# Instructions for Use

## Fiagon Cube Navigation System

**Product:**

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

**Manufacturer:**

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Component/ Model
Navigation Unit Cube$^{4D}$

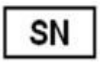
E 01 1106-HD/8 (HD, 8 sensor channels)
E 01 1106-4K/8 (4K, 8 sensor channels)
E 01 1106-HD/4 (HD, 4 sensor channels)

**Content**

## Explanation of Symbols


Manufacturer / Manufacturing date

Reference number / Order number



Serial number


To ensure safety, follow the instructions for use


Marking of conformity to the European Medical Device Directive 93/42/EEC (MDD).

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.


Caution: Consult instructions for use. Follow the supporting documentation

Recommended storage temperature +15°C to +35°C


Applied part type BF


This is the general warning sign. It is used to alert the user to potential hazards. All safety messages that follow this sign shall be obeyed to avoid possible harm

The device is delivered non-sterile


Devices that include RF transmitters or that apply RF electromagnetic energy for diagnosis or treatment. Portable and mobile RF communications equipment can affect the performance of the device. Interference may occur in the vicinity of equipment marked with this symbol.


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.


Consult instructions for use

# 1. General information

The Fiagon 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.

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

## 1.1. Intended use

The Fiagon 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.

**Suitable Environment**

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

## 1.2. Indications for use

The Fiagon 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 can be identified relative to a CT or MR based model of the anatomy.

Specific indications for use related to different fields and procedural examples are given in the instructions for use of the application specific navigation software models.

**CAUTION:** The information provided by the navigation system is intended to support the surgeon. Nevertheless, the 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.

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

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

**Patient groups**

The Fiagon Cube Navigation System can be used on all patients independent e.g. from age, sex, weight, excluding persons with monopolar pacemakers or with implantable body-worn devices such as insulin pumps.

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

**WARNING:** 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 at patients with monopolar pacemakers (older designs, with lower resistance to interference) or ICD's (implantable cardioverter defibrillator).

The system should not be used in patients with implantable, body worn devices such as insulin pumps.

The navigation system may only be used with the components and accessories that the manufacturer indicates as suitable.

The navigation system may only be used with Fiagon Navigation software and accessories that the manufacturer indicates as compatible with the system.

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

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

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

### 1.4. Description of the Fiagon Cube Navigation System

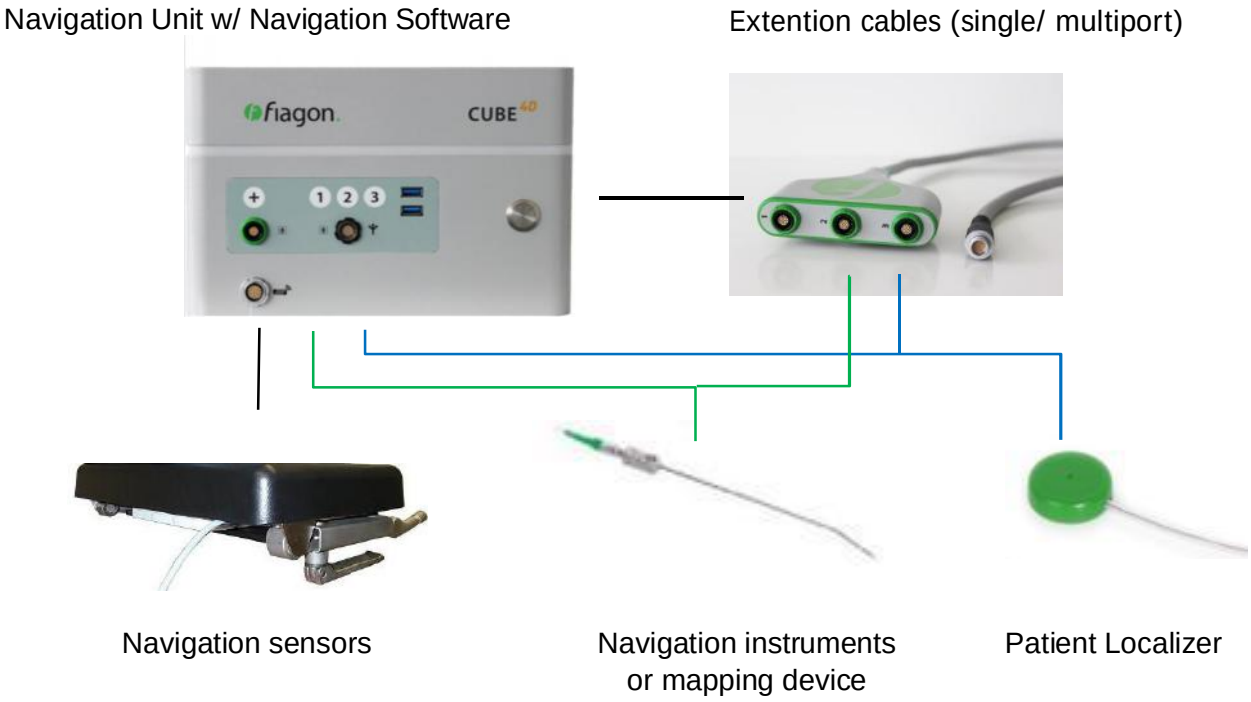
The navigation system allows the tracking and navigation of surgical instruments during surgical procedures using stereotactic techniques. The location and movement information are displayed in preoperative radiological image data (CT, DVT, MRI) of the patient.

