails after another trial, please contact the manufacturer.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

4.2. Use of iSYS 1

The surgical procedure can be divided into several steps. The following workflow, for example, shows the use of the iSYS 1 system for a typical needle procedure under C-arm fluoroscopy.

4.2.1. Checking the Mechanical Setup and the Range of iSYS 1

Position the patient on the treatment table. Before covering the patient and the robot with a sterile cover, make sure that the region of interest is in the field of view of the imaging machine and within the mechanical range of the iSYS 1. Therefore the MFA has to be opened and the RPU roughly positioned manually in the region of interest. During opening of the MFA and checking the range the RPU has to be supported by the physician. The following pictures show different possibilities of potential positions. Please consider the movement of the gantry during imaging to avoid collisions of the iSYS 1 with the gantry.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

In case the robot cannot reach the region of interest, re-position the patient or re-setup the mechanical parts of the system (e.g. mounting the MFA on a different Starburst-adapter or moving the TTA) so that all (potential) entry-points and target points can be reached.

WARNING
The MFA has progressive locking of the joints to allow precise positioning while locking and to avoid sudden movements when opening.
Always be aware that opening the MFA too fast can lead to uncontrolled movements of the arm itself or attached components (i.e. the Robotic Positioning Unit).
Always open the MFA slowly and carefully with one hand and hold the MFA or the attached device (Robotic Positioning Unit) carfully with the other hand!

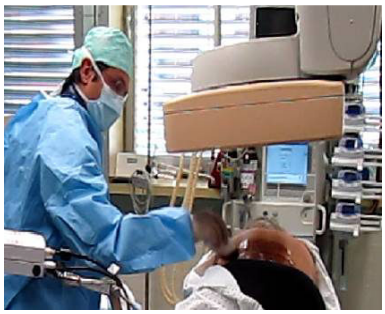
4.2.2. Setup and Preparing the Patient

Setup and prepare the patient for the interventional procedure following the steps below:

Note:	*Let the patient enter the table from the opposite table site of the iSYS 1 setup. Make sure the patient does not collide with any component of iSYS 1.*

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016



Note:	*The following paragraphs describe only the use of the iSYS 1 system. The use of the iSYS 1 system is just a small part of the workflow of an interventional needle procedure.*

This user manual does not take care of all the other important steps (like e.g. preparation of the non-iSYS disposables, cleaning and disinfection of the patient, sterile covering of the patient, use of the imaging machine, use of the planning software etc.). The general workflow for the specific intervention is in the responsibility of the physician.

Depending on the region of interest and of the compliance of the patient, the need of immobilization devices may occur. There are several - commercially available - immobilization devices on the market that can be used for precise patient immobilization.

Depending on the region of interest, respiratory motion may lead to organ movement and therefore to inaccuracy during the targeting process. There are several - commercially available - devices for respiratory motion control available on the market that might be used to overcome this problem.

In some cases - e.g. non cooperative patient - it might even be necessary to sedate/anesthetize the patient.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

WARNING

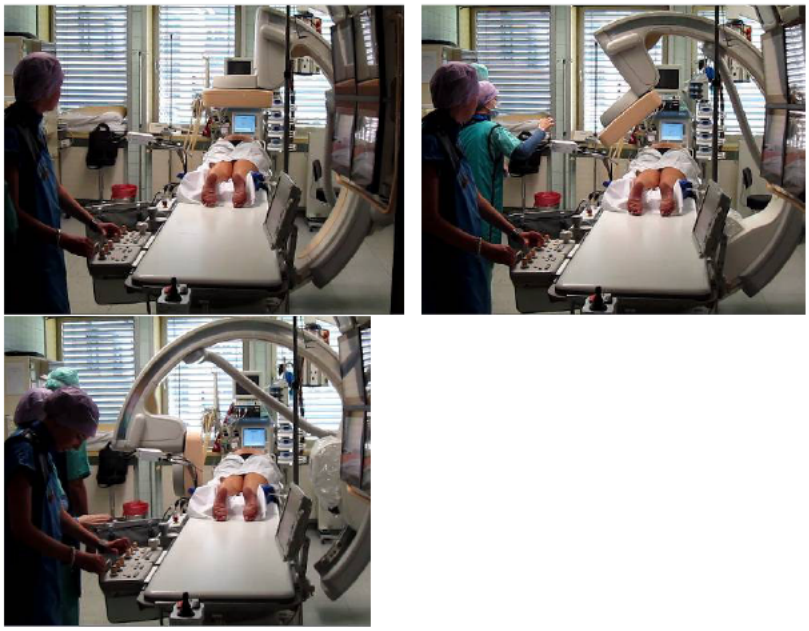
It is in the full responsibility of the physician to use aids e.g. for immobilization, respiratory motion control etc. and/or to sedate the patient.
Criteria for the physician include the physical constitution of the patient, the region of interest, the critical (surrounding) structures/anatomy around the path and the target point and the relation of the region of interest to the lung and other moving organs.

iSYS does not take any responsibility for non-iSYS components and treatment steps e.g. correct patient setup, imaging and planning!

4.2.3. Image Acquisition and Treatment Planning

Before image acquisition, make sure that the gantry does not collide with iSYS 1.

To test this, drive the gantry manually and carefully (slow motion) in all necessary extreme positions and make sure that there are no collisions with the setup.

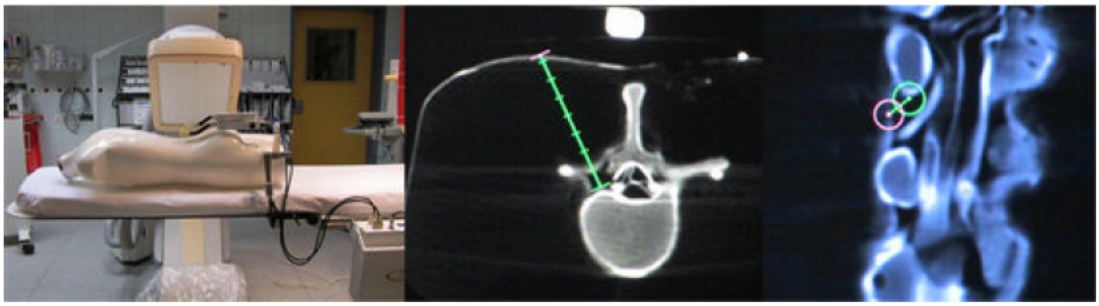


Imaging and planning can be performed with or without the RPU being in the field of view of the imaging device. In case the RPU is placed in the field of view of the imaging device, make sure that only the non-metal parts (plastic NGEs) are in the beam/field of view of the imaging device.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

WARNING
Only the plastic NGEs ("fingers") do not cause imaging artifacts. If the whole RPU or other parts of the mechanical setup are in the field of view, imaging artifacts may occur!



After imaging of the patient, the planning of the path (entrance and target point) can be done with the planning tool of the imaging machine (not part of the iSYS System!).

Note: *Imaging and planning are not in the responsibility of iSYS.*

Always keep in mind that the iSYS 1 system has only a certain range of movement for gross positioning and micro positioning (see specifications)

In case imaging and planning is not done correctly, it might become necessary at a later point of the workflow to redo these steps (potential consequence: bigger time gap between (re-planning) and treatment and thereof (potentially less accuracy and/or additional radiation cause of the need of re-imaging)

4.2.4. Working with the sterile iSYS 1 Disposables

a. General Information on sterile iSYS 1 Disposables

WARNING
In general, all sterile iSYS 1 disposables are intended for single use for one patient. (Re-) Sterilization of these components is not allowed.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

WARNING
Do not attempt to clean, sterilize or reuse single use components of the iSYS 1 system. Reuse of single use components might lead to a malfunction of the system and/or an infection of the patient.

WARNING
According to our present state of knowledge, we want to inform you about following known characteristics and technical factors that can lead to hazardous situations in case of reuse of the disposables.

Sterile Covers:
1. **Improper Folding**
2. **Conglutination of the tapes with the foil**
3. **Labels and stickers no longer usable due to opening**

NGE:
1. **Possibility of cross-contamination**
2. **Mechanical damage**

WARNING
Only labeled sterile products are allowed to be used.

WARNING
The single use components are sterile products intended for single use only. Sterility is guaranteed for unopened and intact packaging up to the indicated expiration date. Do not use sterile products if the package is damaged.

Check the Sterilization Indicator Label to make sure the peel pack bag (sterile package) has been processed.

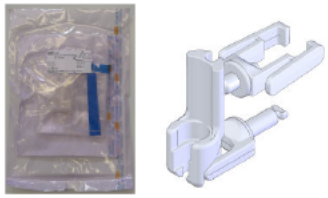
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

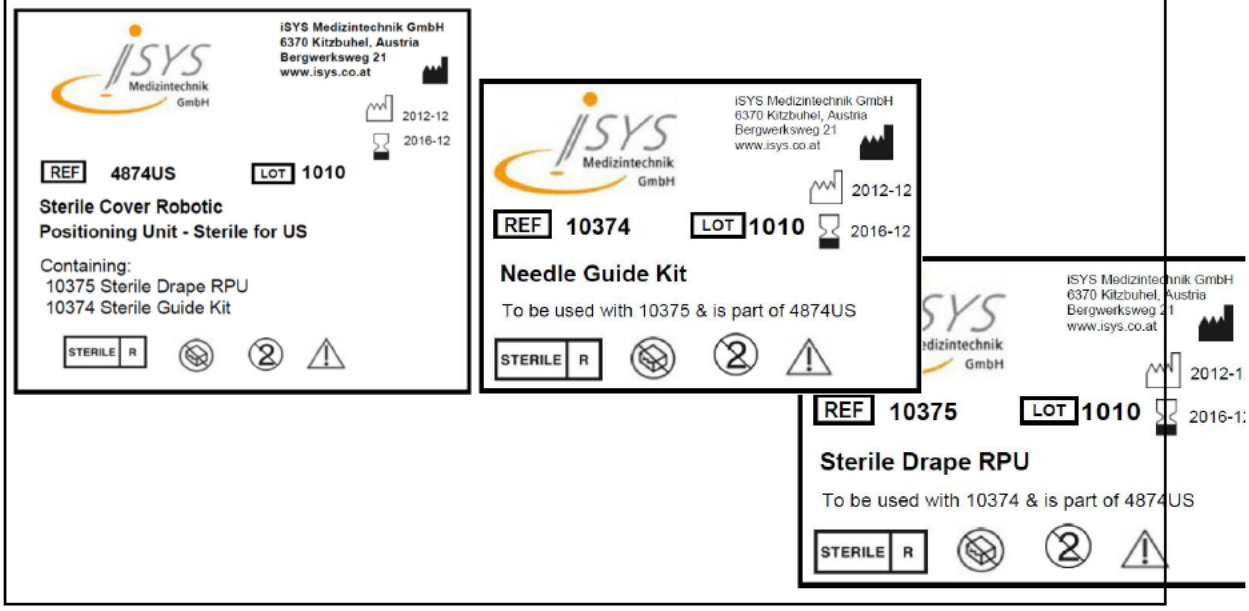
Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

b. Preparation of the Sterile iSYS Disposables

To guarantee a quick and safe workflow, take the iSYS disposables – handed over by a non-sterile assistant – out of the sterile cover and deposit the sterile components on a sterile table/plate.

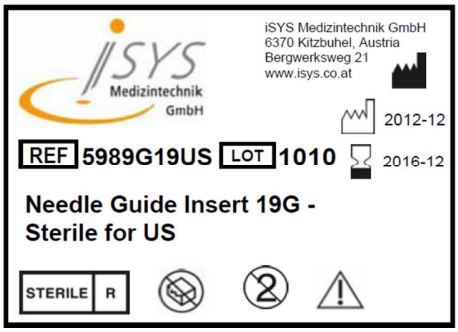
The following disposables are needed for intervention:

Picture	Number of pieces needed	Single Use / Accessories
	1	**Sterile Cover Robotic Positioning Unit** It is a disposable sterile component to cover the RPU and part of the MFA and RPU Cable Set. This assembly consists of a Sterile Drape (Nr. 10375) and the Needle Guide Kit (Nr. 10374) (including 2 Needle Guide Joints with Fixation Rings). Needle Guide Joints allow a quick and reversible connection of the Needle Guide Adapter to the Needle Guide Extension. Order number and name: 4874US Sterile Cover RPU - sterile for US



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

   	Depending on how many needles are placed	**Sterile Needle Guide Insert**: During the intervention the tool is inserted and guided by the (sterile) Needle Guide Insert. NGIs are available for needle diameters given below. The needle diameter of a NGI is printed on the cover bag as well as embossed to the handle of the NGI. Order number and name: 6289G10US Sterile Needle Guide Insert – 10G 5990G11US Sterile Needle Guide Insert – 11G 5991G12US Sterile Needle Guide Insert – 12G 5992G13US Sterile Needle Guide Insert – 13G 5993G14US Sterile Needle Guide Insert – 14G 4877G15US Sterile Needle Guide Insert – 15G 4878G16US Sterile Needle Guide Insert – 16G 4879G17US Sterile Needle Guide Insert – 17G 4880G18US Sterile Needle Guide Insert – 18G 5989G19US Sterile Needle Guide Insert – 19G 4881G20US Sterile Needle Guide Insert – 20G 4882G21US Sterile Needle Guide Insert – 21G
	1	**Sterile Needle Guide Marker Insert:** The Needle Guide Marker Insert allows precise and remote-controlled alignment of the Needle Guide Insert based on real-time imaging data. Order number and name: 4876US NGMI centered - sterile for US

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

iSYS Medizintechnik GmbH 6370 Kitzbuhel, Austria Bergwerksweg 21 www.isys.co.at 2012-12 REF 4876US LOT 1010 2016-12 **Needle Guide Marker Insert centered - Sterile for US** STERILE R		
 iSYS Medizintechnik GmbH 6370 Kitzbuhel, Austria Bergwerksweg 21 www.isys.co.at 2012-12 REF 4883EU LOT 1010 2016-12 **Sterile Cover Handheld Control Unit - Sterile for US** STERILE R	1	**Sterile Cover Handheld Control Unit:** It is a disposable sterile component to cover the HCU during intervention. Order number and name: 4883US Sterile Cover HCU - sterile for US

Make sure all needed disposables are available. Also ensure that extra disposables are available in case a sterile piece is dropped in the non-sterile area (e.g. floor).

WARNING
Be sure the diameter of your instrument complies with the diameter of the Needle Guide Insert.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

4.2.5. Attaching the Sterile Cover over the Robotic Positioning Unit

WARNING
Never continue with your procedure if any of the sterile covers is or gets damaged. Continuing the procedure might lead to serious infection of patient.

WARNING
Never touch the sterile area in the operating room after touching non-sterile components of the iSYS 1 without respective treatment (according to the local regulations).

WARNING
The patient must not touch the sterile cover.

