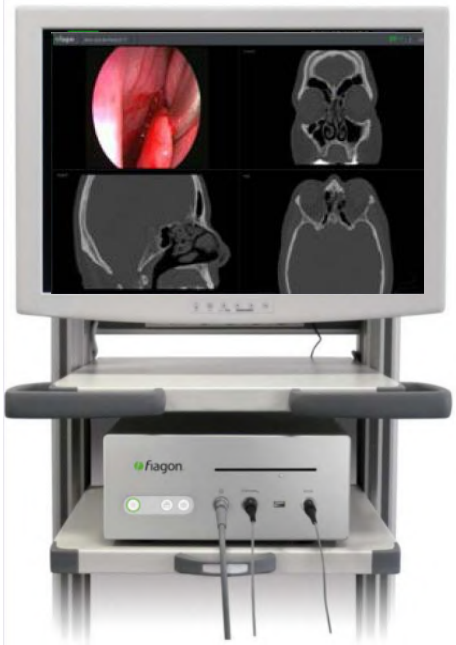
Instructions for Use

Fiagon Navigation System



Product:

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

Manufacturer:

Fiagon GmbH
Neuendorfstraße 23b
D -16761 Hennigsdorf
Germany

Telephone: +49 3302 20121 10
Fax: +49 3302 20121 15

info@fiagon.de

Rx

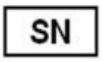
CE

Explanation of Symbols


Manufacturer


Date of manufacture

Reference number/Order number



Batch number


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.


Attention, follow the supporting documentation

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


Applied part type B


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 order of a physician.

1. General information

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

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

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 Navigation System consists of the Navigation unit with the Fiagon Navigation software, the navigation sensor (position measurement device – integrated in e.g. headrest) a patient reference localizer and instruments.

The Fiagon Navigation unit 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 selection of a suitable localizer, sensor and instruments type for each procedure.

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 instrument. Keep the instruction manual close to the device so you can use it at any time.

CAUTION: U.S. Federal law restricts this device to sale by or on the order of a physician.

Indented use

This system is intended for use by healthcare professionals only.

The Fiagon Navigation System is 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) of the patient, thereby, giving aid for positioning other instruments for the ongoing procedure.

Indications for use

The Fiagon Navigation System is intended as an aid for precisely locating anatomical structures in either open or percutaneous procedures. The Fiagon 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;

Transphenoidal access procedures. Intranasal procedures.

Sinus procedures, such as Maxillary antrostomies, Ethmoidectomies, Sphenoidotomies/Sphenoid explorations, Turbinate resections, and Frontal sinusotomies.

ENT related anterior skull base procedures

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 described in the respective indications for use of the navigation software 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.

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.

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.

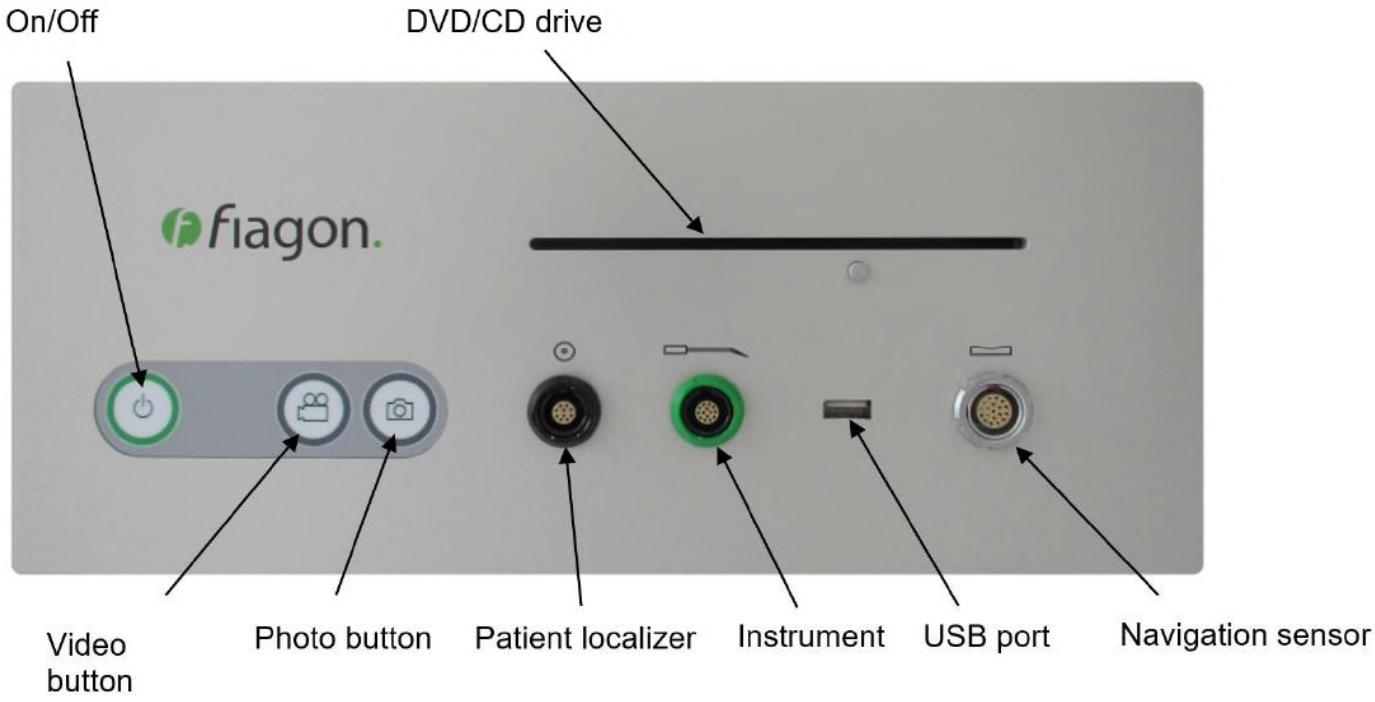
The unauthorized installation of software and modifications or alterations of the device are not permitted due to safety reasons.