The Fiagon Cube Navigation System consists of the components Navigation Unit Cube4D with the Fiagon 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 Fiagon software modules within defined application-related specifications and displays calculated position and/or navigation information (image based and model based).

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

### 1.4.1. Overview of the system components




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.

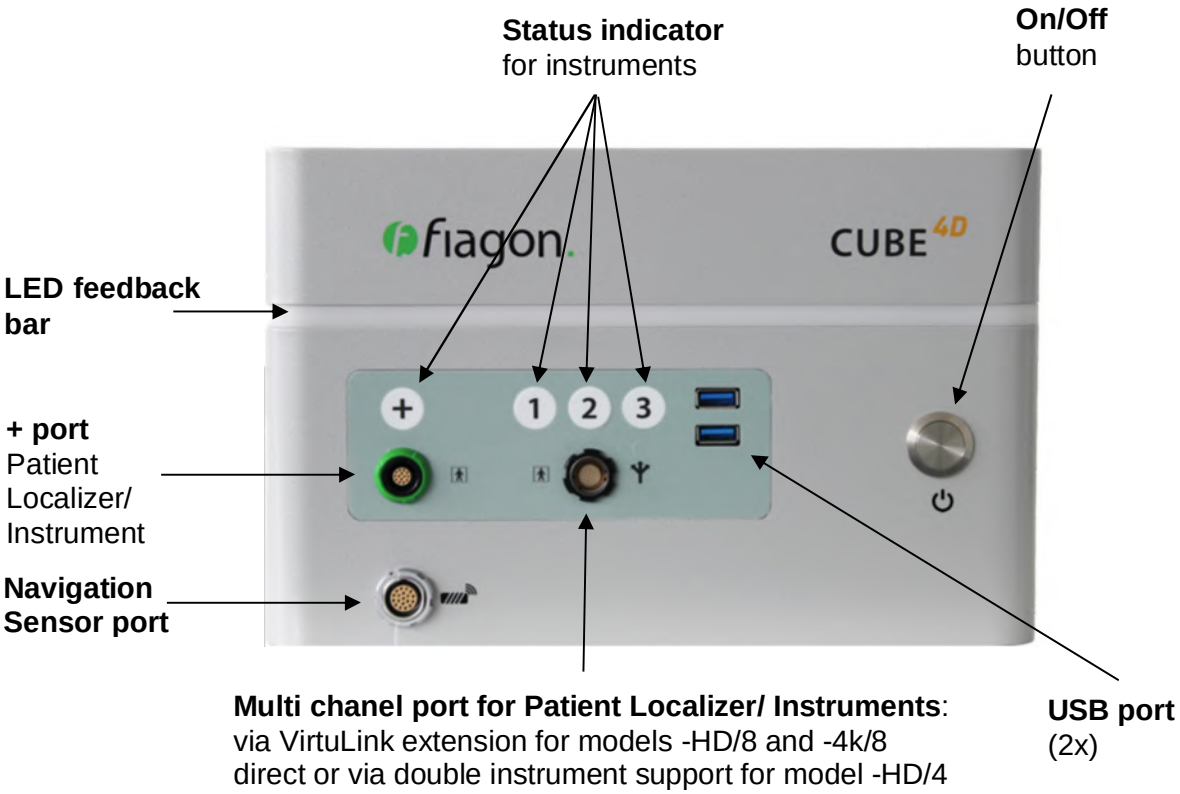
### 1.4.2. Navigation Unit Cube$^{4D}$ models:

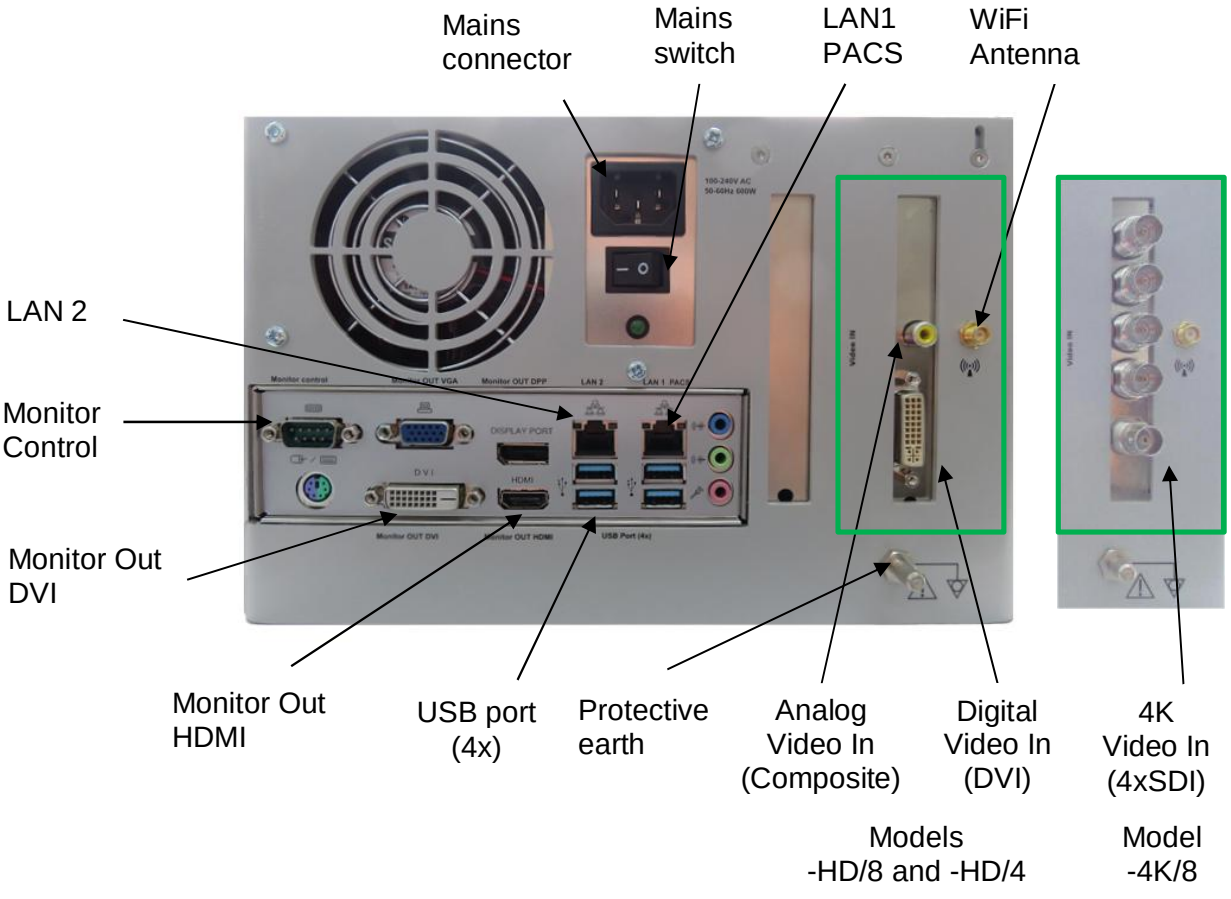
The Navigation Unit Cube$^{4D}$ is available in three models which differ in Video input (HD or 4K) and amount of sensor channel (4 or 8). The following table gives an overview of the models.