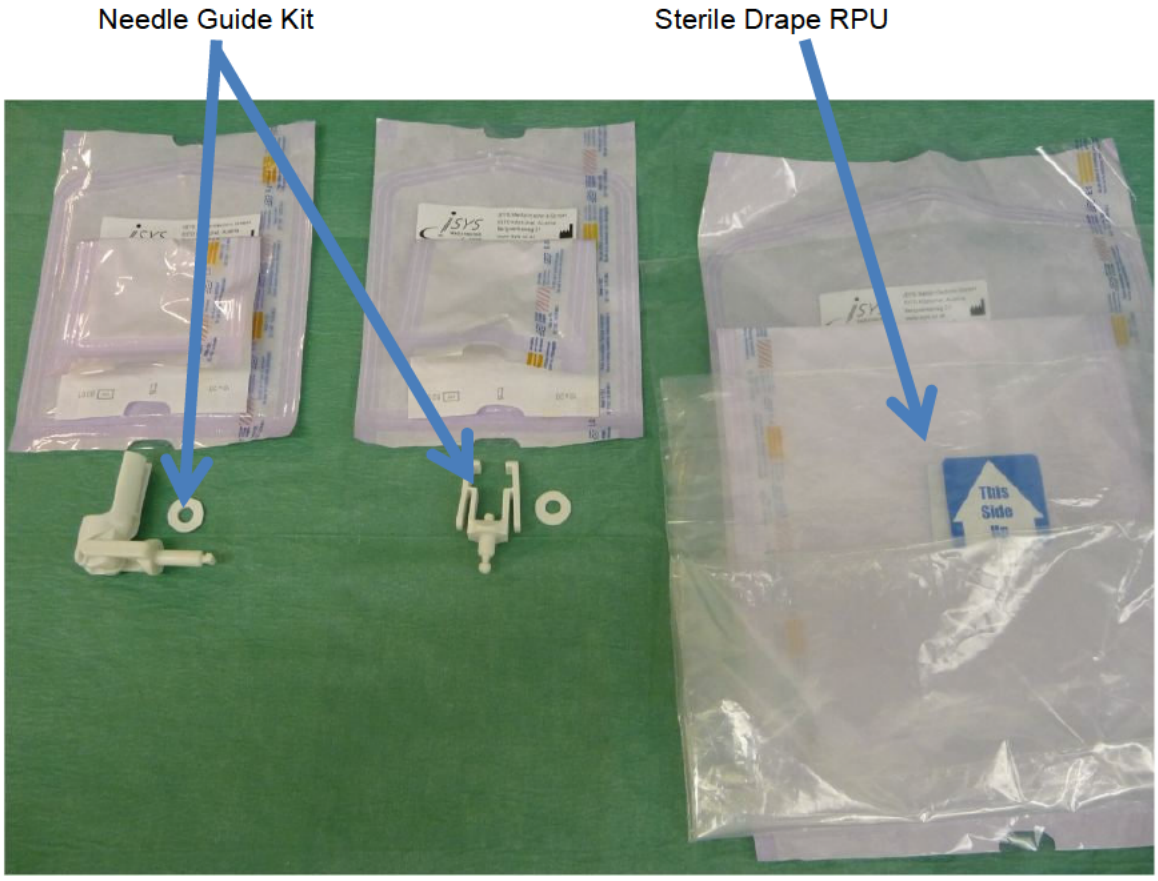
WARNING
Covering the patient's face with the sterile cover can seriously harm the patient.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

The Robot Positioning Unit and the MFA can be completely covered with a sterile (protective) cover in a simple and safe manner. All non-sterile, reusable parts in the operation area are thereby separated from the sterile parts and the sterile operation area.

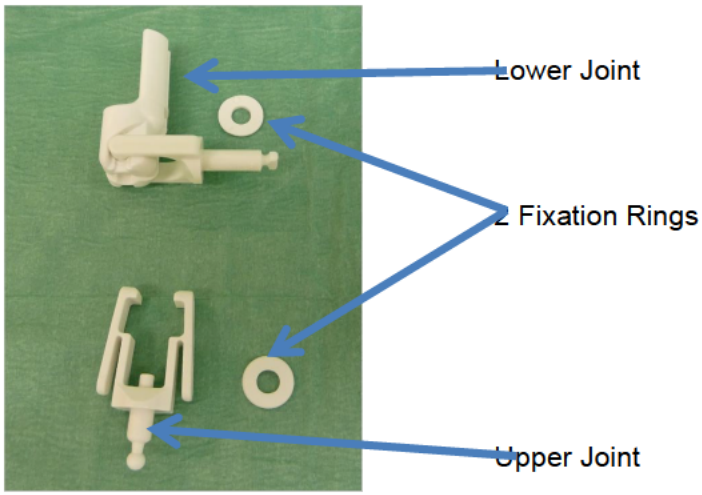
The Sterile Cover RPU consists of 2 parts:



The Needle Guide Kit includes 4 components:

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

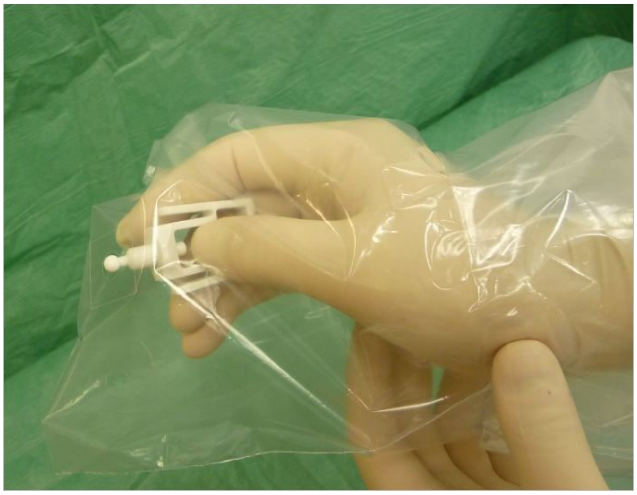


Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Open the sterile packaging and put all components (Sterile Drape, Lower & Upper Joint & 2 Fixation Rings) on the sterile table.

1. Feed the Upper Joint into the sterile drape and stick it through the upper hole.



2. Slip a Fixation Ring onto the Upper Joint

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

3. Feed the Lower Joint from outside the sterile drape into the lower hole.

4. Slip a Fixation Ring onto the Lower Joint from inside the Sterile Drape.

Make sure that both Fixation Rings fixed tight to the Joints!

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

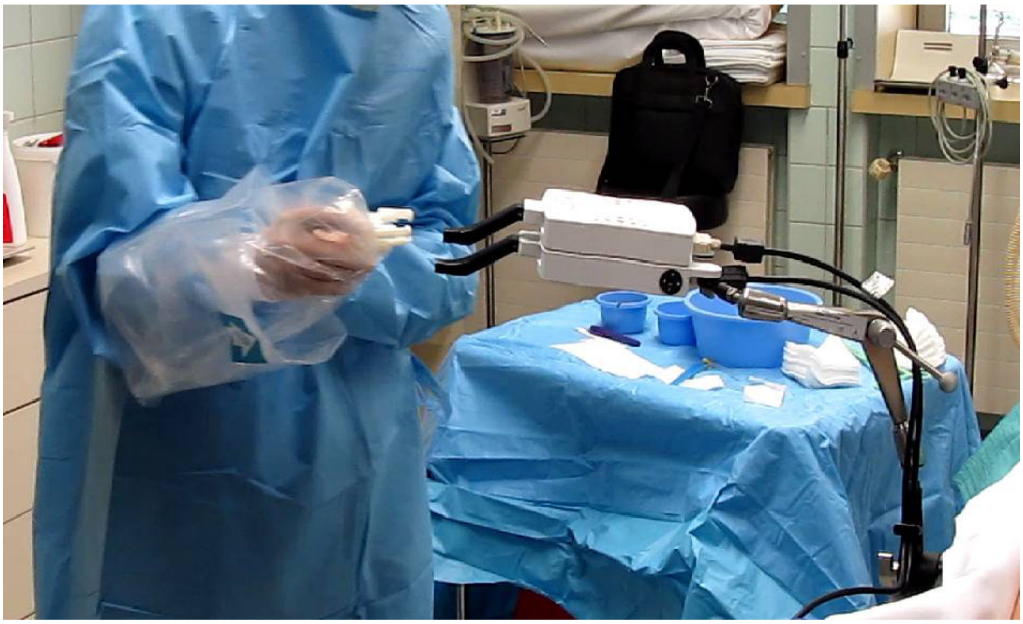
Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

5. Take the Bowl of the Upper Joint and insert it into the guide rail of the Lower Joint.

The final Sterile Cover RPU should look like shown on the pictures.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

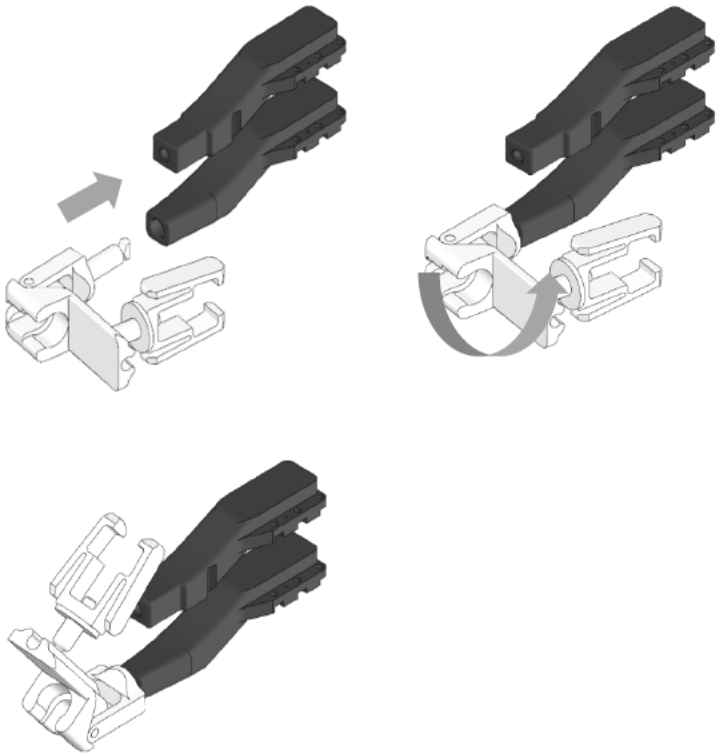


The sterile dressed surgeon grabs the end-effector from inside the plastic tube like shown in the picture above.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

First the lower joint -is attached to the lower NGE ("finger") by bringing in the pin adapter in a 90 degree angle.

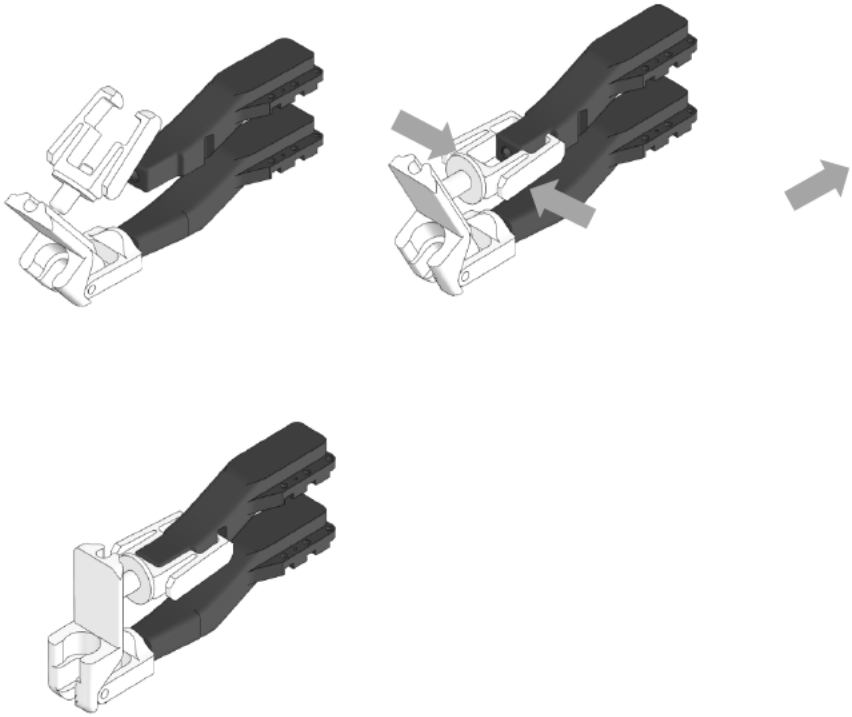


When you have reached the final position, rotate the lower joint 90 degrees up and make sure that the pin is locked safely by gently pulling the lower joint.

Attach the upper joint by attaching the clamp adapter as shown in the picture below:

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

After attachment of the upper joint, let the (non-sterile) assistant catch the white arrow (see blue marking) and pull the cover over the robotic unit.

After the RPU and MFA is totally covered with the sterile cover, the sterile surgeon can touch the sterile cover and pull the protuberance part of the cover (on the side of the sterile cover) over the handle of the arm and push it back.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Use the blue tapes to fix the cover in position and to make sure the cover does not slip away.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

4.2.6. Attaching the Sterile Cover to the HCU

WARNING
The patient or other non-sterile persons must not touch the sterile cover.

WARNING
Covering the patient's face with the sterile cover can seriously harm the patient.

In another simple and safe step, the HCU is completely covered with a sterile protective cover.

The (non-sterile) assistant takes the HCU in his hands. The sterile dressed surgeon takes the Sterile Cover Handheld Control Unit and grabs the HCU from inside the plastic tube.

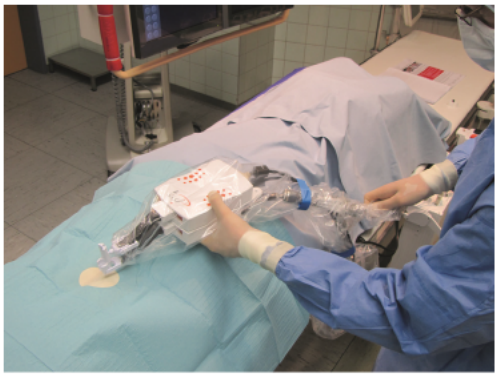
The (non-sterile) assistant catches the end of the plastic tube and pulls the cover over the HCU and its cable.

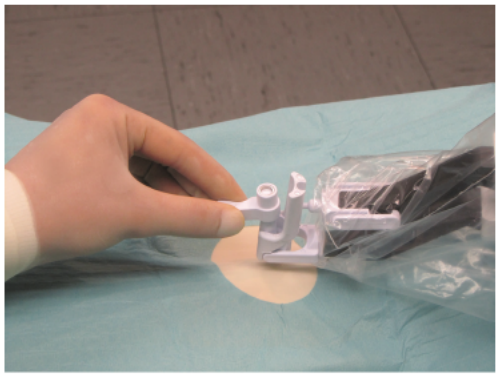
Note:	*This step allows the surgeon to later touch and use the HCU with his sterile hands/gloves. In case a second (assistant) non-sterile surgeon can operate the joystick, a sterile cover for the HCU is not needed and this step can be left out!*

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

4.2.7. Gross-Positioning of the RPU and Insertion of the Sterile Needle Guide Marker Insert into the Needle Guide Adapter





Make sure the entry and target point is in the range of the RU (see specifications above).

Unless it has not already been done before imaging, the RPU needs to be gross-positioned in the region of interest by opening and closing the MFA. To (re-)position the RPU please hold the RPU with one hand and open the MFA handle with the other one.

Please be aware that the MFA offers progressive locking, i.e. the upper link (next to the RPU) opens first, then the middle link and finally the lower link (next to the table/side rail adapter).

WARNING

The MFA has progressive locking of the joints to allow precise positioning while locking and to avoid sudden movements when opening.
Always be aware that opening the MFA too fast can lead to uncontrolled movements of the arm itself or attached components (i.e. the Robotic Positioning Unit).
Always open the MFA slowly and carefully with one hand and hold the MFA or the attached device (Robotic Positioning Unit) carfully with the other hand!

Although the Robotic Positioning Unit has an ergonomic design, always keep in mind that the steril cover may decrease the friction forces: Always hold and handle the MFA and the Robotic Positioning Unit carefully and safely!

Move the robot to the desired position/orientation and lock the MFA after positioning. The MFA handle needs to be tightened firmly so that the MFA can offer its full payload.