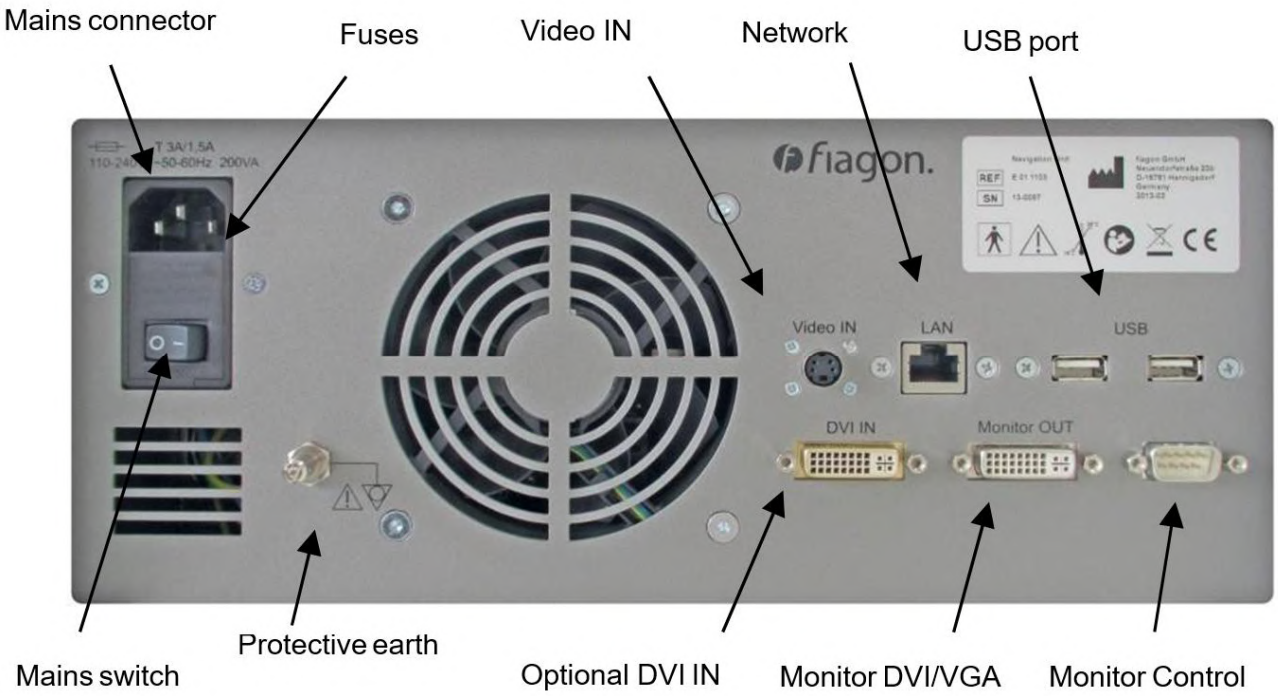
Do not use the system if medical or clinical reasons contraindicate its use.

