

Instructions for Use

Cube Navigation System



Product:

Trade Name: Cube Navigation System
Common Name of Device: Image-guided surgery system

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Component/ Model
Navigation Unit Cube4D

E 01 1106-HD/8 (HD, 8 sensor channels)
E 01 1106-4K/8 (4K, 8 sensor channels)

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Explanation of Symbols



Manufacturer / Manufacturing date



Reference number / Order number



Serial number



To ensure safety, follow the instructions for use



MR UNSAFE. The system must not be used in a Magnetic Resonance Environment. It contains ferromagnetic parts and poses a clear threat to persons and equipment in the magnetic room.



Indicates the temperature limits to which the medical device can be safely exposed.



Indicates the range of humidity to which the medical device can be safely exposed.



Indicates the range of atmospheric pressure to which the medical device can be safely exposed.



Fragile, handle with care (symbol on transport box)



Keep dry (symbol on transport box)



The device must not be opened and repairing must only be done by qualified personal.



Alternating current (AC)



Protective earth (PE)



Federal law (USA) restricts this device to sale by or on the order of a physician.



Marks an information message indicated as a note.



Refers to documentation indicated as a note

1. General information

The Cube Navigation System is a system that is used in surgical computer-assisted instrument navigation.

Please refer to these instructions for use to operate the system correctly and safely. You will find an overview and explanation of all relevant steps to set up the system, which are necessary for a navigated operation.

The system may only be used in accordance with the safety guidelines and instructions for use described in this instruction manual.

Read the instructions for use carefully before using the system. Keep the instruction manual close to the device so you can use it at any time.

The system may only be used in accordance with the safety guidelines and instructions for use described in this instruction manual.



CAUTION: This system is intended for use by healthcare professionals only.

1.1. Intended use

The Cube Navigation System and its components are intended as an aid for precisely locating anatomical structures in either open or percutaneous procedures.

The device is a positioning aid/display for surgical instruments. Surgeons use this system as a tool to locate anatomical structures in the patient during an operation. The location information is displayed in preoperative radiological image data (CT, Cone Beam CT, MRI, Fluoroscopy) of the patient, thereby, giving aid for positioning other instruments for the ongoing procedure.

Performing procedures with the system other than those specified in these instructions or outside of its intended use will compromise the navigation accuracy.

Suitable Environment

The Cube Navigation System is designed to operate in Professional Healthcare Environment.

1.2. Indications for use

The Cube Navigation System and its components are intended as an aid for precisely locating anatomical structures in either open or percutaneous procedures. The Cube Navigation System is indicated for any medical condition in which the use of stereotactic surgery may be appropriate, and where reference to a rigid anatomical structure in the field of ENT surgery, such as the paranasal sinuses, mastoid anatomy, can be identified relative to a CT or MR based model of the anatomy.

Example procedures include, but are not limited to:

- ENT Procedures;
- Transsphenoidal access procedures.
- Intranasal procedures.
- Sinus procedures, such as Maxillary antrastomies, Ethmoidectomies, Sphenoidotomies/Sphenoid explorations, Turbinate resections, and Frontal sinusotomies.
- ENT related anterior skull base procedures

Patient groups

The Cube Navigation System can be used on all patients independent e.g. from age, sex, weight.



DANGER: The system may only be used for the described purpose and in the described manner.



DANGER: Pay attention to the contraindications associated with the use of the navigation system.

1.3. Contraindication

- The navigation system must not be used at patients with electronic devices in direct connection to the brain or the nervous system such as implantable neurostimulators (e.g. deep brain stimulation), programmable CSF shunts.
- The system must not be used in patients with monopolar pacemaker (older design, with lower resistance to interference).
- The system should not be used in patients with implantable, body worn devices such as insulin pumps.



DANGER: Do not use the system if medical or clinical reasons contraindicate its use.

1.4. Description of the Cube Navigation System

The navigation system allows the tracking and navigation of surgical instruments during surgical procedures using stereotactic techniques. The location and movement information are displayed in preoperative radiological image data (CT, DVT, MRI) of the patient.

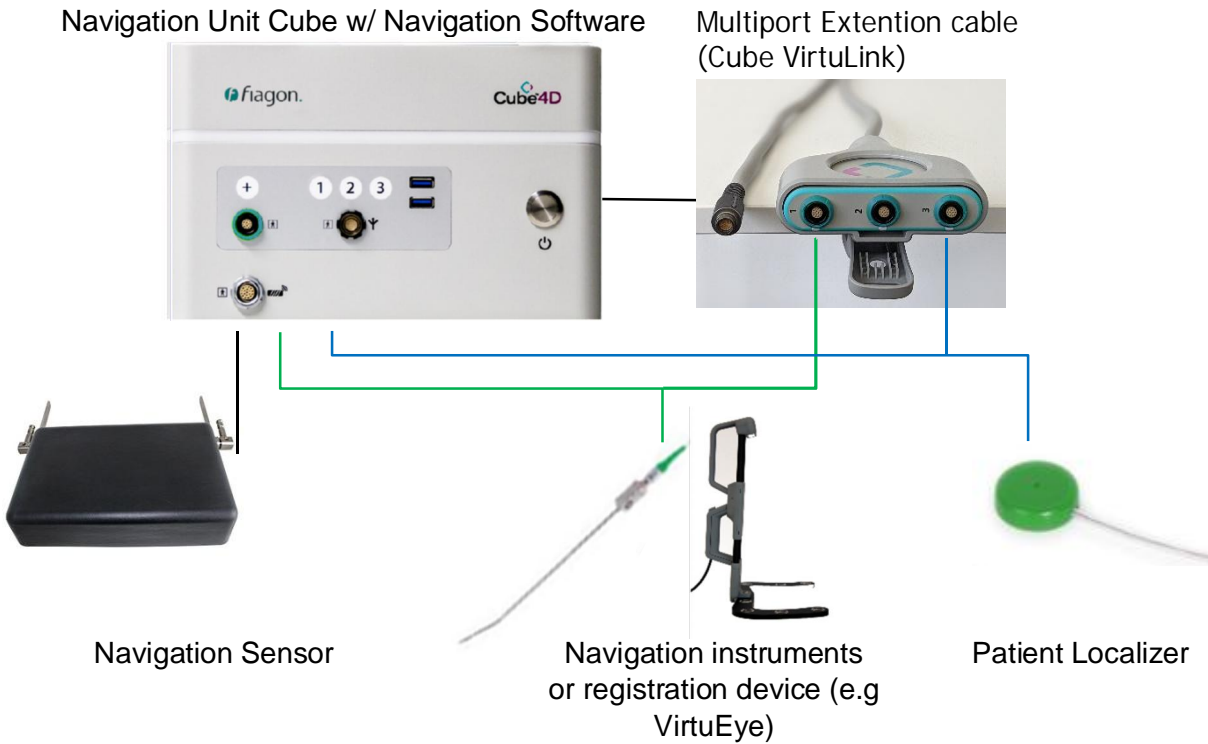
The Cube Navigation System consists of the components Navigation Unit Cube4D with the Navigation Software, the Navigation Sensor (position measurement device – integrated into e.g. headrest) a patient reference localizer, instruments and accessories such as video cables, mouse and instrument extension cables.

