

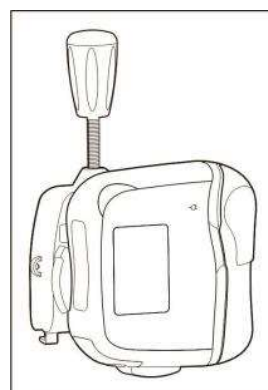
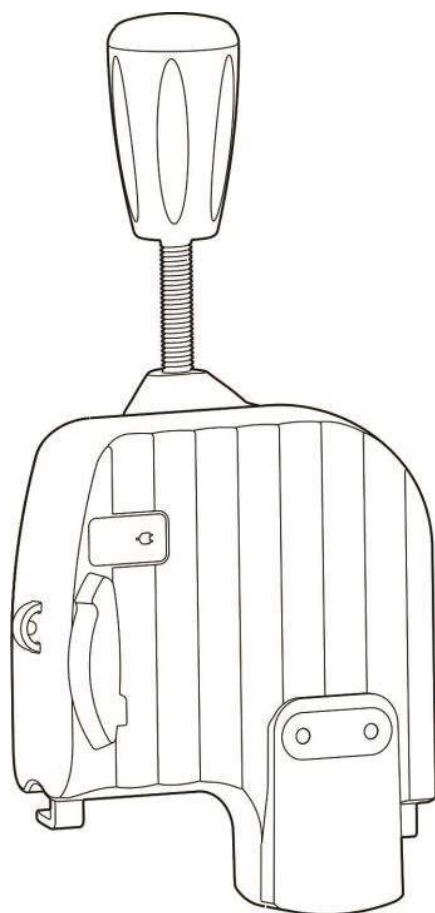


**FRESENIUS  
KABI**

caring for life

## Smart Holder Power

























### Instructions For Use



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## Symbol description

EN

Symbol	Description	Symbol	Description
	Medical Device		Unique Device identifier
	Refer to the Instructions For Use	<b>IP32</b>	Index of protection against solid foreign objects (> 2.5 mm) and dripping liquids
	Manufacturer		Class II equipment
	Defibrillation-proof type CF applied part		Serial number
	Catalogue number		Input terminal – connector
	Output terminal – connector		Alternating current (AC)
	Direct current (DC)		CE Marking
	Part included in a recycling process		Humidity limitation
	Fragile, handle with care		Atmospheric pressure limitation
	This way up		General symbol for recyclable material
	Keep dry		Medical electrical system weight(kg)
	Temperature limit		Name and address of the manufacturing facility
	<b>UDI</b> (01) 04052682037245 (21) 12345678 (11) 200316 (240) CS1000428		(01) Product identifier GTIN (21) Product Serial Number (11) Date of Manufacture (240) Product Reference



**Caution symbol:** Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself.



**Information symbol:** Recommendations to be followed.

### INFORMATION



- Please refer to the Use environment section for additional information on temperature, pressure and humidity limitations, and altitude.
- These Instructions For Use (IFU) are also available online. For further information, check IFU for Amika (ref. 13118) or Amika+ (ref. 13887) on <https://key2.fresenius-kabi.com>.

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# 1 Introduction

EN

This document is written to the attention of:  
End users of Amika / Amika+ with Smart Holder Power.

## 1.1 Scope

These Instructions for Use (IFU) are applicable to the Smart Holder Power referred to as holder. The holder is compatible with Amika enteral feeding pump and Amika+ enteral feeding pump, which are referred to as pump in this IFU.



### CAUTION

The user must follow the instructions specified in this IFU. Failure to observe these instructions may result in damage to the equipment, injury to patients or injury to users. Specific texts are highlighted using the symbols described in *Symbol description*.

## 1.2 Intended use

The holder can be positioned on authorized support such as a pole, rail, bed, wheelchair, table and table stand. It allows the pump to be attached to it to ensure the pump is securely positioned.

It is intended to supply the operating power and to charge the battery for the pump installed on it when it is connected to the mains power supply.