| Model / reference# | Video In specifications | Sensor Channel specifications |
|---|---|---|
| E 01 1106 -HD/8 | Digital Video Input up to HD 1080p, up to 60Hz<br>Analog Video Input PAL or NTSC | 8 sensor channels available for connection of up to 4 Instuments (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 Instuments (via VirtuLink and + port) |
| E 01 1106 -HD/4 | Digital Video Input up to HD 1080p<br>Analog Video Input PAL or NTSC | 4 sensor channels available for connection of up to 2 Instuments |

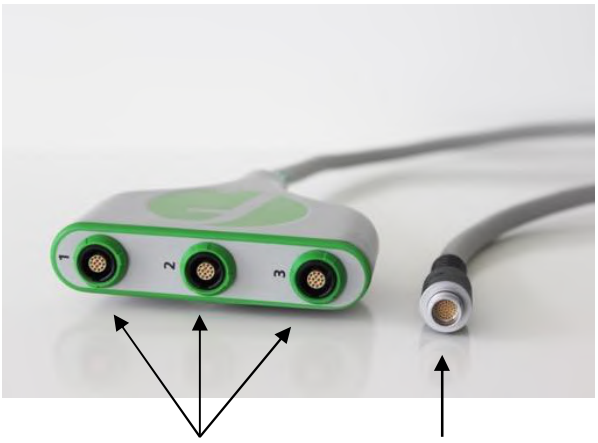
### 1.4.3. Description of interfaces and controls

**Navigation Unit**



**Cube VirtuLink - multiport extention cable**
(included in 8 sensor channel models -HD/8 and 4K/8)




Patient Localizer/ Instrument connector (3x)

Connector to Navigation unit multi channel port

### 1.5. Qualification of the user

The Navigation System may only be used by healthcare professionals (physicians). Also, the users receive training that has been authorized by the manufacturer and distributor before using the system safely and efficiently on the patient. The operator, i.e., the person or facility that is responsible for the use and service of the Navigation System, must ensure that all users of the Navigation System receive an adequate introduction into the Navigation System per valid laws and regulations. An operator is everyone who is using the Navigation System.

**NOTE:** 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 medical or clinical reasons contraindicate its use.

**CAUTION:** Do not use the Navigation System if you have not received appropriate training for the safe and efficient use of the Navigation System.

### 1.6. Patient Data Protection

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

**NOTE:** To protect sensitive healthcare information, Fiagon strongly recommends applying a password to operate the Navigation System.

### 1.7. Cyber and information security

Fiagon strongly recommends to use anti-virus software and to keep the firewall settings of the Operating system (Windows 10 professional) active (delivery settings). We recommend the use of the software Avira Antivirus Premium 2013 (Avira Operations GmbH & Co. KG, Germany, www.avira.com).

During installation of the Navigation System at your facility by Fiagon's authorized personnel, we will inform about the possibilities of security. The bringing into service routine includes the installation of the anti-virus software along with the information updating it.

# 2. Safety notes

## 2.1. Safety notes in this manual

**WARNING:** 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 Navigation System setup is altered by a person, not authorized to do so, this may result in increased electromagnetic radiation or reduced interference resistance of the Navigation System.

**DANGER:** The Navigation System is connected to the protective earth via the power plug. Make sure that the Navigation 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 Navigation System in rooms that comply with applicable laws and regulations regarding the safety of electrical systems.

**DANGER:** The Navigation 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 Navigation System.

**DANGER:** Do not open the Navigation 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 Navigation System.

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

**CAUTION:** Devices emitting electromagnetic radiation to a high degree can influence the proper operation of the Navigation System. Turn off cellular phones and similar devices.

**CAUTION:** Prevent liquids such as water, cleaning agents, and disinfection spray from getting into the interior of the Navigation System.

**CAUTION:** Do not use the Navigation System if it cannot be ensured that all routine checks have been completed successfully 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.

**CAUTION:** Only operate the Navigation System with the voltage indicated on the rating plate.

**NOTE:** During cleaning, the Navigation System must be turned off and disconnected from the power supply.

## 2.3. Safety measures at the installation location

The Navigation Unit Cube[4D] is suitable for a professional healthcare environment.