The Navigation Unit Cube4D runs navigation software modules within defined application-related specifications and displays calculated position and/or navigation information (image based and model based).



NOTE: Refer to the instructions for use of the software and the Application Notes of the procedures for guidance on the selection of a suitable localizer, navigation sensors, and instrument type for each procedure.

1.4.1. Overview of the system components



NOTE: The system components Navigation sensors, Navigation instruments and Patient localizers (all available in different models), will be described in detail in the Instructions for use for each device. Please also refer to these instruction.

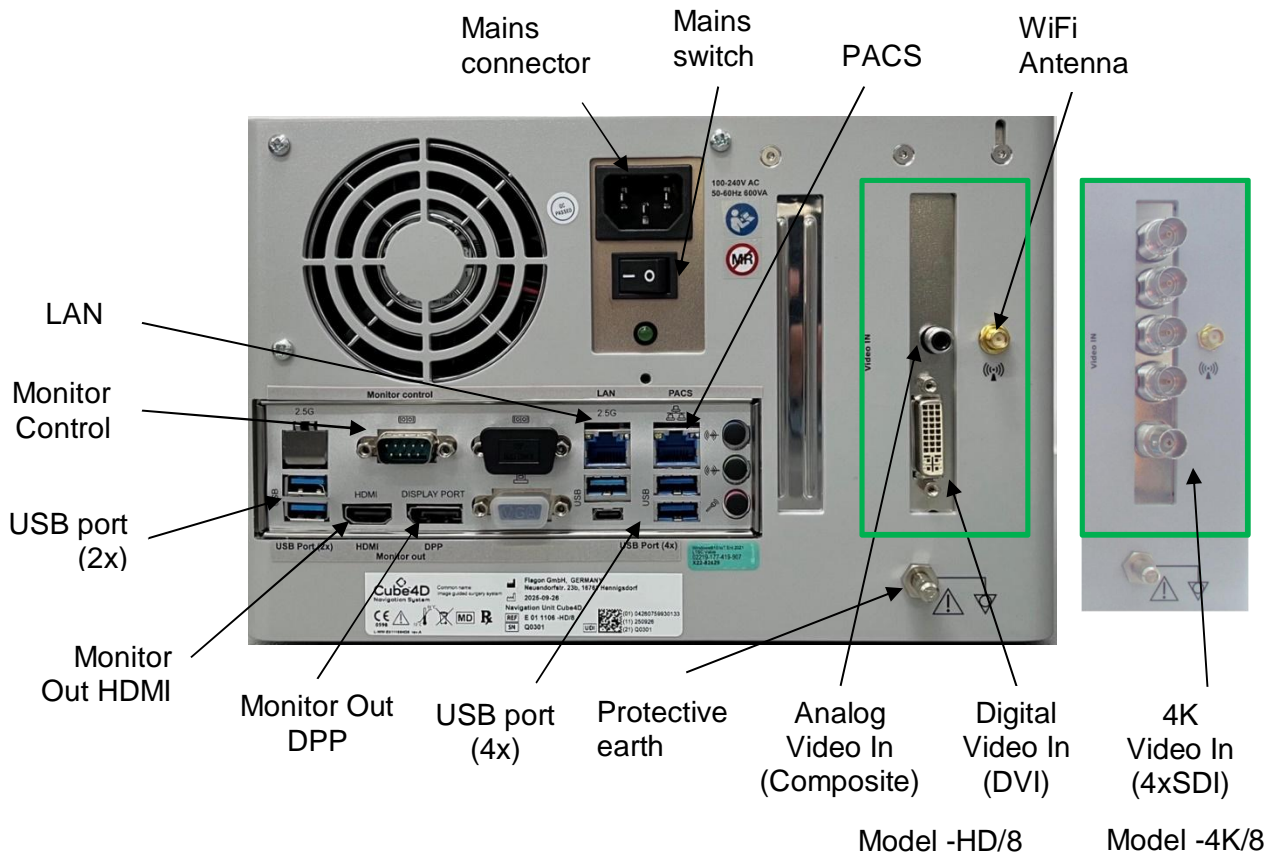
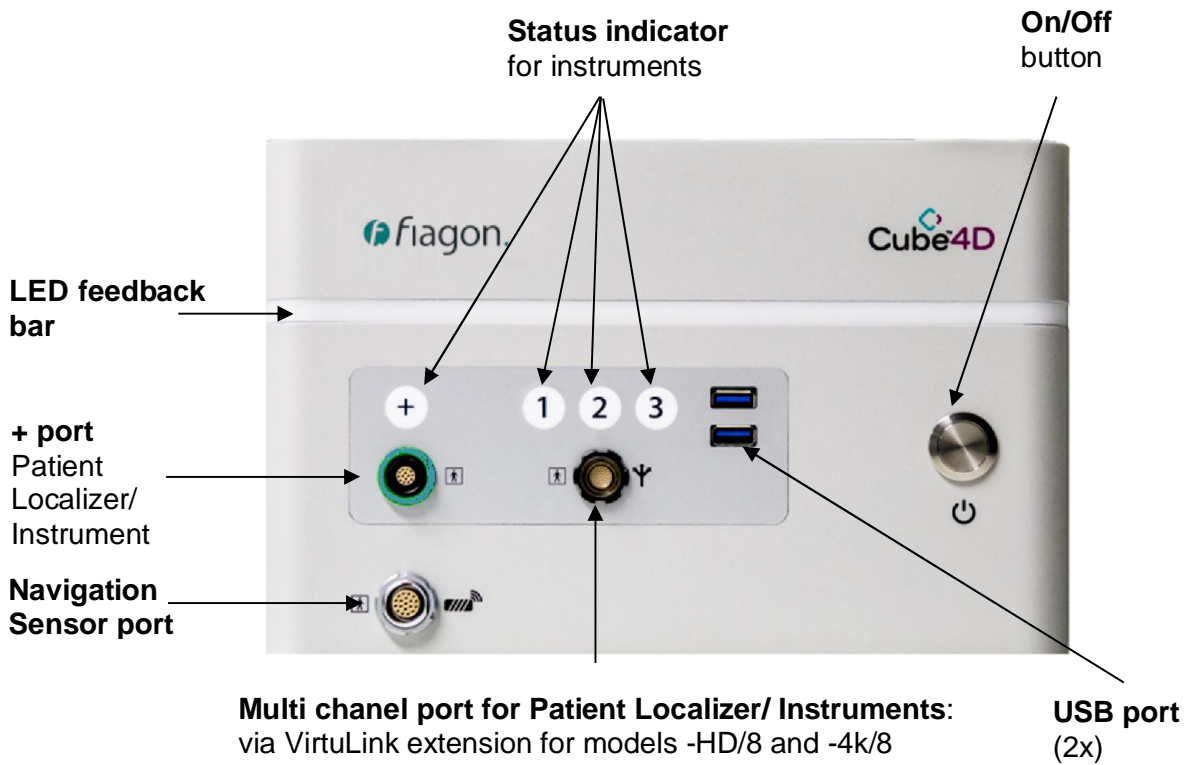
1.4.2. Navigation Unit Cube4D models

The Navigation Unit Cube4D is available in three models which differ in Video input (HD or 4K) and amount of sensor channel (8). The following table gives an overview of the models.