### 1.2.1 Intended user population

The holder must only be used by trained healthcare professionals, patients, and any other relevant users. For training guide, contact your Fresenius Kabi sales representative.

## 1.3 Use environment

The holder is intended to be used inside the hospital, nursing station, home, biomedical office and any other areas involved in technical service.

DO NOT USE:

- in ambulance, helicopter and aircraft
- in Magnetic Resonance Imaging (MRI) environments



### CAUTION

The holder should be used under specified operational, storage and transport conditions listed below.

	Operating	Storage and Transport
<b>Temperature Range</b>	10 °C to 40 °C	-20 °C to +45 °C
<b>Pressure Range</b>	700 hPa to 1060 hPa	500 hPa to 1060 hPa
<b>Humidity Range</b>	30% to 85%, no condensation	10% to 90%, no condensation
<b>Altitude</b>	Less than 3000 m	-

## 2 Description

### 2.1 System definition

Place Amika / Amika+ pump on the holder to form an integrated Amika / Amika+ system.

### 2.2 Packaging content

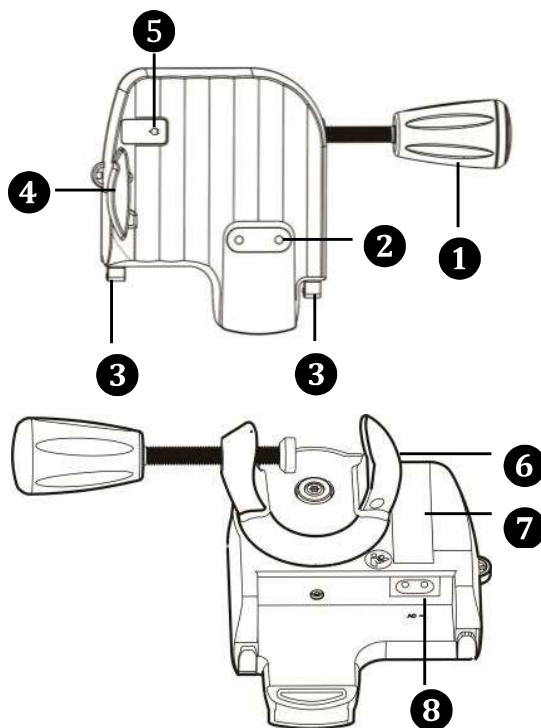
The holder is delivered with the following:

- Smart Holder Power
- Power cable
- User documents


Packaging consists of: recycled cardboard.

Symbols used on packaging are described in *Symbol description*.

### 2.3 Holder description



#### Legend

- |   |  |
|---|--|
| ①   | Clamp handle   |
| ②   | Contact pins for pump to holder connection                     |
| ③   | Slot for cables  |
| ④   | Grey locking lever   |
| ⑤   | Mains supply light indicator                                   |
| ⑥   | Pole clamp   |
| ⑦   | Holder identification label                                    |
| ⑧   | Power cable inlet  |
|  | Mains supply light indicator, on the front panel of the holder |
| AC~   | Near the power cable inlet                                     |

## 3 Holder installation and removal



#### CAUTION

Give particular attention to the risk of strangulation with cables and sets, and with the small parts that could be swallowed or inhaled.

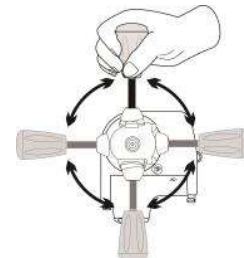
### 3.1 Installation

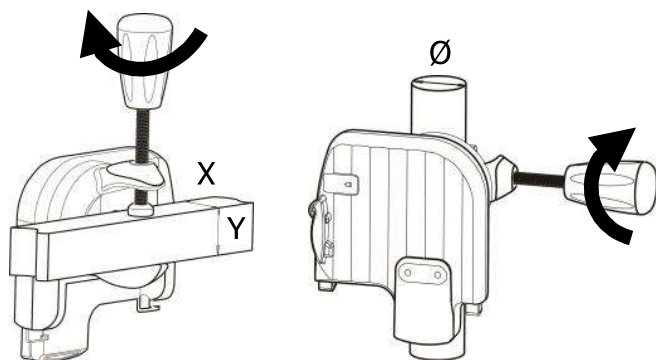
#### 3.1.1 Using the pole clamp

The holder can be attached universally, vertically and horizontally. Turn the pole clamp to the suitable position.