MR UNSAFE: The system must not be used in a Magnetic Resonance Environment. The MRI exposure might lead to a misleading navigation information and it contains ferromagnetic parts and poses a clear threat to persons and equipment in the magnetic room

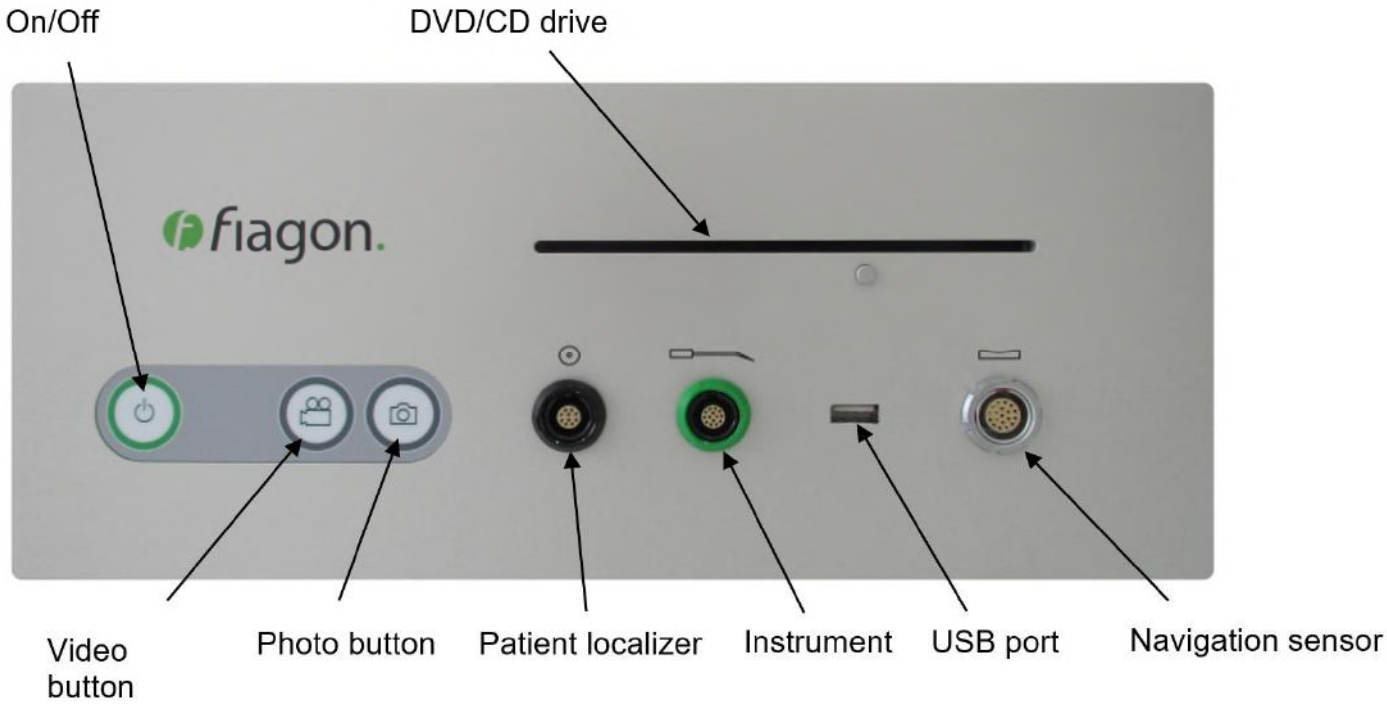
Description of the navigation unit

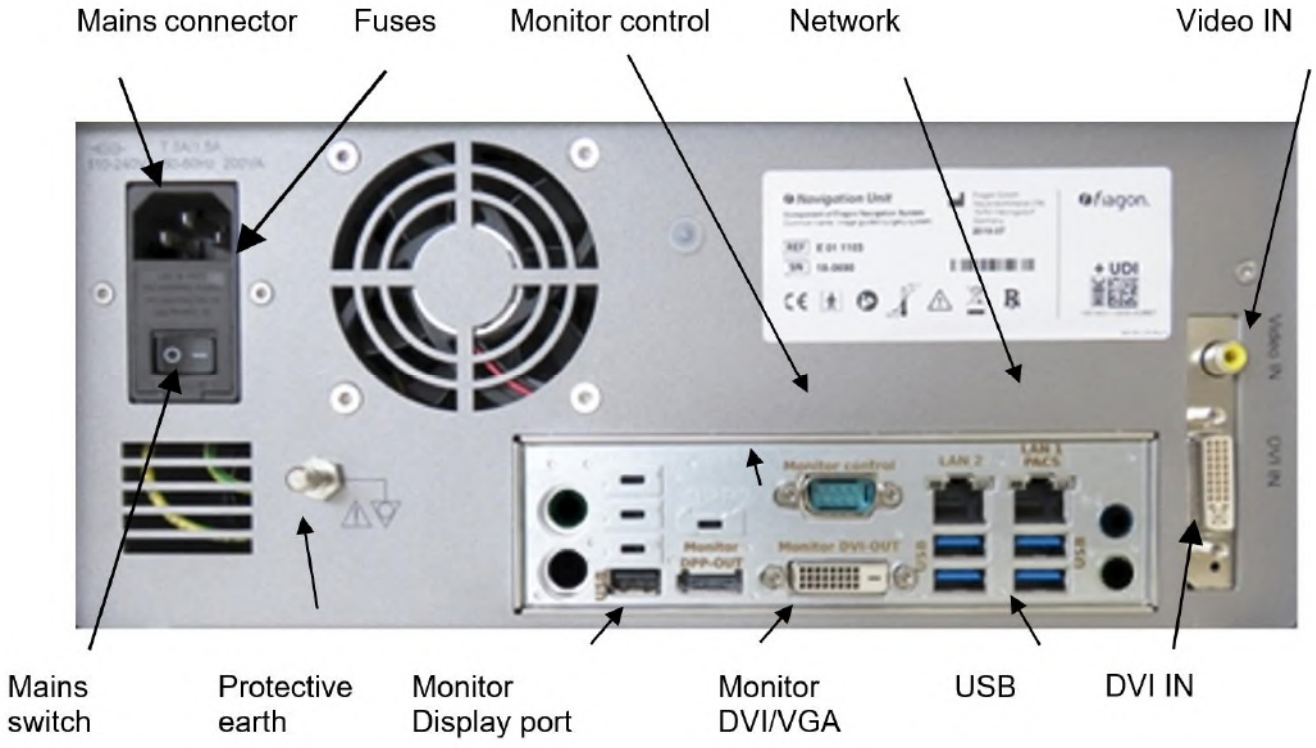
1. **Navigation units (product code E 01 1103) with serial no. before 18-0700**





2. Navigation units (product code E 01 1103) with serial no. starting from 18-0700





Qualification of the user

The navigation system may only be used by healthcare professionals (physicians). In addition 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 system, must ensure that all users of the system receive an adequate introduction into the system in accordance with valid laws and regulations. An operator is everyone who is using the system.

Note: 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.

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

CAUTION: Do not use the system if you have not received an appropriate training for the safe and efficient use of the system.

Patient data protection

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

NOTE: To protect sensitive healthcare information, Fiagon strongly recommends requiring a password to operate the system.

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 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

Safety notes in this manual

WARNING: Read this manual carefully and follow the instructions before operating the Fiagon 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 a safe use of the system. For better emphasis, these notes are accompanied by the warning sign pictogram.

In addition, this manual includes notes for an efficient use of the system. These notes are also accompanied by the information pictogram. Read these notes carefully.

General safety notes

All Fiagon products have been developed and manufactured in compliance with strict safety standards. Nevertheless, a 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 risks 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 an increased electromagnetic radiation or 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 system in rooms that are in compliance with applicable laws and regulations regarding the safety of electrical systems.

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.

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 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 system.

CAUTION: 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.