Model / reference#	Video In specifications	Sensor Channel specifications
E 01 1106 -HD/8	Digital Video Input up to HD 1080p, up to 60Hz Analog Video Input PAL or NTSC	8 sensor channels available for connection of up to 4 Instruments (via VirtuLink and + port)
E 01 1106 -4K/8	Digital Video Input (SDI Only) up to 4KDCI (4096x2160), up to 60Hz	8 sensor channels available for connection of up to 4 Instruments (via VirtuLink and + port)

1.4.3. Description of interfaces and controls

Navigation Unit



Cube VirtuLink - multiport extention cable

Connector to
Navigation unit
multi channel port

Patient Localizer/
Instrument
connector (3x)

Mounting Clamp

i NOTE: The Mounting Clamp may be used to clamp the VirtuLink to a flat shelves less than 2.5cm in thickness or IV poles during use of the system. When connecting or disconnecting instruments to the VirtuLink always use one hand to securely hold the VirtuLink in place.

1.5. Qualification of the user

The navigation system may only be used by healthcare professionals. These instructions for use in combination with other accompanying documentation (instructions for use of the device components and application notes) provided with the system allow the user to get adequate knowledge to use the navigation system safe and effective.

Mandatory training by a Fiagon representative is not required. However, if requested further training or system introductions are available for physicians and medical staff designated to be Fiagon navigation users. Contact your Fiagon representative to arrange training.



CAUTION: The information provided by the Navigation System is intended to support the surgeon. Nevertheless, the Navigation System cannot replace a detailed knowledge of anatomy. All procedures and notes described herein do not release the user from his responsibility regarding the clinical ability to judge and the clinical procedures.



CAUTION: Do not use the navigation system if you have not familiarized with the safe and effective use of the navigation system.

2. Safety notes

2.1. Safety notes in this manual



NOTE: Read this manual carefully and follow the instructions before operating the Navigation System. Pay special attention to all information that is introduced with the following notes: "DANGER", "WARNING" or "CAUTION". These notes are particularly important for the safe use of the system. For better emphasis, these notes are accompanied by the warning sign pictogram.



NOTE: In addition, this manual includes notes for efficient use of the Navigation System. These notes are also accompanied by the information pictogram. Read these notes carefully.

2.2. General safety notes

All Fiagon products have been developed and manufactured in compliance with strict safety standards. Nevertheless, proper use and regular maintenance of the medical system is required. It is indispensable that the users of this system carefully read and pay attention to all risk and safety phrases described in the instruction manual.



DANGER: If the system setup is altered by a person not authorized to do so, this may result in reduced interference resistance of the system.



DANGER: The system is connected to the protective conductor via the power plug. Make sure that the system is only used with power networks that meet the described requirements. The plugs and cables must be routinely checked and replaced if damaged.



DANGER: Only use the systems in rooms that are in compliance with applicable laws and regulations regarding the safety of electrical system.

DANGER: The unauthorized installation of software and modifications or alterations of the device are not permitted due to safety reasons.

DANGER: The navigation system may only be used with Navigation software, components and accessories that the manufacturer indicates as compatible with the system.

DANGER: The documentation of the installed navigation software must be considered at any time. The documentation specifies its proper use.

DANGER: The system must not be used in the presence of combustible gases and vapors. The use of electrical devices in surroundings that are not intended for such use may lead to fire and explosions. There is a risk of explosion when using inflammable anesthetic gases in close proximity of the system.

DANGER: Do not open the system! Danger of electric shock. In the event of unauthorized intervention, any warranty and product liability become null and void. This can result in personal injuries and damage to the system.

DANGER: Do not use the system if it cannot be ensured that all routine checks have been successfully completed and the maintenance activities have been carried out and are up to date. The maintenance activities must be carried out by a person authorized by the manufacturer.

DANGER: Only operate the system with the voltage indicated on the rating plate.

DANGER: Turn off the system at the main switch and pull the plug before cleaning.

DANGER: Devices emitting electromagnetic radiation to a high degree can influence the proper operation of the device. Turn off cellular phones and similar devices.

DANGER: The handling of the electromagnetic measuring technology is described in the user manual.



WARNING: Inflammable and explosive disinfection sprays must be handled with great care, since their vapors are highly flammable.

WARNING: Prevent liquids such as water, cleaning agents and disinfection sprays from getting into the interior of the device.

2.3. Safety measures at the point of use

The Navigation Unit Cube4D is suitable for a professional healthcare environment.

The Navigation System may only be used in medical environments that are in compliance with nationally applicable regulations.

The Navigation System is not designed for use in potentially explosive atmospheres. When using the Navigation System with, e.g., easily inflammable and explosive anesthetics make sure that it is not operated in a danger zone as defined by the manufacturer of these anesthetics.

The Navigation System may only be operated when connected to an outlet with protective earth contact and when using the appropriate plug.



WARNING: Take care that the main power cord can be unplugged easily and that the ventilation slots at the rear and bottom side (Navigation Unit Cube4D) of the enclosure stay clear (at least 5 cm) to prevent overheating of the housing or other components. The navigation module has to be set up accordingly.

Place the device per the table „Recommended separation distances“, chapter 11 “EMC Compliance statement“, to avoid interferences from other equipment.

All components (Navigation Unit Cube4D, VirtuLink splitter cable) are suitable for use within the patient environment. Accessory equipment connected to the analog and digital interfaces must be certified according to the respective IEC standard (e.g. IEC 60950 for mouse and keyboard or IEC 60601-1 for medical equipment). Furthermore, all configurations must comply with the system standard IEC 60601-1 (ed 3.1), Clause 16.

By connecting additional equipment to the signal input port or signal output port, a medical electrical system is configured. It has to be ensured that the Navigation System complies with the requirements of the Navigation System standard 60601-1 (ed. 3.1) Clause 16.



