

Product:

E 01 1008 Navigation Headrest Office

Manufacturer:

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



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



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

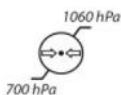
Follow the supporting documentation



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



Maximum load on headrest 15 kg



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

1. General information

Read the instructions for use carefully before using the Headrest.

The Navigation Headrest Office is a product variant of navigation sensor and hereafter referred to as 'Headrest'. The Headrest is mountable on office chairs and enables the usage of the Fiagon image guided surgery system.

It 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 Headrest is not sterilizable.

2. Indications for Use /Field of application



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

The Fiagon Navigation System in connection with the Navigation Headrest Office is mounted on the office chair instead of the original headrest. The Headrest includes the Fiagon Planar Field Generator, which creates an electromagnetic field above the cushion.

The Headrest 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 anrostomies, 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 Headrest Office takes full functionality of the original headrest and houses the Fiagon Planar Field Generator, 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 Headrest 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.

Exclusion of application



- The Headrest should only be mounted to supported office chair models. The safety of the product cannot be guaranteed for unsupported office chairs.
- Please consult a Fiagon support representative, for first time installation on any office chair.



CAUTION: The Headrest must not be loaded with more than 15kg. The maximum overall body weight of the patient should not exceed 180kg

3. Compatible devices

The Headrest is a part of the Fiagon Navigation System of Fiagon GmbH and can only be used with the system. The Headrest can be installed on various office chair models that contain a removable headrest using specific mounting adapters.

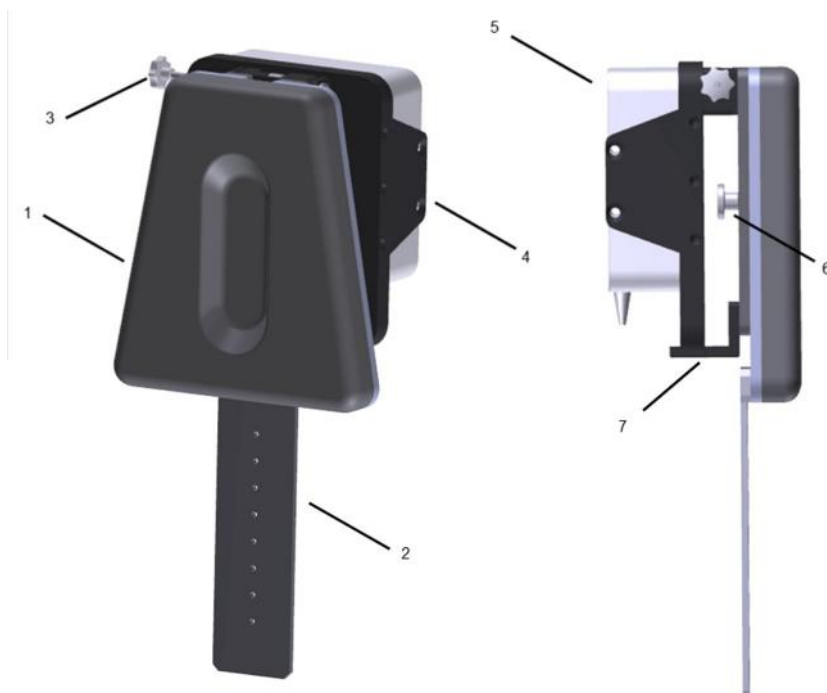
Compatible adapters are listed in the section 8 - “**Specifications**”



The specific headrest mounting bar needed for the procedure chair can be determined by contacting support@fiagon.com to complete the “Office Headrest Mounting Bar Checklist.”

4. Device description

The contents of the product Navigation Headrest Office are displayed in the pictures below.



- 1. Headrest Cushion**
- 2. Headrest Mounting Bar.**
To fix the headrest to the procedure chair.
- 3. Navigation Sensor Locking Knob Screw.** This is for locking the rotation and sliding mechanism of the navigation sensor.
- 4. Navigation Sensor Mounting Bracket.** This secures the navigation sensor to the Headrest.
- 5. Navigation Sensor**
- 6. Locking Screw for Navigation Sensor Plate.** This locks the navigation sensor mounting plate into position behind the headrest cushion.
- 7. Navigation Sensor Support Bracket.** This secures the navigation sensor behind the headrest in the resting position.