#### 3.1.2 Positioning the holder on a rail, pole, bed or wheelchair

Ensure the holder is positioned so that the display is at the suitable height to ensure good visibility and orientation in the reading direction (the contact pins are at the bottom).





X, Y min = 10 mm  
X, Y max = 35 mm

Ø min = 8 mm  
Ø max = 40 mm

Fasten pole clamp firmly on the pole or rail to avoid any movement of the pump.  
Ensure that the pump is securely attached and firmly positioned.

### 3.1.3 Positioning the holder on a table

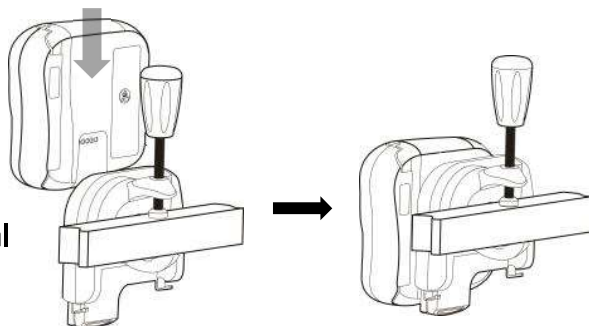
The holder can be placed on a flat and horizontal table as indicated in the figure.



Ensure the holder is positioned away from table edges to avoid being accidentally pushed off the table.

### 3.1.4 Positioning the pump

Slide the pump down until the grey locking lever locks the position



### 3.1.5 Electrical connection and removal



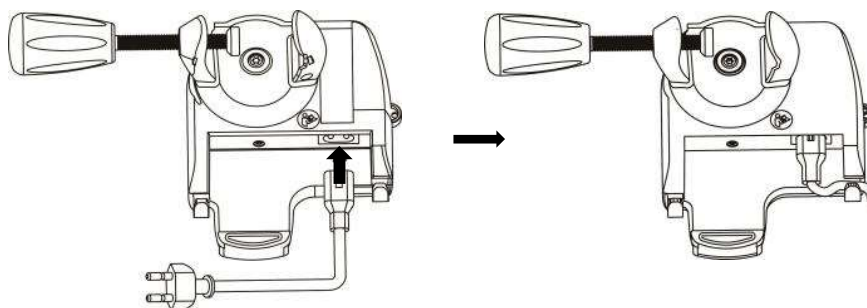
#### CAUTION

ONLY use the power cable delivered with the device. The power socket must remain accessible at all times to allow emergency power supply disconnection.

Ensure power cable is not damaged.

To charge the pump battery or to use the pump on the mains power supply:

1. Connect power cable to the holder.
2. Pinch the cable into the slot provided for this purpose.
3. Plug the power cable to the mains socket.
4. To disconnect, unplug power cable from power socket and remove power cable from holder.



The mains power supply is indicated by a green light on the holder's front panel as well as on the pump's front panel (keypad).

A beep is emitted by the pump when the power cable is disconnected.

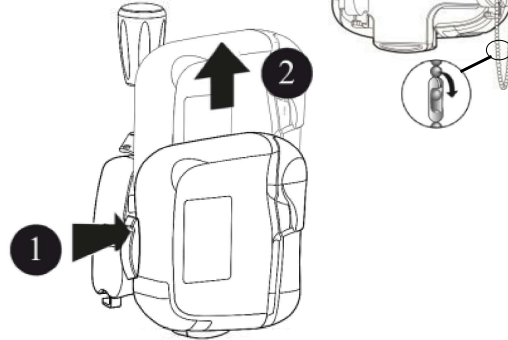
### 3.1.6 Attaching and Removing the Quick Guide

A quick guide can be easily attached and removed from the pump holder as indicated on the figure of the right side.