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

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

Safety measures at the installation location

- The navigation system may only be used in medical environments that are installed in compliance with nationally applicable regulations.
- **MR UNSAFE:** The system must not be used in a Magnetic Resonance Environment. The MRI exposure might lead to misleading navigation information.
- The system is not designed for the use in potentially explosive atmospheres. When using the 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 system may only be operated when connected to an outlet with protective conductor contact and when using the appropriate plug.
- Take care that the mains power cord can be unplugged easily and that the ventilation slots at the rear and bottom side of the enclosure stay clear. The navigation module has to be set up accordingly.
- 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 60601-1:2005, 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 system complies with the requirements of the system standard 60601-1:2005 Clause 16
- Prior to each use, the system should be checked for loose components and damage. DO NOT use if these conditions exist. If service is required, contact your Fiagon Navigation sales representative immediately.
- Use of an uninterrupted power supply (UPS) to the device is mandatory to ensure the device remains on during voltage dips and unintended interruptions for interventions that do not allow for delays in the procedure or absence of image guidance. See section 3 – Bringing into service for details. Otherwhile, there is the risk of an unintended power shutdown which causes a delay of the procedure (80 s) and in some cases loss of navigation information for the remainder of the procedure

Safety measures when using the system

- Prior to its use, the user must check the functionality and the proper condition of the system.
- A treatment may only be carried out if the appropriate use of the system can be ensured.
- 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.
- In order to avoid the danger of electrostatic charging of the housing, the Navigation Unit is equipped with a potential equalization conductor in accordance with IEC 60601-1

WARNING: Connecting the system to the network or with other devices via data coupling may result in compromising the essential performance of the system caused by e.g. viruses, data loss, corrupt files, unauthorized access. Data couplings of the system are the USB interface and the CD/DVD drive.