5. Installation on the Procedure Chair



CAUTION: The Headrest is allowed to be installed by trained staff only.

The Headrest is installed on the procedure chair in place of the existing headrest.

The Headrest will be supplied with the specific mounting bar needed for the procedure chair.

First, remove the existing headrest from the procedure chair, then mount the Fiagon Navigation Headrest Office in place of the existing headrest using the same mounting mechanism.



NOTE: Please refer to the Application Note *Headrest Office* for more detailed information about how to install the Navigation Headrest Office.



CAUTION: Confirm the secure installation of the Headrest before use.

The graphics below show an example of replacing the existing procedure chair headrest with the Fiagon Navigation Headrest Office using the same mounting mechanism.



A - Procedure chair with existing chair headrest



B - Procedure chair with Navigation Headrest Office

6. Operation of the Navigation Headrest Office



CAUTION: For hygienic safety during surgery, please cover the Headrest.

CAUTION: Do not use damaged cushions. Hygienic safety can not be ensured anymore. Replace damaged cushions

After installation at the procedure chair the Headrest can be used for the operation. Insert the plug of the sensor into the appropriate socket "sensor" (metal socket) on the Navigation Unit. Note that the red marking on the plug is in the 12 o'clock position. Using too much force while trying to plug in the sensor cable in a different position may cause damage to the plug and/or the socket.



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

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 Navigation Headrest Office can be rotated into different positions:



45° Vertical Position



Horizontal Position



Side Position



NOTE: The Application Note *Headrest Office* describes in detail how to change the Headrest into different positions during different cases.



CAUTION: While adjusting the Headrest risk of injury may occur. Please ensure safe operation while adjusting to not harm/injure personnel, patient or OR equipment (cables, hoses or tables).

CAUTION: High risk of injury if fixation screws are not tightened properly. The Headrest may loosen during surgery exposing patient and personnel high risk of injury.

CAUTION: Before intended use please ensure proper condition and functionality of the Fiagon Navigation Headrest Office and all connectors.

7. After the operation

Disconnect the Headrest from the Navigation System by pulling the plug directly. Do not pull the cable or the bend protection as this might damage the cable of the navigation sensor.

Return the navigation sensor to the resting position behind the Headrest as shown in picture B, section 4. The Headrest can be stored in a vertical resting position or in a horizontal resting position.



NOTE: Please refer to the Application Note *Headrest Office* for more detailed information about how to return the Headrest to the resting position.



Secure the navigation sensor into the resting position by turning the navigation sensor locking knob screw clockwise until the navigation sensor can no longer be moved.

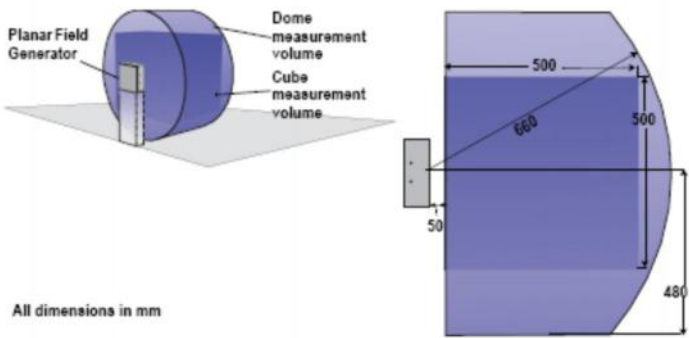


CAUTION: Do not over tighten the locking Knob Screw. Check the secure holding of the Headrest by moving the Headrest slightly.



After the operation, the Headrest should be wiped with an aldehyde-free fluid to disinfect it. Please read the cleaning instructions for the sensor below in section 10 - **“Cleaning instructions”**.