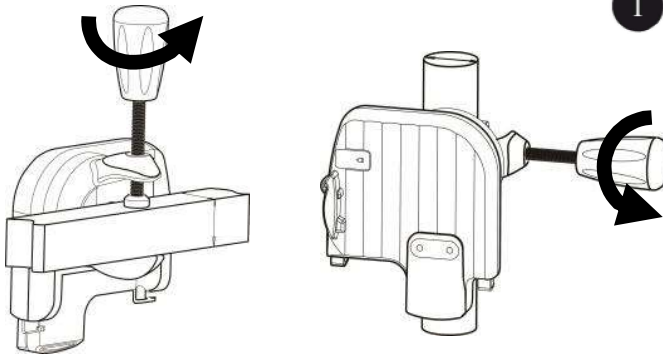
## 3.2 Removal

### 3.2.1 Removing the pump from the pump holder

- 1 Push the grey locking lever.
- 2 Pull the pump up.



### 3.2.2 Removing the pump holder



## 4 Troubleshooting

This section provides information to perform a first troubleshooting of the holder.



### INFORMATION

For additional information about issues and troubleshooting please refer to pump Technical Manual or contact your Fresenius Kabi sales representative.

Issue descriptions	Recommended actions
Power cable cannot be connected or removed from holder	<ul style="list-style-type: none"> <li>● Check the power cable inlet on holder</li> <li>● Check the power cable connector</li> <li>● Consult technical manual</li> <li>● Contact your Fresenius Kabi sales representative</li> </ul>
Mains supply light indicator do not work	<ul style="list-style-type: none"> <li>● Check the power cable installation</li> <li>● Check the power cable</li> <li>● Consult technical manual</li> <li>● Contact your Fresenius Kabi sales representative</li> </ul>
The holder cannot be installed on the position	<ul style="list-style-type: none"> <li>● Check the size of installed position is in the range of the pole clamp defined</li> <li>● Check the pole clamp is operated normally</li> <li>● Consult technical manual</li> <li>● Contact your Fresenius Kabi sales representative</li> </ul>



## 5 Technical information

EN

### 5.1 Operation mode

The holder is a reusable device.

### 5.2 Power supply specifications

The power cable must be connected directly to the mains power socket.




Protection against electric shocks: class II.

<b>Holder input</b>	AC input voltage: 100-240 Vac AC input frequency: 50/60 Hz AC input current: 110 mA-205 mA
<b>Holder output</b>	9 Vdc $\pm$ 5 % / 9 W (maximum load)
<b>Power cable length</b>	Approx. 2 m (Plug type C)

### 5.3 Dimensions – Weight

	<b>Weight</b>	<b>Dimensions (Height × Width × Depth)</b>
<b>Holder</b>	~ 0.45 kg	Approx. 132 mm × 118 mm × 46 mm (without pole clamp)
<b>Gross weigh</b>	~ 1.0 kg	-

### 5.4 Compliance with standards

	Conform to Regulation (EU) 2017/745	Protection against moisture: <b>Holder:</b> IP32 (drip-protected)   Defibrillation-proof type CF applied part   Class II equipment
Safety of ElectroMedical Equipments	Conform to EN/IEC 60601-1 EN/IEC 60601-1-6 EN/IEC 60601-1-11	
EMC	Conform to EN/IEC 60601-1-2	
Labeling	Conform to EN 1041 EN ISO/ISO 15223-1	

Note: The full list of applicable standards is available upon request. The device is protected against leakage current and do not disturb ECG or EEG devices.