The Navigation System may only be used in medical environments that are installed 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.

Take care that the main power cord can be unplugged easily and that the ventilation slots at the rear and bottom side (Navigation Unit Cube[4D]) 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 Cube[4D], 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.

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 Fiagon Navigation sales or service representative immediately.

## 2.4. Safety measure when using the system

Prior to its use, the user must check the functionality and the proper condition of the Navigation System.

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

If you notice visible or audible deviations from normal conditions during the operation of the system, do not use the Navigation 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 Fiagon approved devices to the USB interface.

**CAUTION:** The Network connection must be unplugged from the Fiagon Navigation System during surgery.

**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.

**WARNING:** Do not unplug mains cable during surgery.

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

## 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 Fiagon Service.

**If EM disturbances occur:**

The Fiagon 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, 3.3 feet)
- Diathermy devices
- Security systems such as metal detectors
- Other image-guided surgery systems with EM tracking technology

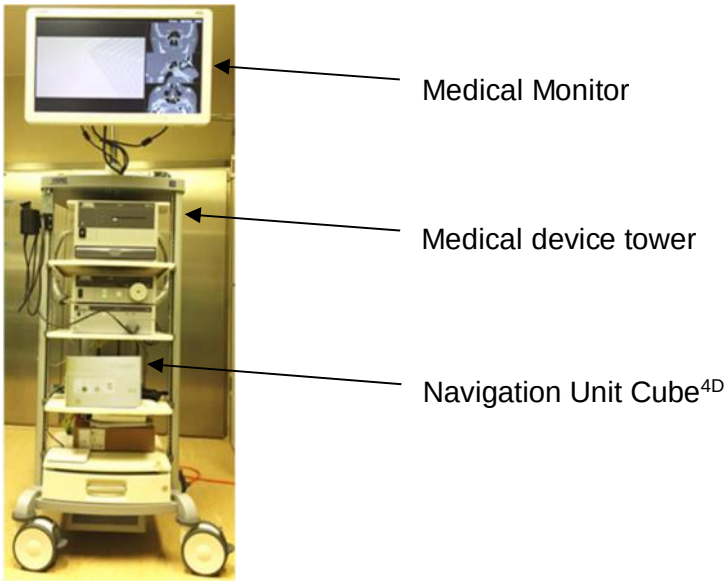
In adjacent rooms:
- MR scanner

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.

## 3. Bringing into service

The installation in the OR, the tower as well as the connection to the monitor and video source are subject to the initial installation. Consult the Fiagon service or refer to the guide “bringing into service after transport”.




Examplified setup on endoscopy tower

### Connection to Potential equalization

Since the housing of the Navigation Unit Cube$^{4D}$ 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 Cube[4D] should only be connected and brought into service with the following cables:

| Interface / port | Cable Type | Max. length | Fiagon 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 |
| Digital Video In | DVI – D, shielded | 2 m | A 00 9201 | For models with HD video in (-HD/8 and -HD/4) |
| 4K Video In | 4x 3G-SDI (coaxial, shielded) | 4 x 2 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 and -HD/4) |
| Monitor Control | RS 232 | 2 m | A 00 9201 | - |
| USB backside | USB – Mouse<br>USB – Service keyboard | 2 m | A 00 9101<br>A 00 9102 | - |
| +port | Extension cable instrument / instrument or patient localizer | 2 m | A 00 1200 | all Fiagon 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)<br>all Fiagon navigation instruments, all C-Type Localizer can be connected. |
| Multi channel port | Double instrument support | 2 m | A 01 1203 | For models with 8 sensor channel (-HD/4)<br>all Fiagon 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 | - |
| | Power Supply Cord Hospital Grade (UL Approved according to UL 817) | 3 m | A 21 9201 | - |

**WARNING:** The cables and accessories provided by Fiagon should only be used in connection with the Navigation Unit Cube[4D]. Other than those specified may result in increased emissions or decreased immunity of the Navigation Unit Cube[4D].

# 4. Set up system

## 4.1. Preparation

1. Place the device tower with the Navigation Unit Cube$^{4D}$ at its usual position, e.g. across from the surgeon.
2. Make sure the mains cable of the Navigation Unit Cube$^{4D}$ is plugged in correctly.