Please check the stability of the setup before proceeding with needle insertion.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

To get a rough estimation about the right gross-positioning, you can use standard (skin) markers, the laser cross-hair (or laser pointer) from the imaging device (that visualizes the path) or fluoroscopy.

In case you use fluoroscopy, be aware to step aside to avoid radiation exposure. Be always aware that this method causes additional radiation to the patient.

WARNING
Make sure that the RPU and the NGE is oriented (approximately) parallel to the patient surface.
Always check if there is a risk of touching or colliding with the patient while remotely driving the robot modules (see chapter 4.2.8).
To double check: Drive the robot with the HCU in all extreme positions under direct visual control.
Collisions of the robot with the patient can cause serious injuries.

After you have reached and checked the desired position, insert the (sterile) Needle Guide Marker Insert into the Needle Guide Adapter.

WARNING
Make sure and double check that the Needle Guide Marker Insert is in the right endposition and is free of play in the NGA.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

4.2.8. Micro-Positioning and Accurate Alignment of the NGA under fluoroscopy

Use the HCU (as described in chapter 4.5.3) to micro-position the NGA.

WARNING
When using the HCU, be aware not to touch the sterile area with the non-sterile cable of the HCU.

WARNING
Repeat imaging procedure if the Robot Positioning Unit has been accidental pushed or the power supply has been interrupted after imaging. Failing to do so may lead to mistreatment of the patient.

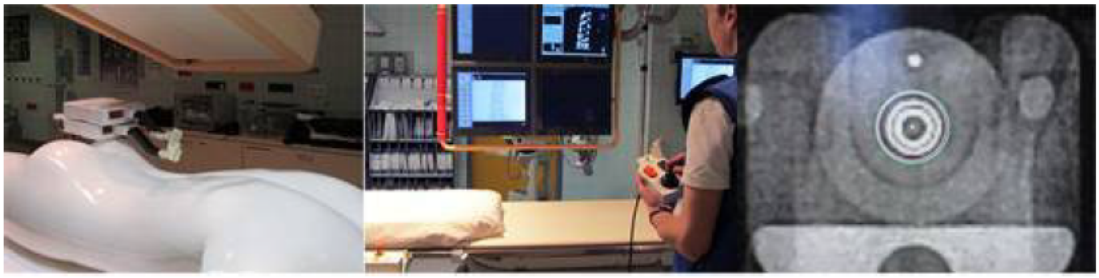
WARNING
Be aware you do not stand on the cables when moving the Robot Positioning Unit. This can lead to wrong positioning of the instrument and mistreatment of the patient.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

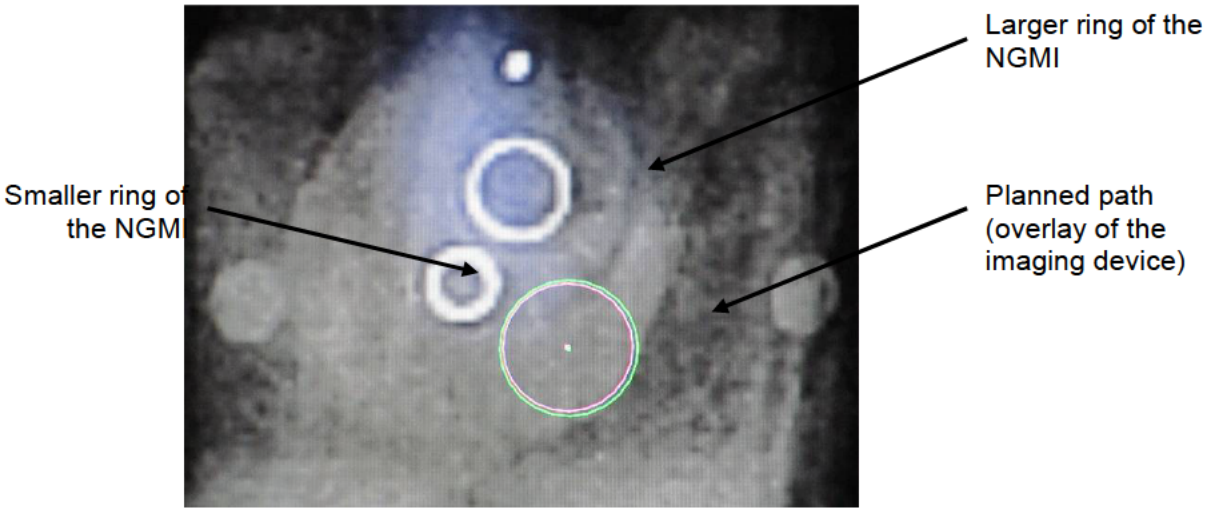
For a first alignment you can use surface markers or the laser cross-hair (or laser pointer) from the imaging device (that visualizes the path). In this case you can stay next to the patient.

If you use real-time-fluoroscopy for the alignment, please stay as far away as possible (minimum 6 feet) from the beam to reduce radiation exposure to a minimum (you just need to have a good view to the monitor that shows the fluoroscopy image).



To avoid unnecessary radiation to the patient, the user can – with the help of the robot – also work "offline" (i.e. without real-time imaging) and use just single Fluoro-Snap-Shots.

For micro-positioning the NG under fluoroscopy the C-Arm has to be orientated perpendicular to the planned path ("entry point view"). To align the Needle Guide with the planned path the user gets the right orientation of the x-, y-, a-, b-axis from the marker Insert:

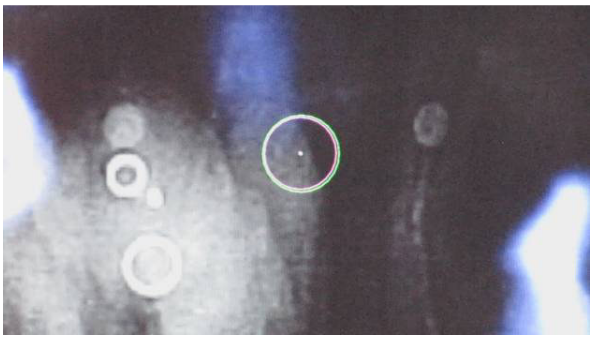


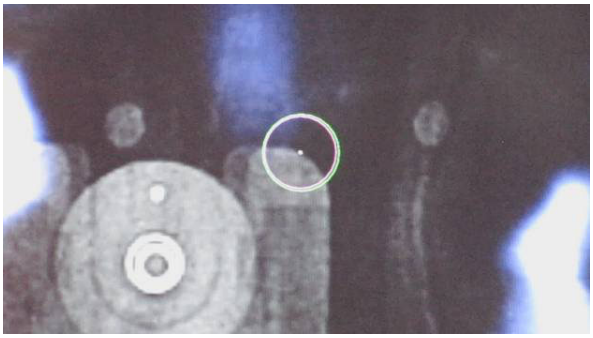
The larger ring of the Needle Guide Marker Insert marks the position of the Needle Guide. The smaller ring indicates the angulation of the Needle Guide.

In a first step the smaller ring has to be aligned roughly with the larger ring by moving the RPU in angulation mode. In this mode only the smaller ring moves as shown in the pictures below.

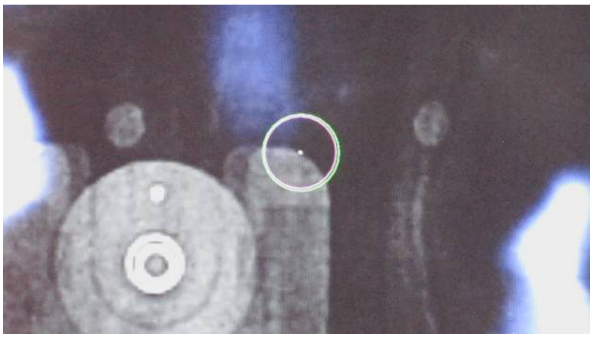
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

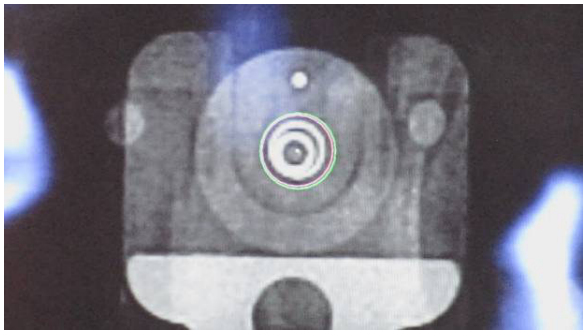
Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016





In the next step, both rings have to be aligned with the planned path (indicated by the two rings overlayed by the imaging device) by moving the RPU in positioning mode. When moving the RPU in positioning mode both rings move:

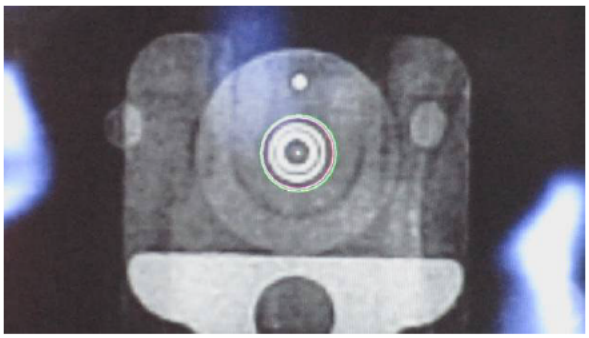


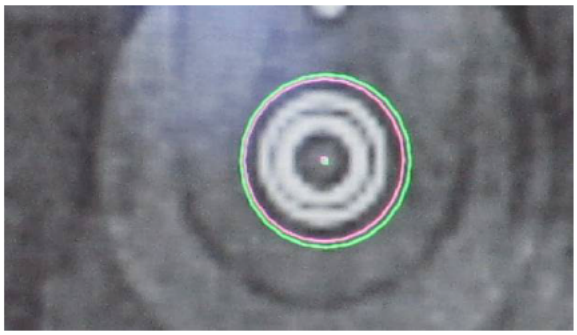


Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Finally the alignment has to be optimized by moving the RPU in positioning and angulation mode as shown below. For easy fine positioning the speed level can be set to slow by pushing the MINUS button on the HCU several times unless you hear a beep signal. The speed level is indicated on the display too.





In case the alignment is done under fluoroscopy, a maximum zoom of the fluoro-image, adjustment of the diameters of the ring (in needle entry view, that represents the preplanned path) to the diameter of the marker and the resolution of the x-ray image (be careful: higher dose!) may increase the accuracy.

As this is not in the responsibility of iSYS, please contact the manufacturer of the imaging device for further information.

After alignment of the NG, remove the NGMI from the NGA.

WARNING
By using only the Marker Insert for Aligment please be aware that you could have an incorrect bearing angle despite the fact that the two rings were positioned correctly. You may have a discrepancy / deviation of the needle tip to the planned target.

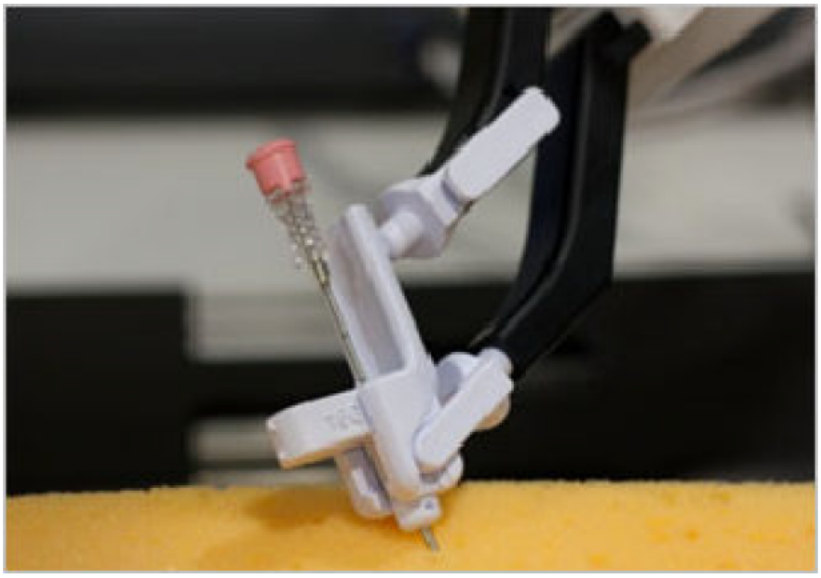
For additional fine alignment please follow next step.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

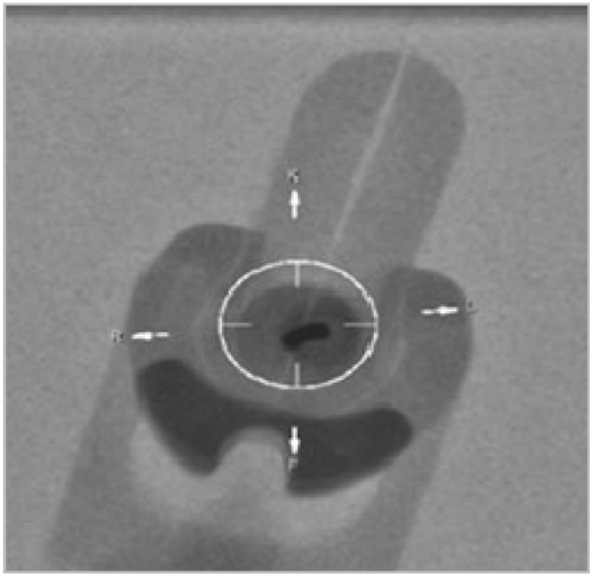
Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

4.2.9. Ultra-fine-Positioning and Accurate Alignment of the Needle under fluoroscopy

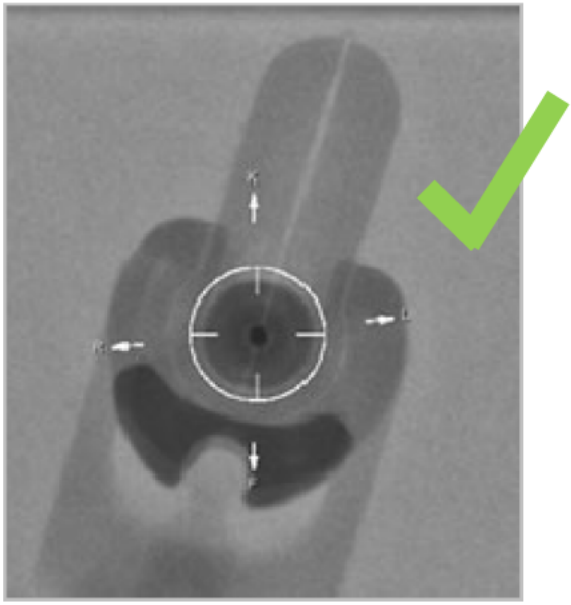
Place the needle into the NGI (see chapter 4.2.9. Attachment of the Needle Guide Insert and Needle Placement). The needle should be 1cm above the surface of the patient.



For micro-positioning the Needle under fluoroscopy the C-Arm has to be orientated perpendicular to the planned path ("entry point view"). To align the Needle with the planned path is done with the HCU as show before.



Before aligment



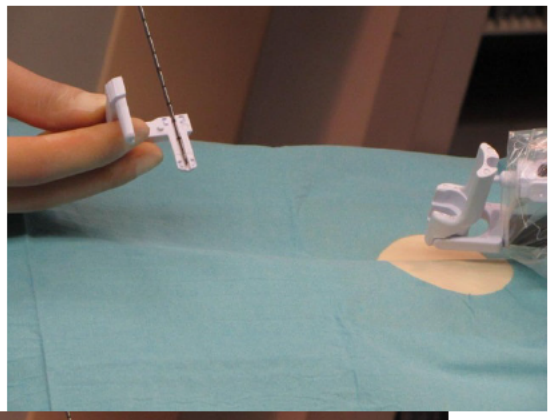
After perfect alignment the needle is shown as a small dot.