## 6 Cleaning and disinfecting



### CAUTION

- Return the device to your biomedical department in case contamination remains visible on the device after cleaning.
- Please follow the disinfecting and cleaning best practices to limit risks of holder damage.
- The holder is a non-sterile medical device

### 6.1 Prohibited cleaning or disinfection agents

Do not use cleaning or disinfection agents that contain the following substances as these aggressive agents may damage the plastic parts of the device and cause the device to malfunction:

- trichloroethylene
- abrasive detergents

### 6.2 Precautions

Clean the holder as soon as it becomes contaminated with tube feed or drugs, and at least once a week. After cleaning, the holder should be left to dry for approximately 5 minutes before being reconnected to the mains.

The holder must be cleaned after each patient usage by a trained nurse or assistant nurse.

### 6.3 Recommended cleaning and disinfection agents

Didecylmethylammonium chloride (example: Wip'Anios Excel by Anios).

Please contact the appropriate service, responsible for cleaning and disinfection products in your establishment for further details.

### 6.4 Cleaning and disinfection guidelines and protocol



### INFORMATION

- Do not immerse holder in liquids or let liquids enter device's housing.
- Holder is resistant to recommended cleaning agents.

#### 6.4.1 Cleaning Instructions

##### Prerequisites

- The power cable is unplugged.
- The pump is disconnected from the holder.
- The air is at room temperature (20 °C to 25 °C).
- The operator is wearing suitable protective equipment.

##### Protocol

1. Place the holder on a cleaned surface or disposable underlay.
2. During cleaning, do not turn the holder over to avoid liquid leak in.
3. Use a ready-to-use wipe to remove any major grime.
4. Thoroughly wipe down all exposed surfaces (housing, pole clamp screw, connection area, power cable) of the holder, from top to bottom.

A minimum cleaning of 1 minute is recommended (allow to remain visibly wet for 1 minute), until all organic matter is dissolved and removed. Do not allow liquids to run, leak, or drip into the holder housing. Use cotton wool to clean the contact pins.

5. Using a fresh ready-to-use wipe, thoroughly wipe down all exposed surfaces. A minimum cleaning of 1 minute is recommended (allow to remain visibly wet for 1 minute), until all organic matter is dissolved and removed.
6. Wipe down the power cable.
7. Allow the device to dry completely at room temperature.

#### 6.4.2 Disinfection instructions

##### Prerequisites

- The cleaning protocol has been performed.
- The power cable is unplugged.
- The pump is disconnected from the holder.
- The air is at room temperature (20 °C to 25 °C).
- The operator is wearing suitable protective equipment.

##### Protocol

1. Place the previously cleaned holder on a cleaned surface or disposable underlay.
2. During disinfection, do not turn the holder over to avoid liquid leak in.
3. Use a ready-to-use wipe to wipe down all exposed surfaces of the holder, making sure to cover all cracks, crevices, and hard-to-reach areas. Do not allow liquids to run, leak, or drip into the holder housing.
4. Using a fresh ready-to-use wipe, repeat steps 3. Ensure that the minimum contact time for each step is 3 minutes for bactericide activity (surface remain visibly wet for 3 minutes). Respect the indicated contact time from the manufacturer recommendations for the required antimicrobial activity.
5. Wipe down the power cable.

## 7 Transport, storage and recycling conditions

### 7.1 Storage and transport conditions

Before transport, disconnect and remove the power cable from the holder. Check power cable is connected and operational after transport.

The holder should be used under specified storage and transport conditions (see *Use environment*) to ensure holder performance and to avoid holder malfunction.

### 7.2 Storage

Please make sure the holder is stored in an appropriate manner so as to avoid holder malfunctioning.



#### INFORMATION

- The storage area must be clean, organized and compliant with the storing conditions mentioned above.
- The holder must be handled with care during storage.



#### CAUTION

The holder must be cleaned and disinfected prior to storage (see *Cleaning and disinfecting*).

In order to prepare the device before storage, proceed as specified below:

1. Disconnect holder power cable.
2. Remove the pump and holder from pole or rails.

3. Clean the holder (see *Cleaning and disinfecting*).
4. Handle the holder with care and store it in a compliant area.

### 7.3 Recycling and Disposal



Devices with this label must not be disposed of with the general waste. They must be collected separately and disposed of according to local regulations.