8. Specifications

Item	<p style="text-align: center;">E 01 1008 Navigation headrest office</p>
Compatible adapters	<p>E 01 1960 Chair Adapter A - Reliance 700, 710, FX 920, FXM 920, 980, 7000</p> <p>E 01 1961 Chair Adapter B - MTI 424, 424-LRX, 423, 423-LRX, 421, 421E, 401. Jedmed Phoenix III</p> <p>E 01 1962 Chair Adapter C - Global Surgical (SMR) Maxi 4500. Maxi 4000, Apex 2300, Apex 2400, Apex 2500</p> <p>E 01 1963 Chair Adapter D - Gio Pelle GP-SH-4626</p> <p>E 01 1964 Chair Adapter E - JedMed SII Plus</p> <p>E 01 1965 Chair Adapter F - MidMark 641</p> <p>E 01 1966 Chair Adapter R - Ritter 391</p>
Operating conditions	<p style="text-align: center;">Temperature: +15°C to + 35°C, Humidity: 30% to 75% without condensation Air pressure: 700 hPa to 1060 hPa</p>
Transport conditions	<p style="text-align: center;">Temperature: +15°C to + 35°C, Humidity: 30% to 75% without condensation Air pressure: 700 hPa to 1060 hPa</p>
Storage conditions	<p style="text-align: center;">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</p>
Integrated sensor type	<p style="text-align: center;">Fiagon Navigation Sensor (A 01 1000)</p>
Dimensions (sensor)	<p style="text-align: center;">200 mm x 200 mm x 71 mm (height x width x depth)</p>
Weight	<p style="text-align: center;">6,0 kg (without mounting adapters)</p>
Measure volume	 <p style="text-align: center;">All dimensions in mm</p>



CAUTION: While adjusting the Headrest risk of injury may occur. Please ensure safe operation while adjusting to not harm/injure personnel, patient or OR equipment (cables, hoses or tables).

Electrical Safety and EMC



The Headrest 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.

10. Cleaning instructions



The Headrest is a reusable component.



WARNING: The Navigation Office Headrest must not be sterilized.

<p>General information about the products</p> 	<p>The device is intended to be used with the Fiagon Navigation System. The usage of the products is described in the instructions for use of the Fiagon Navigation System.</p> <p>The device can be reprocessed. (see below for details)</p>
<p>Warnings:</p> 	<p>Not qualified methods for cleaning and disinfection may damage cables and device.</p> <p>Device is supplied unsterile and must therefore undergo the complete reprocessing cycle prior to the first use.</p> <p>Pay attention to the notes and user manual of the manufacturer as well as the chemicals used.</p>
<p>Restrictions on treatment</p>	<p>Frequent treatment and using has an effect on this device. Check the condition of the Headrest, especially of the cushion, before each usage.</p>

Detailed instructions for reprocessing the Navigation Office Headrest:

<p>Cleaning and disinfection</p>	<p>Materials:</p> <p>Cleaning: Mild soap solution (without plasticizers or bleaching agents)</p> <p>Disinfection: Optisal N (manufacturer: Dr. Schumacher GmbH) or other equivalent aldehyde free disinfectants (wipe and spray disinfection)</p>  <p>Do not use strong alkaline solutions, Formaldehyde solutions or peroxide based disinfections for cleaning of the cushion.</p> <p>Method:</p> <ol style="list-style-type: none"> 1. Remove the cover of the cushion. 2. Wash the inside of the cover (up to 95°C) and let the cover dry sufficiently (drying temperature up to 60°, air or tumble dryer). The zipper should remain open during the washing process. 3. Clean exterior surfaces of the headrest and of the navigation sensor with cable and connector by hand.  <p>Do not iron the cover of the cushion!</p> <p>Do not remove dirt from the cushion's cover with solvent-containing products.</p> <p>Do not comb out the fluffy parts.</p> <ol style="list-style-type: none"> 4. Disinfect surface of all above mentioned parts (Navigation Sensor with cable and plug, cover of the cushion.)
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Cleaning inspection	Examine surfaces for visible remains of soil/detergent/debris. If residual soil or debris are still visible on the device after reprocessing, repeat the cleaning, if necessary..
Inspection	<p>The device should be inspected after cleaning and before use for surgery. Inspect the product visually for damage and wear. Also check cable and connectors for damage. Sort out products that:</p> <ul style="list-style-type: none"> • show indications of damage/crack in the cushion • have damaged cables or connectors <p>Products that have been sorted as damaged prior to their lifetime must not be used for surgery. These products can be disposed or returned to the dealer/manufacturer for clarifications on the reason of the damage.</p>
Maintenance	Refer to forthcoming section "Preventive Maintenance Instructions".



Check the complete functionality of the Headrest after each cleaning and disinfection process.

11. 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.