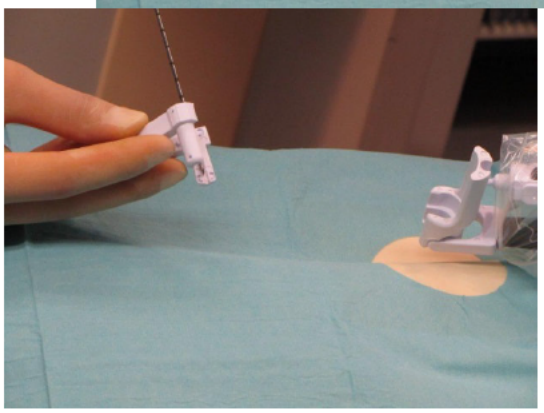
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

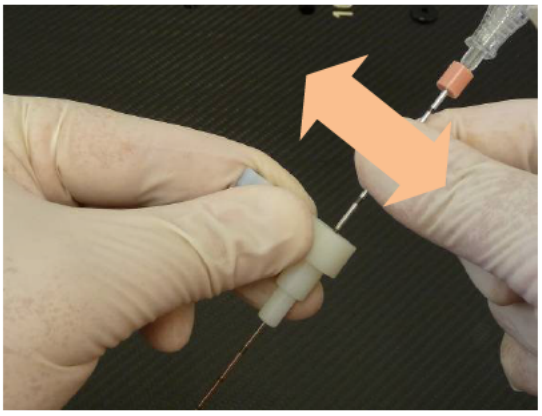
Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

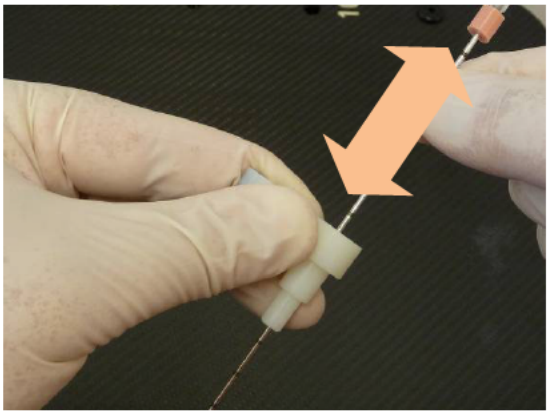
4.2.10. Attachment of the Needle Guide Insert and Needle Placement

The NGI has a very important function for needle guidance and quick release. Before attaching the sterile NGI to the NGA, check if the diameter of the needle fits to the NGI and check with the following manual test if the needle has a play-free and friction free guidance in the needle insert:









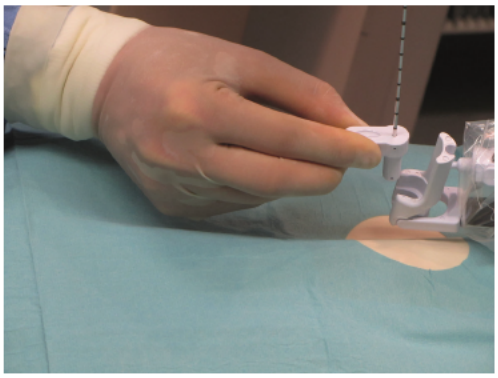
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

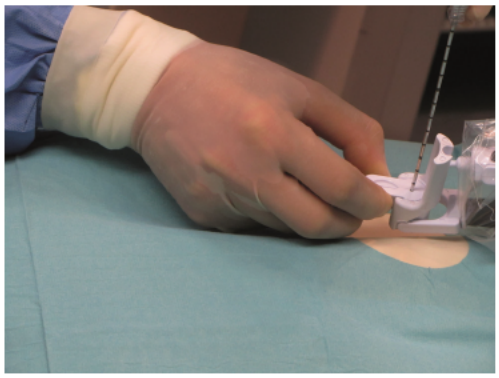
Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

This check takes place in two steps. First insert the needle to the opened NGI, hold the NGI tightly with one hand (pressing the two halves of the NGI together) and try to move the needle in radial direction with the other hand. There should be no detectable play between NGI and needle. For the second step, try to move the needle in axial direction. The needle should move easily – there should be no blocking of the needle during such axial movement.

WARNING
Check the free and easy movement of the needle in the Needle Guide Insert. Be aware that the needle is not clamped.

After you have checked the functionality of the insert, insert the (sterile) Needle Guide Insert into the Needle Guide Adapter.





WARNING
Make sure and double check that the NGI is in the right endposition and that there is no play between NGA and NGI.

WARNING
Precise needle guidance is essential for the accuracy of the needle placement.
Precise needle guidance is only possible, if the needle diameter is in a certain tolerance over the whole length of the needle.
Always check the tolerances of the needle with your needle supplier before using it with the iSYS system!

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

After attachment of the NGI to the NGA, the needle can be introduced manually in z-axis into the patient. This step must be under full control of the surgeon!

Depending on the used imaging device, the depth of the needle placement usually is being calculated by the planning software and is measured between the defined insertion point and the target point. For realization of the correct inserting depth the following procedure is being recommended:

- During planning, define the insertion point exactly on the skin surface of the patient.
- Before insertion of the needle, mark the calculated insertion depth (calculated by the planning system) with a sterile ruler and a sterile pen at the needle.
- Insert the needle until the marked insertion depth is reaching the skin surface
- It is highly recommended to check the needle insertion before reaching the final position by means of an intermediate scan (cf also sub-chapter “Verification and quality assurance” below).

Please note that iSYS is not taking any responsibility for realization of the correct inserting depth!

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

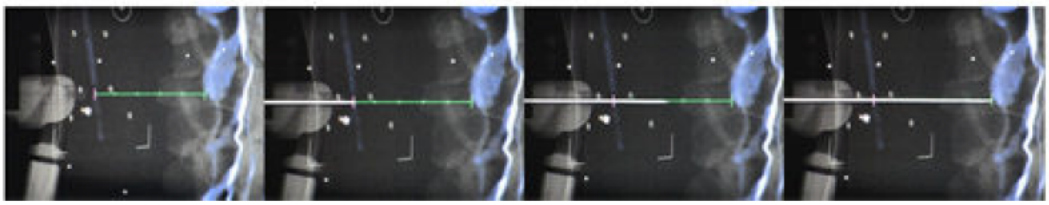
WARNING
Opening the MFA during the needle being inserted and connected to the RPU can lead to serious injuries at the patient.

WARNING
The iSYS 1 system acts as a guidance system. It is not designed to compensate high forces from the needle or the user.

Forces on the mechanical components of iSYS 1 may lead to inaccuracy of the needle placement!

Verification and quality assurance:

As the NGE is radiolucent, the correct needle position can be verified with lateral scans ("needle progress view", "angulated needle guide view", optional: "needle entry view") before, during and after treatment.



It is in the responsibility of the surgeon to decide how often verification scans are necessary (this may depend on the region of interest, planned accuracy, critical/surrounding tissue, etc).

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

WARNING
In case of multiple needle procedures, be aware that the needles do not collide with each other or with iSYS 1 compontents! This can seriously harm the patient.

WARNING
Be aware that the setup of iSYS 1 does not influence the imaging in the area of interest. In case of doubts repeat the imaging procedure to avoid mistreatment of the patient.

WARNING
In case of an error (emergency stop): the error condition has to be resolved and the system has to be in the ready state to go on. The needle position and angulation has to be verified with the imaging device before inserting the needle/tool.

WARNING
The RPU must not be use as a (arm) rest at any time, not even as a support of the surgeons hand while inserting the needle.

WARNING
When inserting the needle avoid forces on the needle except for forces along the needle axis. Otherwise it leads to inaccuracies an may lead to mistreatment or injury of the patient.

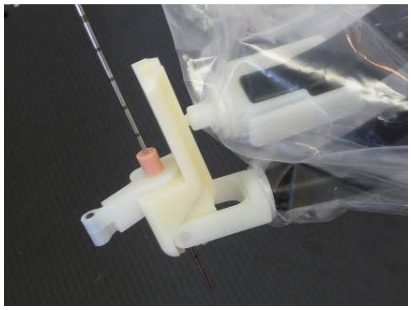
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

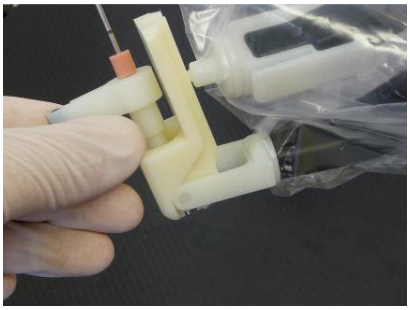
Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

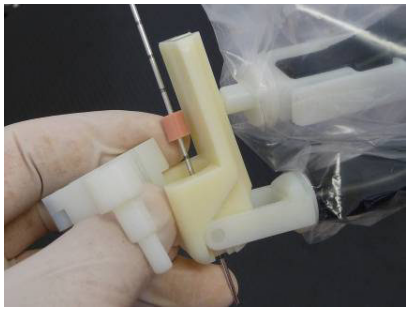
4.2.11. Removing the NGI and Quick-Release

After needle introduction and/or whenever the surgeon steps apart from the patient and/or when the diagnosis/treatment with the needle starts, the NGI has to be removed (i.e. the needle gets decoupled from the robot).

Such decoupling can be easily performed by simply lifting the NGI (along the needle axis) until the NGI is no longer connected to the NGA. In this position the NGI can be opened and the needle is no longer attached to the needle guide.







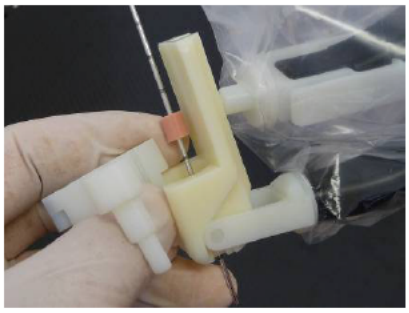
The decoupling also allows free “swinging” of the needle inside the needle guide and a removal of the iSYS 1 system in case of emergency.

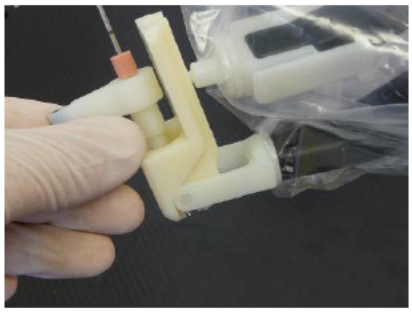
In case of multiple needle placements in larger distance to each other (bigger than the range of the robot), the decoupling also allows the removal of the RPU from the treatment area and a subsequent gross-positioning of the RPU for placement of the next needles.

If decoupling of the needle is only done temporarily (e.g. because the surgeon had to leave the patient for some time), the re-connection between needle and NGA can be done easily in the reverse order. The open NGI is being placed around the needle and being closed afterwards. Then the NGI is moved inside the NGA along the needle axis. Please be sure that the needle is fixed with the other hand during this step in order to avoid unintended needle insertion. For such re-connection the robot must not be moved between decoupling of the needle and re-connection.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016





WARNING
During manipulation of the NGI for decoupling/coupling the needle from/to the NGA, please be sure that the needle is keeping in place (e.g. fixation with the other hand) in order to avoid unintended needle movement.

WARNING
In case of multiple needle procedures, be aware the needles do not collide with each other or with iSYS 1 compontents! This can seriously harm the patient.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

WARNING
The MFA has progressive locking of the joints to allow precise positioning while locking and to avoid sudden movements when opening.
Always be aware that opening the MFA too fast can lead to uncontrolled movements of the arm itself or attached components (the robotic positioning unit).
Always open the MFA slowly and carefully with one hand and hold the arm or the attached device (robotic positioning unit) carefully with the other hand!

Although the RPU has an ergonomic design, always keep in mind that the steril cover may decrease the friction forces: Always hold and handle the MFA and the RPU carefully and safely!

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

4.3. Emergency Release/ Removing the system in case of emergency

In case of an emergency (e.g. patient panics), open the MFA, remove the RPU from the patient and bring it into parking position. Before manipulation of the RPU, please make sure to remove the needle from the NGI by either pulling out the needle or de-coupling the needle from the NGI (cf chapter 4.2.11).

WARNING
Before removing the system, always check that the NGI (or the needle) has been removed!
In case the needle insert has not been removed, friction forces can pull and/or push the needle and this can seriously harm the patient.

4.4. Dismounting

Before dismounting the system, bring the RPU into the "parking position" and remove the patient from the treatment table.

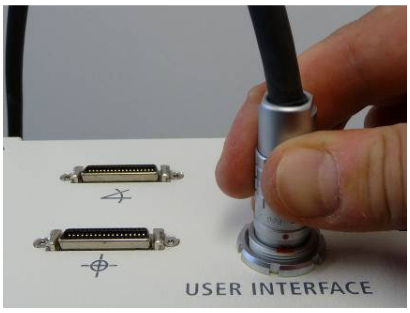
Remove the disposable parts first and dispose them according to the clinic guidelines.

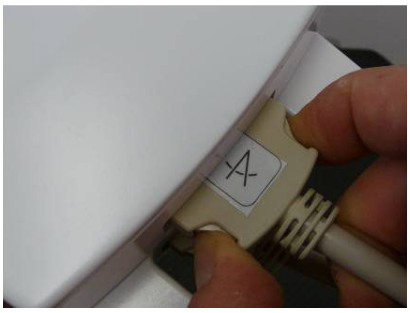
Unplug the system, remove the cables, clean the components and dismount the mechanical parts.

For unplugging of the HCU connection cable please grab the circular connector at the grooved part and simply pull out the plug. For the flat connectors connecting the RPU with the CU please push the two locking rockers of the connector and then pull out the connector.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016





Store the components carefully in the iSYS storage boxes.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

4.5. User Interface

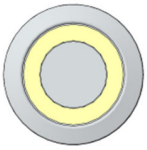
4.5.1. Alarms

This chapter describes the iSYS 1 alarms and what you should do if an alarm occurs.

The device provides only one alarm level, i.e. a technical alarm with low priority. Such a low priority alarm/alert warns you about a condition that prevents the system from operating normally. If, for example, the HCU is not connected to the CU, a runtime error is being detected and reported by triggering a dedicated low priority alarm/alert.

These alarms require your awareness. The alarm signal consists of a yellow LED and a sound that repeats a pattern of two beeps. The display has the message ***EMERGENCY STOP*** and an explanation of the alarm. The tables in Section 4.5.4 explain the alarm conditions and messages in more detail.

