joimax®
Endoscopic Spine Experts

Intracs® em

User Manual

Integrated Navigation Tracking & Control System

Electromagnetic navigation system for endoscopic minimally invasive spine surgery

Table of Contents

1 Legal Notes

This manual contains information subject to copyright. All rights are protected by law. Without explicit written authorization by the manufacturer, it is prohibited to copy, publish or record this manual, wholly or in part, by photocopy, microfilm or other methods.

The manufacturer is grateful for information about any errors or inconsistencies in this document.

Due to continuous improvement of our products, we reserve the right to make technical changes that do not affect functionality and basic safety.

1.1 Liability

All procedures, notes and warnings described in this manual do not release the operator/user from his or her responsibilities regarding clinical judgment, experience and best clinical practice.

2 General Description

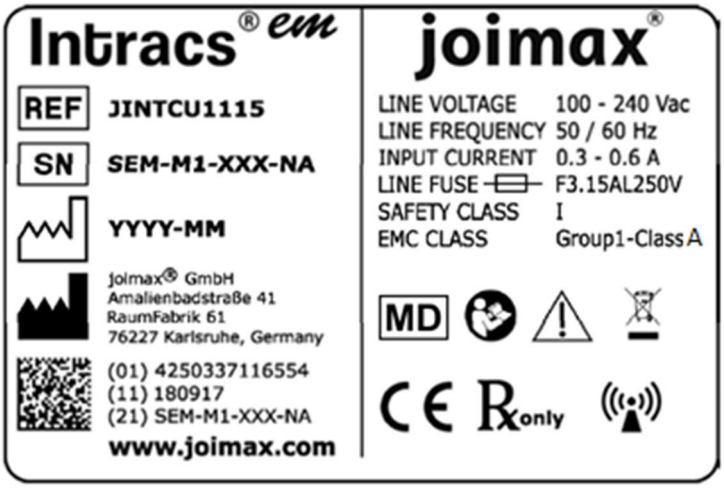
The Intracs® *em* Navigation System is an electromagnetic navigation system specially designed for use in endoscopic minimally invasive surgery at the spine.
It consists of a Panel PC, a control unit, a field generator and different sensors, which can be attached to surgical instruments to track and display them in relation to the patient's anatomy in medical image data on a monitor.

3 Signs and Symbols

	Please note!
	Warning!
	Separate collection of electrical and electronic devices (in accordance with directive 2012/19/EU, WEEE)
	CE mark of the manufacturer according to MDD 93/42/EEC
	Manufacturer
	Date of manufacture
	Follow Instructions for Use
	Item number
	Serial number
	Caution: U.S. federal law restricts this device to sale by or on the order of a physician.
	Non-ionizing electromagnetic radiation
	Applied part type BF
	Equipotential (potential equalization)
	Temperature limitation
	Humidity limitation
	Atmospheric pressure limitation
	Keep away from rain
	Keep away from sunlight
	Non-sterile

MD	Medical Device

3.1 Device Label



4 Intended Purpose and Characteristics

Warning:
The device must be used only for its intended purpose described in this manual!

4.1 Intended Purpose

The joimax® Intracs® *em* Navigation System is intended to continuously display the position and orientation of joimax® surgical instruments relative to the anatomy in medical image data in either open or minimal invasive orthopedic procedures.

Indications for Use
The use of the device is indicated for any medical condition in which the use of stereotactic surgery may be appropriate, and where reference to a rigid anatomical structure, such as the spine or pelvis, can be identified relative to images of the anatomy.
This can include spinal procedures, where the target point for the procedure itself or for the access to the area of interest, is a rigid landmark, such as:

- Transforaminal procedure
- Interlaminar procedure

Warning:
The Intracs® em Navigation System must be considered as a supporting system. In case of a failure of the device, the user must be able to perform the intervention conventionally and the necessary equipment must be available at any time!

Contraindications
The use of the device and its associated applications is contraindicated for any medical condition, that contraindicates the medical procedure itself.

Warning:
The system must not be used during defibrillation or following defibrillation!

Warning:
The EM field generator must not be operated within 20 cm (8”) of an installed pacemaker!

Intended Patient Population
The Intracs® *em* is intended to be used on adult patients of all genders with appropriate indications (except pregnant women). Restrictions on patients with pacemaker (see “Contraindications”). The use of the Intracs® *em* Navigation System is at the discretion of the respective user on the basis of his training and experience.

Intended Users
The Intracs® *em* is intended for use by medical professionals (e.g. surgeons).
It must be operated under the supervision of qualified and authorized personnel. Users are required to be trained and familiar with the basic principles, application rules, and risks of the device in order to reliably avoid a risk to the patient, user, and others.

Intended Use Environment
The Intracs® *em* is intended for use in operating rooms.
The control unit is intended to be positioned stationary outside of the sterile patient environment, e.g. on a medical cart or table that is suitable in terms of tilting stability and weight of the device.

4.2 Characteristics

Performance Characteristics

The joimax® Intracs® *em* Navigation System was developed to support the surgeon during endoscopic spinal treatments. It enables continuous live tracking of surgical instruments in medical images without the need of repeated radiography.
The system follows the surgical workflow and enables the navigation of instruments of joimax® endoscopic techniques including TESSYS®. It displays the exact position and orientation of joimax® instruments relative to the patient in intraoperative acquired X-ray images.
By using the joimax® Intracs® *em* Navigation System, the radiation exposure of the patient and medical staff is reduced to a minimum, while simultaneously increasing the safety and accuracy of the intervention.

Principles of Operation

To enable the tracking and navigation of instruments during joimax® applications, the Intracs® *em* Navigation System is based on an electromagnetic (EM) tracking system. It enables the localization of sensors in a given EM field.
To display the instrument position in medical image data, the Intracs® *em* Navigation System needs the current position and orientation of the real patient and the navigated instrument during the application.
For this purpose, special sensors are attached to joimax® instruments and the patient. The Intracs® *em* Field Generator generates an electromagnetic field, which is detected by these sensors. Field generator and sensors are the applied parts of the system.
The Intracs® *em* Navigation System calculates the relative position and orientation between the patient and the navigated instruments and displays their location in the medical image data on screen.

Key Components

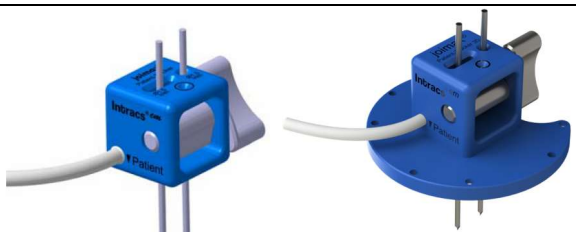
Intracs® *em* Panel PC
A PC with integrated touch screen, running the Intracs® *em* software, enables the control of the system and the display of the medical image data and the relative instrument position.

Intracs® *em* Control Unit
The control unit hosts the main hardware for the navigation system including system control unit (SCU) and sensor interface unit (SIU).
The SIU amplifies and digitizes the electrical signals from the sensors and enables an increased distance between the SCU and sensors while minimizing the potential for data noise.
The SCU collects information from the SIU, calculates the position and orientation of each sensor and interfaces with the Panel PC.

Intracs® em Field Generator
The field generator emits a low-intensity, varying electromagnetic field and establishes the position of the tracking volume.

Intracs® em Mounting Arms for Field Generator and Patient Mappers
The mounting arms are used as holding element for the Field Generator or the Patient Mappers.

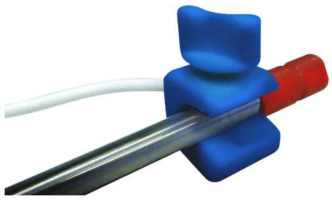
Intracs® em Patient Mapper
The patient mappers are radio translucent housings with integrated radiographic marker spheres. They are inserted into the beam path while acquiring the X-ray images. The Intracs® em Navigation System enables an automatic registration of the X-ray images of the area of intervention within the tracking volume.



2D 3D

Intracs® em Patient Tracker
The patient tracker enables the detection of the position of the patient's vertebrae within the tracking volume and serves as a reference point during navigation. The fixation on the spine of the patient is done via common Kirschner-wires.

Intracs® em Patient Tracker 3D
The **Intracs® em Patient Tracker 3D** for 3D navigation eliminates the need for patient mappers, as it already has the radiographic markers integrated into its plate.



Intracs® em Sensor Clip
The sensor clip is a clamp with a fixation screw, which can be attached to compatible joimax® instruments and enables the detection of the position within the tracking field.

Intracs® em Sensor Wires
The sensor wires consist of two sensors along a wire and a LuerLock connector. They enable the detection of the position of compatible joimax® instruments within the tracking field.

4.3 Clinical Benefits

The application of minimal invasive surgical methods is favorable compared to open surgery in terms of the following clinical benefits: help gain easy access to the pathological site thus reducing the surgical duration, smaller incision/less trauma, preservation of stabilizing structures, less scarring, less pain, faster recovery time/reduced hospitalization time and improved quality of life.

Endoscopic spinal surgery clearly profits from the Intracs® *em* Navigation System in terms of the following clinical benefits:

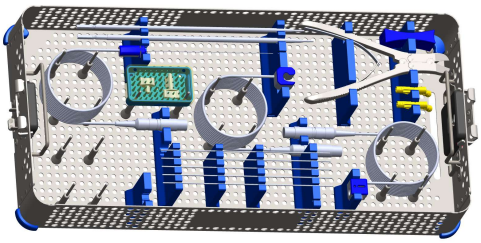
- Reduction of the relatively high X-ray radiation exposure, which is necessary for imaging during minimal invasive surgery
- Precise instrument tracking for safer and more efficient use of surgical instruments
- Shortened learning curve due to easy and user-friendly handling
- Reduced access time, which decreases the total operation time

5 Scope of Delivery

Warning:
After delivery of the joimax® Intracs® *em* Navigation System, the packaging must be checked for external damage. If any components are damaged or missing, please contact joimax® customer service.

Item number	Description		
JINT01S	joimax® Intracs® *em* Navigation System **List of components:**		
	Item number	**Item description**	**Quantity**
	JINTCU1115	joimax® Intracs® *em* Control Unit (incl. connection cable)	1
	JINTPC1105	joimax® Intracs® *em* Panel PC	1
	JINTFG1125	joimax® Intracs® *em* Field Generator	1
	JINTPM2245-AP	joimax® Intracs® *em* Patient Mapper AP (incl. connection cable)	1
	JINTPM2245-LAT	joimax® Intracs® *em* Patient Mapper LAT (incl. connection cable)	1
	JMUSBS10	joimax® USB Flash Drive 16GB	1
	JINTMAP1136	joimax® Intracs® *em* Mounting Arm for Patient Mapper	2
	JINTMA1135	joimax® Intracs® *em* Mounting Arm for Field Generator	1
	JINTAC	joimax® Intracs® *em* Accessory Case for Field Generator and Patient Mapper	1
	JDVIHDMI020	DVI-to-HDMI cable	1
	n/a	Instructions for Use	2
	n/a	Quick-Info	1

JINT01S joimax® Intracs® *em* Navigation System listed above comprises the basic components of the system. For full functionality as well as easy handling and reprocessing of accessories, joimax® provides different Navigation Sensor Trays (see chapter 15).



6 Safety and Warning Notes

6.1 General Safety and Warning Notes

Warning:
This device must be used by trained professionals only!

Warning:
Never touch the patient and any signal input or output connectors on the device at the same time!

Warning:
Installation of the device on a medical trolley with multiple-socket outlet leads to the establishment of a ME system and can lead to a reduced level of safety. The requirements regarding ME systems of IEC 60601-1 must always be observed!

Warning:
The device is not intended for use in explosive areas (e.g. in the presence of anaesthetic gas)!

Warning:
Keep these instructions for use in a conspicuous place near the device!

Warning:
Read this manual carefully before first use. Protect yourself, patients, and third parties from damage by defective devices or improper operation!

Warning:
Mechanical stress, such as from falling, can damage or destroy the device!

Warning:
Never use the device with the housing open.

Warning:
Always make sure blood circulation is not impaired when positioning and sedating the patient.

6.2 Additional Notes regarding Electrosurgical Equipment

Warning:
If the device is used stacked in combination with electrosurgical devices, always position the device above the electrosurgical unit. Ensure that cables of active electrosurgical accessories are not positioned close to the control unit or sensor cables.

6.3 Additional Notes regarding MRI (Magnetic Resonance Imaging) and CT (Computer Tomography)

Warning:
Do not use the Intracs® em Navigation System during MRI or CT scans.
Due to energetic interactions of magnetic fields and X-rays with the material of the sensors, the electrical components of the Intracs® em Navigation System may be damaged. Unforeseeable side effects and visual disturbances may occur.

6.4 Special Safety and Warning Notes related to EM-Field Interferences

Warning:
Due to its functional principle, the accuracy of the Intracs® em Navigation System can be affected by ferrous and conductive metals and by other electromagnetic field sources within the EM tracking field or the operating environment.

Warning:
Ensure to adhere to the following precautions regarding setup and compatibility. Non-observance may lead to unrecognized deterioration of the navigational accuracy of the system and potential patient harm!

No relevant electromagnetic influence was observed with devices based on titanium, CoCrMo and UHMWPE. Due to production-related fluctuations in the material properties, however, no general compatibility for these materials can be guaranteed. Compatibility with existing 3rd party devices in close proximity of the use environment of the Intracs® em Navigation System or 3rd party implants in the patient must individually be checked on a case-by-case basis.

To avoid interferences and to reach highest accuracy and safety, the following special precautions and environmental considerations must be adhered to when setting up and using the Intracs® em Navigation System:

- *No other EM field generator must be placed within 10m (33 ft) of the Intracs® em Field Generator*
- *The Intracs® em Field Generator must not be placed within 1m (40”) of the control unit!*
- *The field generator must not be placed close to objects made from certain metal (e.g. walls, floor, OR table frame, other equipment).*
- *The field generator cable must not be placed within the tracking field.*
- *The field generator cable must not be coiled.*
- *The sensor cables must not be too close to the field generator cable (min. distance 5 cm/2”).*
- *The connection cable between control unit and panel PC must not be in close proximity of any other cable.*
- *The system must not be used during defibrillation or following defibrillation.*
- *No mobile communication devices (e.g. mobile phones) must be placed within the tracking field.*

During navigation, activation of other devices within the tracking field may interfere with the Intracs® em Navigation System. The following joimax® electrical equipment can cause temporary loss of tracking:

- *joimax® Shrill system*
- *joimax® RF surgical equipment*

6.5 Special Safety and Warning Notes related to Compatibility with other Medical Devices

Warning:
The Intracs® em Navigation System must not be used with other medical devices than those explicitly declared compatible by joimax® GmbH in this chapter!
Use of instruments other than those specified or provided by joimax® GmbH may result in improper operation and harm to the patient.

6.5.1 Compatible Sensors

The following sensors can be used with the Intracs® em Navigation System:

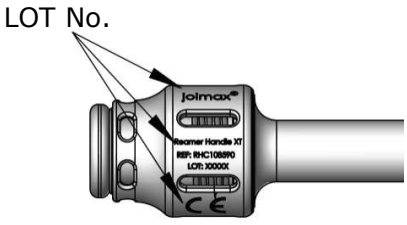
Item number	Item description
JINTPM2245-AP	joimax® Intracs® em Patient Mapper - AP
JINTPM2245-LAT	joimax® Intracs® em Patient Mapper - LAT
JINTPT2235	joimax® Intracs® em Patient Tracker
JINTPT3D	joimax® Intracs® em Patient Tracker 3D
JINTSC2205	joimax® Intracs® em Sensor Clip
JINTSW2215	joimax® Intracs® em Sensor Wire 150
JINTSW2218	joimax® Intracs® em Sensor Wire 180
JINTSW2223	joimax® Intracs® em Sensor Wire 230

6.5.2 Incompatible joimax® Devices

The devices listed in this chapter must not be used in combination with the Intracs® em Navigation System, as they significantly affect the navigational accuracy of the System!

Warning:
RHC108590 is only permitted for use with the Intracs® em Navigation System with a production date later than 2017-10-05 (lot number > 117680).

Products produced before 2017-10-05 (lot number < 117680) must not be used, as their materials disturb the EM Tracking Field.