Before connecting the system to network or data coupling, identify, analyze evaluate and control the resulting risk.

Do not connect equipment other than storage media to the USB interface.

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

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. The device is not intended to use wireless technology and the installation of external wireless devices connected to the system is disabled for all user logins to prevent unauthorized usage.

Electromagnetic interference

The navigation unit and its applied parts comply with the international standard IEC 60601-1-2: 2007.

Risks associated with electromagnetic interference are related to

- electromagnetic environment the system is operated.

  To mitigate risks occurring from inappropriate environments the user of the system should assure that it is used in an environment that is described in the section 12 – EMC statement.

- Electrical equipment used in the direct vicinity or within the measuring field of the navigation system/ navigation sensor.

  Please refer to the next section – Electromagnetic navigation to get information about identifying interferences and ways to mitigate the risk of loss of navigation information due to interference detection of the system.

- Voltage dips (Dip>95% over 5s duration) from the mains supply, may lead to a power loss of the unit. The unit and navigation software will restart automatically on return of the voltage to nominal level. After approx. 40 seconds the unit is back to operation. The registration of the patient will be restored on reloading the patient. Please refer to section - Troubleshooting – unintended power shut down for details for mitigation of this risk.

Electromagnetic navigation

The navigation system uses an electromagnetic position measurement system with interference detection.

The position of the instruments is determined by means of an electromagnetic field generated by a field generator. Frequencies of said field range from 800Hz to 10 kHz. Therefore, instruments emitting electromagnetic signals (e.g., surgical turbines, RF surgery, diathermy devices) or mobile RF equipment (e.g. DECT phones, cellular phones) can influence the system. Do not use the system stacked or adjacent other devices, if adjacent or stacked use is necessary, the system should be observed to verify normal operation in the configuration in which it will be used

The navigation system has an automatic interference detection that shows the user when an 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 remove 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

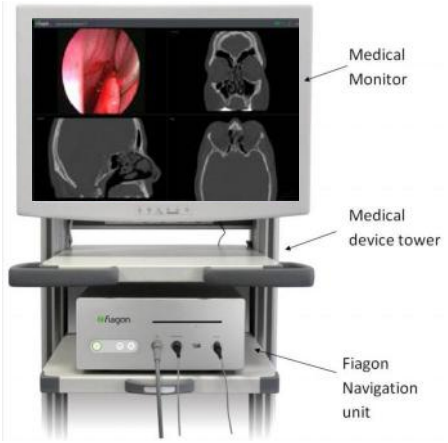
For EMC technical specifications of the system refer to the related chapter in this document.

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 tower as well as the connection to the monitor and video source are subject to the initial installation. Consult the Fiagon service or your dealer. This procedure is done by Fiagon's authorized personnel.

WARNING: Use of an uninterrupted power supply (UPS) to the device is mandatory to ensure the device remains on during voltage dips and unintended interruptions for interventions that do not allow for additional delay in the procedure or absence of image guidance. (See also table below)



The Fiagon navigation should only be connected and brought into service with the following cables.

Interface Type	Cable Type / equipment	Max. length	Fiagon Order No.	Remarks
Monitor Out DVI IN	DVI – D, shielded	2 m	A 00 9201	
Video In	Composite-Video, shielded	2 m	A 00 9202	
Monitor Control	RS 232	2 m	A 00 9204	
USB backside	USB – Mouse	2 m	A 00 9101	
Instrument	Double instrument support	2 m	A 01 1203	
Instrument	Extension cable instrument	2 m	A 00 1200	
Patient localizer	Extension cable localizer	2 m	A 001201	
USB frontside (for pen drives)	-	-	-	Not to be used in navigation mode
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 Fiagon navigation system.

4. Setting up the system

Preparation

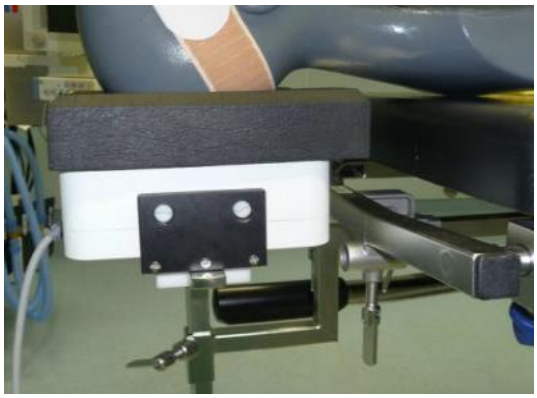
1. Place the device tower with the navigation system at its usual position, e.g. across from the surgeon.
2. Push the main switch of the system tower according to the instruction manual on the backside of the module.