LCD Display



Error LED indicator

Alarm beeper

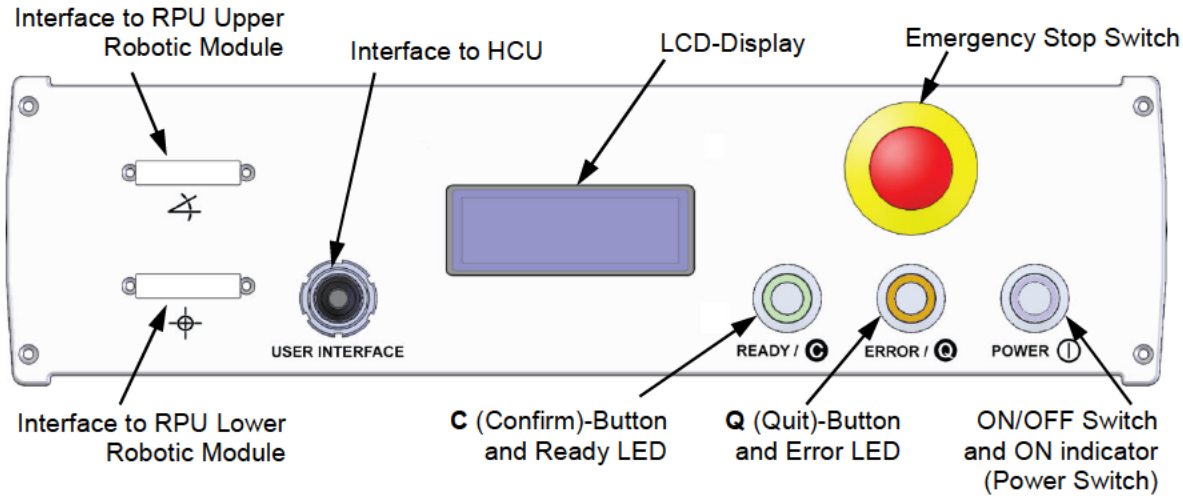
During a low priority alarm/alert:

- Look at the display for text.
- Look up the alarm in the alarm tables in Section 4.5.4 and perform the action specified.
- If the alarm can be cleared: Verify the position and angulation of the tool before you proceed.
- If the alarm persists: Stop the procedure or continue without using iSYS 1. Contact the manufacturer.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

4.5.2. Front-Panel of the Control Unit



The front panel of the iSYS 1 Control Unit contains the following elements:

Buttons:

- ON/OFF Switch — Used to power the system (not accessible via software)
- **C** (Confirm) Button — Used to confirm triggered actions
- **Q** (Quit) Button — Used for controlled error recovering
- Emergency Stop Switch — Used for user initiated emergency stops

Indicators:

- Ready LED (green) — Indicates the system ready state (lighting) or prompts for confirmation input (flashing)
- Error LED (yellow) — Indicates error situations
- ON Indicator (blue) — Indicates if system is powered (not accessible via software)

LCD Display (4rows x 20 ASCII characters)

The LCD Display shows different states of the system.

Interface socket for Handheld Control Unit

The USER INTERFACE socket provides an electrical interface to control elements on the Handheld Control Unit.

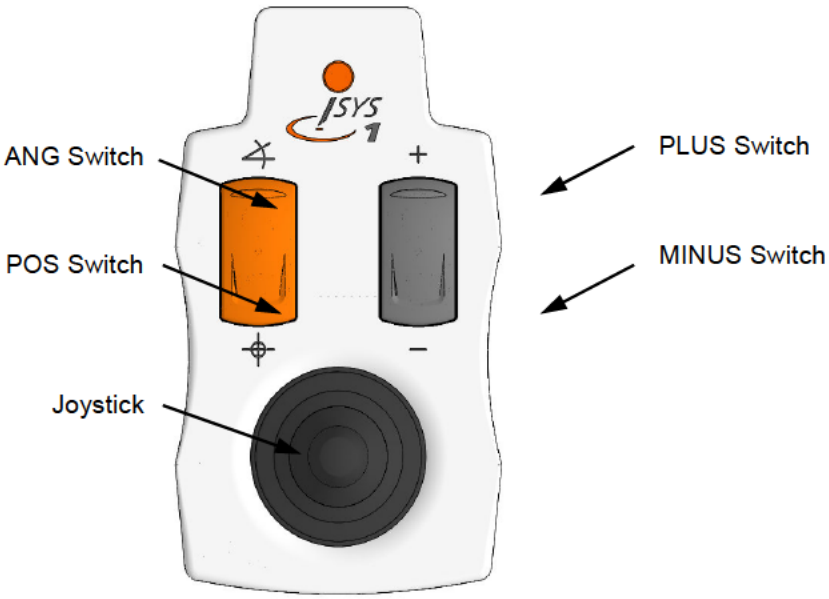
Interface sockets for angulation and positioning module.

..... These sockets provide an electrical interface to the robotic unit.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

4.5.3. Handheld Control Unit



Left Rocker switch:

- ANG Switch — To activate angulation mode of the RPU
- POS Switch — To activate positioning mode of the RPU

Right Rocker switch:

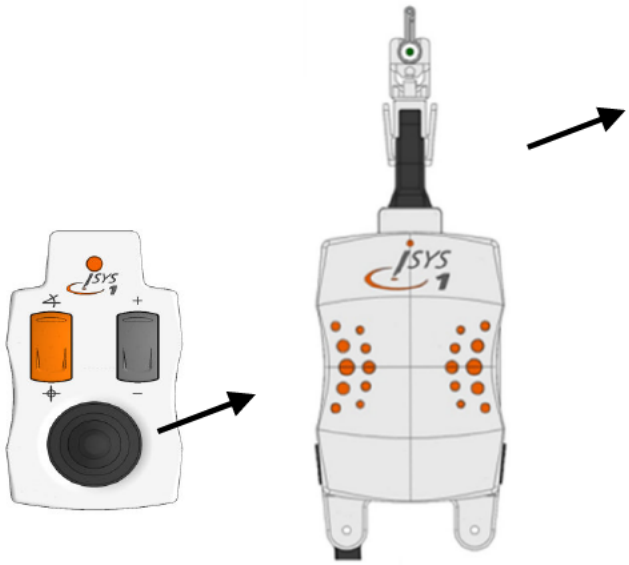
- PLUS Switch (+) — Used to increase the speed limit
- MINUS Switch (-) — Used to decrease the speed limit

Using the PLUS and MINUS button the overall speed level can be switched between 3 levels (100%, 60%, 20%), and thus scales the speed according to the joystick displacement to 100%, 60% or 20%.

Joystick:
The joystick initiates movement of the RPU according to the activated mode (POS or ANG). The shape of the HCU is based on the design of the RPU so that the desired direction of movement can be easily identified.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

4.5.4. Display Messages

Boot-up screen

```
iSYS1 - Needle
Guidance Platform
-------------------
System Bootup....
```

Operation Screen

```
### iSYS1 C-ARM  ###

Speedlevel: fast   *
Joystick Mode  [POS]
```

... Header

... Current Actions (Info Messages)

... Speedlevel and MotionInfo

... Joystickinfo

Message text	Description
Joystickinfo	
Joystick Mode [POS]	The positioning mode is active. Any joystick motion leads to an appropriate motion of the positioning module (lower RM).
Joystick Mode [ANG]	The angulation mode is active. Any joystick motion leads to an appropriate motion of the angulation module (upper RM).
Joystick Mode [ ]	The system is not enabled to perform motions. This steady state is supervised by an electronic circuit.
Speed level+Motion Info	
Speedlevel: {slow|medium|fast} [*] Example: Speedlevel: fast *	The currently active speed level is shown (slow| medium| fast). The asterisk "*" appears if the robotic unit is actually moving. It indicates that the elongation of the joystick is big enough to effectively move the robotic unit.
Info Messages	
Enable System...	The system is activated
Init System	The system is initialized
Starting APP	iSYS 1 application is starting
Rev2 C1.1/M1.6/W1.5	Version info
* Running SELFTEST *	The self-test is running now
Selftest PASSED	The self-test has been completed successfully
Selftest FAILED	Error during self-test

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Error Messages / Emergency Stop Screen

```
### iSYS1 C-ARM ###
***Emergency Stop***
Stationary Error
Press Q to reset ->
```

… Header

… ***Emergency Stop***

… Error in Detail (see table below)

… What to do? (e.g. press the Q-button to reset)

Emergency Stop Reasons:

Error Message	Description	Fault correction
Error Init Axis	The axis controller cannot be initialized.	Press Q to recover the system. If the error still arises, please contact the manufacturer.
Error Detect UI	There is no, or a wrong user interface (HCU) connected to the control unit.	Connect the right user interface to the control unit. Check the connection if already connected. Then press Q to recover the system.
Runtime Err Axis	A runtime error in an axis controller was detected.	Press Q to recover the system (if this error arises frequently, please contact the manufacturer).
Runtime Err Ctrl	A runtime error in the master controller was detected.	Press Q to recover the system (if this error arises frequently, please contact the manufacturer).
Prog Abort Axis	The axis controller program was aborted.	Press Q to recover the system (if this error arises frequently, please contact the manufacturer).
Watchdog Error	The watchdog reports a bad response behavior of the master controller.	Press Q to recover the system (if this error arises frequently, please contact the manufacturer).
Wrong App Config	There are wrong or invalid configuration data detected.	Press Q to recover the system (if this error arises frequently, please contact the manufacturer).
Check HW(5V,Mod)	The modules are not connected properly or the cable for angulation and positioning are switched. There is a problem with the internal power supply.	Check the connection of the module - cables. Press Q to recover the system. If the error still arises, please contact the manufacturer.
Emerg-Stop	No special emergency reason was detected by the system.	Check the emergency stop switch (release).

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Error Message	Description	Fault correction
	Probably the Emergency Stop Switch was pressed.	Press Q to recover the system.
Encoder SigError	An encoder signal error occurred.	Press Q to recover the system. If the error still arises, please contact the manufacturer.
Encoder CmpError	An encoder compare error occurred.	Press Q to recover the system. If the error still arises, please contact the manufacturer.
Axis Param Error	The parameters of an axis controller are invalid.	Press Q to recover the system. If the error still arises, please contact the manufacturer.
APP Config Error	The system parameter configuration is invalid.	Press Q to recover the system. If the error still arises, please contact the manufacturer.
Stationary Error	A motion was detected while the enable button (rocker POS/ANG) was not pressed.	Press Q to recover the system. If the error still arises, please contact the manufacturer.
Motor Fault	A motor fault was detected.	Press Q to recover the system. If the error still arises, please contact the manufacturer.
Overload	The applied load on the robotic unit is beyond the defined threshold.	Check the reason for the overload. Press Q to recover the system. If the error still arises, please contact the manufacturer.
Check HCU Center	The joystick of the HCU is not in its center position (is checked during startup). The change of the HCU can also be the reason for this message.	Ensure that the joystick of the HCU is in its center position during startup. Press Q to recover the system. If the error still arises, please contact the manufacturer.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

5. Maintenance

The product life of the iSYS 1 Unit is **10 years** including a regular service on the device. The service is intended to be performed every year, starting from the 3rd year of use of the device (e.g. device was sold in June 2008; the first service is performed in June 2011). The service includes:

- Detecting wear on the main components
- Detecting failures in the system
- Ensuring the accuracy of the device
- Checking the functionality of the safety relevant components

During the complete lifetime of iSYS 1, all parts and components can be supplied. This means, starting from the end of sale of iSYS 1, the spare parts are available for another ten years.

The lifetime, and thus the end of sales and end of service, might be subject to changes due to growing experience with the product.

For service purposes, iSYS 1 will be sent to iSYS where the service is organized. During that time, the customer will receive a substitute iSYS 1.

WARNING
Changes, additions or maintenance to the equipment carried out by persons without appropriate qualifications and training and/or using unapproved spare parts may lead to fatal or serious personal injury and/or damage to the equipment as well as making the warranty void.

WARNING
Obey the maintenance and service times as given in this section. Disobeying maintanance and service causes loss of warranty and may cause damage of the system and harm of the patient.

WARNING
The housings of the different components may only be opened by an authorized qualified electrician. Before opening a housing, disconnect the iSYS 1 from the main supply.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

5.1. Safety-relevant inspections

Recurrent testing of safety relevant parameters of the iSYS 1 system as given below has to be done every 24 month. When national laws or regulations prescribe further and/or more frequent inspections or maintenance these rules have to be followed. If the iSYS 1 system fails any step of the inspection/testing the iSYS 1 system must not be used and the manufacturer must be contacted.

WARNING
Measurements are only to be performed by a qualified electrician or under supervision of a qualified electrician.

The mentioned inspections are minimum requirements:

Test/Inspection	Item	Inspection
Functional testing	Emergency stop	When the emergency stop button is activated, no motions of the RPU should be possible
	Drive motors	Smooth operation, abnormal noise development
	Strain relief of RPU Cable Set	Secure hold
	CU and HCU	Side rail: safe locking / secure hold / safe unlocking
	TTAA and TTAB	Table top mounting: safe locking / secure hold / safe unlocking
	CU	Check indicators, beeper and display
Visual inspection	Housing enclosure	Look for damage, cracks etc.
	Contamination	Look for obstruction of moving parts, connector pins etc.
	Cabling	Look for cuts etc.
	Fuse rating	Check correct values after replacement
	Markings and Labeling	Check the integrity of safety markings
	Integrity of mechanical parts	Check for any obstructions

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Protective earth testing	Protective earth connection	According IEC 62353
Insulation resistance test	Insulation between mains parts, accessible parts and earth	According IEC 62353
Leakage measurements	Leakage current	According IEC 62353

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

6. Cleaning and Disinfection

It is important that any part of the equipment which may come into direct contact with patients is cleaned and disinfected on a regular basis. Cleaning is an important requirement for a successful chemical disinfection.

WARNING
Only persons instructed in the use of this medical device are allowed to clean the iSYS 1 system.

WARNING
Always clean and disinfect the reusable components of iSYS 1 according to this manual. Never use equipment that is contaminated or uncleaned as this can lead to serious infections.

WARNING
Do not sterilize the re-usable components of the iSYS 1. Sterilizing of any components of iSYS 1 causes loss of warranty and may cause damage of the system and harm to the patient. If components of iSYS 1 are sterilized by mistake contact the manufacturer.

The system must be cleaned and disinfected prior and after to each use. iSYS system components are validated for cleaning and disinfection using the following substances:

Substances:
• 2-Propanol, 1-Propanol
• 94% Ethanol

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

CAUTION

Before beginning cleaning and disinfection, please note:

- **Unplug the power cable**
- **Make sure all other plugs are properly connected.**
- **None of the (electrical) components must show any visible damage; otherwise water or cleaning/disinfection solution could penetrate. This could lead to malfunction or damage to the electrical components.**
- **Before operating the system again, make sure that there is no residual moisture on the electrical contacts.**
- **All iSYS 1 components must not be cleaned with a water jet, a high pressure cleaner or other similar device! Do not use dipping method for cleaning and disinfection!**
- **Clean/disinfect all iSYS 1 components only with a moist towel!**
- **If you suspect that water or any other form of moisture has penetrated the electrical components, disconnect the power plug immediately. If already disconnected from the power supply, make sure it is not plugged in again. Clearly mark the device as "Defective" and take it immediately out of service. Report this to the operator promptly.**
- **Failure to follow these directions could lead to major damage of the system!**

WARNING

After cleaning and disinfection iSYS 1 has to be dried sufficiently. Follow the specific instructions for use and recommended contact times of the used cleaning and disinfection agents.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

iSYS Medizintechnik GmbH
Bergwerksweg 21
6370 Kitzbühel
Austria
www.isys.co.at

Order Nr.: 9567

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Marketing Material

Definition and Analysis of Marketing Material:

This document contains the summarized information for the marketing and sales department as it is released by the general management. The information herein can be used to promote the product, e.g. for marketing material, flyers, meetings with customers, exhibitions and key accounts.