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

**NOTE:** The main switch of the Navigation Unit Cube$^{4D}$ 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 headrest with the Navigation Sensor to the operating table. Place the shaft of the headrest into the appropriate holding fixture of the operating table and lock the headrest.

*Type Navigation headrest Maquet*

*Type Navigation headrest Flat*

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

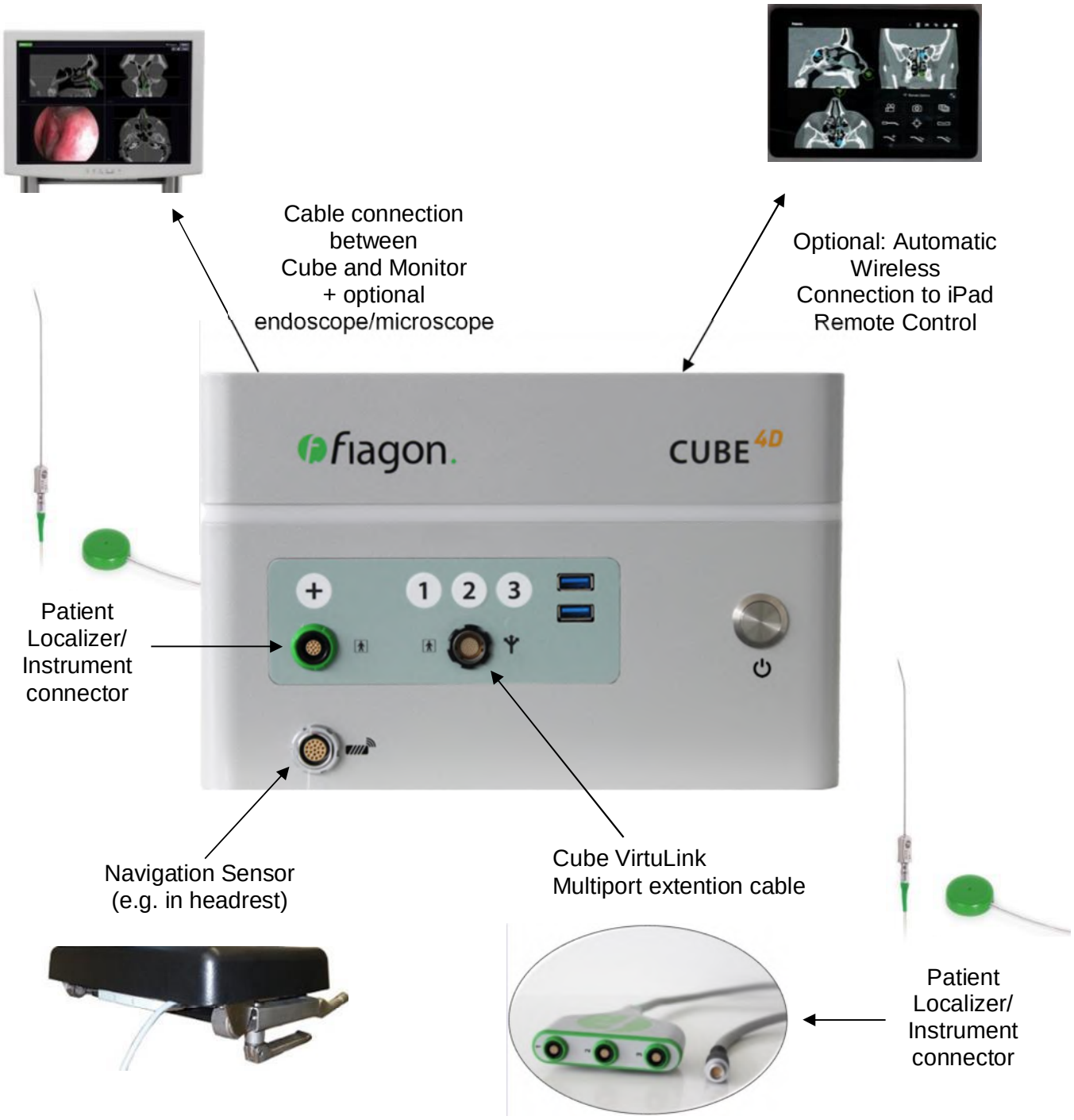
**NOTE:** Use a head positioning cushion or ring on the headrest to support the head of the patient.

