

**Product:**

E 01 1905 Flexarm Adapter for Navigation Sensor  
For side rails 25 x 10 mm



**i** **NOTE:** The Flexarm Adapter is only to be used with the *Fiagon Navigation Sensor (A 01 100)*









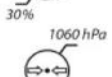



**Manufacturer:**

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
	Date of manufacture
	Reference number/Catalogue number
	Serial number
	Follow the instructions for use
	Marking of conformity to the European Medical Device Directive 93/42/EEC (MDD).
	Caution
	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
	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 *Flexarm Adapter*, hereafter related to as *Navigation Sensor Flexarm*, is a product variant of navigation sensor which is mountable to rails 25x10 mm. The navigation sensor is a part of the *Fiagon Navigation System* produced by *Fiagon GmbH*.



**CAUTION:** Read the instructions for use carefully before using the *Navigation Sensor Flexarm*. To ensure proper use of the product read the manual of the *Fiagon Navigation System*.



**CAUTION:** Before using it, the *Navigation Sensor Flexarm* 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 navigation sensor is limited to the indications for use described here.

The *Navigation Sensor Flexarm* is connected to and used with the *Fiagon Navigation Unit*. The devices are components of the *Fiagon Navigation System*, which 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, such as the skull, a long bone, or vertebra, can be identified relative to a CT or MR based model of the anatomy.

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 that 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 instructions for use of the *Fiagon Navigation System* describe the proper use of the entire system in detail.

The *Navigation Sensor Flexarm* is mounted rails 25 x 10mm, to create an electromagnetic field in the surgical area.



**CAUTION:** The *Navigation Sensor Flexarm* may only be used if the safety instructions of the *Fiagon Navigation System* and other connected devices have been followed.

## 3. Compatible Devices

The *Navigation Sensor Flexarm* can be mounted to rails of the following dimensions:

- Rail: 25 x 10 mm

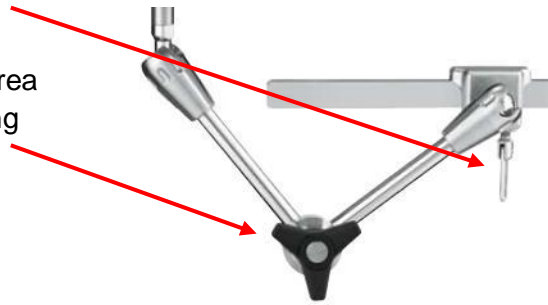
## 4. Device description

The *Navigation Sensor Flexarm* consists of a navigation sensor and an articulating arm with clamp for rails (25 x 10 mm). The navigation sensor creates the surgical navigation workspace.

## 5. Mounting of *Navigation Sensor Flexarm*

To attach the *Navigation Sensor Flexarm* to the rail of 25 x 10 mm please follow the installation steps:

- I. Attach the rail clamp of the device to an appropriate position on the rail.
- II. Fix the clamp firmly with the screw.
- III. Adjust the navigation sensor to the surgical area and fix its position by tightening the articulating arm's knob.



- IV. 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.



**CAUTION:** 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.

## 6. After usage / disassembling

For disassembling please perform installation steps in reverse order.

## 7. Cleaning instructions

The *Navigation Sensor Flexarm* is a reusable component.



**CAUTION:** The navigation sensor or parts of the sensor must not be sterilized.

Clean the *Navigation Sensor Flexarm* by hand and disinfect using an aldehyde-free disinfectant.

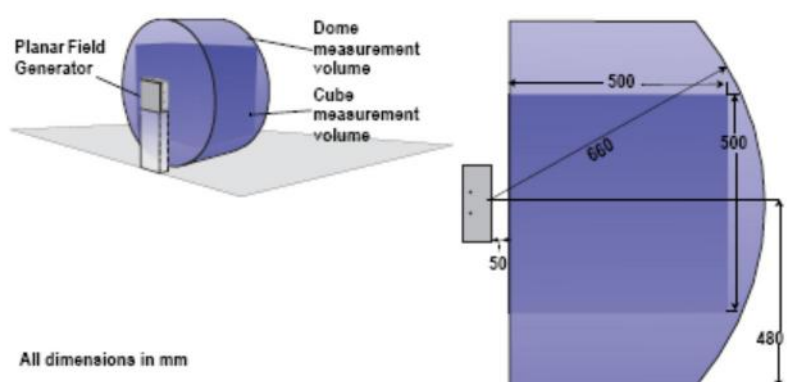


**CAUTION:** Do not immerse the sensor, or parts of the sensor in the disinfectant or cleaning agent

## 8. Preventive Maintenance Instructions

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

## 9. Specifications

Item	E 01 1905 Flexarm Adapter for Navigation Sensor
Dimensions (sensor)	200 mm x 200 mm x 71 mm (height x width x depth)
Weight	2,9 kg (without cable)
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
Compatible sensor type	Fiagon Navigation Sensor (A 01 1000)
Work space volume	 <p>All dimensions in mm</p>

## 10. Electrical safety and EMC

The *Navigation Sensor Flexarm* 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.