Article/Part number:	4268 / 6224
Article/Part name:	iSYS 1 / iSYS 1 U.S.
Clinical Text:	Micro-invasive surgical procedures are gaining increasing importance in medicine due to the high efficiency level (clinical outcome) and low socio-economic costs. Highest quality assurance of medical instrument positioning and mechanical precision is the “sine qua non” for the ever increasing sophistication of interventional radiology and related fields with its concurrent reduction or abolition of safety margins. The iSYS-1 Interventional Platform iSYS Medizintechnik GmbH provides a state-of-the-art solution which is able to fulfill the three main requirements – accurate positioning, easy integration into clinical workflow as well as a simple and fast setup procedure. The iSYS-1 Interventional Platform has clear advantages over alternative methods of instrument placement: - Firstly, the treatment results are markedly improved while the costs of treatment are reduced. - Patient, physician and hospital or practice can all benefit from this situation. - In addition, the radiation exposure for both the patient and the surgical team can be reduced substantially. - In this way, long-term damage to the surgical team carrying out the treatment will be avoided. - Through the use of the iSYS-1 system, it is no longer necessary to work with the "hand in the beam” and / or in the vicinity of the imaging device. Intended Use: The intended use of the iSYS1 device is to function as a remote-operated positioning and guidance system during interventional procedures. Positioning is done in remote control

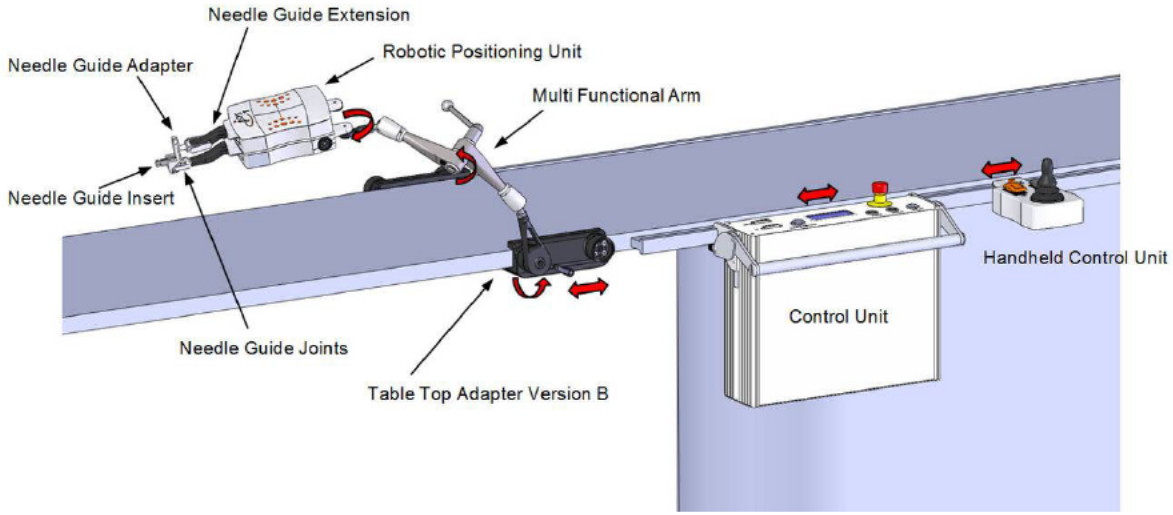
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

	manner; planning of the position/angulation is done based on 2D/3D patient data (CT, cone-beam CT, fluoroscopy) by external planning software – for example using an external navigation system, or planning software coming with the used imaging device. Also verification of the correct position and orientation of the tool prior to/during/after the intervention is done by means of these external devices. The iSYS1-System is then acting as a guideway during the manual insertion of the interventional tool – usually a needle type device, and the like. Applications include, but are not limited to, interventions like biopsy procedures, tumor ablation, nerve blocking, electrode placement, etc.
Technical Text:	The iSYS 1 Interventional Platform is a modular needle guidance platform for interventional radiology and related fields. Core components are a 4 DOF Robotic Positioning Unit which allows submillimetric needle positioning as well as angulation and a Control Unit which is controlled by a cable connected Handheld Control Unit. The passive macro positioning unit and different table adapters allow different setups of the system around the patient in the region of interest by still providing maximum rigidity. The needle-guide-set provides disposable components that ensure precise and sterile needle guidance. Planning of the intervention is based on digital image data acquired intra-operatively using different kinds of modalities, like CT or fluoroscopy (standard C-arms and/or cone-beam CT systems). Planning and verification of both the entry position of the needle-type tool as well as the angulation is performed with the aid of the used imaging device or by an external navigation system. By using the iSYS 1 Handheld Control Unit the surgeon can remotely move the tool to the desired position and angulation in order to start the clinical procedure.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016



The system includes the following mechanical parts:

- one Control Unit
- one Table Top Adapter Version B (Bottom Mounted)
- optional: Side Rail Adapter or Table Top Adapter Version A (Top Mounted)
- one Multi-Functional Arm
- one Robotic Positioning Unit
- two Needle Guide Extensions

The sterile disposables for each procedure are:

- Sterile Cover Robotic Positioning Unit (not reusable) including Needle Guide Joints and Needle Guide Adapter (not reusable)
- Sterile Cover Handheld Control Unit (not reusable)
- Needle Guide Insert (not reusable)
- Marker Insert (not reusable)

Compatibility:

Equipment described in this manual shall only be used in combination with other equipment or components, if these are expressly approved by iSYS as compatible. A list of such equipment and

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

	components is available from iSYS upon request. Changes and/or additions to the equipment shall only be carried out by persons expressly authorized by iSYS to do so. Such changes shall comply with best engineering practice and all applicable laws and regulations that have the force of law within the jurisdiction the equipment will be used within. The following components are compatible with the system but are optional: • Table Adapters • Needles • CT-Systems • System Carts
Technical Data/Information (including photos, drawings if available etc.):	The interface and mounting of the Side-Rail-Adapters of the Control Unit, the Handheld Control Unit as well as the MFA is adjustable along the whole side rail as needed by the user. Additionally the MFA can be rotated in a half circle of 450mm, with the center of rotation being the interface MFA to Side-Rail-Adapter. All starburst or spoon interfaces can be set up in the angle needed, between at least 0-180°. The maximum reachable straight length is 300mm Side Rail Adapter Extension Rod, MFA 450mm, Robotic Positioning Unit 170mm plus 20mm adjustability, Needle Guide Extension and Holder 120mm, leading to an overall length of 940mm. When using any of the Table Top Adapters, the 300mm extension rod is not available, therefore maximum reachable straight length lies at about 640mm. The Robotic Positioning Unit is a robotic unit consisting of two 2DOF modules which allows tool angulation (± 30° for both pitch and yaw angle) and needle positioning (± 20 mm for both lateral and longitudinal direction) with a weight of max. 1,5kg, size is 170x120x70mm. Additional weight is strongly depending on the setup used. The MFA weights 1,3kg with 450x140x60mm, the Control Unit, 700x350x105mm, being the heaviest component with 6 kg. All components can be set up separately. Operating temperature/humidity range: 15 to 30°C; 30 to 70% relative humidity with no condensation Storage temperature/humidity range: 10 to 50°C; 30 to 70% relative humidity with no condensation Power Supply: 50W; 115VAC/230VAC; 50-60Hz; cable: C14 according to IEC/EN 60320-1, US498, CSA C22.2 no. 42
Remarks:	Claimed benefit of the medical product - Firstly, the treatment results are markedly improved while the costs of treatment are reduced. - Patient, physician and hospital or practice can all benefit from this situation. - In addition, the radiation exposure for both the patient and the surgical team is being reduced substantially.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

- In this way, long-term damage to the surgical team carrying out the treatment will be avoided.
- Through the use of the iSYS-1 system, it is no longer necessary to work with the "hand in the beam" and / or in the vicinity of the imaging device.

Clinical studies/ Pre-clinical investigations for reference

From the given literature, we conclude that video-assisted and computer-assisted robotic techniques are safe and may be the pathway to improve minimal invasive operations. The damage to healthy tissue can be significantly reduced which results in shorter operating times and hospital length of stay. The data proves that robotic systems in general are capable to achieve the performances intended by the manufacturer. The iSYS 1 is designed, manufactured and packaged in a way that it is suitable for the functions referred to in the intended use, and thus fulfills Annex I.3 of MDD.

CAS (computer assisted surgery) allows for increased three-dimensional accuracy, improved precision and the reproducibility of procedures. The ability to transmit to the other side of the operating room or to a remote site via high-speed communications links is an additional advantage. Furthermore, the surgeon will be able to share his expertise and skill through teleconsultation and telemanipulation, bringing the patient closer to the expert surgical team.

Surgical robotics is the study and application of advanced robotic technology to diverse surgical procedures, particularly to minimally invasive surgery. The advanced robotic technology in minimally invasive surgery leads to momentous change in and generates a tremendous impact on surgery, resulting in less pain and scarring, reduced blood loss and transfusions, lower risk of complication, shorter hospital stays and faster recovery periods. Systems such as the da VinciTM surgical system of Intuitive Surgical Inc., which facilitates minimally invasive surgery with increased dexterity, are commercially available. Preoperative simulation and planning of surgical robot setups should accompany advanced robotic surgery if their advantages are to be further pursued. Feedback from the planning system will play an essential role in computer-aided robotic surgery in addition to preoperative detailed geometric information from patient CT/MRI images.

While other authors find no statistical differences between experienced surgeons and non-surgeons in the number of errors (block drooping) as well as the completion time and the tool tip path length at different time delays, the CEDIT considers robots to meet the requirements of accuracy, innocuity and minimal invasion characterizing neurosurgical practice. No other technique of neuronavigation currently provides this degree of accuracy. The CEDIT recommends the NeuroMate (R) stereotactic robot for centres handling a large number of patients with stereotactic neurosurgery indications, but also recommends a harnessing of expertise (neurology, neuroradiology, neurosurgery, and neurophysiology) with recognized experience in the field. The neurosurgery department of the Henri-Mondor hospital

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

	corresponds to these requirements. Limitations: Robotic surgical systems, such as the da Vinci Surgical System (Intuitive Surgical, Inc., Sunnyvale, California), have revolutionized laparoscopic surgery but are limited by large size, increased costs, and limitations in imaging. Miniature in vivo robots are being developed that are inserted entirely into the peritoneal cavity for laparoscopic and natural orifice transluminal endoscopic surgical procedures. In the future, miniature camera robots and microrobots should be able to provide a mobile viewing platform. CAS is a more expensive technology on a per case basis due to more expensive robot specific instrumentation and physician labour reflected by increased OR time reported in the clinical literature. There is insufficient evidence to conclude that any of the three surgical approaches is superior with regard to functional and oncological outcomes. Despite implicit or explicit claims that this technology is superior, for most indications its distinct advantages are currently unproven and highly dependent on surgical skills and professional experience.
Marketing material requested?	☒ yes What kind of: Flyers and Marketing Material for ECR 2011 (see PDM "Marketing"). ☐ no
Analysis of Marketing Information:	**Costs and effectiveness:** EX_66_2396_wi_FIC-2008: "*The use of the robotic assistant did not slow down the procedure, which must be considered as a very positive result for a pilot clinical trial.*" EX_73_09750_wi_SCH-2012: "*Results All phantom interventions (n040) could be performed successfully. Mean target access path within the phantom was 8.5 cm (min 4.2 cm, max 13.5 cm). Average needle tip deviation was 1.1 mm (min 0 mm, max 4.5 mm), time duration was 3:59 min (min 2:07 min, max 10:37 min). Conclusion When using the proposed robot device in a CBCT intervention suite, highly accurate needle-based interventional punctures are possible in a reasonable timely manner in single as well as in double oblique trajectories.*" → Higher patient throughput EX_66_2706_wi_KRO-2003: "*Reduced treatment costs due to lower morbidity*"…"*Shortening of the interventional procedure*".

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

→ Better cost-benefit ratio

EX_66_2396_wi_FIC-2008: "*The system provided needle placement accuracy superior to that of conventional templates while offering much greater flexibility, owing to its biaxial needle angulation and continuum Cartesian needle spacing. These features were achieved without causing interference with established clinical hardware, workflow, or calibration standards.*"

EX_66_2706_wi_KRO-2003: "*Improved accuracy and consistent results of biopsy samples*".

EX_73_09750_wi_SCH-2012: "*Results: All phantom interventions (n040) could be performed successfully. Mean target access path within the phantom was 8.5 cm (min 4.2 cm, max 13.5 cm). Average needle tip deviation was 1.1 mm (min 0 mm, max 4.5 mm), time duration was 3:59 min (min 2:07 min, max 10:37 min). Conclusion When using the proposed robot device in a CBCT intervention suite, highly accurate needle-based interventional punctures are possible in a reasonable timely manner in single as well as in double oblique trajectories.*"

→ Higher precision

EX_66_2396_wi_FIC-2008: "*Robotic needle positioning offers potential for more conformal treatment planning due to the capability for finer adjustments in needle positioning, as well as the potential for reduced number of needles required for a given volume. "*

EX_66_2706_wi_KRO-2003: "*Planning of complex access routes*".

EX_66_6855_wi_BAL-2012: "*The drawbacks of conventional computed tomography/ ultrasound/magnetic resonance imaging (CT/US/MRI) guided radiofrequency ablation (RFA) are the absence of planning software, imprecise probe placement, imprecise control of probe placement and the ablation zone as well as the lack of reliability and reproducibility.*

Methodological innovations: Stereotactic and robot-assisted systems allow planning of multiple probe positions based on CT/MRI and positron emission tomography (PET) planning data. The probes can be precisely placed according to the coordinates of the image datasets.

Performance: The 1 and 3 year survival rates after stereotactic RFA (SRFA) of cholangiocellular carcinoma were 91% and 70% respectively and the median overall survival was 60 months. After SRFA of 189 colorectal liver metastases in 63 patients there was no significant difference in local recurrence rates between tumors < 3 cm (17.7%), 3–5 cm (11.1%) and > 5 cm (17.4%). The median overall survival was 33.2 months and the 1, 3, and 5 year overall survival rates after SRFA in patients with resectable colorectal cancer were 92%, 66% and 48%, respectively.

Achievements: In our opinion the excellent and, to a large extent user-independent results justify the

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

increased efforts in time and costs especially for the treatment of patients with large and irregular tumors."

→ Better clinical outcomes

Patient benefits:

EX_66_2706_wi_KRO-2003: "*Reduced radiation dose for the radiologist and patient during intervention*". See also Kato et al.: "Radiation dosimetry at CT fluoroscopy".

EX_66_5705_wi_BRA-2011: "*Total mean effective doses with cone-beam CT guidance were 7.6 mSv in the upper thorax, 12.3 mSv in the lower thorax, 16.1 mSv in the upper abdomen, and 13.4 mSV in the lower abdomen. Effective doses with uncollimated cone-beam CT alone were 2.0, 2.9, 4.2 and 3.5 mSv in the respective regions. Effective doses with CT-guided interventions were 13.0, 15.1, 20.4 and 15.4 mSv in the respective regions. Cone-beam CT guidance results in reduction of 13% - 42% of total effective dose compared with conventional CT guidance.*"

EX_66_09749_wi_SCH-2012: "*The high accuracy finally might save the patient from a dose of radiation because the intervention time can be kept at a low level.*"

→ Reduced radiation exposure; Fewer side effects due to less radiation dose and higher accuracy; Faster recovery due to fewer side effects.

Ergonomics:

Test Reports: Test 1/3, Test 1/4, Test 2/4, Test 4

→ Intuitive and fast use

Test Reports: Test 1/3, Test 1/4

→ iSYS 1 is the most advanced needle guidance platform for interventional radiology

Safety:

Use of watchdog, dead man switch, reduced translation speed, and visual and acoustic alarm system, interrupting the current flow immediately, cannot be found in predicate devices or concurrent systems. For validation of safety systems and integration see PD_73_3872 (safety structure of iSYS 1).

EX_66_2706_wi_KRO-2003: "*Reduced radiation dose for the radiologist and patient during intervention*". See also Kato et al.: "Radiation dosimetry at CT fluoroscopy".