### 4.2. Starting the system

Make sure the main switch of the Navigation Unit Cube[4D] 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 Fiagon 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.

| *status indicator of patient localizer* | *status indicator of instrument* |
|---|---|
|  |  |

Insert the plug of VirtuLink extention cable into the appropriate socket small metal socket) on the Navigation Unit Cube[4D]. 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 Cube[4D]/ Cube VirtuLink. Note that the white marking at the Navigation Unit Cube[4D] plug is at 12 o'clock position.


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

This socket is suitable to connect Fiagon 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 Cube[4D]/ Cube VirtuLink. Note that the white marking at the Navigation Unit Cube[4D] plug is at 12 o'clock position.


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

This socket is suitable to connect to all Fiagon Instruments (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*

**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.

**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 Fiagon 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 Fiagon 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 Cube[4D]

The following table states the status of different lighting:

| LED bar signal | Status |
|---|---|
| Off – no emitting | System powered off |
| Fading in and out green | *System is busy:*<br>Software loading a dataset<br>Software calculating registration |
| Solid green | *System is ready to be used:*<br>· Software startup completed<br>· Software finished loading dataset<br>· Software in Navigation Mode |
| Fading green-orange forth and back | *System is waiting for user interaction:*<br>· Touch landmarks/Take photo/Hold to start surface recording<br>· Connect mapper/camera<br>· Confirm registration/use registration-ready instrument |
| Fading in and out orange | *System warning:*<br>· Line feature is activated and the user gets close to the set line<br>· Localizer connected and distortion threshold reached or localizer out of the electromagnetic field |
| Solid orange | *System start:*<br>· System powered on and booting up<br>· Software starting<br>· Software in Mouse Mode<br>· Field generator is connected and turned off/<br>· Default state if software does not start or if the software is closed |
| Solid red | *Issue detected:*<br>· Broken instrument or localizer is detected in Mouse Mode or Navigation Mode<br>· 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. |

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 Cube[4D]. 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 Cube[4D].

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 Cube[4D] 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 Cube[4D] is achieved only by disconnecting the power connection from the power grid.

## 9. Cleaning and reconditioning

### 9.1. Cleaning the surface of the device

Manual cleaning is recommended. Turn off the Navigation Unit Cube[4D] at the main switch and remove the power connection. Clean the whole surface of the Navigation Unit Cube[4D] 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 Cube[4D].

For cleaning the components and accessories (headrest, surgical instruments and the localizer), refer to the cleaning recommendations included in the corresponding instructions for use.

**CAUTION:** Never spray or pour cleaning agent 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 to the electrical components. Spilling liquids on any electrical device attached to the system should warrant inspection by an authorized Fiagon service representative.

### 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

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 Navigation Unit Cube4D requires regular maintenance by the manufacturer and general routine checks by the operator/user. The control involves performing safety tests and is required with a period of 12 months by the manufacturer unless it is otherwise provided. These maintenance activities are necessary to allow for safe and reliable use of the system.

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 special instructions for maintaining Basic safety and essential performance regarding electromagnetic disturbances.

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

Even if the operator does not execute the maintenance activities, he is responsible that all necessary maintenance work has been carried out before using the Navigation System on a patient.

**DANGER:** The Navigation System must not be operated if maintenance activities and checks are not regularly carried out in compliance with the requirements and guidelines of applicable laws.

**WARNING:** Maintenance work may only be carried out by qualified and authorized personnel**.**

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

**NOTE:** Fiagon recommends keeping a medical devices book for the repair and 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

Each time before using the device, check that the necessary maintenance work has been carried out (medical devices book).

Check the system for functionality before using it.

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

Check the system components for external damages.

## 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 Navigation System must not be used without a valid instruction manual. The instruction manual corresponds to this new version.