NOTE: The main switch of the navigation module is located on the back. It should be switched to "On". If the system does not start, check the position of the main switch.

3. Mount navigation sensor

Attach a head rest with the navigation sensor to the operating table. Place the shaft of the head rest into the appropriate holding fixture of the operating table and lock the head rest.

Type navigation headrest Maquet



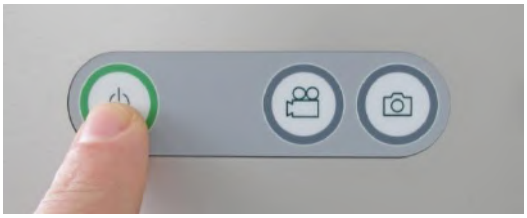
Type navigation headrest Flat

Refer to the instructions for use of the specific navigation sensor type for detailed mounting and placement instructions

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

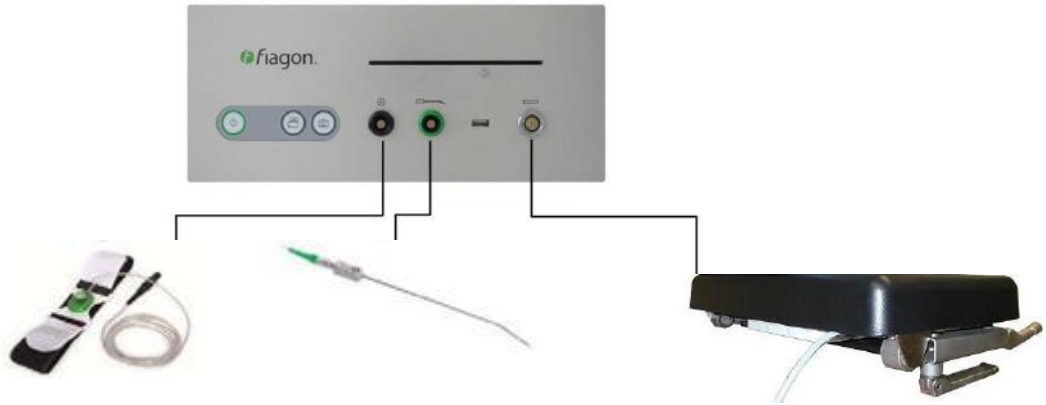
Starting the system

Press the On/Off button on the front panel. You will hear a confirmation tone if the system starts.



Overview of the connections

Platform



Patient Localizer

Navigation instrument or mapping device

Navigation sensor

Connecting the navigation sensor with the system

Insert the plug of the navigation sensor, e.g. Navigation Headrest Maquet, into the appropriate socket “sensor” (metal socket) on the navigation module. Note that the red marking at the plug is at 12 o'clock position.

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

Connecting the patient localizer with the system

Insert the plug of the patient localizer into the appropriate socket “Patient localizer” (black socket) on the navigation module. Note that the white marking at the plug is at 12 o'clock position.

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

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.

Connecting the navigated instrument/ mapping device with the system

Take the instrument or mapping device out of the sterile pouch, and place it on the instrument table.

Insert the plug of the component into the appropriate socket “Instrument” (green socket) on the navigation module. Note that the white marking at the plug is at 12 o'clock position.

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

Once the navigated instrument or mapping device is connected, you will hear a confirmation tone and the status indicator of the plugged component is displayed in color (green or red). In case of the navigation instrumentsthe 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.

status indicator of instrument

Green indicator denotes instrument is in measurement field, Red indicator denotes instrument is outside measurement field or a distortion is detected

NOTE: Before using the navigation the patient registration has to be done accordingly to the description of the application. Consult the instructions for use of the software and navigation application respectively.

NOTE: If the instrument or the localizer does not register at the navigation system, it cannot be used for the navigation**.** It needs to be exchanged**.**

5. Modes of operation

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

- Navigation Mode (for navigation interaction)
- Mouse mode (for software operation interaction)
- Full screen video mode

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 the navigation information. All software interaction buttons and the mouse cursor are blinded out. The navigation instrument has the focus.

Full screen 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 full screen 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 optimized full screen display.

Mouse mode

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

The interaction buttons and the mouse cursor are faded in. The mouse cursor has the focus and operation by mouse is possible.