EX_66_2400_wi_WAG-2009: "*By using the technology [fluoroscopy], they're [physician] achieving better*

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

accuracy than before – and leaving themselves open to various forms of cancer and other conditions known to develop after years of radiation exposure….The first line of protection is to keep yourself out of the beam. The second line of protection is to keep yourself 6 feet away from the beam."

Test Reports: Test 2/5, Test 2/6, Test 3/2, Test 5, Test 6

→ Safer work environment

EX_66_2706_wi_KRO-2003: "*Reduced radiation dose for the radiologist and patient during intervention*". See also Kato et al.: "Radiation dosimetry at CT fluoroscopy".

EX_66_09749_wi_SCH-2012: "*Measurements showed the highest radiation dose at the eye and thyroid level. In comparison to 2D-DSA (3.9 Sv eye-exposure), the 3D procedures caused an increased radiation exposure both in standard FOV (8 s/rotation: 28.0 Sv, 20 s/rotation: 79.3 Sv, 5 s/2 rotations: 32.5 Sv) and large FOV (37.6 Sv). Proportional distributions were measured for the residual heights. With the use of lead glass, irradiation of the eye lens was reduced to 0.2 Sv (2D DSA) and 10.6 Sv (3D technique with 20 s/rotation). Conclusion: Rotational flat-panel angiography and C-arm cone beam applications significantly increase radiation exposure to the attending operator in comparison to 2D angiography. Our study indicates that the physician should wear protective devices and leave the examination room when performing 3D examinations.*"

EX_66_09749_wi_SCH-2012: "*Apart from the improved accuracy, an advantage of using a mechanical device for needle guidance could be the reduced x-ray exposure to the attending staff because the robot can be aligned to the correct bearing from a safe distance. Both before and during the needle insertion, neither a direct exposure of the interventionalist's hands to the radiation beam will occur, nor are inaccurate holding devices such as forceps necessary. The high accuracy finally might save the patient from a dose of radiation because the intervention time can be kept at a low level.*"

Test Reports: Test 6

→ Safer for the physician

Safer work environment and higher safety for the physician

Operator controls the robot from the control room → no radiation exposure for the user

The „Joystick"-extension cable allows an extension of the standard „Joystick"-cable from 3 meters to 11 meters.

The higher the radiation dose for the user, the more health risk for the user (see publication EX_66_2400_wi_WAG-2009)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

The greater the distance to the beam results in less radiation exposure (see publication EX_66_2400_wi_WAG-2009)

The user knows that radiation harms him, so he stresses himself to be very fast. At the same point of time he should not make a mistake when placing the needle, this causes additional stress

With the iSYS 1 he can easily make the needle alignment under fluoroscopy outside the 6 foot line. Being inside the 6 foot line is seen as critical, even with radiation protection.

→ Less risk and stress during interventions

EX_66_2396_wi_FIC-2008: "*A Phase-I clinical feasibility and safety trial has been successfully completed with the system. We encountered needle tip positioning errors of a magnitude greater than 4 mm in only 2 of 179 robotically guided needles, in contrast to manual template guidance where errors of this magnitude are much more common. Further clinical trials are necessary to determine whether the apparent benefits of the robotic assistant will lead to improvements in clinical efficacy and outcomes.*"…" *The robot allowed for fine adjustments in needle/seed positioning, which we used at times to achieve insertion points between the standard template positions. In addition, the ability to easily shift the frame of reference of the robotic needle guide avoids a difficult situation encountered in standard procedures where systematic errors in needle placement are often observed despite careful pre-clinical calibration. In such cases, we could easily compensate for the apparent bias…*"

EX_66_2706_wi_KRO-2003: "*Reduced radiation dose for the radiologist and patient during intervention*". See also Kato et al.: "Radiation dosimetry at CT fluoroscopy".

Test reports: Test 1/1

→ Safer for the patient; higher accuracy than manual procedures

Use of watchdog, dead man switch, reduced translation speed, and visual and acoustic alarm system, interrupting the current flow immediately, cannot be found in predicate devices or concurrent systems. For validation of safety systems and integration see PD_73_3872 (safety structure of iSYS 1).

Test reports: Test 2/1, Test 2/2, Test 2/3, Test 3/1, Test 5, Test 8 – 10

→ Higher safety standards; Best safety standards

EX_66_2396_wi_FIC-2008: "*In contrast to actual needle tip positions, the Polaris measurements consistently showed the robotic positioning of the needle guide to be accurate generally to within 1mm. Given that the Polaris measurements were of the robot arm position instead of needle position at depth,*

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

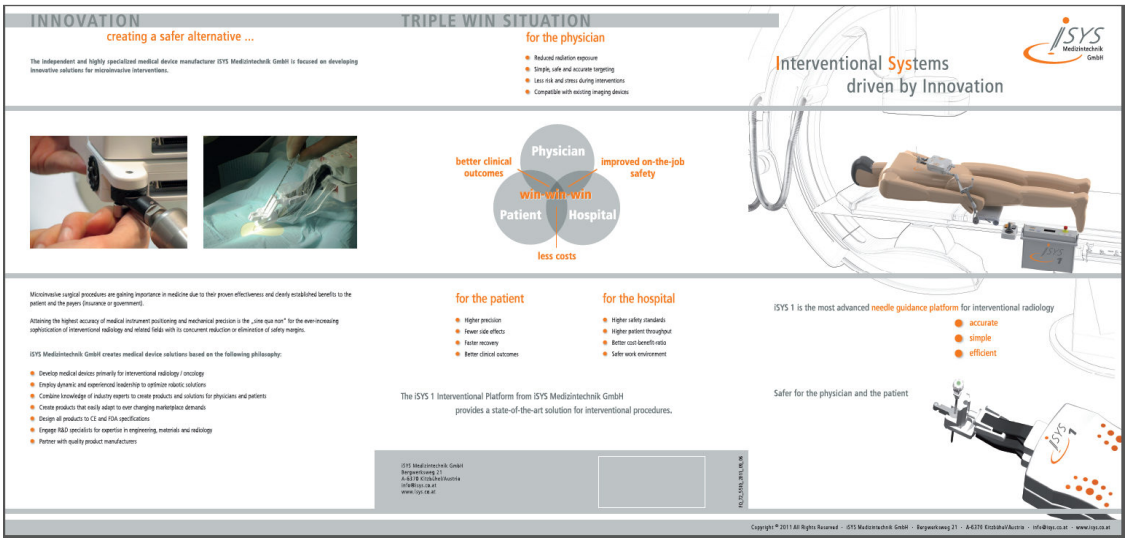
	they are not affected by tissue deflection of the needle upon insertion and thus are a more relevant indication of robotic positioning accuracy versus the template." Test reports: Test 2/1, Test 2/2, Test 2/3, Test 2/4, Test 3/1 → Maximum mechanical stability/compatibility **Multicenter study:** (covering several phrases) EX_66_11430_wi_KRO-2013: "*The outlined work-flow has been evaluated in a series of ex vivo trials in 5 different institutions and with different imaging systems. Tests have been performed with different protocols, e.g. for usability evaluation, evaluation of radiation dose, accuracy, and others. The following group of results should serve as an example for these multi-centric tests (n=35 needle placements):* • *avg. alignment time: 21.23 sec (min. 11 s, max. 35s)* • *avg. additional dose: 2.076 mGy (min. 1.389 mGy, max. 3.243 mGy)* • *mean deviation 0.4 mm (RMS) from planned path with a mean insertion length of 6.73 cm* *DISCUSSION* *A work-flow has been developed in order to allow a seamless integration of a novel robot system for percutaneous needle placement with CBCT imaging. Evaluation has been performed in a series of ex vivo tests and multi-centric patient trials for different applications and target regions. All (in vivo) procedures were successfully conducted without any technical problems.* ***By using the developed work-flow the procedures have been rated as simpler, more comfortable, safer for patient and physician, and faster."***

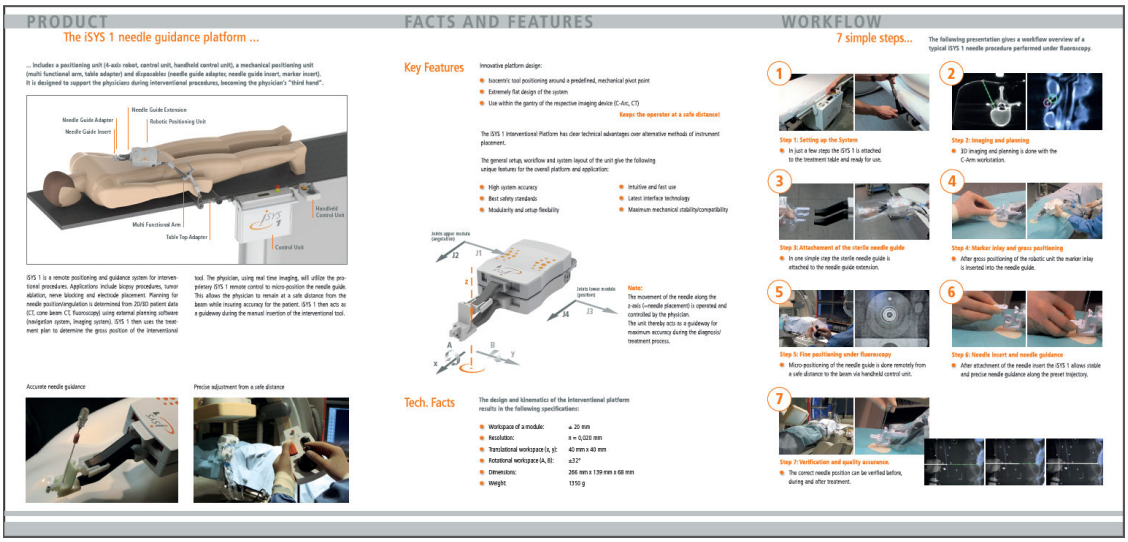
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Section 013	Proposed Labeling 510(k) Number: K131433	iSYS Medizintechnik GmbH

Flyer (6 pages):





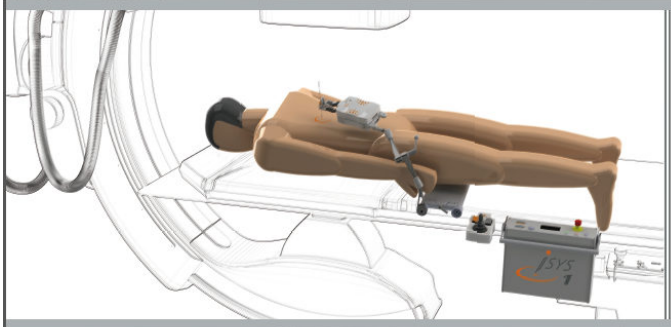
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

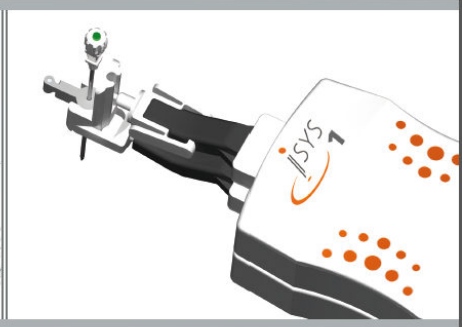
Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Product Flyer (2 pages):

Interventional Systems driven by Innovation

iSYS Medizintechnik GmbH





iSYS 1 is the most advanced needle guidance platform for interventional radiology

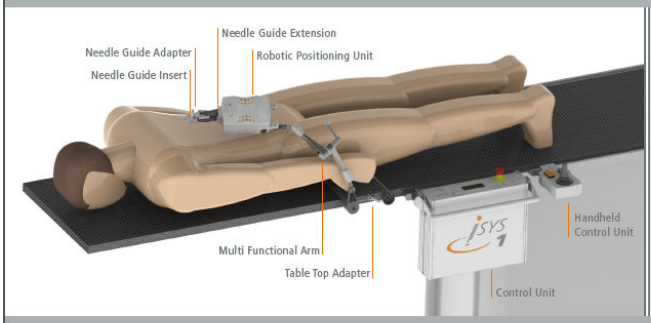
- accurate
- simple
- efficient

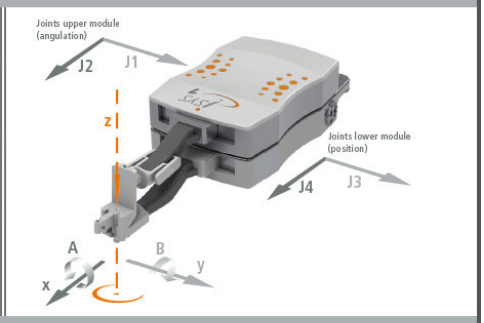
Safer for the physician and the patient

Copyright © 2011 All Rights Reserved · iSYS Medizintechnik GmbH · Bergwerksweg 21 · A-6370 Kitzbühel/Austria · info@isys.co.at · www.isys.co.at

On target from a safe distance.

iSYS Medizintechnik GmbH





System description:

The intended use of the iSYS 1 device is to function as a remote-operated positioning and guidance system during interventional procedures.

Core component is a robotic-positioning unit with 4 degrees of freedom which allows submillimetric needle positioning in x, y (range +/- 20mm) and angulation in A, B (range +/- 35°) around a fixed pivot point.

The passive gross positioning unit and variety of table adaptors allow for different system configurations of the system around the patient in the region of interest while providing maximum rigidity.
Planning of the desired position/angulation is done based on 2D/3D patient data (CT, cone-beam CT, fluoroscopy).

Fine positioning/angulation is done remotely from a safe distance.

After adjustment of the needle guide, the iSYS 1 acts as a guideway during the manual insertion of the interventional tool.

System benefits:

- High system accuracy — better clinical outcomes
- Small and lightweight robot — high safety standards
- Modularity and compatibility — maximum setup flexibility
- Intuitive use — easy and fast handling
- Latest technology — good cost-benefit ratio
- Extremely flat design — use inside the gantry

Keeps the operator at a safe distance!

FO_72_395 from 16.03.2011

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Form FDA 3654

Form Approved: OMB No. 0910-0120; Expiration Date: 12/31/13

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

ISO 15223-1 Second Edition 2012-07-01, Medical devices - Symbols to be used with medical device labels, labelling, and informati

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	#5-73	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☐	☒
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☒
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☒	☐
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☒	☐
If yes, was the guidance document followed in preparation of this 510k?	☒	☐

Title of guidance: Guidance for the Content of Premarket Submissions, Guidance for Off-the-Shelf Software, et. al.

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

[5] The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[6] The online search for CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html

FORM FDA 3654 (12/10) Page 1

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE
ISO 15223-1 Second Edition 2012-07-01, Medical devices - Symbols to be used with medical device labels, labelling, and informati

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
5	Symbols	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *
Symbol 5.2.8. is used although not recognized (see SIS)

DESCRIPTION

JUSTIFICATION
Symbol is common and used in the U.S. Use of it does not bear any risk. The meaning is described in the User Manual.

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

* Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

Paperwork Reduction Act Statement

Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and 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:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
1350 Piccard Drive, Room 400
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 number.

FORM FDA 3654 (12/10) Page 2

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Sterilization and Shelf Life

Table of Content

	Page
In General	2
Proposed Labeling	7
Validation Report (Packaging)	11
Summary Report Bioseal	28
Sterilization Validation Bioseal	34
Summary Report Preferred Medical	59
Sterilization Validation Preferred Medical	61
Bioburden Routine Report	75
Validation of Bioburden Determination	89
Data Sheets	100
Certificates	135

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

In General

With the iSYS 1 system several single use sterile devices are supplied. They are not meant to be reused or user sterilized, but are for single use only.

