

## Instruction for Use: Holder

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This device may only be used by trained medical professionals.



Read instructions prior to use.



Only use the Holder according to the intended use stated in this document.

## Device description

The Holder device consists of two main parts made of Aluminum and PC (Polycarbonate):

- A curved surface base adjusted to a CT scanner table, made of PC (a). The PC base is attached to the holding system.
- An adjustable arm, made of Aluminum and consists of one locking knob (b) and a clamp screw (c).

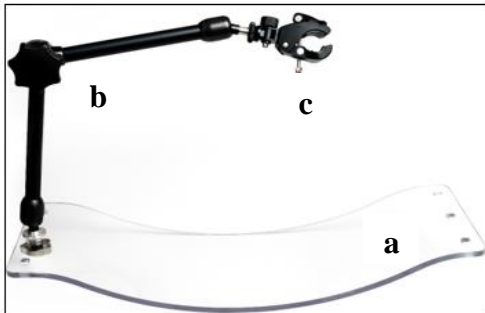


Figure 1: Illustration of the Holder device - base (a) and arm (b)+(c)

## Intended use/ Indications for Use

The holder is a manual instrument for general use, intended to support the system flexible hose during procedures under CT scanning system.

This device enables the operating physician and/or a third party to position the hose with ease and keep it in place.

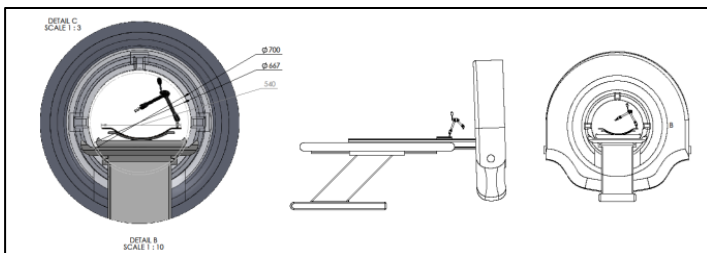


Figure 2: Illustration of intended use

## Operation Instruction

The system is supplied in a preassembled mode and can be easily placed on a CT curved bed.



**Inspect the device for functionality before use.**

**Do not use if a mechanical damage is found!**

- Pre-plan the best side to locate the arm before procedure.
- Locate the holder on the CT bed (Fig. 2)
- Open the locking knob and locate the adjustable arm, which can be moved in all directions, in a position that allows the patient to lie comfortably on the holder base (Fig. 1)
- Locate the adjustable arm over the patient in the treating area and turn the locking knob (single-knob movement system) (Fig. 1).
- Adjust the clamp screw to the hose size and lock over the hose in a distance of about 20cm/8" from the handle (Fig. 1 and 3)
- To adjust the holder, turn the knob gently and slowly.
- Lock the clamp on the hose tube to secure fixation (Fig. 1 and 3).



Fig. 3: Holder clamp positioning on the hose

When locking the knob (Fig 3) make sure it is locked tightly to prevent movement during procedure.

**To re-adjust the holder, turn the knob gently and safely support the hose.**



When you locate the clamp on the hose, take into consideration possible movement of the holder and the hose due to patient breathing.



Do not release the hose from the holder with rapid movement.



Holder maximal load is 3Kg.



**Holders are not compatible with magnetic resonance imaging**

### Cleaning and Maintenance

Before and after every procedure, carefully clean the Holder according to the cleaning instructions acceptable for permanent equipment in your institution.

Use a damp cloth soaked with 90% alcohol or warm water with soap. Afterwards, dry it with a clean cloth.



Do not use aggressive solvents other than alcohol.

### Packaging and Storage

The packed Holder shall be stored in a clean environment without sun exposure.








The Holder device is a non-sterile device.



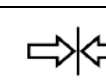
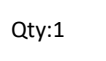



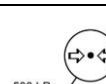





Figure 5: Holder labels (Product Label: I, Packaging Label: I+ II)

A number of internationally recognized symbols relating to safety requirements and standards are found on the Holder label. These symbols are listed in the table below.

Holder reference number	Base Length	Base Width	Maximum Height	Minimum Height
FAG3000000	56 cm/22"	20 cm/7.8"	66 cm/26"	10 cm/4"

Symbol	Meaning
	Caution-Warning
	Manufacturer
	Date of manufacture
	Catalogue number
	Serial Number
	CE mark- mandatory conformity mark for products placed on the market in the European Economic Area
	Fragile, handle with care

Symbol	Meaning
	Keep away from sunlight
	Non-Sterile Device
	Lock; tighten two parts together in a fixed position
Qty:1	Quantity
	Sale by or on the order of a physician
	MedNet EC-REP GmbH – Authorized Representative with contact details
	UDI Barcode and number
	Transportation and storage atmospheric pressure limits
	Transportation and storage humidity limits
	Storage temperature limits
	Keep dry
	MR safety warning: system materials are not compatible with magnetic resonance imaging

### Holder technical specifications

Holder Device characteristics are listed in the table below:

**Base material:** Polycarbonate

**Arm length:** 43 cm

**Arm material:** Aluminum

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