The mouse mode automatically returns to navigation mode or Full screen 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 full-screen mode or navigation mode and to display the cursor. You can operate the software now with the mouse. The system will exit this mode automatically 5 seconds after you stopped using the mouse.

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 photo button on the navigation module. Once the screenshot has been taken, you will hear a confirmation tone.

To record a video sequence, press the video button on the navigation module.

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

To stop the recording, press the video button once more.

You can export the documentation after the operation and save it on a CD-R, a DVD or a USB stick.

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

7. After the operation

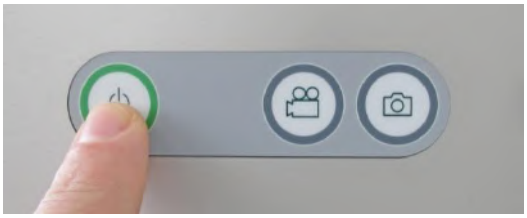
Disconnecting the components

After the operation disconnect the instrument and the patient localizer from the navigation unit. Do this by pulling the plug directly. Do not pull the cable or the bend protection. This might damage the cable.

Disconnect the navigation sensor from the navigation unit as well.

Shutting down the system

After the operation you can shut down the system by pressing the ON/OFF button on the navigation unit.



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 bend protection. This might damage the cable.

8. Removal from service

For removing the system from service switch off the navigation module at the main switch and remove the mains power cord.

9. Troubleshooting – unintended power shut down

Power shut down of Fiagon navigation system can occur by e.g. unintended removal of power plug, necessary change of the location of the device during surgery, power loss due to voltage dips (Dip>95% over 5s duration) or a power shut down due to electrical failures.

Under these circumstances, the computer screen is blank and does not show the intra-operative images. Also the green power indicator LED light on the navigation unit is turned off.

The system starts automatically immediately after the power returns. It takes 40s till the navigation software is ready for the user to interact. User interaction is needed to re-load the patient data (from system) and only confirming the registration. No additional registration is necessary. The complete time that no navigation information is available is approx. 80s.

Risk Mitigation

The mitigation of this hazard is performed by ensuring that the last state is saved. Also recovering registration after restart is possible. Valid patient registrations are stored in the patient data on the system (Patient planning file). Loading the patient data from the system will recover the last registration. In this way, time losses in surgery are tried to be minimized.

To reduce the likelihood of the event of power loss please ensure that the system is placed at the right position for the complete procedure even if the microscope is used during the surgery

Place mains cable of the unit such way that unintended removal is prevented.

Connect the unit to mains that are stable with respect to voltage dips.

10. Cleaning and reconditioning

Cleaning the surface of the device

Manual cleaning only. Turn off the system at the main switch and pull the plug before cleaning.

Clean the whole surfaces of the system 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 wipe 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 system.

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

CAUTION: 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. Spilling liquids on any electrical device attached to the system should warrant inspection by an authorized Fiagon service technician.

Inspection instructions

After cleaning, visually inspect the system under good 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.

11. Notes for maintenance and service

Maintenance

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

The navigation system requires regular maintenance by the manufacturer and general routine checks by the operator/user. These maintenance activities are necessary to allow for a 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.

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 system on a patient.

DANGER: The 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: We recommend to keep 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.

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

Check the system components for external damages.

Updates

These instructions for use have been written in German and translated to and delivered in English by the manufacturer.

The instruction manual is valid for the software version described on the cover sheet.

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

Updates will be provided along with a software update of the current version (e.g., update of Fiagon Navigation 3.6.5 to Fiagon Navigation 3.7.5).

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

12. Technical description

Conformity

The 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

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 us under the following address:

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

Technical data

Navigation module

- Energy consumption: 200 VA
- Electric supply: 110V-240V, 60/50Hz, single-phase
- Classification according to MDD 93/42/EEC: Class 1
- Protection class I, application part type BF
- Protection against ingress: IP20

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

Navigation sensor

- Electromagnetic position measurement system

Operating conditions	Temperature: +15°C to + 35°C, Humidity: 30% to 75% without condensation Air pressure: 1060 hPa to 700 hPa
Transport conditions	Temperature: -10°C to + 35°C, Humidity: 30% to 75% without condensation Air pressure: 1060 hPa to 700 hPa
Storage conditions	Protected against dust, and moisture. Recommended storage temperature: +15° to +35°C Humidity: 30% to 75% without condensation Air pressure: 1060 hPa to 700 hPa

Warning: If the system is transported indoor after outdoor placement, wait two hours prior to use. Otherwise, condensed water on the components could compromise 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)

total accuracy on anatomic preparation (mean value < 2 mm and < 2°)

