

Item:

A 01 1000 Navigation Sensor

Available in following configurations/products:

E 01 1001 Navigation Headrest Flat

E 01 1002 Navigation Headrest Maquet

E 01 1003 Navigation Headrest Universal

E 01 1008 Navigation Headrest Office

E 01 1905 Flexarm Adapter for side rail

E 01 1970 Integrated Headrest

E 01 1973 Flexarm Universal



NOTE: The Navigation Sensor is only to be used with one of the approved configurations listed above.

Manufacturer:

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For US market only. - This document is intended to provide information to an audience of the US.

Explanation of symbols

Manufacturer



Manufacturing date



Reference number/Order number



Serial number



To ensure safety, follow the instructions for use



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



Attention
Follow the supporting documentation



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



Indicates the humidity limits to which the medical device can be safely exposed



Indicates the atmospheric pressure limits to which the medical device can be safely exposed



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



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

1. General information

The Navigation Sensor generates the electromagnetic field used for determining the position of instruments. This enables the usage of the image guided surgery system and is referred to as a '*navigation sensor*'.

The Navigation Sensor is a component of the Cube Navigation System produced by Fiagon GmbH.



CAUTION: Before using it, the navigation sensor must be cleaned according to the cleaning instructions. The Navigation Sensor is not sterilizable.

2. Indications for Use /Field of application



The application of the Headrest is limited to the intended purpose described here.

The Navigation Sensor is mounted in close proximity to the desired operating space in different mounting options for the purpose of producing an electromagnetic field encompassing the intended operating space.

The Navigation Sensor 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 can be identified relative to a CT or MR based model of the anatomy. Example procedures include, but are not limited to:

- ENT Procedures;
Transsphenoidal access procedures.
- Intranasal procedures.
- Sinus procedures, such as Maxillary antrostomies, Ethmoidectomies, Sphenoidotomies/Sphenoid explorations, Turbinate resections, and Frontal sinusotomies.
- Skull base procedures for ENT access

The Cube Navigation System and its components are intended for use by healthcare professionals (physicians) only. In addition, the users must receive training. The operator, i.e., the person or facility who is responsible for the use and service of the system, must ensure that all users of the system receive an adequate briefing in accordance with valid laws and regulations. An operator is anyone who uses the system.

The Navigation Sensor produces the electromagnetic field used to determine the position of instruments, which is a part of the Cube Navigation System. The instructions for use of the Cube Navigation system describe the proper use of the entire system in detail.



The Navigation Sensor may only be used if the safety instructions of the Cube Navigation System and other connected devices have been followed.



NOTE: The navigation sensor can only be used and only works in connection with the Navigation System of Fiagon GmbH. Please take carefully notice of the instructions for the use of the navigation device.

3. Verified configurations

The Navigation Sensor comes with different mounting configurations listed below:

- E 01 1001 Navigation Headrest Flat
- E 01 1002 Navigation Headrest Maquet
- E 01 1003 Navigation Headrest Universal
- E 01 1008 Navigation Headrest Office
- E 01 1905 Flexarm Adapter for side rail
- E 01 1970 Integrated Headrest
- E 01 1973 Flexarm Universal



CAUTION: Verify the secure mount and stability of the device before operation.



CAUTION: Drape the headrest to prevent direct contact with the patient.

4. Navigation Sensor operation

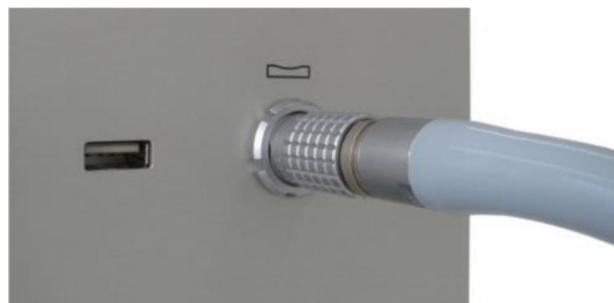
The Navigation Sensor must be positioned correctly in order to ensure navigation. The patient localizer is used to as the indicator for the positioning and proper function of the navigation sensor. Follow the steps below for checking the position and proper function of the navigation sensor.



NOTE: For first time setup and use refer to the **Navigation Sensor Brining into Service Protocol**.

- a. Power on the Cube Navigation System and wait for the Software Application to start
- b. Connecting the Navigation Sensor with the Navigation System

Insert the plug of the navigation sensor 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 indicator for the Navigation Sensor will be displayed in black and white indicating that they are not connected.



Navigation Sensor is not plugged in.

Check if the navigation sensor is plugged in correctly.



Navigation Sensor is subject to interference.

Check if there are any heavy metal objects close to the Navigation Sensor.