WARNING: Prior to each use, the user must check the functionality and the proper condition of the Navigation System, check for loose components and damage. DO NOT use the Navigation System if these conditions exist. If service is required, contact your sales or service representative immediately.

2.4. Safety measure when using the system

Treatment may only be carried out if the appropriate use of the Navigation System can be ensured.



DANGER: During surgery, make sure not to touch the patient and the metallic housing of the Cube simultaneously. Failure to do so may result in personal or patients injury.



WARNING: Prior to its use, the user must check if the components of the Navigation System are in proper conditions.

WARNING: If you notice visible or audible deviations from normal conditions during the operation of the system, do not use the system until these deviations have been eliminated by a service representative.

WARNING: Connecting the system to the network or with other devices via data coupling may result in compromising the essential performance of the Navigation System caused by e.g. viruses, data loss, corrupt files, unauthorized access. The data coupling of the Navigation System is the USB interface. Before connecting the Navigation System to network or data coupling, identify, analyze, evaluate, and control the resulting risk.



WARNING: Do not connect devices other than storage media or VirtuEye device to the USB interface.

WARNING: Do not unplug mains cables during surgery.

2.5. Electromagnetic navigation

The Navigation System uses an electromagnetic position measurement system with interference detection.

The position of the instruments is determined using an electromagnetic field generated by a field generator. Frequencies of said field range from 800Hz to 10 kHz with a magnetic field strength of 1 Am^{-1} in a distance of 0,5m to the field generator. Therefore, instruments emitting electromagnetic signals (e.g., surgical turbines, HF surgery, DECT phones) or mobile RF equipment (e.g. cellular phone) can influence the Navigation System.



WARNING: Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation of the Navigation System and/or other equipment. If such use is necessary, the Navigation System and the other equipment should be observed to verify that they are operating normally, e.g. ECG is commonly used adjacent to the Navigation System. Please check for artefacts and verify proper operation. In case interference occurs contact Service.

If EM disturbances occur:

The Cube Navigation System has an automatic interference detection that shows the user when interference occurs during navigation. Standard instruments such as endoscopes or forceps normally do not cause any interference.

If interference occurs, the navigation data are not displayed, because they may be inaccurate. Once the source of interference has been eliminated, navigation will continue automatically.

If interference occurs repeatedly, check for and dispose of the metal parts that cause this interference such as ferrous retractors near the patient localizer.

If the source of interference cannot be located, contact your service representative.

Possible sources of interference are

Directly in the measuring field:

- surgical turbines
- RF surgery
- DECT phones, cellular phones
- RFID tags

In close vicinity, (e.g. operating area/ 2 m radius, 6.6 feet)

- Diathermy devices
- Security systems such as metal detectors
- Other image-guided surgery systems with EM tracking technology

In adjacent rooms:

- MR scanner

For EMC technical specifications of the system refer to the related chapter in this document.



NOTE: RFID tags are not likely to interfere with the system unless they are positioned directly between the field generating device and the sensor. Make sure the instruments and equipment used for the surgery do not contain any RFID tags that will be in the measuring field. Consult the Instructions for use of the devices to check whether and where RFID technology is used.

2.6. Patient Data Protection

HIPAA Privacy Rule Compliance: Users of the Cube Navigation System have the option of assigning a password before system operation to prevent unauthorized access to individually identifiable health information.



CAUTION: To protect sensitive healthcare information, The manufacturer strongly recommends applying a password to operate the Navigation System.

2.7. Cyber and information security

Do not install unauthorized software on the Navigation unit.

To protect against computer viruses, do not use the Navigation Unit for any other purpose.

The navigation unit runs the pre-installed Windows Defender as antivirus software. Using other third-party antivirus software automatically disables Windows Defender, which may result in loss of system files and system crash.

Further information about the possibilities of security when connecting the system to the network (PACS communication, Firewall settings and secured Wireless connection) can be provided.

If no other measures have been made the Network connection must be unplugged from the Cube Navigation System during surgery.



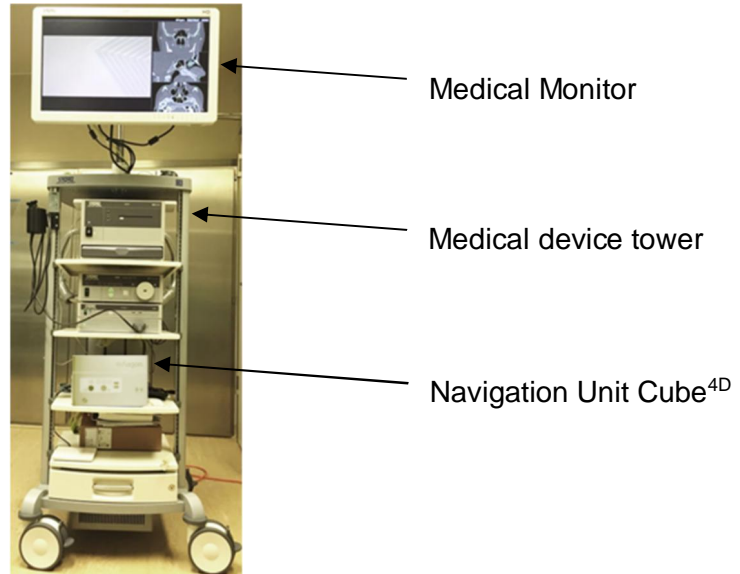
WARNING: Our wireless communication network is password protected



CAUTION: Make sure Storage media are free of viruses before connecting to the system. Do not connect any third-party wireless capabilities to the device, for instance by placing a wireless dongle (e.g. Bluetooth or WiFi) into the USB or LAN ports.

3. Bringing into service

Setting up the navigation system on a trolley or integrating it into an endoscopy tower as well as the connection to the monitor and video source are subject to the initial bringing into service routine. Consult the service provider for setting up the system or for providing additional instructions. The navigation system does not require an installation in the meaning of ISO 13485..



Exemplified setup on endoscopy tower

Connection to Potential equalization

Since the housing of the Navigation Unit Cube4D unit is made of touchable, conductible parts (metal), etc., and is categorized as protection class 1 and having touchable, conductible housing parts, the part is required to be provided with an additional potential equalization and to be included in the overall potential equalization.



Connect this pin to the central potential equalization pin of the endoscopy tower or the room.