Cleaning and disinfection procedures according to regular clinical standards are recommended in the user manual and should be applied to the hardware modules only, as they are reusable.

1. Sterile Equipment Covers (Drapes)

The sterile equipment covers for the US market are obtained from (b)(4) [redacted] (b)(4) [redacted] and are part of the PM product family covered by their 510(k) K863853. They are delivered ready packaged, labelled, and sterilized by (b) [redacted] Thereafter, they are added to the final iSYS products at (b)(4) [redacted] (b)(4) [redacted]

For a comparison of the iSYS equipment covers with the existing products from Preferred Medical see below chapter (b)(4) [redacted] (b)(4) [redacted]

2. Needle Guide Adapter, Needle Guide Inserts, and Needle Guide Marker Inserts:

The Needle Guide Adapters, Inserts, and Marker Inserts are part of the robotic system manufactured by iSYS. Bioseal (Reg. No. 2027062) performs packaging and sterilization under 510(k) K893814.

For the “Sterile Cover RPU” the Needle Guide Adapter is packed in a kit together with the drape.

Kit Certification:

We certify that the following components of our kit have been found to be substantially equivalent through the premarket notification process for the use for which the kit is intended (i.e., I am not claiming or causing a new use for the components). We further certify that these components are not purchased in bulk, but are purchased in finished form, i.e., they are packaged, labeled, etc., and consistent with their premarket notification criteria and status.

Sterilization method:

(b)(4) [redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

(b)(4)

[redacted]

Description of packaging:

All components are double packed and sealed with peel packs in different sizes (Tool 3.2 or 2.1) and “Internal Pouch 4x5 w”. For details on the packaging or the packaging material see below (Data Sheets) and the following table:

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

(b)(4)

[redacted]

Device Description

Details see Section 011, pages 26 – 36 and 56 – 57, for technical data sheets see below.

Flammability:

See TDS below: according to UL 94, IEC 60695-2-12 and FMVSS 302.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Proposed Labeling

Safety Symbols:

STERILE EO	Symbol for STERILIZED USING ETHYLENE OXIDE
STERILE R	Symbol for STERILIZED USING RADIATION
	Symbol for DO NOT USE IF PACKAGE IS DAMAGED
	Symbol for DO NOT REUSE
MR	Symbol for NOT MRI SAFE
	Symbol for CAUTION, CONSULT ACCOMPANYING DOCUMENTS
	Symbol for STORAGE TEMPERATURE
	Symbol for DO NOT LITTER IN DOMESTIC WASTE

Product Identification:

SN	Symbol for SERIAL NUMBER
REF	Symbol for ORDER NUMBER
LOT	Symbol for BATCH NUMBER

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Additional Information

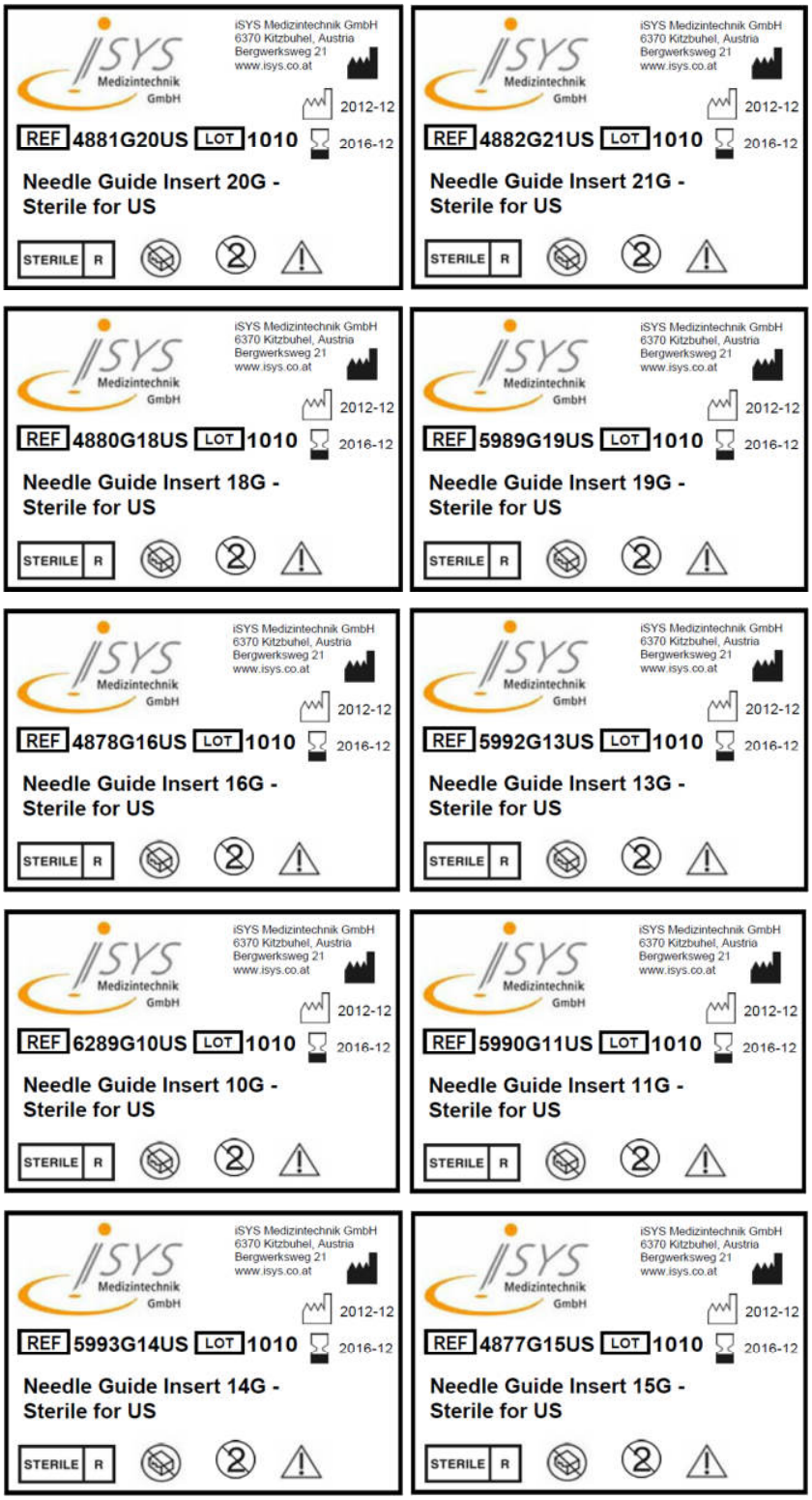
CE	Symbol for CE-conformity
	Symbol for MANUFACTURER
	Symbol for DATE OF MANUFACTURE
	Symbol for USE BY

Samples of Labels:

The presented labels are examples for the final product and packaging labels. Lot numbers and dates on these examples are placeholders only. They do not define any format of lot numbers, production or expiry dates.

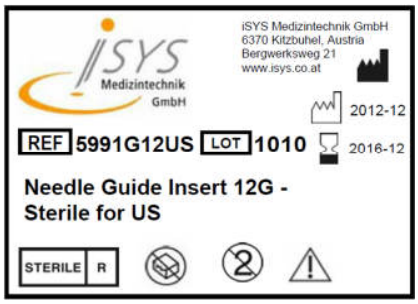
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

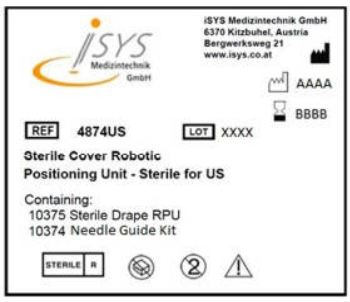
Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

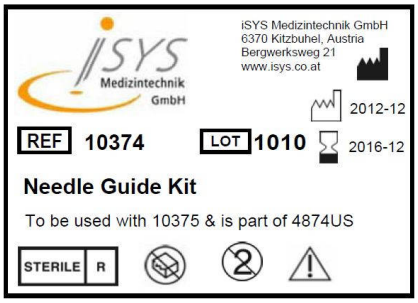


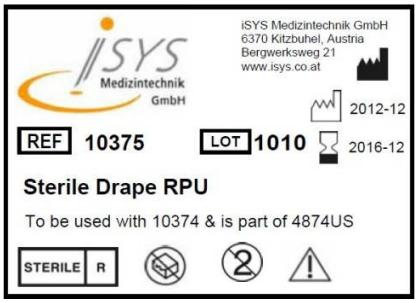
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016









Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Section 014	Sterilization and Shelf Life 510(k) Number: K131433	

(b)(4) Third Party Test Data

[redacted]

Q

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Section 014	Sterilization and Shelf Life 510(k) Number: K131433	

(b)(4) Third Party Test Data

[redacted]

Qu

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Section 014	Sterilization and Shelf Life 510(k) Number: K131433	

(b)(4) Third Party Test Data

[redacted]

(b)(4)

(b)(4)

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4)

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Software

Table of Content

	Page
In General	2
Software Description	4
Software Risk List	30
Verification and Validation	35
Standards Data Reports	37

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

In General

The iSYS 1 (U.S.) is controlled by software, used with the help of a Handheld Control Unit (HCU) and user relevant information is displayed on the Control Unit.

The *Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices*, published on May 11, 2005 by *Center for Devices and Radiological Health (CDRH) – Office of Device Evaluation* complements the *guidance documents General Principals of Software Validation and Guidance for Off-the-Shelf Software Use in Medical Devices. ISYS shall utilize these guidance documents* for the purpose of validating the software associated with the ISYS 1.

The standard report forms can be found at the end of the document (pages 39 and 40). The documentation of the design process for usability is part of the risk management and can be found in section “009 Declarations of Conformity and Summary Reports”.

Level of concern:

According to the figure below the determination of the Level of Concern for the iSYS1 software results in a “**Moderate level of concern**”.

According to Chapter 3 of the *Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices* and the *Level of Concern* of this product, the following documentation will provide the following content:

SOFTWARE DOCUMENTATION	MINOR CONCERN	MODERATE CONCERN	MAJOR CONCERN
Level of Concern	A statement indicating the Level of Concern and a description of the rationale for that level.		
Software Description	A summary overview of the features and software operating environment.		
Device Hazard Analysis	Tabular description of identified hardware and software hazards, including severity assessment and mitigations.		
Software Requirements Specification (SRS)	Summary of functional requirements from SRS.	**The complete SRS document.**	
Architecture Design Chart	No documentation is necessary in the submission.	**Detailed depiction of functional units and software modules. May include state diagrams as well as flow charts.**	
Software Design Specification (SDS)	No documentation is necessary in the submission.	**Software design specification document.**	
Traceability Analysis	Traceability among requirements, specifications, identified hazards and mitigations, and Verification and Validation testing.		
Software Development Environment Description	No documentation is necessary in the submission.	**Summary of software life cycle development plan, including a summary of the configuration**	Summary of software life cycle development plan. Annotated list of control documents generated during

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

		management and maintenance activities.	**development process. Include the configuration management and maintenance plan documents.**
Verification and Validation Documentation	Software functional test plan, pass / fail criteria, and results.	**Description of V&V activities at the unit, integration, and system level. System level test protocol, including pass/fail criteria, and tests results.**	**Description of V&V activities at the unit, integration, and system level. Unit, integration and system level test protocols, including pass/fail criteria, test report, summary, and tests results.**
Revision Level History	Revision history log, including release version number and date.		
Unresolved Anomalies (Bugs or Defects)	**No documentation is necessary in the submission.**	**List of remaining software anomalies, annotated with an explanation of the impact on safety or effectiveness, including operator usage and human factors.**	

No software anomalies were remaining.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Standards Data Reports

Form Approved: OMB No. 0910-0120; Expiration Date: 12/31/13

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

IEC 62366, Medical devices - Application of usability engineering to medical devices

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	#5-50	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☐	☒
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☒
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☒	☐
If yes, was the guidance document followed in preparation of this 510k?	☒	☐

Title of guidance: Medical Device Use-Safety: Incorporating Human Factors into Risk Management

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

[5] The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[6] The online search for CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html

FORM FDA 3654 (12/10) Page 1

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Form Approved: OMB No. 0910-0120; Expiration Date: 12/31/13

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

IEC 62304 First edition 2006-05, Medical device software - Software life cycle processes

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	#13-8	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☐	☒
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☒
Were there any deviations or adaptations made in the use of the standard? If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐ ☐	☒ ☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard? If yes, was the guidance document followed in preparation of this 510k?	☒ ☒	☐ ☐

Title of guidance: Guidance for the Content of Premarket Submissions, Guidance for Off-the-Shelf Software, et. al.

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

[5] The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[6] The online search for CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html

FORM FDA 3654 (12/10) Page 1

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Electromagnetic Compatibility and Electrical Safety

Table of Content

General	2
Forms FDA 3654	3
Test Report “Electrical Safety”	6
Test Report “Electromagnetic Compatibility”	8
Test Report “FCC 47 CFR Part 15”	34
Test Report “RFID and WLAN”	49
Certificates	65

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Electromagnetic Compatibility:

Tests according to ÖNORM EN ISO 60601-1-2 and FCC requirements performed at seibersdorf laboratories. Additional test performed for influences of RFID devices and WLAN. For test report and certificates see below.

Electrical Safety:

At the **present and until April 2013** (EN ISO 60601-1 2nd edition becoming invalid) testing of each individual system at the Notified Body 0408 (TUV Austria) according to:

- EN 60601-1:1990 + A1:1993 + A2:1995
- EN 60601-1-8:2004 + A1:2006

Example of test report and certificates can be found in below.

Starting from **QIII/2013** type testing including CB-test report and UL-listing at the Notified Body 0408 (TUV Austria) according to:

- IEC 60601-1 3rd Edition
- IEC 60601-1-8

Test strategy is prepared and a risk analysis is already running.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Forms FDA 3654

Form Approved: OMB No. 0910-0120; Expiration Date: 12/31/13

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

IEC 60601-1, Medical Electrical Equipment - Part 1: General Requirements for Safety, 1988; Amendment 1, 1991-11, Amendment

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	#5-4	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☒
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: _____

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

[5] The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[6] The online search for CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html

FORM FDA 3654 (12/10) Page 1

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Form Approved: OMB No. 0910-0120; Expiration Date: 12/31/13

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

IEC 60601-1-2, Medical Electrical Equipment - Part 1-2: General Requirements for Safety - Collateral standard: Electromagnetic C

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3] #5-34		
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☒
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☒	☐
If yes, was the guidance document followed in preparation of this 510k?	☐	☒

Title of guidance: _____

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

[5] The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[6] The online search for CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html

FORM FDA 3654 (12/10) Page 1

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Form Approved: OMB No. 0910-0120; Expiration Date: 12/31/13

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

IEC 60601-1-8 Ed. 1, Medical electrical equipment - Part 1-8: General requirements for safety - Collateral Standard: Alarm System

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3] #5-49		
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☒
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510k?	☐	☐
Title of guidance:		

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

[5] The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[6] The online search for CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html

FORM FDA 3654 (12/10) Page 1

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Section 017	Electromagnetic Compatibility and Electrical Safety 510(k) Number: K131433	iSYS Medizintechnik GmbH

Test Report "Electrical Safety" (Example)

(b)(4) Third Party Test Data

[redacted]

Que

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

Records Processed under FOIA request 2015-10247; Released by CDRH on 07/08/2016

Performance Testing – Bench

Table of Content

	Page
V&V Plan iSYS 1 (Summary of Test Protocols)	2
V&V-Plan Sterile Components	25
V&V-Report iSYS 1	43
V&V-Report Sterile Components	76

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)