Or

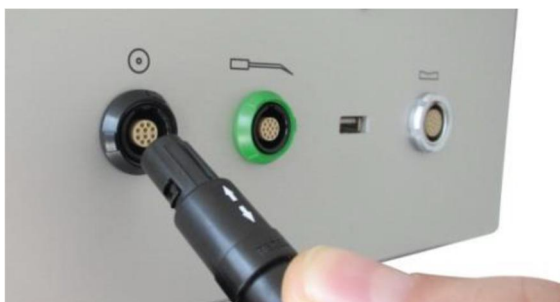
Navigation Sensor is turned off manually by foot switch.

To turn the navigation sensor on again hit the button "Sensor" on the foot switch once or press "b" on the Keyboard.

If neither of the above icons are displayed then the Navigation Sensor is plugged in and working properly.

c. Connect the Patient Localizer with the Navigation 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.



Patient Localizer is not plugged in.

Check connection to the system, if necessary, plug in again



Patient Localizer detects disturbances.

Eliminate possible sources of interference:

- An instrument on the localizer?
- Instrument table on/under the top plate.

Or

Patient Locator is not optimally positioned in the navigation area.

Check the location.



NOTE: The Navigation Sensor emits an electromagnetic field with a volume described in the Specifications table.

The entire operating region of the patient must be contained within the electromagnetic volume emitted by the navigation sensor.

NOTE: The Navigation Sensor must be a minimum distance of 5cm away from the Patient Localizer.

5. During operation

The navigation system has an automatic interference detection that shows the user when an interference occurs during navigation. This is indicated when the Patient Localizer icon appears in red. Standard instruments such as endoscopes or forceps normally do not cause any interference.

If interference occurs, the navigation data is not displayed, because they may be inaccurate. Once the source of interference has been eliminated, the Patient Localizer icon will disappear, and 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 directly in the measuring field can include:

- 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

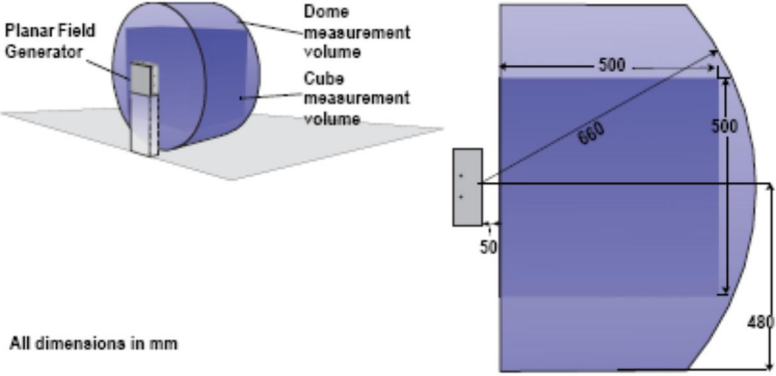
6. After the operation



NOTE: Refer to the instructions for use for the specific mounting configuration you are using for more detailed information on how to disintegrate the navigation sensor and mounting configuration.

After operation the navigation sensor should be wiped with an alcoholic fluid to disinfect the cushion.

7. Specifications

Item	A 01 1000 Navigation Sensor
Verified Configurations	<p>E 01 1001 Navigation Headrest Flat E 01 1002 Navigation Headrest Maquet E 01 1003 Navigation Headrest Universal E 01 1008 Navigation Headrest Office E 01 1905 Flexarm Adapter for side rail E 01 1970 Integrated Headrest E 01 1973 Flexarm Universal</p>
Operating conditions	<p>Temperature: +15°C to + 30°C, Humidity: 30% to 75% without condensation Air pressure: 700 hPa to 1060 hPa</p>
Transport conditions	<p>Temperature: -10°C to +40°C, Humidity: 10% to 90% without condensation Air pressure: 700 hPa to 1060 hPa</p>
Storage conditions	<p>Protected against dust, moisture and recontamination. Temperature: -10°C to +40°C Humidity: 10% to 90% without condensation Air pressure: 700 hPa to 1060 hPa</p>
Dimensions (sensor)	200 mm x 200 mm x 71 mm (height x width x depth)
Weight	2,6 kg (without cable)
Measure volume	 <p style="text-align: center;">All dimensions in mm</p>

8. Electrical safety and EMC

The Navigation Sensor is a part of the Cube4D Navigation System and can only be used in combination with the Cube 4D Navigation unit. All Electrical safety and EMC testing has been performed with this combination. Please refer to the instructions for use of the Cube4D Navigation System for details and tables.

9. Cleaning instructions

The Navigation Sensor is a reusable component.



WARNING: The Navigation Sensor must not be sterilized.

Clean the navigation sensor by hand and disinfect using an aldehyde-free disinfectant.

Do not immerse the navigation sensor, or parts of the sensor in the disinfectant or cleaning agent.

10. Preventive maintenance instructions

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

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