The additional potential equalization serves for the limitation of possible potential differences between different conductible parts of a system within the patient's environment:

The Navigation Unit Cube4D should only be connected and brought into service with the following cables:

Interface / port	Cable Type	Max. length	Order No.	Remarks
Monitor Out DVI	DVI – D, shielded	2 m	A 00 9201	-
Monitor Out HDMI	HDMI 2.0 shielded	2 m	A 00 9210	
Monitor Out DVI /HDMI	DVI – HDMI, shielded	2 m	A 00 9207	To be used on DVI out for HDMI Monitor or on HDMI out for DVI Monitor
Monitor Out DPP	DPP shielded	2 m	A 00 9212	To be used for 4K version for DPP Monitor
Monitor Out DPP /HDMI	DPP – HDMI, shielded	2 m	A 00 9213	To be used for 4K version for HDMI Monitor
Digital Video In	DVI – D, shielded	2 m	A 00 9201	For models with HD video in (-HD/8)
4K Video In	4x SDI (min. 3G, coaxial, shielded) or 1x 12G-SDI (coaxial, shielded)	3 m	(4 x) A 00 9211	For models with 4K video in (-4K/8)
Analogue Video In	Composite-Video, shielded	2 m	A 00 9208	For models with analogue video in (-HD/8)
Monitor Control	RS 232	2 m	A 00 9204	-
USB backside	USB – Mouse USB – Service keyboard	2 m	A 00 9101 A 00 9102	-
+port	Extension cable instrument / instrument or patient localizer	2 m	A 00 1200	all Cube navigation instruments, all C-Type Localizer can be connected
Multi channel port	Cube VirtuLink for up to 3 instruments or patient localizer	2 m	E 01 1136	For models with 8 sensor channel (-HD/8 and -4K/8) all Cube navigation instruments, all C-Type Localizer can be connected.
Ethernet	CAT 5 cable	-	-	Not to be used in navigation mode
Mains connector	Mains power cord (UL Approved)	1.80 m	A 21 9200 (US) / A 01 9200 (EU)	-
	Power Supply Cord Hospital Grade (UL Approved according to UL 817)	3 m	A 21 9201 (US)	-



CAUTION: The cables and accessories provided by Fiagon should only be used in connection with the Cube Navigation system. Other than those specified may result in increased emissions or decreased immunity of the Cube Navigation System.

4. Set up system

4.1. Preparation

1. Place the device tower with the Navigation Unit Cube4D at its usual position, e.g. across from the surgeon.
2. Make sure the mains cable of the Navigation Unit Cube4D is plugged in correctly.

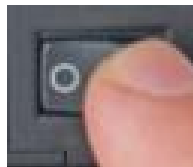


DANGER: When using multiple socket make sure it is equipped with protective earth connection, otherwise at a malfunction there is a risk of electric shock.

DANGER: To reduce the risk of electrical shock, the connection to mains needs to be equipped with a protective earth connection.



NOTE: The main switch of the Navigation Unit Cube4D is located on the backside. It should be switched to "On". If the system does not start, check the position of the main switch



3. Push the main switch of the system tower on the backside of the module.
4. Attach a Navigation Sensor to the operating table or procedure chair.



Type Navigation headrest Universal



Refer to the instructions for use of the specific Navigation sensor type for detailed mounting instructions.



NOTE: Use a head positioning cushion or ring on the headrest to support the head of the patient.

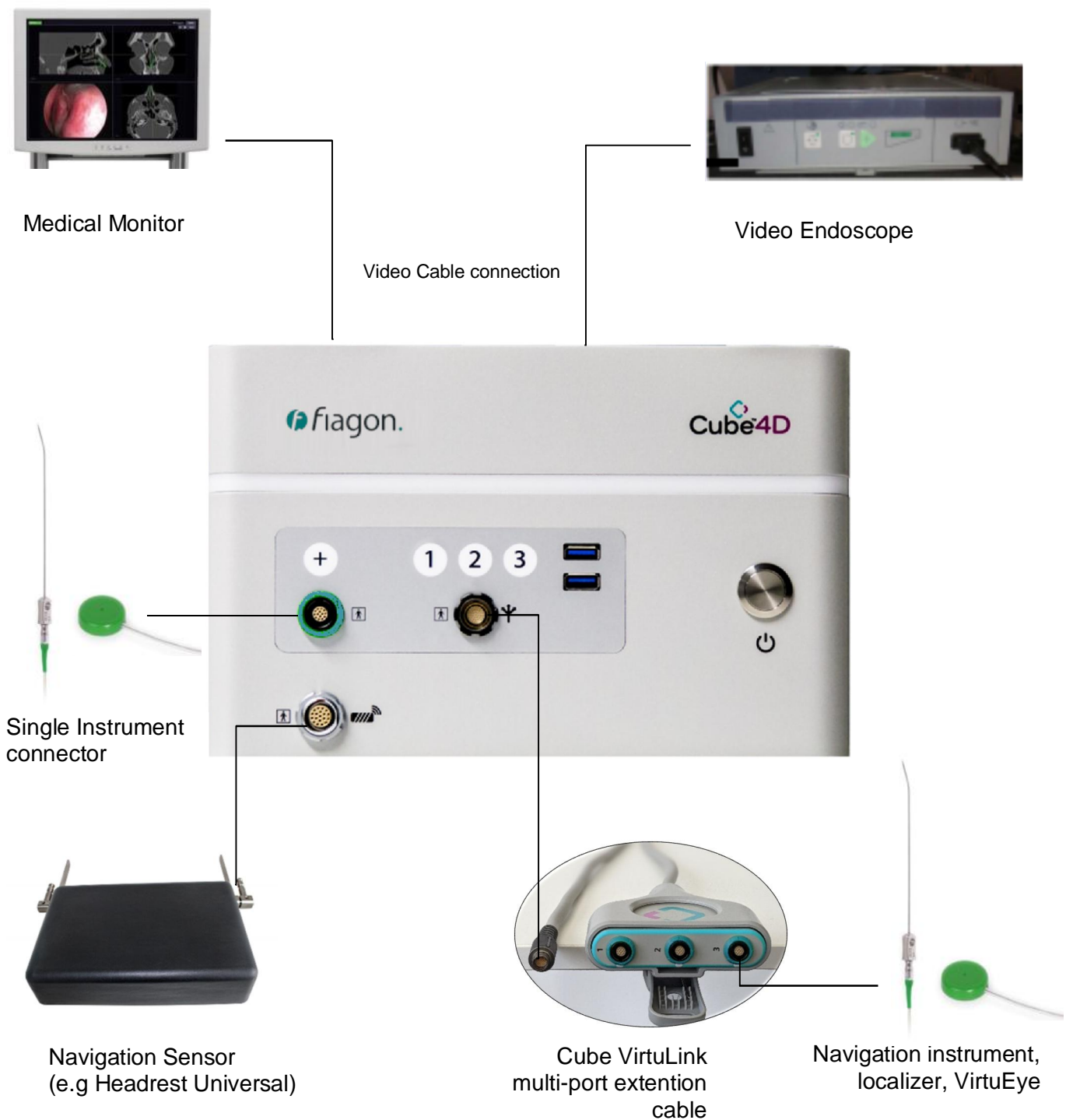
4.2. Starting the system

Make sure the main switch of the Navigation Unit Cube4D is switched on.