For further information regarding waste processing regulations, contact your local Fresenius Kabi sales representative.

## 8 Guidance and manufacturer's declaration of EMC



### CAUTION

- The holder is intended to be used with Amika or Amika+ enteral feeding pump in the specified electromagnetic environment. The customer or the user should ensure that it is used in such an environment. For information on EMC compliance, please refer to Amika pump IFU (ref. 13118) or Amika+ pump IFU (ref. 13887), section Guidance and manufacturer's declaration on EMC.
- The device should not be used next to other equipment. If adjacent use is necessary, the device should be observed to verify normal operation in the configuration in which it will be used.
- Prolonged exposure to X-ray environments can damage the electronic components of the device. Please check pump's IFU for recommendations of safe usage in such environments.

## 9 Services

### 9.1 Warranty

#### 9.1.1 General conditions of warranty

Fresenius Kabi guarantees that the holder is free from defects in material and workmanship during the period defined by the accepted sales conditions, except for the accessories. Accessories may have specific conditions of warranty. Please contact your Fresenius Kabi sales representative for additional information.

#### 9.2 Limited warranty

To benefit from the materials and workmanship guarantee from our sales representative or agent authorized by Fresenius Kabi, the following conditions must be respected:

- Fresenius Kabi is not liable for loss or damage to the device during transport.
- The device must have been used according to the instructions described in this user guide and other accompanying documents;
- The device must not have been damaged when in storage, at the time of repair, or show signs of improper handling;
- The device must not have been altered or repaired by non-qualified personnel;
- The serial number must not have been altered, changed, or erased.



### INFORMATION

- In case of failure to comply with these conditions, Fresenius Kabi will prepare an estimate for repairs covering the parts and labour required.
- When a return and/or repair of the device are required, please contact your Fresenius Kabi sales representative.

## 9.3 Maintenance requirements



### CAUTION

- The qualified personnel must be informed if the device is dropped or if any malfunction occurs. In this case, the device must not be used. Please contact your biomedical department or Fresenius Kabi.
- When replacing components, only use Fresenius Kabi spare parts.
- No maintenance action should be performed when device is in use.

Life time of Holder: 10 years.

## 9.4 Service policy and rules

For further information concerning the device servicing or use, please contact our sale representative.

If the device must be sent for servicing, contact Fresenius Kabi to have packaging shipped to your facility. To avoid of potential harm or risks to staff, please clean and disinfect the device and pack it in the provided package before ship it to Fresenius Kabi.



### INFORMATION

Fresenius Kabi is not liable for loss or damage to the device during transport.

## 9.5 Notification of serious incident

Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority.

Information and contact information:

Fresenius Kabi AG  
61346 Bad Homburg  
Germany  
Tel.: +49 (0) 6172 / 686-0  
[www.fresenius-kabi.com](http://www.fresenius-kabi.com)

## 10 Ordering information



### CAUTION

- The holder is compatible with the range of Amika pumps and Amika+ pumps only.
- Use only recommended accessories from Fresenius Kabi.

For operating with these pumps or any further information, please contact our sales Department.

For further information regarding Amika / Amika+ accessories, please refer to Amika pump IFU (ref. 13118) or Amika+ pump IFU (ref. 13887), section Ordering information.

## 11 Glossary of terms

Term	Description
°C	Celsius Degree
CE marking	European Conformity Mark
cm	Centimeters
ECG	Electrocardiogram
EEG	Electroencephalogram
EMC	Electromagnetic compatibility
hPa	Hecto Pascal
Hz	Hertz
kg	Kilogram
m	Meters
mA	Milliampere
Max.	Maximum
Min.	Minimum
mm	Millimeters
MRI	Magnetic Resonance Imaging
Vac	Volt Alternating Current
Vdc	Volt Direct Current
W	Watt