Item:
A 01 1000 Fiagon 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 Navigation Sensor

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

Manufacturer:
Fiagon GmbH
Neuendorfstraße 23b
D -16761 Hennigsdorf
Germany
Tel: +49 3302 20121 10
Fax: +49 3302 20121 15
info@fiagon.de

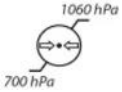
CE

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

Explanation of symbols

	Manufacturer
	Manufacturing date
REF	Reference number/Order number
SN	Serial number
	Follow the instructions for use
CE	Marking of conformity to the European Medical Device Directive 93/42/EEC (MDD).
MR	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
35°C 15°C	Recommended storage temperature +15°C to +35°C

Recommended storage humidity
30% to 75% without condensation



Recommended storage air pressure
700 hPa to 1060 hPa

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 is a product variant of the Fiagon Surgical Navigation System which produces the electromagnetic field used for determining the position of instruments. This enables the usage of the Fiagon image guided surgery system and is referred to as a '*navigation sensor*'.

The Navigation Sensor is a component of the Fiagon 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 Fiagon 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 Fiagon Navigation System. The instructions for use of the Fiagon 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 Fiagon Navigation System and other connected devices have been followed.

NOTE: The navigation 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 can only be used in connection with the Navigation Systems of Fiagon GmbH.

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 Navigation Sensor

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

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 **Fiagon Navigation Sensor Brining into Service Protocol.**

a. Power on the Fiagon Navigation System and start the Fiagon Software Application

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 Fiagon 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:

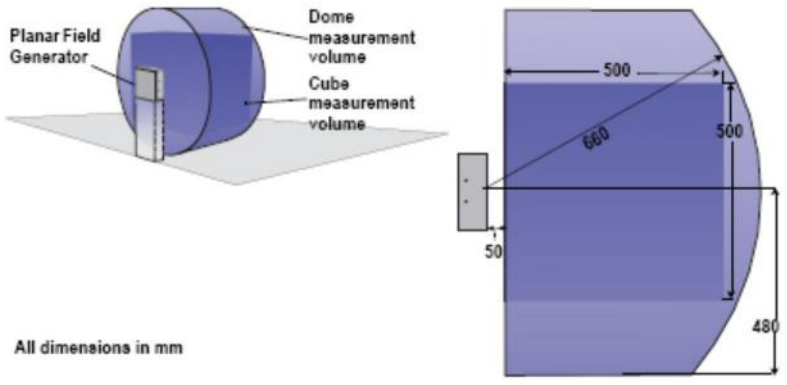
- MR scanner

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	**Fiagon Navigation Sensor**
Verified Configurations	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 Navigation Sensor
Operating conditions	Temperature: +15°C to + 35°C, Humidity: 30% to 75% without condensation Air pressure: 700 hPa to 1060 hPa
Transport conditions	Temperature: +15°C to + 35°C, Humidity: 30% to 75% without condensation Air pressure: 700 hPa to 1060 hPa
Storage conditions	Protected against dust, moisture and recontamination. Recommended storage temperature: +15° to +35°C Recommended storage humidity: 30% to 75% without condensation Recommended air pressure: 700 hPa to 1060 hPa
Integrated sensor type	Fiagon Navigation Sensor (A 01 1000)
Dimensions (sensor)	200 mm x 200 mm x 71 mm (height x width x depth)
Weight	2,6 kg (without cable)
Measure volume	

8. Electrical safety and EMC

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

The maintenance is done by authorized personnel only. Recommended maintenance period is 1 year and includes accuracy test according to a described procedure.