Press the On/Off button on the front panel of the unit. You will hear a confirmation tone after the Navigation Software has started.



4.3. Overview of the connections





4.4. Connecting the Navigation Sensor and VirtuLink Splitter cable with the system

Insert the plug of the Navigation Sensor into the appropriate socket “sensor” (large metal socket, lowest possible socket) on the Cube. Note that the red marking at the plug is at 12 o'clock position.



This socket is suitable to connect to all Navigation Sensors.

Once the Navigation Sensor is connected, you will hear a confirmation tone and the status bar will appear on the top of the navigation screen. The Status indicators for the Patient Localizer and the Instrument will be displayed in black and white indicating that they are not connected.

<p><i>status indicator of patient localizer</i></p> 	<p><i>status indicator of instrument</i></p> 
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Insert the plug of VirtuLink extension cable into the appropriate socket (small metal socket) on the Navigation Unit Cube4D. Note that the red dot marking of the plug is at 12 o'clock position.



Only the Splitter cable connects to this socket.

4.5. Connecting the applied part Patient Localizer with the system

Insert the plug of the Patient Localizer into the appropriate green socket on the Navigation Unit Cube4D/ Cube VirtuLink. Note that the white marking at the Navigation Unit Cube4D plug is at 12 o'clock position.



DANGER: Be careful throughout the procedure that the localizer does not slip. Otherwise, the navigation information is no longer correct. The registration must be repeated.



CAUTION: Note that you are inserting the plug of the Localizer into a non-sterile device.

This socket is suitable to connect C-Type Localizers (applied parts), which can be identified by their blue marked plug.

Once the Patient Localizer is connected, you will hear a confirmation tone and the status indicator of the patient localizer disappears indicating that it is connected and working correctly. The Localizer is accepted and registered to the Navigation System.

4.6. Connecting the applied part navigated instrument with the system

Take the instrument out of the sterile pouch, and place it on the instrument table. Insert the plug of the instrument into the appropriate green socket on the Navigation Unit Cube4D/ Cube VirtuLink. Note that the white marking at the plug aligns with the marking at the socket.



WARNING: Note that you are inserting the plug of the instrument into a non-sterile device.

This socket is suitable to connect to all CubeInstruments (applied parts), which can be identified by their green marked plug.

Once the navigated instrument is connected, you will hear a confirmation tone and the status indicator of the instrument is displayed in color (green or red). The number of remaining uses is displayed in the status indicator of the instrument on the navigation screen. The instrument is accepted and registered to the Navigation System.

Three instruments can be connected to the VirtuLink in parallel.

Status indicator of instrument



Green indicator denotes instrument is in the measurement field



Red indicator denotes instrument is outside the measurement field or distortion is detected

- i** **NOTE:** Before using the navigation the patient registration has to be done according to the description of the application. Consult the instructions for use of the software and respective navigation application.
- i** **NOTE:** If the instrument or the localizer does not register at the Navigation System, it cannot be used for navigation and needs to be exchanged.

5. Modes of operation

The Cube Navigation System has three modes of operation that are automatically switched depending on the situation and user interaction.

- Navigation Mode (for navigation interaction)
- Fullscreen video mode
- Interaction mode (for software operation interaction)

5.1. Navigation mode

In this mode, the navigation information of the instrument is displayed in the image data. The mode is activated automatically when the instrument is being guided in the measurement field of the Navigation Sensor.



The status indicator turns green

The display is optimized for displaying navigation information. All software interaction buttons and the mouse cursor are blinded out. The navigation instrument has the focus.

5.2. Fullscreen video mode

This mode is configured in the applications (modules) offered by Fiagon that utilize a video signal of a medical video device (endoscope or microscope).

In this mode, the connected video signal is displayed in fullscreen on the display. The mode is activated when no navigation information is available for 3 seconds. That is when the navigation instrument is currently not used and is guided out of the measurement field of the navigation sensor



The status indicator is red

The user automatically gets the available video information in an optimized fullscreen display.

5.3. Interaction mode / mouse mode

In this mode, the user can interact with the functions of the navigation software by using the mouse. The mode can be activated at any time by clicking once on any of the mouse buttons.

With optional usage of the mouse: The interaction buttons and the mouse cursor are faded in. The mouse cursor has the focus and operation by the mouse is possible.

The interaction mode automatically returns to navigation mode or Fullscreen video mode after 5 seconds of inactivity (of the mouse).



NOTE: If you want to operate the system with the mouse (mouse-mode), click once to leave the fullscreen video mode or navigation mode and to display the cursor. You can operate the software now with the mouse. The system will exit automatically 5 seconds after you stopped using the mouse.

5.4. LED feedback

The Cube Navigation System gives the user real-time feedback about its status and the status of connected instruments and localizers via the LED feedback bar of the Navigation Unit Cube4D

The following table states the status of different lighting:

LED bar signal	Status
Off – no emitting	System powered off
Fading in and out green	<i>System is busy:</i> <ul style="list-style-type: none"> Software loading a dataset Software calculating registration
Solid green	<i>System is ready to be used:</i> <ul style="list-style-type: none"> Software startup completed Software finished loading dataset Software in Navigation Mode
Fading green-orange forth and back	<i>System is waiting for user interaction:</i> <ul style="list-style-type: none"> Touch landmarks/Take photo/Hold to start surface recording Connect mapper/camera Confirm registration/use registration-ready instrument
Fading in and out orange	<i>System warning:</i> <ul style="list-style-type: none"> Line feature is activated and the user gets close to the set line Localizer connected and distortion threshold reached or localizer out of the electromagnetic field
Solid orange	<i>System start:</i> <ul style="list-style-type: none"> System powered on and booting up Software starting Software in Mouse Mode Field generator is connected and turned off/ Default state if software does not start or if the software is closed
Solid red	<i>Issue detected:</i> <ul style="list-style-type: none"> Broken instrument or localizer is detected in Mouse Mode or Navigation Mode Instrument with 0 uses remaining detected

The LED instrument ports give feedback about the connected instrument. The following table states the status of different lighting:

LED instrument signal	Status
Off	Instrument disconnected or not recognized
Dim solid green	Instrument connected, recognized by the software, but non active instrument
Solid green	Instrument connected, recognized by the software, and current active instrument
Blinking red	Instrument/localizer connected, recognized by the software, but broken or instrument has zero uses remaining
Solid blue	Patient localizer connected, recognized by software, and in tracking field without distortion
Solid orange	Patient localizer detects distortion or out of tracking field.

i NOTE: If the software application is not running and you connect an instrument or localizer, then the LED is still off.