Item number	Item description
TRPH25100	Palm Handle
RHC108590	TESSYS® Reamer Handle XT, cannulated, production date before 2017-10-05, LOT < 117680
GRF182500	TESSYS® Guiding Rod Forceps
BFS235081	Biopsy Forceps, Spoon

6.5.3 Compatible joimax® Devices

The following joimax® medical devices have been verified to be compatible for navigation with the Intracs® *em* Navigation System only and can be used within the EM Tracking Field:

Item number	Description
Intracs® Instrument Set	
GRC275210N	Guiding Rod Navi, double-cannulated, yellow
GRC276310N	Guiding Rod Navi, double-cannulated, red
JINTYA35	Y-Adapter
JKW1515	K-Wire
JINTWC	Wire Cutter
JINTDG182860	joimax® Intracs® em Drill Guide
TESSYS® Instrument Set	
FS6342181C/O	Foraminoscope
FX6342208C/O	Foraminoscope XT
JMSN18G	18G Needle 150 mm
JMSN18G180	18G Needle 180 mm
JMSN18G23	18G Needle 230 mm
CRF215565	TESSYS® Crown Reamer, yellow, fine
CRF216575	TESSYS® Crown Reamer, red, fine
GRB251025	TESSYS® Guiding Rod, blunt, green
GRB251540	TESSYS® Guiding Rod, blunt, yellow
GRB252050	TESSYS® Guiding Rod, blunt, red
GRC241025	TESSYS® Guiding Rod, conical, green
GRC241540	TESSYS® Guiding Rod, conical, yellow
GRC242050	TESSYS® Guiding Rod, conical, red
GRT241025S	TESSYS® Guiding Rod, curved, green
GTC202838	TESSYS® Guiding Tube, conical, green
GTC194353	TESSYS® Guiding Tube, conical, yellow
GTC185363	TESSYS® Guiding Tube, conical, red
WTS176575	Working Tube with Handle, standard Lip
GRD226315	Guiding Rod, conical with center and excenter bore
JAF180023	Tweezers
RPE280380	Reamer Push-Ejector, green
RPE280500	Reamer Push-Ejector, yellow
RPE280600	Reamer Push-Ejector, red
TEFH45025	TESSYS® Endo-Flexprobe Handle
TEFP32020	Endo-Flexprobe, standard
TNH322533	NiTi Nerve Hook, superelastic
TSR25010	TESSYS® Steel Ruler
TMH200170B	Metal Hammer
RHC108590	TESSYS® Reamer Handle XT, cannulated, production date after 2017-10-05, LOT > 117680
THF322041	Biopsy Forceps, Spoon, angled
THF323541	Biopsy Forceps, Spoon
THG323555	Grasper Forceps, Spoon

Item number	Description
TFG322522U	Semi-Flexible Grasper Forceps, curved, up-biting
BFS323061	Biopsy Forceps, Blakesley
THF322541	Biopsy Forceps, Spoon
JFST061427	Stopper
JFST061434	Stopper
EKS32351540	Endo-Kerrsion-Shaft
EKS32351590	Endo-Kerrison-Shaft
EKH550000	Endo-Kerrison Pistol Handle
WTS177503	Working Tube with Handle, oblique 45°
SWTDR6312	Scope Working Tube Distance Ring
TCC150700	Closing Cap for joimax® Endoscopes
JMSDL001	Silicone Sealing Cap for Luer-Lock, blue
Percusys® System	
JMPS0650PS	Percusys® Pedicle Screw polyaxial
JMPS0045RL	Percusys® Rod Ti-Alloy
JMPS0300RS	Percusys® Rod Ti-Alloy
EndoLIF® System	
ELON643514	EndoLIF® On-Cage 14
Camsource® LED System	
CSFHD01CC	Camera Head Combo for Camsource® LED
CSFHD01CO	Camera Head Ocular for Camsource® LED
Camsource® HD Twister System	
CSCHDC80P	Camera Head C-Camsource® HD Twister (PAL)
Shrill® System	
JSHRI02CU	Shrill Control Unit
JSHRI02SHL	Shrill® Shaver Handpiece large
JSHRI02SHS	Shrill® Shaver Handpiece small
JSHPP8000	Shaver Hand Piece Plus
JSBDS3522	Deflector Shaft
Endovapor® System	
JMPH352504	Legato® Monopolar Hand Piece
JMPP27025*	Legato® Monopolar Probe
JEVNC0001	Neutral Electrode Cable
816/141	Neutral Electrode
JVH32030	Vaporflex® Hand Piece Set
JVP32024	Vaporflex® Probe
VBFRH82	Vaporflex® Ring handle for bipolar forceps
VBF2730R	Vaporflex® Ring handle shaft for bipolar forceps
VBF2730G	Vaporflex® Bipolar Grasping forceps fenestrated

6.5.4 Navigable joimax® Instruments

Warning:
Keep navigable joimax® surgical instruments away from strong magnetic sources to avoid magnetization and, therefore, electromagnetic signal interferences and registration failure.

The following combinations of sensors and joimax® surgical instruments are verified for best accuracy. Non-observance will result in an unsuccessful instrument registration and discontinuation of navigation.

To reach the highest accuracy, it is recommended to always choose the longest compatible Intracs® em Sensor Wire from the list below.

The following joimax® surgical instruments can be navigated via the Intracs® em System:

Item number	Item description
With JINTSW2215 - joimax® Intracs® em Sensor Wire 150	
JMSN18G	joimax® Needle 18G, L 150 mm
JINTJT123010	J-Needle Navi WL 120, trocar, 11G
FS6342181C	TESSYS® HD Foraminoscope, Combo
FS6342181O	TESSYS® HD Foraminoscope, Ocular
FS6342181C-4K	TESSYS® 4K Foraminoscope, Combo
FS6342181O-4K	TESSYS® 4K Foraminoscope, Ocular
FS5831120C	TESSYS® Thorax Foraminoscope, Combo
FS5831120O	TESSYS® Thorax Foraminoscope, Ocular
LS6342125C	iLESSYS® FHD Laminoscope / MultiZYTE®, Combo
LS6342125O	iLESSYS® FHD Laminoscope / MultiZYTE®, Ocular
LS6342125C-4K	iLESSYS® 4K Laminoscope / MultiZYTE® 4K, Combo
LS6342125O-4K	iLESSYS® 4K Laminoscope / MultiZYTE® 4K, Ocular
LS7347150C	iLESSYS® Pro Laminoscope, Combo
LS7347150O	iLESSYS® Pro Laminoscope, Ocular
With JINTSW2218 - joimax® Intracs® em Sensor Wire 180	
JMSN18XG	joimax® Needle 18G, L 180 mm
FS6342181C	TESSYS® HD Foraminoscope, Combo
FS6342181O	TESSYS® HD Foraminoscope, Ocular
FS6342181C-4K	TESSYS® 4K Foraminoscope, Combo
FS6342181O-4K	TESSYS® 4K Foraminoscope, Ocular
With JINTSW2223 - joimax® Intracs® em Sensor Wire 230	
JMSN18G23	joimax® Needle 18G, L 230 mm
JINTJT203010	J-Needle Navi WL 200, trocar, 11G
FX6342208C	TESSYS® HD Foraminoscope XT, Combo
FX6342208O	TESSYS® HD Foraminoscope XT, Ocular
FX6342208C-4K	TESSYS® 4K Foraminoscope XT, Combo
FX6342208O-4K	TESSYS® 4K Foraminoscope XT, Ocular
GRC275210N	Guiding Rod Navi, double-cannulated, yellow
GRC276310N	Guiding Rod Navi, double-cannulated, red

With JINTSC2205 - joimax® Intracs® em Sensor Clip	
CRF215565	TESSYS® Crown Reamer, yellow, fine
CRC215565	TESSYS® Crown Reamer, yellow, coarse
CRF216575	TESSYS® Crown Reamer, red, fine
CRC216575	TESSYS® Crown Reamer, red, coarse

6.6 IT Security Requirements

Warning:
Good physical security must be provided to prevent unauthorized physical access to the device.

Warning:
This device must only be used by trained and authorized professionals.

Warning:
Service activities must only be carried out by authorized service personnel.

Cybersecurity considerations were made in accordance with the nature of the device, including the device type and the use environment (operating room) during its lifetime.

The Intracs® *em* software is embedded into the panel PC and the system does not provide any network functionality.
Therefore, no requirements concerning hardware and IT network characteristics are necessary to run the software as intended.

The healthcare provider is responsible to provide good physical security to prevent unauthorized physical access to the system. The following common best practice security controls ("security hygiene") in the operating environment are recommended to be followed:

- Ensure regulated and authenticated physical access via suitable technical measures (e.g. badges).
- Define roles and access rights, including those for physical access to medical devices
- Provide security awareness training.
- Ensure that prescribed maintenance is done as required, including installation of security patches/updates.

Contact the joimax® technical support for further information provided on device cybersecurity.

Cybersecurity Vulnerability Reporting
If you detect a cybersecurity weakness or vulnerability of the device or if a cybersecurity incident takes place involving the device, contact joimax® technical support. Depending on the actual event, joimax® technical support will advise which steps to take.

Security Patches/Updates
Security patches/updates are provided by joimax® and may only be installed by authorized personnel. Intracs® *em* does not allow additional software for malware detection or anti-virus.

6.7 Residual Risks and Side-Effects

When using the product, residual risks exist and may lead to the following side effects for patient, user or third parties: complete loss of navigation, electric shock, disturbance of pacemakers / defibrillator and software errors.

7 Installation and Commissioning

Warning:
Examine the device, the accessories, and all electrical connections for function and damage prior to use! Defects in cables, connectors, housings, or loose parts can impair performance and safety and must be rectified immediately!

Warning:
The joimax® Intracs® em Navigation System must be cleaned and disinfected before first use according to the cleaning instructions!

Warning:
This device must be installed and commissioned by authorized personnel only. Improper installation could cause damage to the user, the patient, or others, and might damage the device or other medical equipment.

Warning:
Place the devices in a way that allows easy disconnection from the mains!

Warning:
The ambient temperature must not exceed 30 °C (86 °F) during operation!

Warning:
Place the control unit on a clean, flat surface. Ensure that you keep sufficient space behind the device for efficient airflow. Make sure that a minimum distance of 15 cm (6”) is maintained between the back of the device and other objects. All ventilation openings must not be obstructed.

Warning:
Ensure to take the operation environment considerations stated in chapter 6.4 into account when installing the system to minimize interferences and to achieve the best performance and accuracy.

The Intracs® em System is recommended to be installed in the joimax® endoscopic trolley.

Keep the original packaging for possible shipment of the device.

The system and its accessories must be checked immediately upon receipt for completeness and obvious damage. Damages may be claimed only if the manufacturer is notified immediately (within a 24-hour period).

Standard 75x75 mm/100x100 mm VESA mounts can be used for the Panel PC. Max. screw length for 75x75mm VESA is 12 mm; max. screw length for 100x100 mm VESA is 16 mm.

7.1 Connection of the System

Warning:
To avoid the risk of electric shock, this equipment must always be connected to potential equalization and a power supply with protective earth!

Warning:
Only joimax® accessories (cables, etc.) may be used for connection!

Warning:
Always keep cables out of passage areas in order to reduce the risk of stumbling.

Warning:
Make sure all connectors are free of coarse soiling before insertion.

Warning:
Before connecting and starting the system, all components must be visually inspected for integrity! Damaged parts must be replaced. This must be done by experts.

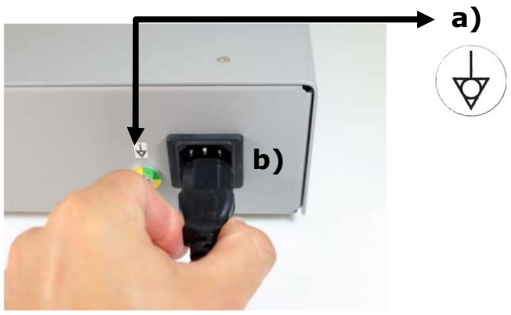
1) Connecting the Devices to a Power Supply Network and Potential Equalization

Warning:
Always connect the devices to a buffered power supply and make sure that the nominal voltage and power values are respected.

Respect the requirements of section 8.6.7 of IEC 60601-1 regarding medical electrical systems.

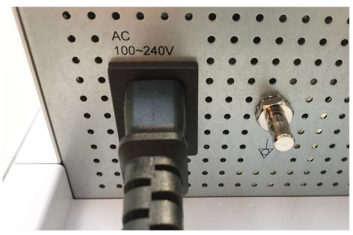
To safely disconnect the Intracs® em Navigation System from the power supply network, perform the steps below in reverse order.

Control Unit



a) Connect the potential equalization plug at the back of the control unit to grounding.
b) Connect the power inlet at the back of the device to a power outlet.

Panel PC



a) Onyx Panel PC: Connect the power supply cable to the power inlet at the back of the device and to a power outlet. Cybernet Panel PC: Connect the power supply unit to the panel PC via DC in connector at the back of the device. Use the original power cord to connect the power supply unit to the mains outlet.

2) Connecting the Control Unit to the Panel PC

Connect the Intracs® *em* Control Unit to an USB socket of the Intracs® *em* Panel PC via appropriate connection cable (Intracs® *em* USB connection cable).

a) **b)**

a) Plug the USB connection cable into the "NAV" connector of the control unit.
b) Plug the other end of the connection cable to an USB port at the back of the panel PC.

3) Connecting an endoscopic camera to the Panel PC

Connect the video output of the endoscopic camera via appropriate video cable to the HDMI-IN connector of the Intracs® *em* Panel PC (3).

The use of the joimax® Camsource® LED endoscopic camera is recommended.

Adjust the output of the connected video capture device until a satisfactory image quality is displayed on the screen of the Panel PC.

4) Connecting the Field Generator and the Sensors to the Control Unit

Warning:
The cable of the field generator must not be coiled or placed within the generated EM field.

Connect the field generator cable to the single socket marked with ((•)) at the front of the control unit.

Connect the sensors to any of the sockets marked with 1-4 at the front of the control unit.

Make sure that the plug is in the correct position (red dot on plug and socket), and the locking sleeve snaps forward with an audible click and locks after insertion of the plug.

To pull the plug, the locking sleeve must be pulled backward (release the lock).

A status LED above each sensor socket indicates the connection status of the sensor:

Off	No sensor connected/detected
Orange	Sensor connected but not initialized
Green	Sensor connected and initialized

7.2 Functional Tests

After correct wiring, start all connected devices according to their respective instructions for use, then start the Intracs® *em* Navigation System.

Check the screen for any errors given by the system.

7.2.1 Behavior in the Event of Malfunctions

In the event of malfunction of the device or changes in its performance that may affect safety (e.g., deviations from the permissible operating conditions) have the faults corrected immediately.

The Intracs® em Navigation System can be switched off at any time by using the power switch as an emergency stop switch.

Proceed as follows in case of malfunctions:

1. Immediately stop using the navigated instruments.
2. Inspect the Intracs® *em* Navigation System and perform a functional test.
3. Contact the joimax® technical support.
4. Report any serious incident to joimax® GmbH and the competent authority having jurisdiction in your locale, see Chapter 17.

7.3 Intraoperative Setup

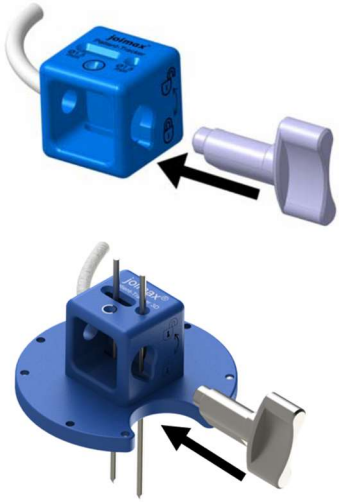
7.3.1 Attaching the Patient Tracker to the Patient

Warning:
Only K-wires provided by joimax® (JKW1515) must be used for fixation of the patient tracker. Use of K-wires other than those specified or provided by joimax® may result in improper operation and harm to the patient.

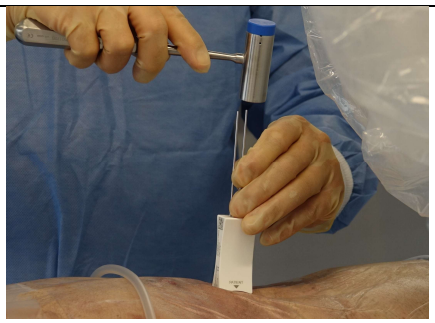
Warning:
The Patient Tracker must be placed as close as possible to the pathology without obstructing the view during X-ray.

Warning:
Make sure to cut the K-wires as close as possible to the upper surface of the patient tracker to avoid protruding edges.

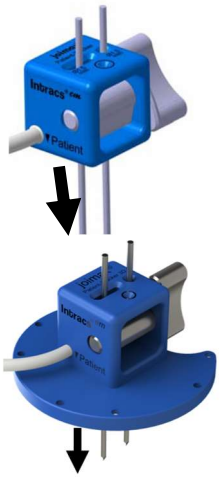
After positioning of the patient, two K-wires for attachment of the patient tracker (2D/3D) must be placed.