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

## 11. Preparation for disposal

If the device should be finally shut down at the end of its lifetime 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. Conformity

The Navigation System was found to be in compliance with the European Medical device directive and has been affixed with the CE marking. Therefore, it is compliant with the following directive:

MDD 93/42/EEC

CE

### 12.2. 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
Neuendorfstrasse 23b
16761 Hennigsdorf
Germany
Phone: +49 3302 201 21 10
Fax: +49 3302 201 21 15
http://www.Fiagon.com

### 12.3. Technical data

Navigation Unit Cube[4D]

- 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 Fiagon 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,<br>Humidity: 30% to 75% without condensation<br>Air pressure: 700 hPa to 1060 hPa |
| Transport conditions | Temperature: -10°C to + 35°C,<br>Humidity: 30% to 75% without condensation<br>Air pressure: 700 hPa to 1060 hPa |
| Storage conditions | Protected against dust, and moisture.<br>Recommended storage temperature: +15° to +35°C<br>Recommended storage humidity: 30% to 75% without condensation<br>Recommended 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 technical phantom (including registration process, mean value < 1,5 mm)
- Distortion detection method. Field distortions are detected. (95% confidence interval is < 2mm)
- Clinical total accuracy on anatomic preparation (mean value < 2 mm)

## 13. EMC compliance statement

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

| Electromagnetic emission<br>The Fiagon 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 Fiagon 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 B | The Fiagon Cube Navigation System is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes. |
| Generation of mains harmonics following IEC 61000-3-2 | Class A | |
| Generation of voltage Fluctuations/ flicker following IEC 61000-3-3 | Complies | |

| **Electromagnetic immunity**<br>The Fiagon Cube Navigation System is intended for use in the electromagnetic environment specified below. The customer or the user of the Fiagon 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<br>+/- 8 kV ad<br>+/- 15 kV ad | +/- 6 kV cd<br>+/- 8 kV ad<br>+/- 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<br>IEC 61000-4-4 | +/- 2 kV mains<br>+/- 1 kV I/O | +/- 2 kV mains<br>+/- 1 kV I/O | Mains power quality should be that of a typical commercial or hospital environment. |
| Surges<br>IEC 61000-4-5 | +/- 1 kV dm<br>+/- 2 kV cm | +/- 1 kV dm<br>+/- 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,<br>EN 61000-4-11 | Reduction to:<br>0 % $U_T$ for 0,5 cycles<br><br>0 % $U_T$ for 1 cycle<br><br>70 % $U_T$ for 25 cycles (50Hz)<br>30 cycles (60Hz)<br><br>0 % $U_T$ for 250 cycles (50Hz)<br>300 cycles (60Hz) | Reduction to:<br>0 % $U_T$ for 0,5 cycles<br><br>0 % $U_T$ for 1 cycle<br><br>70 % $U_T$ for 25 cycles (50Hz)<br>30 cycles (60Hz)<br><br>0 % $U_T$ for 250 cycles (50Hz)<br>300 cycles (60Hz) | Mains power quality should be that of a typical commercial or hospital environment.<br><br>If the user of the Fiagon Cube Navigation System requires continued operation during power mains interruptions, it is recommended that the Fiagon Cube Navigation System be powered from an uninterruptible power supply or battery. |
| Power frequency (50/60 Hz)<br>Magnetic field,<br>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 Fiagon Cube Navigation System is intended for use in the electromagnetic environment specified below. The customer or the user of the Fiagon 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 to80 MHz | 3 V | 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.<br><br>Recommended Separation Distance<br><br>$d=1,2\sqrt{P}$<br><br>$d=1,2\sqrt{P}$ 80 MHz to 800 MHz<br>$d=2,3\sqrt{P}$ f800 MHz to 2,7 GHz<br><br>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).<br><br>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].<br><br>Interference may occur in the vicinity of equipment marked with this symbol.  |
| 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 Fiagon Cube Navigation System is used exceeds the applicable RF compliance level above, the Fiagon 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 Fiagon 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 Fiagon Cube Navigation System | | | |
|---|---|---|---|
| The Fiagon 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 Fiagon Cube Navigation System can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Fiagon 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.<br><br>NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.<br>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 Fiagon Cube Navigation System Cube 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 Fiagon 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 Fiagon 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.

⚠ **Warning:** Only connect items/devices that have been specified as part of the Fiagon Cube Navigation System or specified as being compatible with the Fiagon 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 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 models of Navigation Unit Cube[4D]

- Equipped with DVI output
- Equipped with composite video output

For 4K models of Navigation Unit Cube[4D]

- Equipped with SDI output