6. Screenshot and video recording

During the procedure, you can take screenshots and record video sequences for documentation of the operation. To take a screenshot, press the button “p” on the keyboard. Once the screenshots have been taken, you will hear a confirmation tone.

To record a video sequence, press the button “v” on the keyboard.

You will hear a confirmation tone. The video recording will be displayed by a green camera symbol in the status bar.



To stop the recording, press the button “v” on the keyboard once more.

You can export the documentation after the operation and save it on a USB stick.



USB ports



NOTE: Further information to export the documentation is described in the instructions for use of the navigation software.

7. After the operation

7.1. Disconnecting the components

After the operation, disconnect the instrument and the patient localizer from the Navigation Unit Cube4D. Do this by pulling the plug directly. Do not pull the cable or the kink protection. This might damage the cable.

Disconnect the navigation sensor from the navigation unit, as well.

7.2. Shutting down the system

After the operation, you can shut down the system by pressing the ON/OFF button on the Navigation Unit Cube4D.



The system will shut down automatically. Once the shut-down has been completed, you can pull the plug of the device tower. Do not pull the cable or the kink protection. This might damage the cable.

Turn the main switch of the Navigation Unit Cube4D to “Off Position” à O at the back.



8. Removal from service

For removing the Navigation System from service, shut down the system completely, and remove the main power cord. Complete isolation of the Navigation Unit Cube4D is achieved only by disconnecting the power connection from the power grid.

9. Cleaning and reconditioning

9.1. Cleaning the surface of the device and accessories

Navigation Unit Cube4D

Manual cleaning is recommended. Turn off the Navigation Unit Cube4D at the main switch and remove the power connection. Clean the whole surface of the Navigation Unit Cube4D with a dust-free soft cloth only if required. The cloth may be moistened with water and a mild, soap-based, non-corrosive cleaning agent. Prevent liquids from getting into the housing. For the disinfection of the surfaces, use an aldehyde-free quick-acting disinfectant that allows wiping disinfection. Apply the solution onto a soft cloth and wipe the entire surface of the housing.

Wait until the solution has dried off before switching on the Navigation Unit Cube4D.

VirtuLink and other extension cables

The components are suitable for manual cleaning and disinfection.

Material:

- CaviWipes™ (mid-level disinfectant wipe, aldehyde-free) or similar disinfectant wipes

Procedure:

1. Clean the outer surface, the cable and the plug with a disinfectant wipe, to remove debris and bacteria. Discard the used disinfectant wipe.
2. Disinfect all the components listed under 1. with a second new/unused disinfectant wipe. Leave the surface wet for around three (3) minutes. Discard the used disinfectant wipe.

Other Components of the Navigation System

For cleaning the headrest, navigation sensor, navigation instruments and the localizer refer to the cleaning instructions included in the corresponding instructions for use.



DANGER: Not qualified methods for cleaning and sterilization can damage cables and instruments.



WARNING: Never spray or pour cleaning solution or disinfectant directly onto the surface, because there is a risk that the cleaning agent comes into direct contact with the components within the device and causes irreparable damage of the electrical components.

9.2. Inspection Instructions

After cleaning, visually inspect the system under appropriate light conditions for remaining debris. Repeat cleaning procedures if required. Refer to the Instructions For Use of the components and accessories for the inspection recommendations related to the components and accessories.

10. Notes for maintenance and service

10.1. Maintenance

The Navigation Unit Cube4D does not require mandatory checks or calibration activities. However, national laws or hospital guidelines may require regular checks of devices connected to mains. These standard inspections can be carried out by instructed and qualified personnel for these kind of inspections.

General routine checks by the operator/user are described in next section.

Checking or Recalibrations of the navigation field generating and sensing electronics are not needed in order to keep the device safely over the service life. Unlikely failures or decalibration are recognized by Navigation System and Navigation Software.

The manufacturer, however, recommends and offers preventive maintenance activities, which shall ensure reliable functionality of the device over the service life and shall prevent hardware failures due to wear and tear. The maintenance is done by instructed personnel. Recommended maximum maintenance cycles are 2 year.

After the warranty period has ended, we ask you to take precautionary measures in consultation with your regional partner regarding the execution of the maintenance activities. Fiagon provides special service contracts for you.

All changes and/or repairs within the warranty period will be carried out exclusively by the manufacturer and distributor or by authorized third parties.

There are no hardware and software components inside the housing of the Navigation Unit Cube4D which must be maintained by the customer. Contact the manufacturer instantly if a problem with the Navigation System occurs to repair the system.

The expected service life of the Cube Navigation System is seven years if the recommended preventive maintenance cycles are done.



DANGER: The Navigation System must not be operated if maintenance activities and checks, required by applicable laws or other national guidelines are not carried out (e.g. regular electrical safety test).

DANGER: Maintenance work may only be carried out by instructed and qualified personnel.

DANGER: Make sure that all necessary safety measures are taken into account during maintenance work to prevent damage and injuries.



NOTE: The manufacturer recommends keeping a medical devices book for the repair and preventive maintenance work carried out. Take notes of relevant information regarding the type of work, the company that carried out the work, and other important information.

10.2. Routine checks

Check the connection cables and connectors of the system routinely for damages of any kind. If needed, ask for replacement parts.

Check the system components, housing and sockets routinely for external damages. If needed, ask for repair or maintenance.

Each time the system is used check for noticable visible or audible deviations from normal conditions during the operation of the system (e.g. abnormal noise of fans) Do not use the system until these deviations have been eliminated. If needed, ask for repair or maintenance.

10.3. Updates

Updates of this instruction manual will be published as soon as updated information or corrections are available.

When purchasing a new software version, the supplied instruction manual corresponds to this new version.



CAUTION: The device must not be used without a valid instruction manual.



NOTE: For information on current hardware and software products, please visit the manufacturer's website.

11. Preparation for disposal

If the device should be finally shut down at the end of its service life it is necessary to contact the manufacturer or the local representative of the company in your country to get the valid instructions needed for disposal of the device in compliance with the standards applying. If components of the device should be disposed it is also necessary to contact the manufacturer or the local representative of the company in your country to get the valid instructions needed for disposal of these components in compliance with the standards applying.

12. Technical description

12.1. Manufacturer

The manufacturer acts in compliance with international and national standards and laws. Information about the compliance can be provided on request. Please contact your regional consultant or contact Fiagon using the following contact details :

Fiagon GmbH
Neuendorfstr. 23b
16761 Hennigsdorf
Germany
Phone: +49 3302 201 21 10
Fax: +49 3302 201 21 15
<http://www.fiagon.com>

12.2. Technical data

Navigation Unit Cube4D

- Energy consumption: 600 VA
- Electric supply: 100 V-240 V AC, 50-60 Hz
- Classification according to MDD 93/42/EEC: Class I
- Protection class I, interface to applied part type BF

The device is not designed for use with or near inflammable or explosive gases.