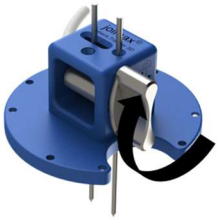
1) Insert the fixation screw into the patient tracker.



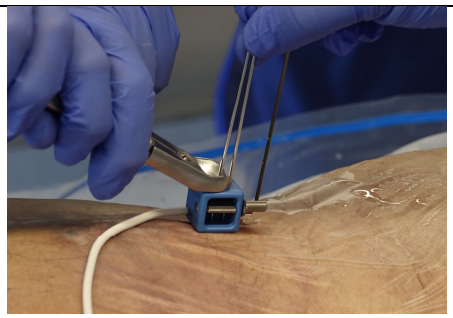
2) Place one K-wire close to the target area and place the second K-wire in optimal distance via the joimax® K-Wire Drill Guide.



3) Slide the patient tracker onto the K-wires and push it down until it contacts the skin surface.



4) Hold the patient tracker and turn the screw clockwise.



5) Cut the protruding K-wires

7.3.2 Placing the Field Generator at the Operating Table

Warning:
Only the mounting arm provided by joimax® (JINTMA1135) must be used for placing the field generator at the operation table. Use of a mounting arm other than the one specified or provided by joimax® may result in improper operation and harm to the patient.

Warning:
Do not drop the field generator! This might lead to decalibration and improper operation.

Warning:
Always hold the field generator firmly when adjusting the mounting arm.
All joints of the mounting arm must be locked before releasing the suspended field generator.

Make sure there are no ferromagnetic metals between the field generator and the working area and within the EM field.

The field generator should be mounted caudal of the site of intervention and be aligned towards the patient tracker. The area of intervention should be located in the center of the EM field.

1) Attach the base of the mounting arm to the rail of the surgical table and fix it.

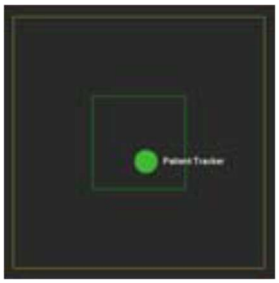
2) Place the column into the column opening of the rail clamping base and fix it.

3) Hold the articulated arm with one hand in the anterior segment and operate the central clamping handle with the other hand.

4) Fixate the field generator on the mounting arm via plastic screw.

5) Check if everything is fixed securely and firmly.

The field generator must be placed in a way that enables collision-free movement of the C-Arm between LAT and AP position.



The Intracs® *em* software assists the user with achieving the optimal alignment of the field generator towards the patient tracker and the patient mappers via displayed instructions and visual guidance. The anatomical area of interest, however, must be considered by the user.

Reposition the field generator until the patient tracker (green dot) is located within the optimal area of the EM field (green square).

7.3.3 Placing the Patient Mappers at the Operating Table (only for 2D Navigation)

Warning:
Only the mounting arms provided by joimax® (JINTMAP1136) must be used for placing the patient mappers at the operation table. Use of a mounting arm other than the one specified or provided by joimax® may result in improper operation and harm to the patient.

Warning:
Do not drop the patient mappers! This might lead to decalibration and improper operation.

Warning:
Always hold the patient mappers firmly when adjusting the mounting arm.
All stressed joints of the mounting arm must be locked before releasing the respective patient mapper.

The joimax® Intracs® *em* Mounting Arm for patient mappers should be placed on the opposite side of the surgeon with the sensors in the patient mappers facing towards the center of the EM field and placed as close as possible to the patient tracker.

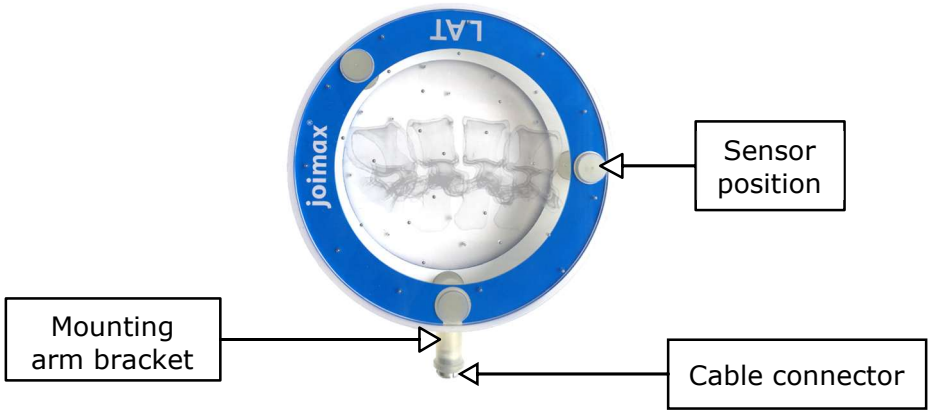
1) Attach the base of the mounting arm to the rail of the surgical table and fix it.

2) Hold the articulated arm with one hand in the anterior segment and operate the central clamping handle with the other hand.

3) Fixate the patient mapper on the mounting arm via clamp screw.

4) Check if everything is fixed securely and firmly.

Do not reposition the patient mappers without releasing the fixation clamps. This might damage the mounting arm bracket of the patient mappers.



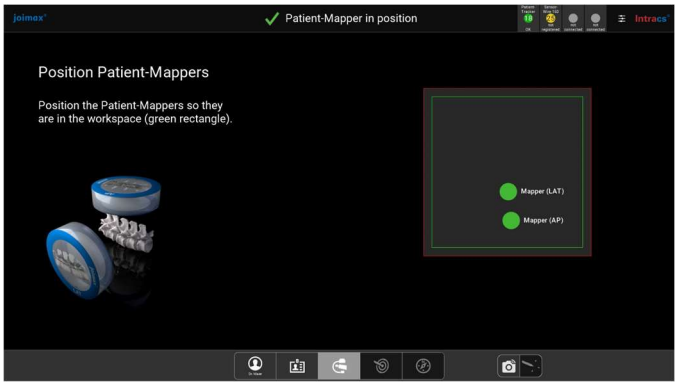
The lateral mapper must be aligned parallel to the sagittal plane within the beam path while acquiring a lateral X-ray and the AP mapper must be aligned parallel to the frontal plane within the beam path while acquiring an anterior-posterior X-ray.

For optimal patient registration results, the patient mappers should be placed on the detector side of the C-arm, in the center of the beam path not covered by the mounting arm or cables and not overlapping.

The patient mappers must be placed in a way that enables collision-free movement of the C-arm between LAT and AP position.

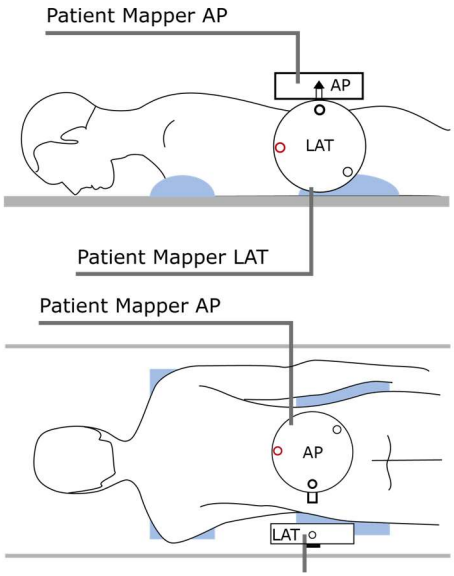
When operating in lateral position, it is recommended to place the AP patient mapper anterior.

The Intracs® *em* software assists the user with achieving the optimal alignment of the field generator towards the patient tracker and the patient mappers via displayed instructions and visual guidance. The anatomical area of interest, however, must be considered by the user.

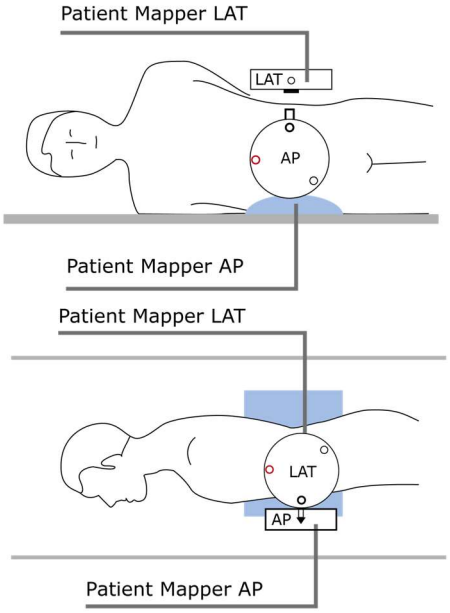


Reposition the patient mappers until both mappers (green dots) are located within the optimal area of the EM field (green square).

Exemplary positioning of the patient mappers on **a patient in prone position**:

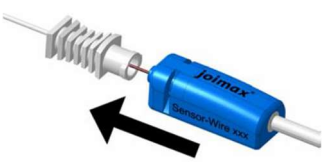


Exemplary positioning of the patient mappers on **a patient in lateral position:**

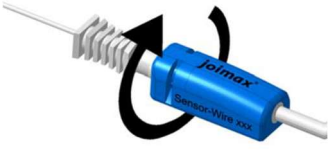


7.3.4 Attaching the Sensor Wire to compatible Instruments

joimax® Needles

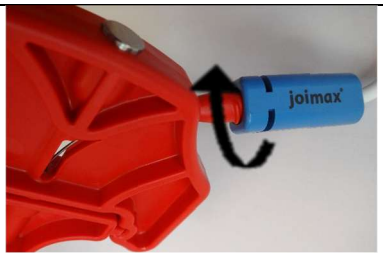


1) Insert the sensor wire through the Luer opening into the needle.



2) Fix the sensor wire by turning it clockwise.

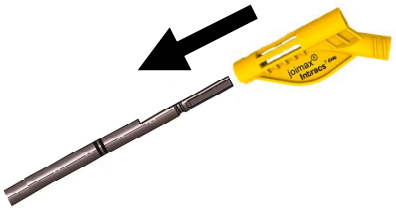
1) Insert the sensor wire through the Luer opening into the needle.



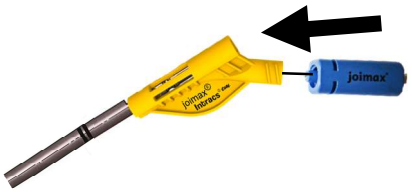
2) Fix the sensor wire by turning it clockwise.

joimax® Guiding Rods

Warning:
Make sure the Y-adapter is attached to the guiding rod before inserting the sensor wire. Never attach the Y-adapter into the guiding rod with an already attached sensor wire! This might damage the sensor wire.



1) Attach the Y-adapter to the guiding rod.



2) Insert the sensor wire through the Luer opening of the Y-adapter into the guiding rod.

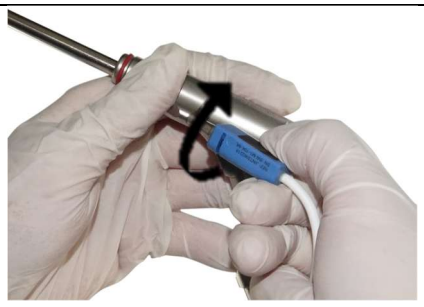
3) Fix the sensor wire by turning it clockwise.

For dismantling, pull the Y-adapter with the connected sensor wire off the guiding rod and then remove the sensor wire by turning it counterclockwise.

joimax® Endoscopes

Warning:
*For endoscope navigation, the sensor wire must always be inserted into the **left** irrigation channel.*

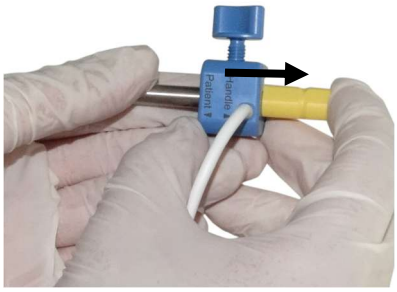
1) Insert the sensor wire through the Luer opening into the left irrigation channel of the endoscope.



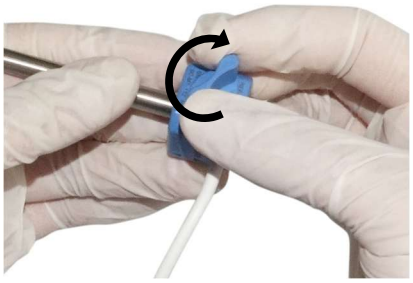
2) Fix the sensor wire by turning it clockwise.

For dismantling, turn the sensor wire counterclockwise and pull it from the instrument.

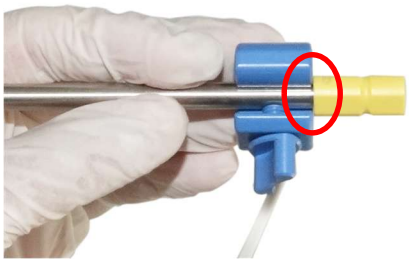
7.3.5 Attaching the Sensor Clip to compatible Instruments



1) Insert the instrument into the sensor clip, make sure to face the correct side towards the patient and push the sensor clip along the instrument towards the handle as far as it will go.



2) Fixate the sensor clip by tightening the fixation screw.



3) For optimal positioning, ensure there is no space between the sensor clip and the reamer shank.

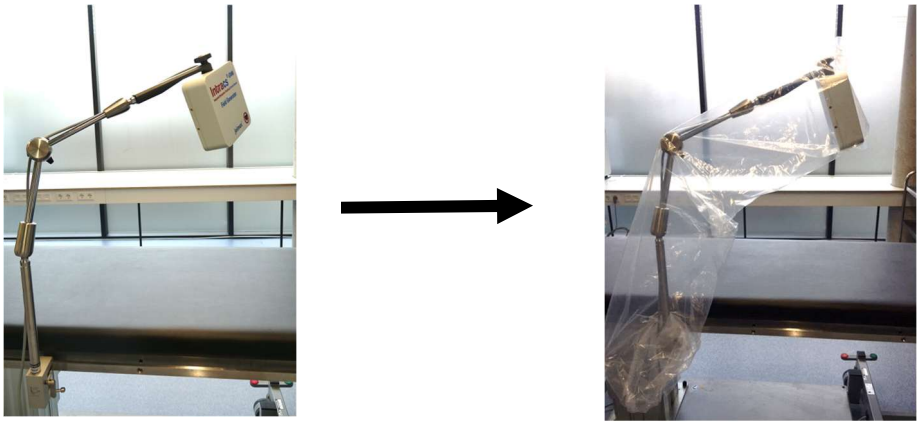
7.4 Sterile Preparation of Field Generator and Patient Mappers

Warning:
The field generator and the patient mappers with their respective mounting arms are not sterilizable and have to be covered by sterile covers during use. joimax® recommends use of FDA-cleared covers.

The joimax® sterile covers for Intracs® em Field Generator and Patient Mappers are sterilized using ethylene oxide and delivered in sterile packaging.

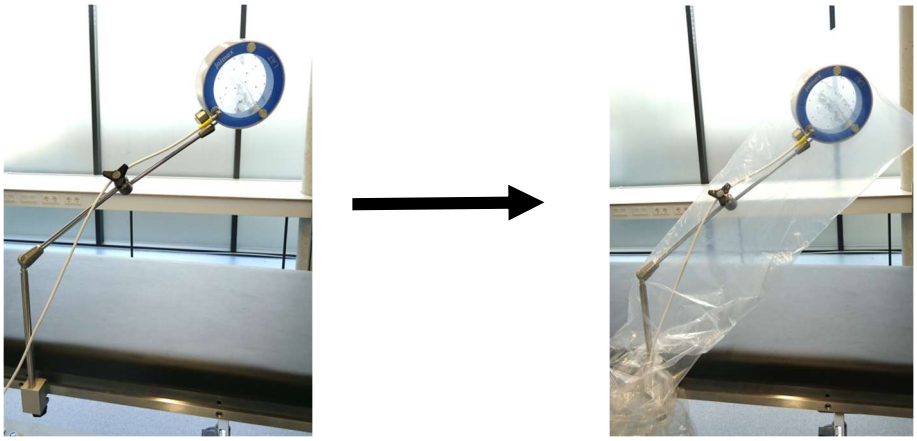
Field Generator and Holding Arm

1) The non-sterile nurse opens the sterile packaging of the sterile cover, and the sterile nurse takes the sterile cover.
2) The sterile nurse unfolds the sterile cover and puts it on the field generator.
3) The sterile nurse then pulls the telescopically folded cover over the mounting arm towards the bed rail.
4) The cover is fixated with sterile adhesive tape to avoid unintentional release.