13. EMC compliance statement

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

<table>
<tr><td colspan="3">Electromagnetic emission
The Fiagon 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.</td></tr>
<tr><td>Emission Test</td><td>Compliance</td><td>Electromagnetic Environment Guidance</td></tr>
<tr><td>RF-emissions following IEC/CISPR 11</td><td>group 1</td><td>The 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.</td></tr>
<tr><td>RF-emissions following IEC/CISPR 11</td><td>class B</td><td rowspan="3">The Fiagon 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.
The intended use environment is hospital environment.</td></tr>
<tr><td>Generation of mains harmonics
Following IEC 61000-3-3</td><td>class A</td></tr>
<tr><td>Generation of voltage Fluctuations/ flicker following IEC 61000-3-3</td><td>Complies</td></tr>
</table>

Electromagnetic immunity

The Fiagon 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.

Immunity Test	IEC 60601-1-2 Test Level	Compliance Level Level	Electromagnetic Environment Guidance
ESD IEC 61000-4-2	+/-6kV cd +/-8kV ad	+/-6kV cd +/-8kV 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	+/-2kV mains +/-1kV I/O	+/-2kV mains +/-1kV I/O	Mains power quality should be that of a typical commercial or hospital environment.
Surges IEC 61000-4-5	+/-1kV dm +/-2kV cm	+/-1kV dm +/-2kV 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, IEC 61000-4-11	Reduction to: 5% for 10 ms/positive amplitude 5 % U_T for 10ms/ negative amplitude 5 % U_T for 10ms/ negative amplitude 40 % U_T for 100 ms 70 % U_T for 500 ms 5 % U_T 5000 ms	Reduction to: 5% for 10 ms/positive amplitude 5 % U_T for 10ms/ negative amplitude 5 % U_T for 10ms/ negative amplitude 40 % U_T for 100 ms 70 % U_T for 500 ms 5 % U_T 5000 ms	Mains power quality should be that of a typical commercial or hospital environment.
Power frequency (50/60 Hz) Magnetic field, IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

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

Electromagnetic immunity

The Fiagon 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.

Immunity Test	**IEC 60601-1-2 Test Level**	**Compliance Level Level**	**Electromagnetic Environment Guidance**
			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.
Conducted RF, IEC 61000-4-6	3 V_{rms} 150 kHz to 80 MHz	3 V	Recommended Separation Distance $d=1.2\sqrt{P}$
radiated RF, IEC 61000-4-3	3 V/m 80 MHz bis 2,5 GHz	3 V/m	$d=1.2\sqrt{P}$ 80 MHz to 800 MHz $d=2.3\sqrt{P}$ f800 MHz to 2,5 GHz where, P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[a] should be less than the compliance level in each frequency range[b.] Interference may occur in the vicinity of equipment marked with this symbol.

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

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

Recommended separation distances between portable and mobile RF communications equipment and the Fiagon system

The Fiagon system is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Fiagon system can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Fiagon 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 frequency of 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 2,5 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 metres (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.

NOTE: Portable and mobile RF communication equipment can affect the Fiagon Navigation system.

The Fiagon navigation should only be connected with the following accessories and cables to comply with the standards mentioned above.

Interface Type	Cable Type / accessory	Max. length	Fiagon Order No.	Remarks
Monitor Out/ DVI in	DVI – D, shielded	2 m	A 00 9201	
Video In	composite, shielded	2 m	A 00 9202	
Monitor Control	RS 232	2 m	A 00 9204	
USB backside	USB – Mouse	2 m	A 00 9101	
Instrument	Double instrument support	2 m	A 01 1203	
Instrument	Extension cable instrument	2 m	A 00 1200	
Instrument	Fiagon instruments		various	Surgical instruments provided by Fiagon or its representatives
Patient localizer	Extension cable localizer	2 m	A 001201	
Patient localizer	Patient localizers		various	Patient localizers provided by Fiagon or its representatives
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 use of accessories and cables other than those specified above, may result in increased emissions or decrease immunity of the system.

Warning: The cables and accessories provided by Fiagon should only be used in connection with the Fiagon navigation system.

Warning: The use of the ACCESSORY, transducer or cable of the Fiagon Navigation system with ME EQUIPMENT and ME SYSTEMS other than those specified may result in increased EMISSIONS or decreased IMMUNITY of the ME EQUIPMENT or ME 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

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.

Monitors

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

- Approved according IEC 60601-1
- Equipped with either DVI or VGA 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 IEC 60601-1
- Equipped with DVI signal-out port or composite video out port.