The Cube Navigation System WiFi works in the 2,4 GHz frequency band according to the standards 802.11 ac/a/b/g/n with a transmission power of 100 mW maximum.

Navigation sensor

- Electromagnetic position measurement system

Operating conditions	Temperature: +15°C to + 35°C, Humidity: 30% to 75% without condensation Air pressure: 700 hPa to 1060 hPa
Transport conditions	Temperature: -10°C to + 50°C, Humidity: 10% to 90% without condensation Air pressure: 700 hPa to 1060 hPa
Storage conditions	Protected against dust, and moisture. It is recommended to store at ambient conditions. Limits: Storage temperature: -10° to +50°C Storage humidity: 10% to 90% without condensation Storage air pressure: 700 hPa to 1060 hPa



WARNING: If the Navigation System is transported indoors after outdoor placement, wait two hours before use. Otherwise, condensed water on the components could compromise the proper functioning of the system.

Essential Performance

- Positioning accuracy on anatomical phantom (including registration process, mean value < 1,5 mm)
- Distortion detection method. Field distortions are detected. (95% confidence interval is < 2mm)

13. EMC compliance statement

The Cube Navigation System needs special precautions regarding EMC and needs to be brought into service according to the following described EMC information.

Electromagnetic emission		
The Cube Navigation System is intended for use in the electromagnetic environment specified below. The customer or the user of the system should assure that it is used in such an environment.		
Emission Test	Compliance	Electromagnetic Environment Guidance
RF-emissions following IEC/CISPR 11	Group 1	The Cube Navigation System uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF-emissions following IEC/CISPR 11	Class A	The Cube Navigation System is suitable for use in all establishments other than domestic.
Generation of mains harmonics following IEC 61000-3-2	Class A	
Generation of voltage Fluctuations/ flicker following IEC 61000-3-3	Complies	

i **NOTE:** The EMISSIONS characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 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.

Electromagnetic immunity

The Cube Navigation System is intended for use in the electromagnetic environment specified below. The customer or the user of the Cube Navigation System should assure that it is used in such an environment.

Immunity Test	EN 60601-1-2 Test Level	Compliance Level	Electromagnetic Environment Guidance
ESD IEC 61000-4-2	+/- 6 kV cd +/- 8 kV ad +/- 15 kV ad	+/- 6 kV cd +/- 8 kV ad +/- 15 kV ad	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Burst IEC 61000-4-4	+/- 2 kV mains +/- 1 kV I/O	+/- 2 kV mains +/- 1 kV I/O	Mains power quality should be that of a typical commercial or hospital environment.
Surges IEC 61000-4-5	+/- 1 kV dm +/- 2 kV cm	+/- 1 kV dm +/- 2 kV cm	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines, EN 61000-4-11	Reduction to: 0 % U_T for 0,5 cycles 0 % U_T for 1 cycle 70 % U_T for 25 cycles (50Hz) 30 cycles (60Hz) 0 % U_T for 250 cycles (50Hz) 300 cycles (60Hz)	Reduction to: 0 % U_T for 0,5 cycles 0 % U_T for 1 cycle 70 % U_T for 25 cycles (50Hz) 30 cycles (60Hz) 0 % U_T for 250 cycles (50Hz) 300 cycles (60Hz)	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Cube Navigation System requires continued operation during power mains interruptions, it is recommended that the Cube Navigation System be powered from an uninterruptible power supply.
Power frequency (50/60 Hz) Magnetic field, EN 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

U_T is the a.c. mains voltage before application of the test level.

Electromagnetic immunity

The Cube Navigation System is intended for use in the electromagnetic environment specified below. The customer or the user of the Cube Navigation System should assure that it is used in such an environment.

Immunity Test	IEC 60601-1-2 Test Level	Compliance Level Level	Electromagnetic Environment Guidance
Conducted RF, 61000-4-6	3 V _{rms} 150 kHz to 80 MHz	3 V	<p>Portable and mobile RF communications equipment should be used no closer to any part of the system, including cables, than the recommended separation distance calculated from the equation appropriate for the frequency of the transmitter.</p> <p>Recommended Separation Distance</p> $d=1,2\sqrt{P}$ $d=1,2\sqrt{P} \text{ 80 MHz to 800 MHz}$ $d=2,3\sqrt{P} \text{ 800 MHz to 2,7 GHz}$ <p>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).</p> <p>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey^a should be less than the compliance level in each frequency range^b.</p> <p>Interference may occur in the vicinity of equipment marked with this symbol. ((⦿)) ▲</p>
Radiated RF IEC 61000-4-3	3 V/m 80 MHz bis 2,7 GHz	3 V/m	

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

^b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m. These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

Recommended separation distances between portable and mobile RF communications equipment and the Cube Navigation System

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

Rated maximum output power of transmitter W	Separation distance according to the frequency of the transmitter m		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	80 MHz to 800 MHz $d = 1.2\sqrt{P}$	800 MHz to 2,7 GHz $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

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

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

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

The magnetic field strength at a distance of 0,5m to the field generator is 1A/m.



WARNING: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the [ME EQUIPMENT or ME SYSTEM], including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

The Cube Navigation System should only be connected with its components and cables as listed in the table in section 3 – 'Bringing into service' to comply with the standards mentioned above.



WARNING: The use of accessories and cables other than those specified above, may result in increased emissions or decrease the immunity of the system.

14. Appendix-Compatible devices and materials

Imaging systems

The navigation software can import DICOM 3.0 standard image data. This standard is supported by all devices of manufacturers that are relevant in the market. Therefore, the software should be compatible with all CT scanners and DVTs (digital volume tomography).

The list of compatible devices includes devices by the following manufacturers:

Philips, Siemens, GE, Kodak, Morita, Xoran

Contact a service representative if you plan to use a different device.

Before using the Cube Navigation System for the first time in clinical routine, it is necessary to check its compatibility with the CT scanner or DVT. If problems arise regarding the loading process of image data sets, please contact your service representative.



CAUTION: Only connect items/devices that have been specified as part of the Cube Navigation System or specified as being compatible with the Cube Navigation System.

Monitors

The navigation module can only be connected to medical monitors that are:

- Approved according to IEC 60601-1
- Equipped with either DVI, DisplayPort or HDMI signal-in port

Medical video systems

The navigation module can only be connected to medical video systems (e.g. endoscopic camera module) that are:

- Approved according to IEC 60601-1

For HD model of Navigation Unit Cube4D

- Equipped with DVI output
or
- Equipped with composite video output

For 4K models of Navigation Unit Cube4D

- Equipped with SDI output (4x 3G or 1x 12G)