Patient Mappers and Holding Arms (only for 2D Navigation)

1) The non-sterile nurse opens the sterile packaging of the sterile cover, and the sterile nurse takes the sterile cover.
2) The sterile nurse unfolds the sterile cover and puts it on the patient mapper.
3) The sterile nurse then pulls the telescopically folded cover over the mounting arm towards the bed rail.
4) The cover is fixated with sterile adhesive tape to avoid unintentional release.

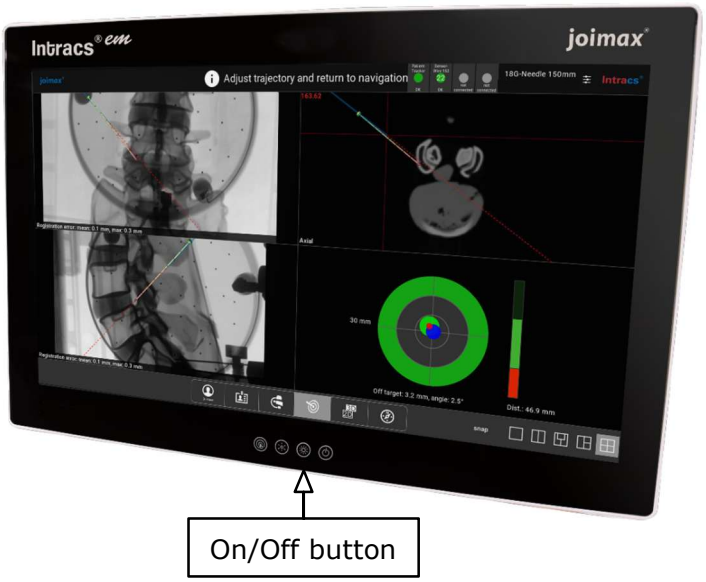


When covering the holding arms, make sure that the clamping handles can still be operated without damaging the covers.

8 Operation

8.1 Control Elements on the Device

The Intracs® *em* Navigation System is operated via the Intracs® *em* Panel PC by simply pressing the finger on the corresponding function field of the user interface displayed on the screen. A so-called double-click is not necessary for operation and causes no effect other than repeated execution of the selected function.



8.2 Starting the Device

1) Make sure that the devices are wired correctly according to the connection instructions above.
2) Switch on any other connected devices or accessories (e.g., endoscopic camera).
3) Push the "On/Off" button at the front panel of the control unit to activate it.
4) Press and hold the On/Off button at the front of the panel PC for about 2 seconds to boot the system.
5) Wait for 20 - 30 seconds until the user login appears on the screen.

8.3 Shutting Down the Device

1) The control unit is shut down by pressing the "On/Off" button at the device front.
2) Press the On/Off button at the front of the panel PC to shut down the panel PC.

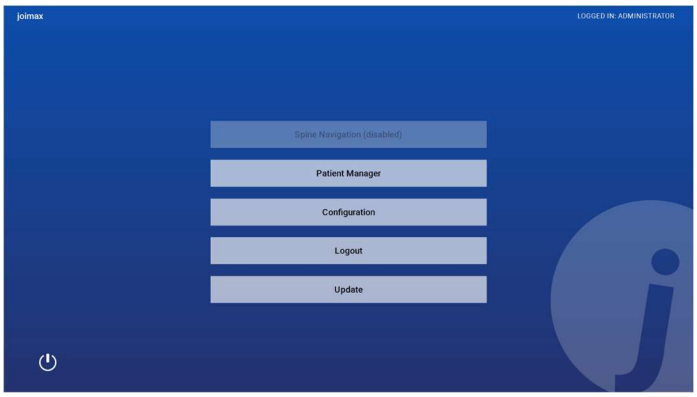
For full disconnection from the power supply, the power supply cable at the back of the control unit and the power supply cable of the panel PC must be disconnected.

8.4 Operation of the Software

8.4.1 Administrator Interface

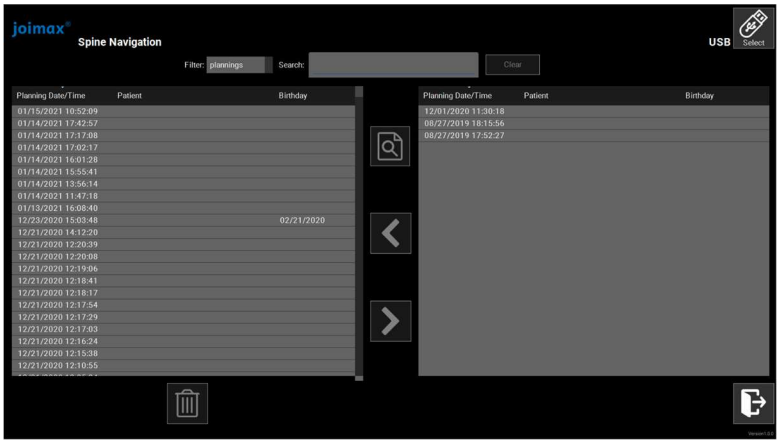
After starting the device, click on "Administrator" and use the password "joimax" to enter the administrator account.

After logging in, the following screen is displayed:



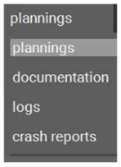
Spine Navigation (disabled)
The Spine Navigation is not available in the administrator account. Create a user account to use this option.

Patient Manager
The Patient Manager allows to transfer data saved on the Intracs® *em* Panel PC to an external storage device (USB or CD/DVD).



The table on the left shows all entries saved on the Panel PC, while the table on the right lists the data saved on the external storage device.
To save a data set to the external storage device, click on one or more specific data sets on the left and move them to the external storage device on the right by using the corresponding arrow button.

Click on one or more data sets and then press  to view the pictures saved in this data set. These pictures can be either X-rays that are connected to the specific patient or screenshots that have been taken during the navigation process.

All data sets can be filtered by using the filter function. 

To delete data sets, click on one or more data sets and then press  .

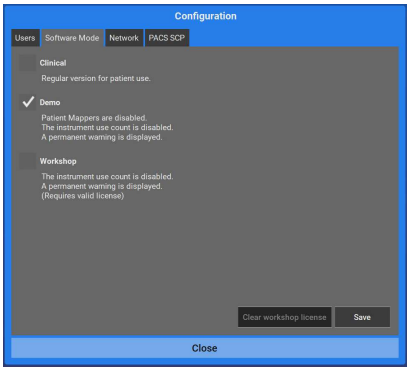
To change the external storage device, press  in the upper right corner of the screen .

Configuration

The User´s tab is used to create or delete users.

To create a user, press "Add user" and type "Username" and "Password".
To delete a user, click on a user and press "Delete user".
Press "Save" before closing the configuration menu.

In the Software Mode tab, the behavior of the software can be altered.

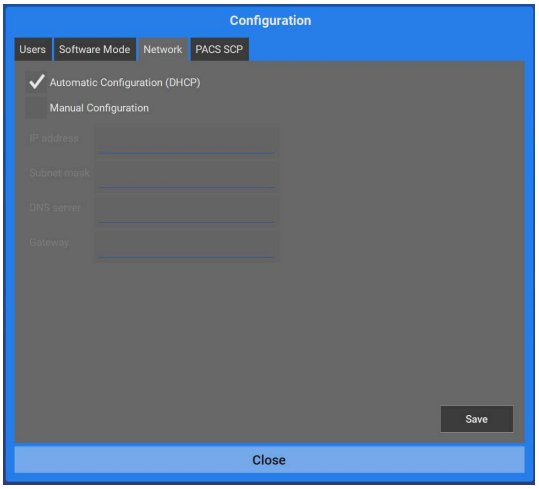


Clinical:
The regular mode for clinical use with full functionality.

Demo:
This mode is used for system demonstrations. Patient Mappers are disabled. The instrument use count is disabled.

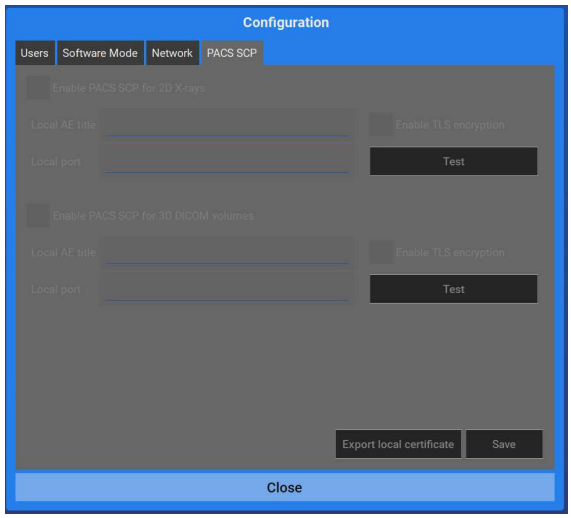
Workshop:
This mode is intended to teach the use of the system. The instrument use count is disabled. To activate this software mode, a valid license key is required. The license key can be requested from joimax® GmbH. Please provide the serial number of the Panel PC. It is displayed by clicking on the Workshop checkbox:

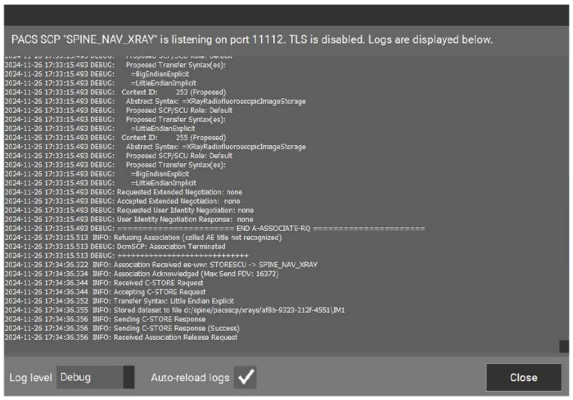
Network Configuration



Switch to the Network tab using the Configuration button to configure the network connection. Fill in the mask according to the information provided by your network administrator and confirm the information with Save.

PACS Configuration





Switch to the Network tab using the Configuration button to configure the PACS connection.
Activate the PACS SCPs for 2D X-ray images and/or 3D volumes as required and enter the AE titles and ports assigned by your network/PACS administrator.

The respective PACS SCP only opens the configured port during the import of 2D or 3D image data. Therefore, either different AE titles and ports can be assigned or both SCPs can use the same AE title and port.

To encrypt the PACS connection using TLS, activate the enable TLS encryption option. Click on export local certificate to export the local certificate to a USB stick if it is required externally.
Click the Test button to start the respective PACS SCP and obtain information about the incoming connections.

For more information, refer to the DICOM Conformance Statements of the Spine Navigation Software and your C-arm.

Logout

Log out of the Administrator account to choose a user account or to shut down the device.

Software Update

To update the software, follow the instructions in chapter 12.2.

8.4.2 User Interface

The user interface is divided into three areas:

- A status bar at the top of the screen with information about the patient on the left and information about the currently registered instrument on the right. In the middle, distinct system notes and warnings are displayed as well as a status indicator for the connected sensors and attached instruments.

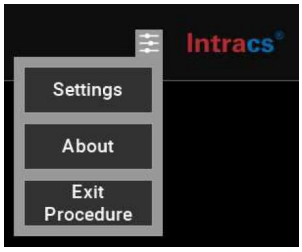
The status indicator shows the use count and the status of the sensors currently connected to the control unit.

grey	No sensor connected
red	Sensor cannot be detected or out of the EM field
yellow	Sensor detected, instrument not registered
green	Sensor detected, instrument registered

Indicator Value:
For the patient tracker, patient mapper, and sensor clip, a graphical representation of the measurement quality is also displayed in the form of a bar chart. If the display is in the yellow or red area, this indicates EM interference. In this case, check the surgical setup.

The indicator value is only an additional guide. Even if good quality is indicated, EM interference may be present that cannot be detected by the system. Always check the accuracy of navigation using anatomical landmarks.

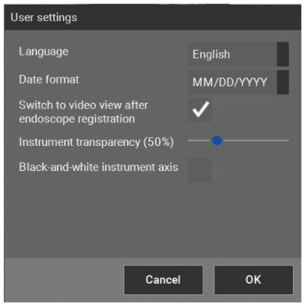
A settings button on the right side allows the user to exit the current procedure, to configure settings and to view information about the software and license:



Settings – Enter system settings.

About – View information about the software.

Exit Procedure – Close the current procedure and restart the software.



Language – Select the user interface language (EN/DE/ES/FR/IT/PT/RU/CN)

Date format – Select the date format used in the user interface.

Upper Checkbox - select automated or manual switching to the endoscope view when navigating an endoscope.

Transparency – Slide to adjust transparency of the instruments.

Lower Checkbox – Enable black/white instrument axis.

- A workflow bar at the bottom of the screen with buttons for switching between the different workflow steps. The current step is highlighted.

  - **1** – User login
  - **2** – Enter patient data
  - **3** – Patient registration
  - **4** – Target Planning
  - **5** – Navigation
  - **6 –** Screenshot Button
  - **7 –** SNAP function

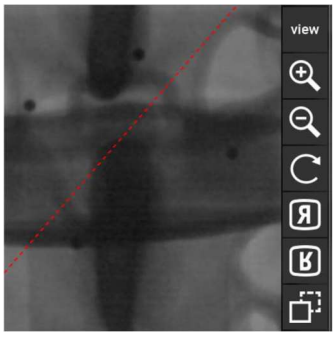
A warning message about demo or workshop mode is displayed on the left side if this mode has been activated. The current status of the PACS connection is displayed next to it.

The workflow bar is automatically hidden during navigation and can be shown by tapping the screen.

Screenshots taken with the Screenshot Button can be transferred to an external medium within the Patient Manager window (administrator account only).

- The center of the screen displays instructions and guidance during all preoperative steps and the medical images and navigated instruments during intraoperative navigation.

  The medical image geometry can be changed by tapping the screen and using the respective function:

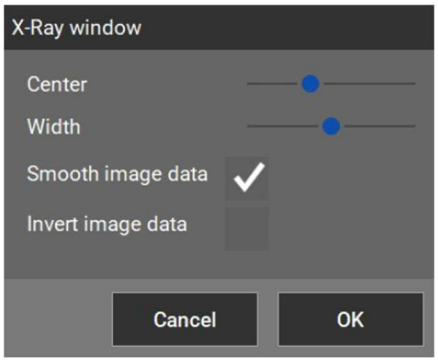


Switch view
Zoom in
Zoom out
Rotate
Mirror
Flip
X-ray window

To change the windowing, press the Windowing button and use the two sliders to set the center and width of the window.

Change the Smooth Image Data option to smooth the image data or display it unfiltered.

The Invert Image Data option can be used to invert the image data in some views.



To change the X-ray window, press the X-ray window button and use the two sliders to set the center and width of the window.

Change the Smooth Image Data option to smooth the image data or display it unfiltered.

The Invert Image Data option can be used to invert the image data in some views.

The smoothed display of radiological image data does not increase its information content. The filter merely leads to a smoothed image.

8.4.3 General Workflow

Preparation

1) User login
2) Select navigation mode (2D or 3D)
3) Enter patient data (only 2D)

Patient Registration

4) Attach the patient tracker to the patient.
5) Position the patient mappers (only 2D) and the field generator at the operating table.
6) Acquire X-ray images of the area of interest and load them into the navigation system.
7) Validate the patient registration.

Guidance View (optional)

8) Set trajectory of approach by defining a target point and an entry point. Use the SNAP function for additional support with setup of entry point (optional).
9) Approach your instrument with support of the Guidance View to reach the target point.

Navigation

10) Register the instruments and perform the intervention as usual but with navigation support.
11) When the intervention is finished, shut down the system or start from 1.

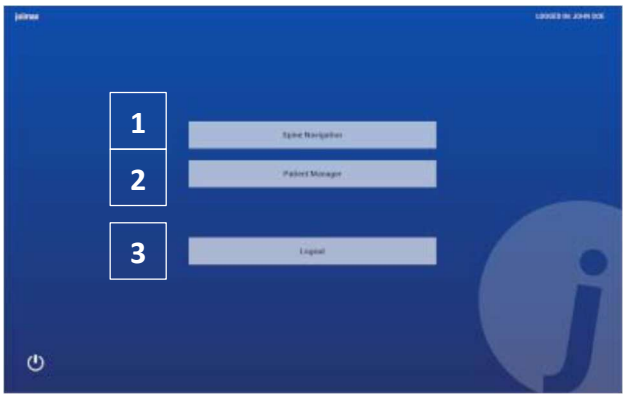
8.4.4 User Login

After starting the Intracs® *em* Navigation System, the login screen is displayed.
To select a user, tap the relevant user icon on the screen and enter the password.

When tapping an input field in the Intracs® em software, a country-specific virtual keyboard is displayed. The language setting of the keyboard can be changed directly on the keyboard. Language settings for the user interface itself can be changed via the settings.
As per factory default, only the administrator user is displayed.

Additional users can be created via the configuration menu available within the administrator user (Password: "joimax").

After user login, a menu with the following items is displayed on the screen:



1 – Spine Navigation, press to load the Intracs® *em* Navigation software and proceed with the workflow.

2 – Patient Manager, press to load the optional patient manager (deactivated here, available in the administrator interface, see chapter 8.4.1)

3 – Logout, press to log out the currently logged in user.

8.4.5 Enter Patient Data

After loading the Intracs® *em* Navigation software, the patient data can manually be entered (only 2D):

This step can be skipped entirely.
It is recommended, however, to always enter the complete patient data.

8.4.6 Patient Registration

After input of patient data, the system components are initialized.
The control unit must be switched on and the field generator and all necessary sensors must be connected. The system instructs the user, which sensors are needed.

Next, the patient tracker must be attached to the patient as close as possible to the area of intervention using two K-wires (see chap. 7.3.1).

Warning:
The patient tracker must not be loosened or moved during the following steps.

Then, the field generator (see chap. 7.3.2) and the patient mappers (see chap. 7.3.3) must be placed at the operating table and aligned correctly.

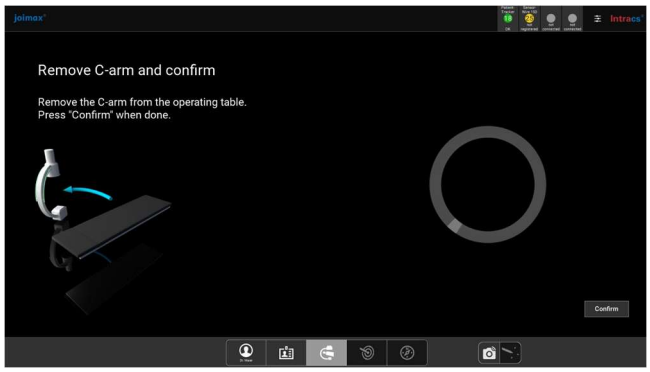
Warning:
During the whole patient registration, neither the patient nor the complete assembly of field generator, patient tracker and patient mappers must be moved or changed. Always ensure you have sufficient space to acquire X-ray images in both the lateral and anterior-posterior direction without touching the patient tracker, the field generator, the patient mappers, or their mounting arms!

When positioning, ensure that both the patient mappers and the relevant anatomical structures can be seen in the X-ray images.
If necessary, reposition the field generator.

The acquisition of the X-ray images is carried out in three steps:

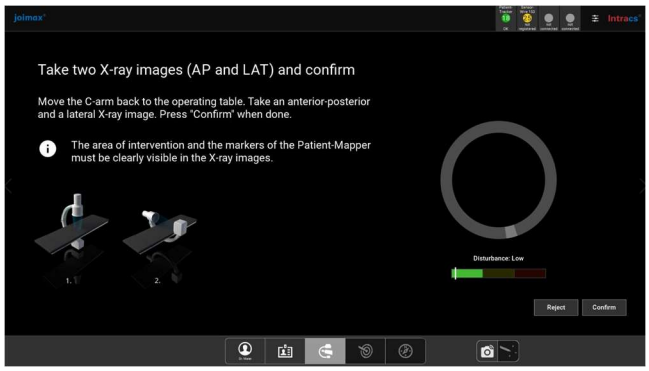
For 2D Navigation:

1) Save the alignment of the Patient Mappers



Remove the C-arm as far as possible from the operating table. Press "Confirm" to save the alignment.

2) Acquire the X-ray images



Move the C-arm back to the operating table. Acquire a lateral and an anterior-posterior X-ray. Continue with "Confirm".

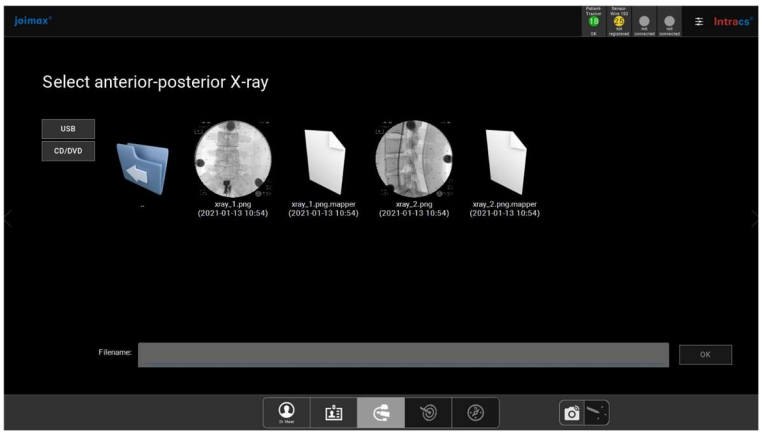
3) Check the alignment of the Patient Mappers.

Remove the C-arm from the operating table again. The disturbance value should stay green. Continue with "Confirm".

If the disturbance value on the right stays in the red area after removing the C-arm from the operating table again, movement was detected during X-ray and the whole patient registration should be repeated by pressing "Reject".

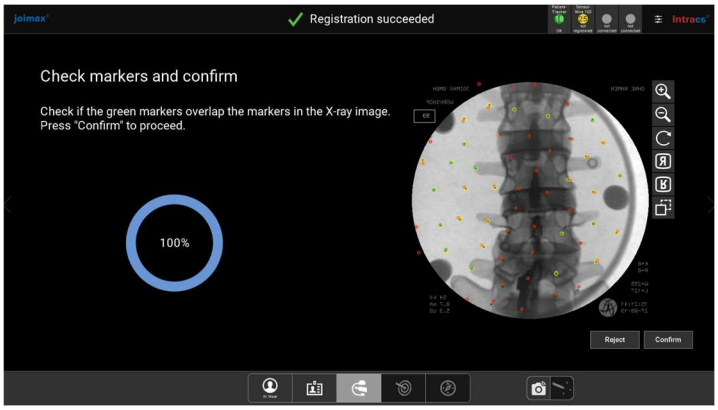
The acquired lateral and anterior-posterior X-ray images are then transferred to the Intracs® *em* Navigation System via CD/DVD (left side Panel PC) or USB (at the lower side of the Onyx/Cybernet Panel PC and additionally at the right side of the Cybernet Panel PC) or via PACS

Follow the instructions on the screen and first select the anterior-posterior and next the lateral X-ray. The registration starts automatically.



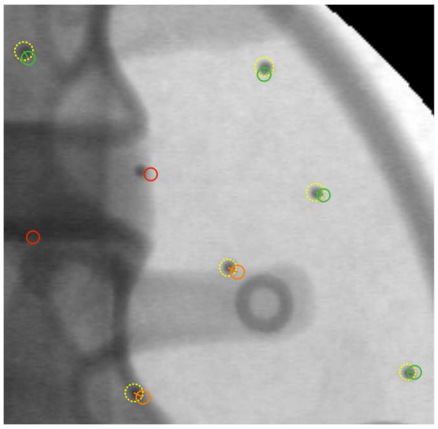
The Intracs® em software supports the following image formats:

- *DICOM 3.0*
- *BMP, GIF, JPG, PNG, TIFF.*



Different colored circles appear in the selected X-ray image on the screen:

yellow	Detected marker balls in the X-ray image.
green	Detected marker ball matches the calculated position.
orange	Detected marker ball matches the calculated position (distance between the markers is greater than expected but still acceptable).
red	Detected marker ball does not match the calculated position; No marker ball detected at the calculated position.



After completing the registration, the system will display whether the registration process was successful. Check the matching of the green and orange circles with the X-ray shadow of the marker balls in the X-ray image on the screen. If the system accepts the registration, continue with "Confirm".

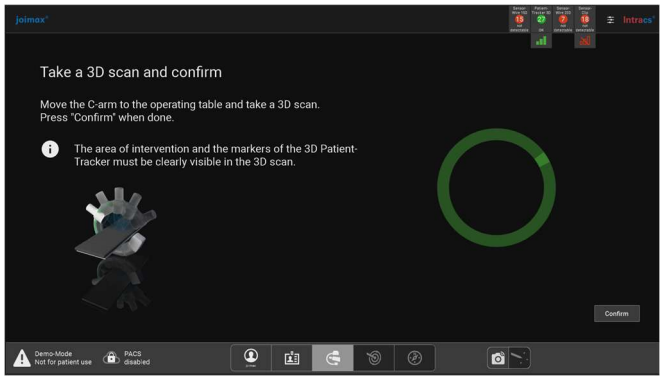
If the registration fails, the following steps may improve the registration result:

- If red circles are shown, manually detect the X-ray shadows of the marker balls by tapping on them to add yellow circles. The image registration restarts automatically.
- Check for yellow circles that do not match with the X-ray shadow of the marker balls and reposition them by tapping on a yellow circle to remove it. Then, tap again on the X-ray shadow of the marker to add a new yellow circle. The image registration restarts automatically.
- Press "X-ray adjustment" to adjust the image settings of the X-ray images. The image registration restarts automatically taking the adjustments of the X-ray images into account.
- Restart the registration and take new X-ray images with a higher contrast. Therefore, press "Reject" to select different X-ray images or the "Registration" button in the workflow bar at the bottom to repeat the acquisition of the X-ray images.

Once registration is complete, the location of the patient tracker is displayed in the images. Check that the blue rear projection of the patient tracker matches its shadow on the X-ray image.

For 3D Navigation:

1) Take a 3D scan



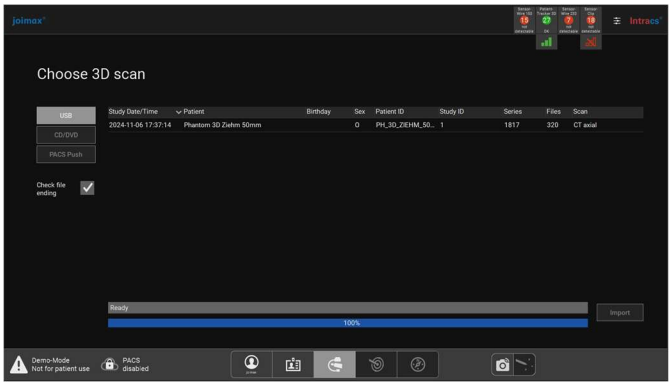
Move the C-arm to the operating table and take a 3D scan.

In the 3D workflow, the titanium markers required for registration are permanently integrated into the Patient Tracker 3D. The Patient Mappers used in the 2D workflow are no longer required. No measurement data needs to be recorded during image acquisition. It is therefore permissible to remove the field generator from the operating table for the duration of the acquisition and to disconnect the field generator and/or the Patient Tracker 3D from the console in order to facilitate the movement and swiveling of the C-arm or O-arm for 3D acquisition.

When taking the 3D scan, make sure that the entire Patient Tracker 3D, including its titanium markers, and the relevant anatomical structures are visible in the 3D images.

The acquired 3D scan is then transferred to the Intracs® *em* Navigation System via CD/DVD (left side Panel PC) or USB (at the lower side of the Onyx/Cybernet Panel PC and additionally at the right side of the Cybernet Panel PC) or via PACS.

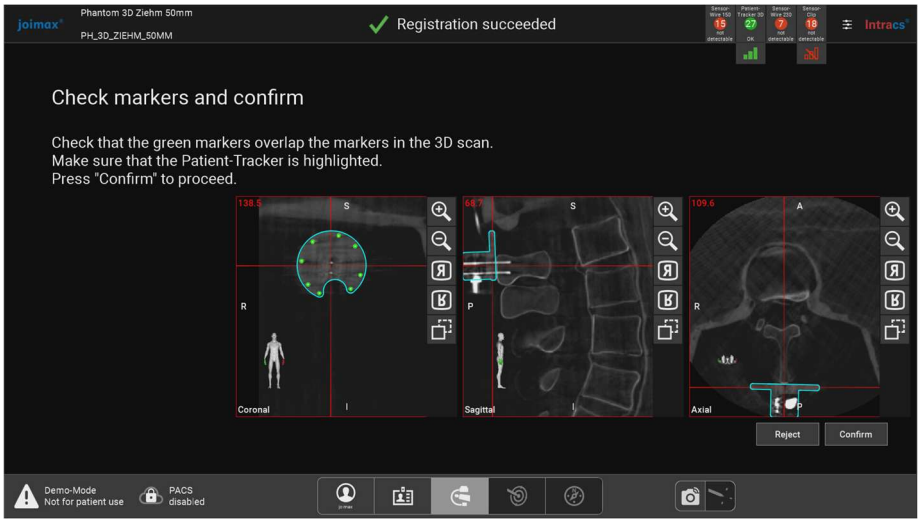
2) Follow the instructions on the screen and choose a 3D scan. The registration starts automatically.



⚠	***Warning:*** *Make sure that you import the most recently captured images. Outdated image data can lead to inaccurate navigation.*

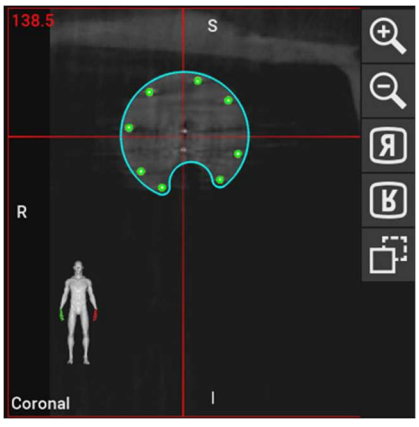
The Intracs® em software supports the following image formats:

- *DICOM 3.0*
- *BMP, GIF, JPG, PNG, TIFF.*



The Patient Tracker is highlighted, and different colored circles appear in the selected 3D scan on the screen:

yellow	Detected marker balls in the X-ray image.
green	Detected marker ball matches the calculated position.
red	Detected marker ball does not match the calculated position; No marker ball detected at the calculated position.



After completing the registration, the system will display whether the registration process was successful. Check the matching of the green circles with the X-ray shadow of the marker balls in the X-ray image on the screen. If the system accepts the registration, continue with "Confirm". If registration is unsuccessful or the Patient Tracker 3D and its markers are not marked correctly, you can manually add or remove markers in the image to correct the registration.

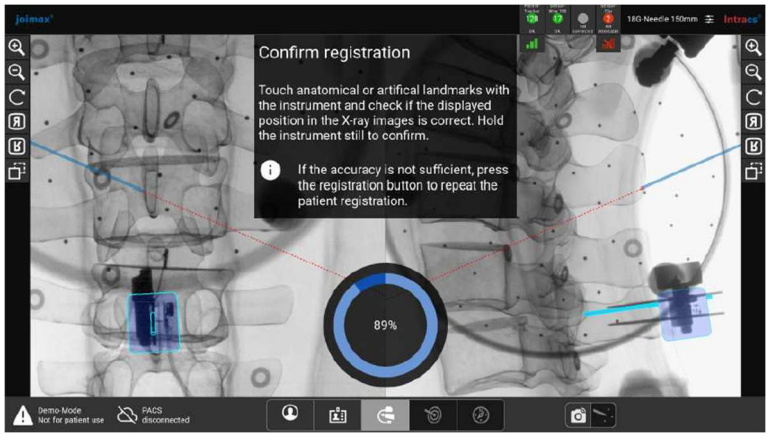
Once registration is complete, the position of the Patient Tracker 3D is displayed in the images. Repeat the registration if the needle displayed on the screen differs from its actual position in the patient or if the blue projection of the patient tracker does not match its X-ray shadow in the sectional images of the 3D volume.

For 2D and 3D Navigation

After successful registration of the X-ray images, the accuracy must be confirmed by the user.
A sensor wire must be connected, and a needle must be registered.
The previously imported X-ray images are displayed with the navigated access needle.
The X-ray images can be moved and zoomed.

Move the tip of the needle close to known anatomical landmarks or artificial markers and compare the displayed position of the needle on the screen with the real position.

If the accuracy of the registration is assessed acceptable, keep the needle steady until the progress circle reaches 100% to confirm.
If the accuracy is assessed as insufficient, press the registration button in the workflow bar to repeat the patient registration.



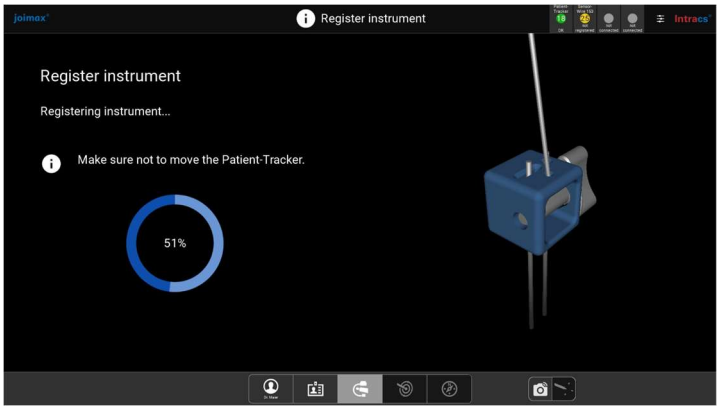
After the accuracy has been assessed and confirmed by the user, the patient registration is finished and the Intracs® *em* Navigation System is ready for navigation.

Only for 2D Navigation: The patient mappers are no longer needed and can be removed from the operating table and disconnected from the control unit.

8.4.7 Registration/Selection of the instrument

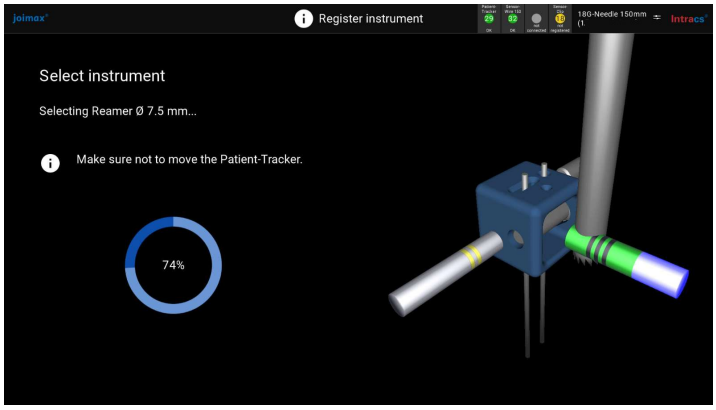
Prior to navigation, the desired instrument must be registered or selected.

To register an instrument navigated via the sensor wire, put the tip of the instrument into the registration notch of the patient tracker. A 3D view of the patient tracker appears on the screen. Keep the instrument steady until the progress circle reaches 100%.

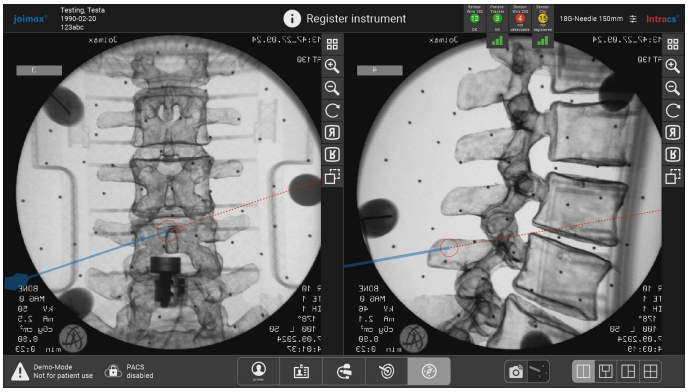


In case of the endoscopes, the instrument must be placed orthogonally in the registration notch for a successful registration.

Instruments navigated via the sensor clip are not registered but selected.
To select an instrument, move the tip of the instrument close to the patient tracker. A 3D view of the patient tracker with color coded selectors on the sides appears on the screen.
Move the instrument to the side of the patient tracker and keep it steady to select the relevant instrument.

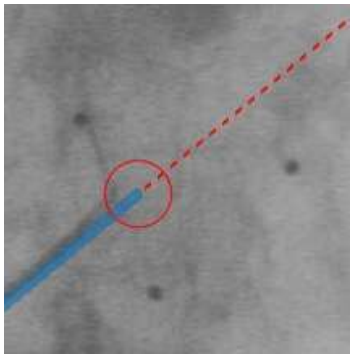


8.4.8 Navigation



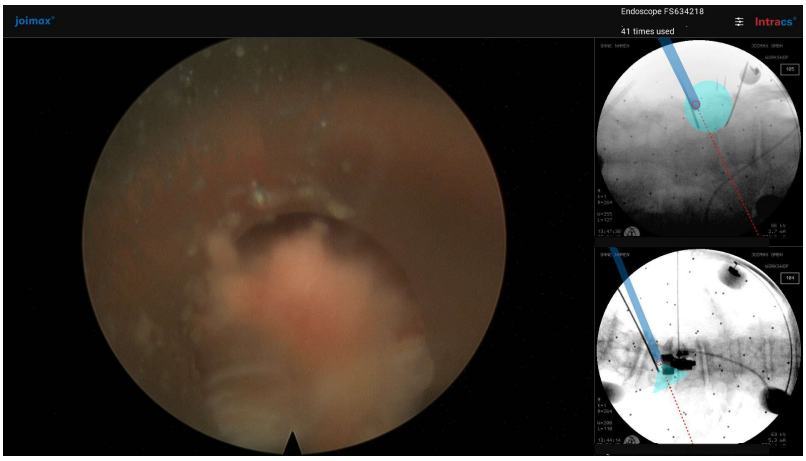
During navigation, the registered instruments are displayed as overlay in the X-rays as soon as they enter the EM field.

The instrument tip is shown as a red circle. The diameter of the red circle represents the registration error. Additionally, the virtual extension of the instrument is displayed as a red dotted trajectory.



The accuracy of the navigation can regularly be checked during the intervention by holding the navigated instrument close to an identifiably anatomical landmark and comparing the displayed instrument position with the real instrument position.

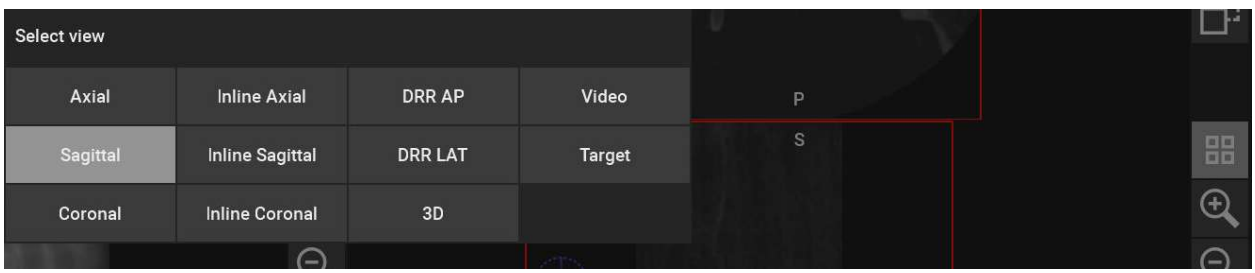
If an endoscope is registered for navigation, the view automatically changes to the endoscope view with the X-rays on the right edge of the screen with the view cone of the endoscope displayed.



With the buttons on the far right of the workflow bar, the view can be manually switched from endoscope view to side-by-side view during navigation.

In the settings the automated or manual switching to the endoscope view when navigating an endoscope can be selected.

View selection:



Depending on the activated workflow, a selection of the following views is available:

X-Ray
Displays an imported 2D X-ray image

Slice (Axial, Sagittal, Coronal)
Displays a layer of the imported 3D scan. The layer is always aligned perpendicular to the edges of the 3D volume.

Inline Slice (Axial, Sagittal, Coronal)
Displays a layer of the imported 3D scan. The layer is aligned with the currently navigated instrument or the currently selected trajectory.

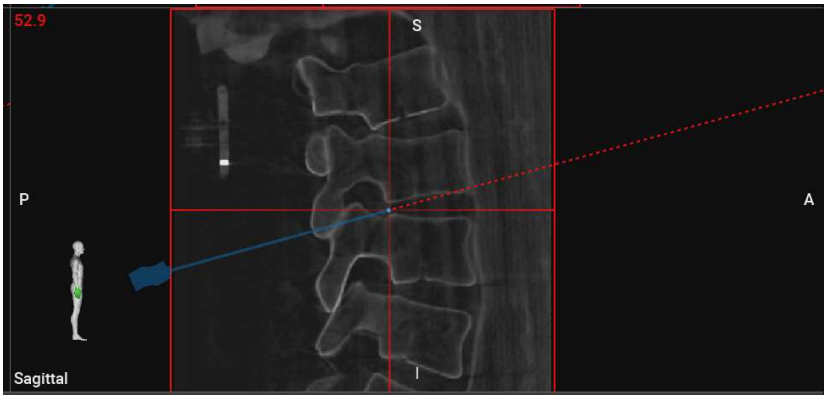
DRR (AP / LAT)
Displays a digitally reconstructed X-ray image calculated from the imported 3D scan.

3D
Displays a 3D representation of the imported 3D scan and the currently navigated instruments.

Video
Displays the video from a connected video source.

Target
Displays the target view of the trajectory.

Directional information for 3D Navigation



In the 3D workflow, directional information and an orientation model are displayed in most views to describe the position of the patient relative to the view.
The abbreviations at the edges of the view represent the following directions:

A: Anterior
P: Posterior
R: Right
L: Left
S: Superior
I: Inferior

The orientation model is always displayed in the lower left corner of the view. The right hand is colored green, the left hand red.

The direction information and the orientation model are based on the information in the DICOM tags of the imported 3D scan. If these were stored incorrectly, the direction information is also incorrect.

8.4.9 Target Planning (optional)

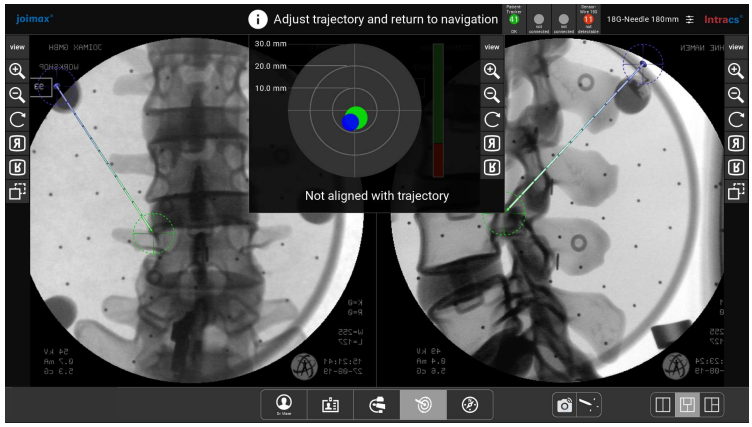
The Target Planning mode is a tool that supports the user to reach a certain target point with the instrument's tip in the patient's body. The target point position is set in the X-rays. An additionally defined entry point marks the position where the support shall start, e.g. the skin surface. The trajectory between the entry point and the target point can then be followed precisely using the guidance view. The Guidance View provides the user with an additional visual support to align the navigated instrument with the planned trajectory and reach the set target point.

1) Click on the Target Planning button in the workflow bar at the bottom of the screen.
2) Touch any point of the AP or LAT X-ray to create a sample trajectory represented by a nail on the screen (to remove it, double tap on the nail).
3) Adjust the trajectory by touching and dragging either the target point (nail tip, green) or the entry point (nail head, blue) to the desired position in both X-rays.
4) Continue the normal workflow to the navigation step.

The trajectory markings represent steps of 1 cm (0,4") to show the distance between entry and target point.

If a target point is set, the Guidance View appears in the upper center of the screen. It indicates the alignment of the instrument axis with the planned trajectory.

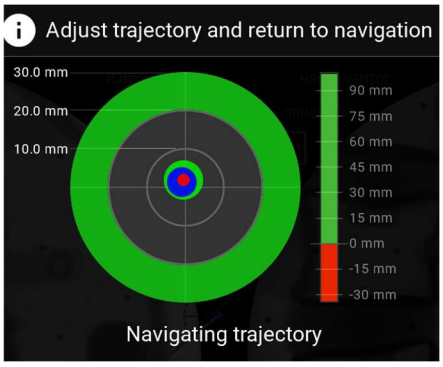
With the buttons on the far right of the workflow bar, the Guidance View can manually be switched on and off.



The blue dot represents the entry point, the green dot represents the target point position in relation to the instrument axis.

For optimal instrument alignment along the planned trajectory, the position and angle of the instrument need to be adjusted until both dots are superimposed in the center of the guidance view.

1) Move the tip of the currently registered instrument to the position of the entry point until the blue circle is placed in the center of the guidance view.
2) Adjust the angle of the instrument so that the green dot moves to the center of the guidance view. As soon as the green dot enters the inner circle of the guidance view, a red dot appears.



3) Move the instrument towards the target point while keeping the green dot in the center of the guidance view as shown above until the target point is reached.

Some positions (e.g., the skin surface) are barely visible on an X-ray and moving the entry point to that position can be challenging. Use the SNAP function to temporarily bind the entry point of the trajectory to the tip of the instrument.

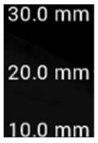
1) Click on the SNAP-icon  *in the bottom right corner of the screen.*
2) The background of the button changes to a light grey, indicating that the entry point position of the trajectory follows the tip of the currently navigated instrument.
3) Move the instrument tip to the desired entry point (e.g., the patient's skin surface).
4) Click the SNAP-icon again. Now the blue circle is exactly positioned in the center of the guidance view.

The outer circle turns green as long as the target point is in the center of the guidance view, indicating that the instrument's axis is aligned directly to the target point.

The exact overlay of the trajectory and the virtual instrument axis can additionally be checked in the X-rays in the background.

Additional assistance information is displayed around the guidance view:

- Visual representation of the remaining distance between the instrument tip and the target point.



- Current zoom level of the guidance view. Every number indicates the lateral distance between the instrument axis and the entry or target point. The zoom level can be adjusted by clicking on  .

9 Processing

9.1 Overview and General Notes

Warning:
The Intracs® em components must be cleaned and disinfected before first use.

Warning:
The Intracs® em Control Unit, the panel PC, the patient mappers, the field generator, and the mounting arms are not suitable for sterilization and must not be sterilized.

Warning:
Before cleaning or disinfection, turn off the device and disconnect it from the power source. Also, disconnect it from all other devices connected to a power source.

Warning:
Check the components and all accessories after processing and prior to each use for damage and for proper operation.

Always respect locally applicable regulations and hygiene procedures of the hospital.

The reprocessing instructions in this user manual describe the cleaning, disinfection, and partial sterilization of the following components of the Intracs® em Navigation System:

- JINTCU1115 – joimax® Intracs® em Control Unit
- JINTPC1105 – joimax® Intracs® em Panel PC
- JINTFG1125 – joimax® Intracs® em Field Generator
- JINTPM2245-AP/LAT – joimax® Intracs® em Patient Mapper AP/LAT
- JINTMAP1136 - joimax® Intracs® em Mounting Arm for Patient Mapper
- JINTMA1135 - joimax® Intracs® em Mounting Arm for Field Generator
- JINTPT2235 – joimax® Intracs® em Patient Tracker
- JINTPT3D – joimax® Intracs® em Patient Tracker 3D
- JINTSC2205 - joimax® Intracs® em Sensor Clip
- JINTSW2215/18/23 - joimax® Intracs® em Sensor Wire 150/180/230

Reprocessing instructions for the following components of the Intracs® em Navigation System can be found in the "User Manual and Reprocessing Instructions for joimax® GmbH Medical Devices":

- JINTYA35 - joimax® Intracs® em Y-Adapter
- JKW1515 – K-wire with thread
- JINTDG182860 - joimax® Intracs® em K-wire Drill Guide
- JINTWC – Wire Cutter
- GRC275210N – Guiding Rod Navi, double-cannulated, yellow
- GRC276310N – Guiding Rod Navi, double-cannulated, red

Information about the suitable reprocessing method of all components can be found in the following table:

Component	Cleaning	Disinfection	Sterilization	Chapter
JINTCU1115 – joimax® Intracs® em Control Unit	X	X	-	9.2
JINTPC1105 – joimax® Intracs® em Panel PC	X	X	-	9.2
JINTFG1125 – joimax® Intracs® em Field Generator	X	X	-	9.2
JINTPM2245-AP/LAT – joimax® Intracs® em Patient Mapper AP/LA	X	X	-	9.2
JINTMAP1136 - joimax® Intracs® em Mounting Arm for Patient Mapper	X	X	-	9.2
JINTMA1135 - joimax® Intracs® em Mounting Arm for Field Generator	X	X	-	9.2
JINTPT2235 – joimax® Intracs® em Patient Tracker	X	X	X	9.3
JINTPT3D – joimax® Intracs® em Patient Tracker 3D	X	X	X	9.3
JINTSC2205 - joimax® Intracs® em Sensor Clip	X	X	X	9.3
JINTSW2215/18/23 - joimax® Intracs® em Sensor Wire 150/180/230	X	X	X	9.3

Detailed instructions for each method can be found in the respective chapter of this user manual.

9.2 Reprocessing of the Control Unit, the Panel PC, the Field Generator and the Patient Mappers with respective mounting arms

Warning:
Ensure no liquid enters the control unit during cleaning and disinfection.

Warning:
Before cleaning or disinfection, disconnect all components from the joimax® Intracs® em Control Unit and disconnect the control unit from its power source.

Warning:
The Intracs® em Field Generator and the patient mappers, as well as their respective holding arms, must be covered by a sterile cover during use (For this, the joimax® sterile covers listed in Chapter 15 are recommended).

Warning:
The surfaces of the patient mappers are sensitive to alcohol. Be sure to use a non-alcoholic detergent or disinfectant suitable for plastic!

Warning:
In case of severe soiling, the front panel of the Control Unit and the Panel PC can be carefully cleaned with a cotton swab soaked in alcohol. Do not use any sharp objects for cleaning!

For effective wipe disinfection of all components, use of Mikrozid® sensitive wipes (Schülke & Mayr) is recommended by joimax® GmbH.

Pay particular attention to the connectors at the front of the control unit and the plugs of the sensors. Make sure to let them dry thoroughly before connecting any components.

The surfaces of the Intracs® *em* Control Unit, the panel PC, the field generator, and the patient mappers can be cleaned and disinfected with a suitable alcohol-free varnish- and plastic-friendly cleaning and disinfection detergent using the following procedure:

1) Switch off the components and disconnect them from the power supply/control unit.
2) Wipe the surface of the components with a clean, soft cloth, moistened with a suitable detergent or disinfectant.
3) Wipe the surface of the components again with a sponge or a soft cloth, moistened with clean water.
4) Dry the surface of the components with a clean and lint-free cloth.

9.3 Reprocessing of the Patient Tracker (3D), the Sensor Wire and the Sensor Clip

Warning:
The Intracs® em Patient Tracker (3D), Sensor Wire and Sensor Clip are not suitable for ultrasonic cleaning.

Warning:
Immediately after use (within a maximum of 2 hours), coarse soiling must be removed from the sensors with running water or a disinfectant solution.

For easy and convenient reprocessing, the joimax® Sensor Trays (JINTST15, JINTST18, JINTSTR) are recommended.

For cleaning and disinfection, an automated procedure should be used if possible. A manual method should be used only in case of unavailability of an automated method due to the significantly lower efficiency and reproducibility.
The pretreatment must be carried out in both cases!

9.3.1 Pre-treatment

Warning:
To remove soiling manually, use a soft brush or a clean, soft cloth designed exclusively for this purpose. Never use a metal brush, steel wool or any sharp objects for cleaning.

***Warning**:*
Do not use abrasive cleaners, waxes, or solvents for cleaning.

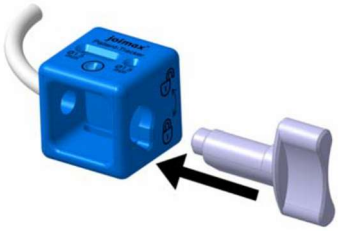
Please note that the disinfectant used in the pre-treatment cannot replace the later disinfection to be performed after cleaning.

The disinfectant should:
- be aldehyde-free, otherwise there is the possibility of fixation of blood contaminants.
- have proven effectiveness (e.g. VAH/DGHM or FDA approval or CE marking).
- be suitable for the disinfection of surgical instruments.
- be compatible with the materials of the sensors.

Moving parts are to be moved back and forth several times during the pre-cleaning.

9.3.2 Assembly / Disassembly of the Patient Tracker and Sensor Clip

Assembly



1) Insert the fixation screw into the screw hole of the **Patient Tracker (3D)** sensor body.

2) Turn the fixation screw clockwise in the sensor body until a clearly noticeable pressure point is overcome.

3) Screw the fixation screw into the threaded hole of the **Sensor Clip** sensor body.

4) Screw the fixation screw clockwise into the sensor body.

Disassembly

For disassembly, apply the assembly instructions above in reverse order.

9.3.3 Cleaning and Disinfection

9.3.3.1 Automated Cleaning and Disinfection

Warning:
The concentrations and exposure times specified by the manufacturer of the cleaning agents and disinfectants must be strictly adhered to.

Warning:
With chemical disinfection, there is a risk of disinfectant residues remaining on the sensors.

For effective automated cleaning and disinfection, use of the cleaner Neodisher MediClean forte (Chemische Fabrik Dr. Weigert) is recommended by joimax® GmbH.

When selecting the disinfector, make sure that:

- the disinfector has proven effectiveness (e.g. DGHM or FDA approval or CE marking according to DIN EN ISO 15883)
- if possible, a tested program for thermal disinfection (A0 value > 3000, i. e. at least 5 min at 90° C/194° F) is used.
- the used program is suitable for plastics/PEEK (see chapter 9.4) and contains sufficient rinsing cycles.
- for rinsing only sterile or low-germ (max 10 germs/ml) and endotoxin-poor (maximum 0.25 endotoxin units/ml) water (e.g. purified water/highly purified water) is used
- the air used for drying is filtered.
- the disinfector is regularly maintained and checked.

When selecting the detergent, make sure that:

- it is suitable for the cleaning of medical products made of metals and plastics/PEEK (see chapter 9.4).
- if thermal disinfection is not used, in addition, a suitable disinfectant with tested effectiveness (e.g. VAH/DGHM or FDA approval or CE marking) is used and that it is compatible with the cleaning agent used.

Procedure:

1) Disassemble the components as far as possible following the instructions in chapter 9.3.2.
2) Place the disassembled components in the disinfector. Make sure that the components do not touch each other. Loosely insert the cables; they must not be kinked or squashed.
3) Start the program.
4) At the end of the program, remove the components from the disinfector.
5) Inspect, dry and pack the sensors immediately after removal in a clean place.

9.3.3.2 Manual Cleaning and Disinfection

Warning:
The concentrations and exposure times specified by the manufacturer of the cleaning agents and disinfectants must be strictly adhered to.

Warning:
Use appropriate cleaning agents and disinfectants.

For effective manual cleaning and disinfection, use of the cleaner Cidezyme® (Johnson & Johnson Medical) and the disinfectant CIDEX® OPA (Johnson & Johnson Medical) is recommended by joimax® GmbH.

Combined cleaning/disinfecting agents should not be used!

When selecting the cleaning agents and disinfectants, make sure that:

- they are suitable for the cleaning or disinfection of medical products made of metals and plastics/PEEK (see chapter 9.4).
- a disinfectant with proven effectiveness (e.g., VAH/DGHM or FDA approval or CE marking) is used and that it is compatible with the used cleaning agent.

Procedure:

1) Disassemble the components as far as possible following the instructions in chapter 9.3.2.
2) Insert the disassembled components into the cleaning bath for the given soaking time specified by the manufacturer so that the components are sufficiently covered (if

necessary, gently brush with a soft brush). Make sure, the components do not touch each other. Loosely insert the cables; they must not be kinked or crushed.

3) Then remove the components from the cleaning bath and rinse them thoroughly with deionized (DI) or reverse osmosis (RO) water at least 3 times.
4) Ensure that the device is thoroughly cleaned and visually clean. Repeat (steps 2. – 4.) if necessary.
5) Check the components for damage.
6) Place the disassembled, cleaned, and controlled components in the disinfectant bath for the given soaking time specified by the manufacturer so that the components are sufficiently covered. Make sure the components do not touch each other. Loosely insert the cables; they must not be kinked or crushed.
7) Then remove the components from the disinfection bath and rinse them thoroughly with deionized (DI) or reverse osmosis (RO) water at least 5 times.
8) Dry the components with filtered compressed air.
9) Inspect, dry and pack the components immediately after removal in a clean place.

9.3.4 Inspection

After cleaning and disinfection, check all components for corrosion, damaged surfaces, chipping or any remaining soiling and cleaning and disinfection agents.

9.3.5 Packing

Warning:
Do not assemble the dismounted sensors before packing!

Put the components in disposable packaging (single or double) and/or sterilization containers that meet the following requirements:

- DIN EN ISO/ANSI AAMI ISO 11607-1; 11607-2.
- suitable for steam sterilization (temperature resistance up to at least 141 °C (286 °F), sufficient vapor permeability).
- adequate protection of the sensors or sterilization packaging against mechanical damage.
- regular maintenance according to the manufacturer's instructions (sterilization container).
- cleared by the FDA (No. K953776, K973827).

9.3.6 Sterilization

Warning:
The Intracs® em sensors must be sterilized before first and every use.

Warning:
Uncleaned components must not be sterilized as the effectiveness of the sterilization is only guaranteed after prior cleaning and disinfection. Make sure the components are clean before sterilization!

Warning:
Other autoclave settings and cycles than specified may have negative effects on the sterilization result and the function of the components.

Warning:
Please note that overloading the sterilizer may reduce the sterilization result. Also, in case of overload there is the possibility of undesirable condensation, which increases the formation of corrosion on components. Observe the manufacturer's instructions for maximum loading of the sterilizer.

It is the responsibility of the user to carry out the recommended sterilization procedures with regard to achieving the desired or required sterilization effect.

Applicable national legal regulations must be observed.

It is not recommended to use other sterilization methods (such as flash sterilization, hot air sterilization, radiation sterilization, formaldehyde, ethylene oxide sterilization, or plasma sterilization).

When selecting the steam sterilizer, make sure that:

- the steam sterilizer has proven effectiveness (according to EN 13060/EN 285 or ANSI AAMI ST79, for USA: FDA clearance).
- the steam sterilizer is validated according to EN ISO 17665 (valid IQ/OQ (commissioning) and product specific performance qualification (PQ)).

The joimax® Intracs® em Patient Tracker, Sensor Wire and Sensor Clip can be sterilized using the following methods:

Out of the United States (not FDA cleared):

Sterilization method	Temperature	Exposure time	Min. drying time
Fractionated Vacuum/ Dynamic-Air-Removal Steam Sterilization	121 °C 250 °F	20 minutes	20 minutes
Fractionated Vacuum/ Dynamic-air-removal Steam Sterilization	132 / 134 °C 270 / 273 °F	3 minutes	20 minutes
Gravity-Displacement Steam Sterilization	132 / 134 °C 270 / 273 °F	60 minutes	20 minutes

In the United States (FDA cleared):

Sterilization method	Temperature	Exposure time	Min. drying time
Dynamic-Air-Removal Steam Sterilization	132 °C 270 °F	4 minutes	20 - 30 minutes

Only the sterilization method and cycle marked as "FDA cleared" above is valid in the United States. Other sterilization methods must be considered valid only out of the United States!

Effectiveness of steam sterilization (fractionated vacuum cycle / dynamic-air-removal cycle and gravity-displacement cycle) was validated by an independent accredited testing laboratory with the use of a hospital common steam sterilizer Getinge 400HC and 500HC (FDA clearance K103504) and FDA cleared sterilization packaging. Typical conditions prevalent at a clinic or physician's practice as well as the above-mentioned procedure were taken into consideration.

9.3.7 Storage

After sterilization, the components must be stored dry and dust-free in the sterilization packaging.

9.4 Reusability

Warning:
When selecting cleaning agents and disinfectants, make sure they do not contain the followings substances:

- *organic, mineral, and oxidizing acids (minimum permissible pH 5.5)*
- *strong alkalis (maximum permissible pH 11, neutral/enzymatic, slightly alkaline, or alkaline cleaner recommended)*
- *Organic solvents (e.g., alcohols, ethers, ketones, gasolines)*
- *Oxidizing agents (e.g., hydrogen peroxide)*
- *halogens (chlorine, iodine, bromine)*
- *aromatic/halogenated hydrocarbons*
- *salts of heavy metals*

Warning:
The lifetime of the sensors is limited because they are subject to natural wear and aging. Inappropriate handling, e.g., overloading, unsuitable cleaning agents, high temperatures, etc. may reduce the lifetime of the equipment.

The lifetime of Intracs® *em* Patient Tracker, Sensor Wire and Sensor Clip is limited to 30 reprocessing cycles. Improper handling, e.g., by overload, unsuitable detergents, high sterilization temperatures etc. may reduce the lifetime of the components.

The system will prompt a warning message if 5 uses of the respective sensor are left, so a new sensor can be ordered in time.

An inspection of the components for integrity must be carried out during the reprocessing process after disinfection and prior to sterilization. If a defect is detected, the component must be replaced immediately and must not be used any further. The use of damaged and/or contaminated components is the responsibility of the user.
Failure to comply will exclude any liability of joimax®.

10 Technical Data

Intracs® *em* Panel PC	
Display	24” Capacitive Multi-Touch LCD Panel 1920 x 1080 pixels
Video & Graphics	Intel HD Graphics
Network	2x Isolated Gigabit LAN
Input/Output	4x USB 3.0 1x AC Input 1x Display port 1.4 (not in use) 1x HDMI-In (Video Capture Card) 1x HDMI-Out, left (not in use) 1x HDMI-Out, right (optional connection to external screen) 2x Ethernet (not in use)
Power Supply	Internal Power Supply Unit Input: 100 – 240 V AC; 50/60 Hz; 4.8-2.1 A
Safety Class	I
Dimensions	595 x 387 x 95 mm (LxWxD)
Weight	11 kg/24.3 lb
Transport and Storage Conditions	Temperature: -20 °C to +60 °C / -4 °F to 140 °F Relative humidity: 10 % to 90 %, non-condensing Air pressure: 70 kPa to 106 kPa Keep the device dry and protected from sunlight.
Operating Conditions	Temperature: 0 °C to +35 °C / +32 °F to 95 °F Relative humidity: 10 % to 90 % non-condensing Air pressure: 70 kPa to 106 kPa

Intracs® *em* Control Unit	
Input/Output	1x Connector for Intracs® *em* Field Generator 4x Connector for Intracs® *em* Sensors 1x NAV connector for Intracs® *em* Panel PC
Power Supply	100 W Medical Grade Internal Power Supply Input: 100 – 240 V AC; 50/60 Hz; 0.6 – 0.3 A Output: 24 V DC, 4.5 A
Safety Class	I
Dimensions	10.5 x 37.5 x 35 cm (LxHxD)
Weight	7.0 kg/15.5 lb
Transport and Storage Conditions	Temperature: -20 °C to +50 °C / -4 °F to 122 °F Relative humidity: 0 % to 75 %, non-condensing Air pressure: 50 kPa to 106 kPa Keep the device dry and protected from sunlight.
Operating Conditions	Temperature: +10 °C to +30 °C / +50 °F to 86 °F Relative humidity: 30 % to 75 %, non-condensing Air pressure: 70 kPa to 106 kPa

Intracs® *em* Field Generator	
Dimensions	20 x 20 x 7.1 cm (HxWxD)
Weight	2.6 kg/5.7 lb
Transport and Storage Conditions	Temperature: -10 °C to +50 °C / +14 °F to 122 °F Relative humidity: 10% to 90%, non-condensing Air pressure: 50 kPa to 106 kPa Keep the device dry and protected from sunlight.
Operating Conditions	Temperature: +10 °C to +30 °C / +50 °F to 86 °F Relative humidity: 30 % to 75 %, non-condensing Air pressure: 70 kPa to 106 kPa

Intracs® *em* Sensors	
Dimensions	Patient Mappers: 20 x 20 x 5.8 cm (LxWxD) Patient Tracker: 2.0 x 2.0 x 2.0 cm (LxWxD) Patient Tracker 3D: 2.4 x 5.0 x 5.0 cm (LxWxD) Sensor Wire: 19.3/22.4/27.5 x 1.2. x 10 cm (LxWxD) Sensor Clip: 1.8 x 2.2 x 2.2 cm (LxWxD)
Weight	Patient Mappers: 800 g/28.2 oz Patient Tracker: 80 g/2.8 oz Patient Tracker 3D: 85 g/3,0 oz Sensor Wire: 80 g/2.8 oz Sensor Clip: 74g/2.6 oz
Transport and Storage Conditions	Temperature: -10 °C to +50 °C / +14 °F to 122 °F Relative humidity: 10 % to 90 %, non-condensing Air pressure: 50 kPa to 106 kPa Keep the device dry and protected from sunlight.
Operating Conditions	Temperature: +10 °C to +30 °C / +50 °F to 86 °F Relative humidity: 30 % to 75 %, non-condensing Air pressure: 70 kPa to 106 kPa

joimax® Intracs® *em* Navigation System	
Applied standards	IEC 60601-1:2020, IEC 60601-1-2:2020

11 EMC Notes

Warning:
The joimax® Intracs® em Navigation System mandates special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided.

Warning:
The use of the accessories or cables of the Intracs® em Navigation System with medical electrical equipment and medical electrical systems other than those specified may result in increased emissions or decreased immunity of the medical electrical equipment or medical electrical system.

Warning:
Use of this device adjacent to or stacked with other devices should be avoided because it might result in improper operation. If the device must be used in a stacked configuration or adjacent with other electronic devices, this device and the other devices must be observed to ensure normal operation.

Warning:
This product may emit radio frequency energy and, if not installed and used according to the instructions, may cause harmful interferences to other devices in the vicinity. If this product interferes with other devices, the user is encouraged to try the following in order to correct the interference:

- *Increase the distance between interfering components.*
- *Consult the manufacturer of the other device for help.*

Warning:
Portable RF communications equipment should be used no closer than 30 cm (12”) to any part of the joimax® Intracs® em Navigation System. Otherwise, the performance of this equipment might be impaired.

Warning:
Magnetic field sources, e.g. RFID systems, should be used no closer than 15 cm (5,9”) to any part of the joimax® Intracs® em Navigation System. Otherwise, the performance of the system might be impaired.

This equipment has been tested and found to comply with the requirements regarding electromagnetic compatibility (EMC) according to IEC 60601-1-2:2014 (Ed.4). The customer or user of the Intracs® em Navigation System has to ensure that it is operated in such environments.

The Intracs® em Navigation System is suitable to be used in close proximity of RF surgical equipment (both the enclosure and the cables). The device was tested according to IEC 60601-2-2, BB.4 and can withstand the emissions produced by such equipment.
No specific conditions of intended use are required during RF surgery.

The emissions characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 group 1, class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.

The Intracs® em Navigation System is suitable for use in professional healthcare facility environments according to IEC 60601-1-2:2014 (Ed.4).

Phenomenon	Compliance	Electromagnetic environment – guidance
Conducted and radiated RF emissions	Group 1	The joimax® Intracs® *em* 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.
	Class A	The characteristics of this device determined by its emissions allow its use in the industrial sector and in hospitals. When used in domestic areas, this device does not provide adequate protection against RF communication equipment. The user may be required to take corrective action such as re-arrangement of the device.
Harmonic distortion	Class A	
Voltage fluctuations and flickers	Compliant	

Phenomenon	Basic EMC standard or test method	Immunity Test Levels	Compliance Levels	Electromagnetic environment – guidance
Enclosure Port				
Electrostatic Discharge	IEC 61000-4-2	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	Floors should be made from wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Radiated RF EM fields	IEC 61000-4-3	3 V/m 80 MHz – 2.7 GHz 80 % AM at 1 kHz	3 V/m 80 MHz – 2.7 GHz 80 % AM at 1 kHz	Portable and mobile RF communications equipment should be used no closer to any part of the joimax® Intracs® *em* including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** d= 1.2 √P d= 1.2 √P 80 MHz to 800 MHz d= 2.3 √P 800 MHz to 2.7 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, should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol: 
Proximity fields from RF wireless communication equipment	IEC 61000-4-3	See table "Enclosure port immunity to RF wireless communication equipment" below		Minimum distances between the joimax® Intracs® *em* and wireless communication equipment as specified in table "Enclosure port immunity to RF wireless communication equipment" must not be undercut.
Rated power frequency magnetic fields	IEC 61000-4-8	30 A/m 50 / 60 Hz	30 A/m 50 / 60 Hz	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Input AC power port				
Electrical fast transients/ bursts	IEC 61000-4-4	±2 kV 100 kHz repetition frequency	±2 kV 100 kHz repetition frequency	The quality of the supply voltage must be that of a typical business or hospital environment.
Surges Line-to-line	IEC 61000-4-5	±0.5 kV, ±1 kV	±0.5 kV, ±1 kV	
Surges Line-to-ground	IEC 61000-4-5	±0.5 kV, ±1 kV, ±2kV	±0.5 kV, ±1 kV, ±2kV	
Conducted disturbances induced by RF fields	IEC 61000-4-6	3 V 0.15 MHz – 80 MHz 6 V in ISM bands between 0.15 MHz and 80 MHz 80 % AM at 1 kHz	3 V 0.15 MHz – 80 MHz 6 V in ISM bands between 0.15 MHz and 80 MHz 80 % AM at 1 kHz	Portable and mobile RF communications equipment should be used no closer to any part of the Intracs® *em* including cables than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance d= 1.2 √P d= 1.2 √P 80 MHz to 800 MHz d= 2.3 √P 800 MHz to 2.7 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, should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol: 
Voltage dips	IEC 61000-4-11	0 % U T; 0.5 cycles At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°	0 % U T; 0.5 cycles At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°	Mains power quality should be that of a typical commercial or hospital environment. If the user of the joimax® Intracs® *em* requires continued operation during power mains interruptions, it is recommended that the joimax® Intracs® *em* be powered from an uninterruptible power supply or a battery.
		0 % U T; 1 cycle and 70 % U T; 25/30 cycles Single phase: at 0°	0 % U T; 1 cycle and 70 % U T; 25/30 cycles Single phase: at 0°	
Voltage interruptions	IEC 61000-4-11	0 % U T; 250/300 cycles	0 % U T; 250/300 cycles	
Signal input/output parts port				
Electrostatic discharge	IEC 61000-4-2	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	Floors should be made from wood, concrete or ceramic tiled. If floors are covered with synthetic material, relative humidity should be at least 30 %.
Electrical fast transients/ bursts	IEC 61000-4-4	±1 kV 100 kHz repetition frequency	±1 kV 100 kHz repetition frequency	The quality of the supply voltage must be that of a typical business or hospital environment.

Signal input/output parts port				
Conducted disturbances induced by RF fields	IEC 61000-4-6	3 V 0.15 MHz – 80 MHz 6 V in ISM bands between 0.15 MHz and 80 MHz 80 % AM at 1 kHz	3 V 0.15 MHz – 80 MHz 6 V in ISM bands between 0.15 MHz and 80 MHz 80 % AM at 1 kHz	Portable and mobile RF communications equipment should be used no closer to any part of the Intracs® *em* including cables than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance d= 1.2 √P d= 1.2 √P 80 MHz to 800 MHz d= 2.3 √P 800 MHz to 2.7 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, should be less than the compliance level in each frequency range.

Enclosure port immunity to RF wireless communication equipment							
Test Frequency (MHz)	**Band**	**Service**	**Modulation**	**Max. Power** (W)	**Distance** (m)	**Immunity Test Level** (V/m)	**Compliance Level** (V/m)
385	380 – 390	TETRA 400	Pulse modulation 18 Hz	1.8	0.3	27	27
450	430 – 470	GMRS 460, FRS 460	FM ± 5 kHz deviation 1 kHz sine	2	0.3	28	28
710	704 – 787	LTE Band 13, 17	Pulse modulation 217 Hz	0.2	0.3	9	9
745							
780							
810	800 – 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation 18 Hz	2	0.3	28	28
870							
930							
1720	1700 – 1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation 217 Hz	2	0.3	28	28
1845							
1970							
2450	2400 – 2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation 217 Hz	2	0.3	28	28
5240	5100 – 5800	WLAN 802.11 a/n	Pulse modulation 217 Hz	0.2	0.3	9	9
5500							
5785							

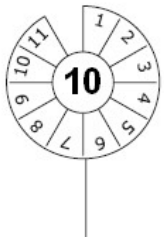
12 Service/Maintenance

Warning:
Do not use the device during service activities.

joimax® GmbH recommends performing a function and safety inspection at regular intervals according to EN 62353 or to other corresponding country-specific regulation.

All maintenance activities (including fuse replacement and software updates) shall only be conducted by authorized personnel.

The Intracs® *em* Navigation System is low maintenance. Regardless of the device being low maintenance, regular service can contribute to early detection of defects and faults and thus extend the operating life of the devices.



Next inspection

An operating life of 7 years is specified for the electronic components of the Intracs® *em* Navigation System. Any use beyond this depends on the results of the safety inspections. The operating life of the reusable Intracs® sensors (Sensor Wires, Sensor Clip, Patient Tracker) are limited to 30 applications to avoid improper function caused by too many sterilization cycles.

joimax® GmbH recommends this inspection to be performed at least once a year.
This inspection should be documented with a test-label on the device.

12.1 Replacing the Fuse

Warning:
Always observe the specifications on the device label and follow the instructions below when replacing the fuse. Non-observance may result in malfunction of the device and possible injury.

Warning:
Always disconnect the device from the power supply when performing service activities.

1) Turn off the device via the power switch at the rear side of the control unit.
2) Unplug the power cord from the control unit.
3) Open the fuse holder.
4) Check the type of replacement fuse on the device label and replace the defective fuses.
5) Plug the power cord into the control unit.
6) Turn on the control unit via the power switch at the rear side, press the "On/Off" switch at the device front and check the function of the device.

12.2 Software Update

1) Insert the update CD/DVD into the optical drive or plug in the update USB stick.
2) Log into the Intracs® *em* software as *Administrator* (password: "joimax").
3) Press the "Update" icon; the software update starts automatically.
4) After a successful update, the Intracs® *em* software restarts and the disc or the USB stick can be removed.
5) Check the software version and the function of the device.

13 Troubleshooting

Problem	Possible cause	Possible solution
No operation	- No power supply.	- Check power supply connection. - Check main fuses. - Send the device to joimax® service.
No image on the panel PC	- Device is not turned on. - Defective Panel PC.	- Switch on the device. - Check cable connections. - Check the panel PC settings. - Send the device to joimax® service.
No endoscopic image during navigation	- Signal source is not turned on. - Signal source is not connected properly. - Wrong signal. - Video cable defective/broken.	- Turn on the signal source. - Check the cable connections. - See technical data for suitable video signals. - Replace the video cable.
Image data cannot be imported	- No external storage device connected. - No optical disc inserted. - No data available on the external storage.	- Connect an external USB storage device. - Insert an optical disc (check technical data for suitable medium). - make sure the correct image data is stored on the external storage.
Touch monitor does not respond to touch	- Device is defective. - Software failure.	- Restart the panel PC.
Low navigation accuracy	- Bad/poor patient registration. - Patient tracker moved after patient registration. - Bad/poor positioning of field generator.	- Restart/repeat patient registration. - Be sure no components moved through patient registration. - Correct the position of the field generator. - Remove disturbing components.
No instrument registration	- One sensor is outside of the EM field. - Maximum count of sensor reached. - Patient tracker mounted in the wrong way. - Sensor clip wrongly mounted.	- Correct the position of the field generator. - Change sensor. - Correct patient tracker and restart patient registration. - Mount sensor clip correctly.
No navigation	- EM field disturbed. - Poor positioning of field generator.	- Remove disturbing components from the EM field (e.g., C-arm). - Correct the position of the field generator.
Registration of X-ray images not successful	- Wrong X-ray image selected.	- Select the correct X-ray image to the corresponding patient mapper.
Wrong orientation with endoscope	- Sensor wire inserted into the wrong irrigation channel.	- Insert the sensor wire to the left irrigation channel.
Others	- Others	- Send the device to joimax® service.

14 Warranty

Warning:
Do not open any component of the joimax® Intracs® em Navigation System. Unauthorized opening, repair or modification of the devices releases joimax® GmbH from any liability for the operating safety of the devices and results in any claims becoming void even during the warranty period.

Warning:
In case of return of the devices or accessories, the original packaging material must always be used!

Warning:
To protect your staff and the joimax® GmbH employees, please clean the unit and its accessories and disinfect it before sending it.
Should this be impossible due to temporal constraints, please reprocess the components as much as possible and label it accordingly.

The warranty period for the Intracs® em Navigation System depends on the legal regulations of the specific country. Failure due to faulty material and/or poor processing must be rectified by the manufacturer free of charge within this period.
Transport costs and shipment risks are excluded hereof.
In addition, the details in our general terms and conditions apply.

To facilitate quick processing of service requests, we ask you to send the product with the following information:

- Model/Item number (REF)
- Serial number (SN)
- A description of the error as accurate as possible
- Invoice of the device if available
- Contact person for questions

15 Consumables / Accessories

Warning:
Only the consumables/accessories by joimax® GmbH listed below are to be used with the Intracs® em Navigation System! Use of accessories other than those specified or provided by joimax® GmbH may result in improper operation.

Warning:
Make sure to follow the instructions for use of accessories to be used with the device (e.g. mounting arms, wire cutter etc.).

Consumables

All consumables are provided by joimax® GmbH. Replacements for all consumables can be ordered from joimax® GmbH or via the respective local joimax® distributor.

Item number	Item description
Single use	
JKW1515	K-wire with thread
JINTMA1135C	Sterile Cover for Field Generator/Patient Mapper
JINTMA1135CUS	Sterile Cover for Field Generator/Patient Mapper (for US only)
JINTMAP1136C	Sterile Cover for Patient Mappers
30 times use	
JINTPT2235	joimax® Intracs® em Patient Tracker
JINTPT3D	joimax® Intracs® em Patient Tracker 3D
JINTSC2205	joimax® Intracs® em Sensor Clip
JINTSW2215	joimax® Intracs® em Sensor Wire 150
JINTSW2218	joimax® Intracs® em Sensor Wire 180
JINTSW2223	joimax® Intracs® em Sensor Wire 230

Accessories

Item number	Item description
JINTPM2245-AP	joimax® Intracs® em Patient Mapper AP (incl. connection cable)
JINTPM2245-LAT	joimax® Intracs® em Patient Mapper LAT (incl. connection cable)
JINTYA35	joimax® Intracs® em Y-adapter
JINTDG182860	joimax® Intracs® em K-wire Drill Guide
JINTWC	Wire cutter
JEST1390N	joimax® Endoscopic Trolley small
JESTNA	Lat. Mounting Arm for joimax® Endoscopic Trolley
JINTAC	joimax® Intracs® em Accessory Case for Field Generator and Patient Mapper
JINTST15	joimax® Intracs® em Navigation Sensor Tray 150 **List of components:**

Item number	Description	Quantity

Item number	Item description		
	JINTPT3D	joimax® Intracs® em Patient Tracker 3D	1
	JINTSC2205	joimax® Intracs® em Sensor Clip	1
	JINTSW2215	joimax® Intracs® em Sensor Wire 150	1
	JINTSW2223	joimax® Intracs® em Sensor Wire 230	1
	JKW1515	K-wire with thread	5
	JINTWC	Wire cutter	1
	JINTDG182860	joimax® Intracs® em K-wire Drill Guide	1
	GRC275210N	Guiding Rod Navi, double-cannulated, yellow	1
	GRC276310N	Guiding Rod Navi, double-cannulated, red	1
	JINTYA35	joimax® Intracs® em Y-adapter	2
JINTST18	joimax® Intracs® em Navigation Sensor Tray 180 **List of components:**		
	Item number	**Description**	**Quantity**
	JINTPT3D	joimax® Intracs® em Patient Tracker 3D	1
	JINTSC2205	joimax® Intracs® em Sensor Clip	1
	JINTSW2218	joimax® Intracs® em Sensor Wire 180	1
	JINTSW2223	joimax® Intracs® em Sensor Wire 230	1
	JKW1515	K-wire with thread	5
	JINTWC	Wire cutter	1
	JINTDG182860	joimax® Intracs® em K-wire Drill Guide	1
	GRC275210N	Guiding Rod Navi, double-cannulated, yellow	1
	GRC276310N	Guiding Rod Navi, double-cannulated, red	1
	JINTYA35	joimax® Intracs® em Y-adapter	2
JINTSTR	joimax® Intracs® em Navigation Tray without disposables **List of components:**		
	Item number	**Description**	**Quantity**
	JINTWC	Wire cutter	1
	JINTDG182860	joimax® Intracs® em K-wire Drill Guide	1
	GRC275210N	Guiding Rod Navi, double-cannulated, yellow	1
	GRC276310N	Guiding Rod Navi, double-cannulated, red	1
	JINTYA35	joimax® Intracs® em Y-adapter	2

16 Disposal of the Device

Warning:
This symbol indicates that medical devices must be disposed of separately from household waste. Dispose of electrical waste in accordance with the applicable national and local regulations.

Warning:
This symbol must be affixed to the waste container or the device when discarding it.

Dispose of packing material, unless it is contaminated, in accordance with national and local regulations.

According to the implementation of European law into national laws and regulations, you are obliged to properly dispose of medical devices.

Discard used and contaminated medical devices at a collection point of an appropriate disposal carrier. "Medical waste" is classified according to dangerous goods law (for transportation) by UN number UN 3291.

17 Incidents Reporting

Any serious incident that has occurred in relation to the device should be reported to joimax® GmbH and the competent authority having jurisdiction in your locale.

Please notify us at the following telephone number:

For the US	**+1 949-859-3472**	**(24-hour availability)**
For all other countries	**+49 (0)721 25514 – 999**	**(24-hour availability)**

Thank you for your support!

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