FRESENIUS KABI
caring for life

Amika+

Enteral Feeding Pump
Software Version 1.0

Technical Manual

Revision table

TM AMIKA+ ENG V1.0 ref CC13638

Date	Revision	Chapter	Description
May 17th, 2018	0	Index "a"	Creation

Table of contents

1 Introduction

Amika+ is an enteral feeding pump with a holder and disposables dedicated to enteral feeding and hydration. The intended use of Amika+ pump and sets is to deliver nutrition and hydration fluids to the patient through a feeding tube, in a safe, instinctive and convenient manner.

Amika+ Instructions For Use (IFU) are appended at the end of this Technical manual.

1.1 Patient Data Management System (PDMS)

INFORMATION

The PDMS is not a real time remote monitoring system.

The data must be ciphered through EAP-TLS when exchanged with Hospital Information System (HIS).

1.2 Description of symbols

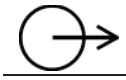
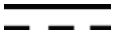
WARNING

*Warning of a **potential hazard** that could result in **serious** personal **injury** and/or product **damage** if the written instructions are not followed.*

INFORMATION

Recommendations to be followed.

1.3 Device identification labels symbols

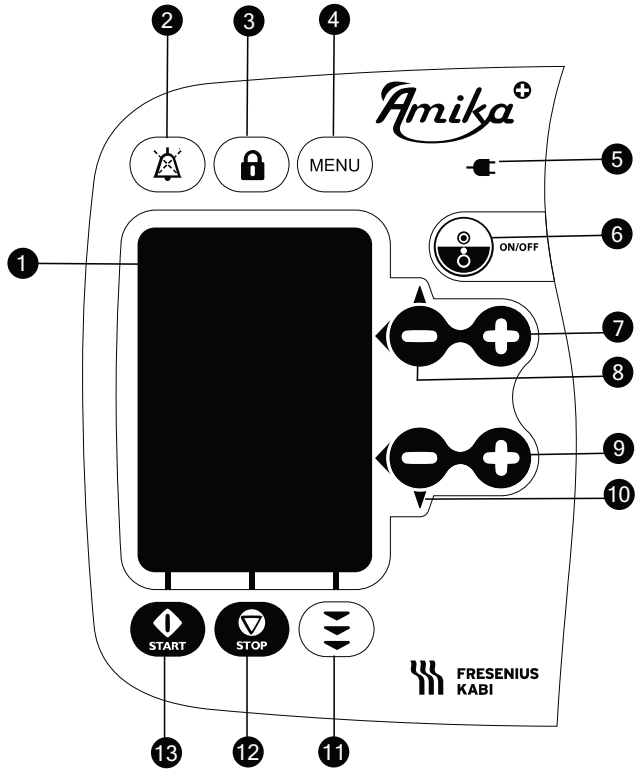
Symbol	Description
	Warning (Refer to the Instructions For Use)
	Refer to the Instructions For Use
	Protection against leakage current; defibrillation-proof type CF applied part
REF	Product reference / part number
SN	Product serial number
	Output terminal – connector
	Input terminal – connector
	Direct current (DC)
	Alternating Current (AC)
	Part included in a recycling process
IP32	Holder: IP32-Index of protection against solid foreign objects (> 2.5 mm) and dripping liquids
IP35	Pump: IP35-Index of protection against solid foreign objects (> 2.5 mm) and water jets from any direction
IP41	AC/DC Adapter: IP41-Index of protection against solid foreign objects (> 1 mm) and dripping liquids
	Protection against electric shock: Class II
	Battery specification
CE 0123	CE mark
	Medical electrical system weight (kg)
	Name and address of the manufacturing facility
	Name and address of the manufacturer / Date of manufacture

1.4 Packaging symbols

INFORMATION

Refer to the Symbol descriptions section in the Amika+ IFU.

1.5 Front panel and display description



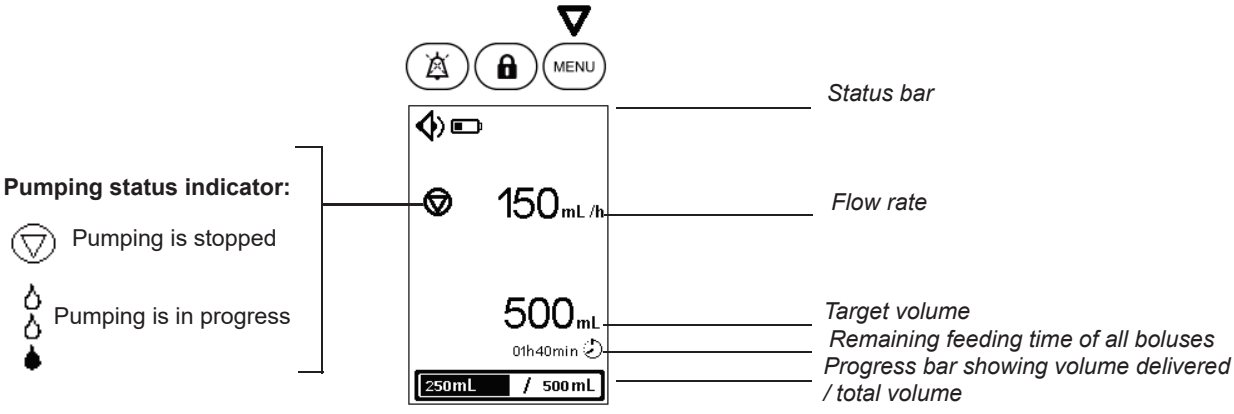
1 - Display
2 - Mute key
3 - Keypad lock key
4 - Menu key
5 - Mains supply light indicator
6 - Power ON/OFF key
7 - Flow rate Up (+)
8 - Flow rate Down (–) / Scroll up in Menu (▲)
9 - Target volume Up (+)
10 - Target volume Down (–) / Scroll down in Menu (▼)
11 - Priming function key
12 - Stop / Cancel / Back key
13 - Start / Enter / OK key

1.5.1 Display description

Status Bar icons

Symbols	Description	Symbols	Description
	Sound level icons		Alarm icon
	Battery icon		Muted alarm icon
	Keypad locked		Settings lock icon

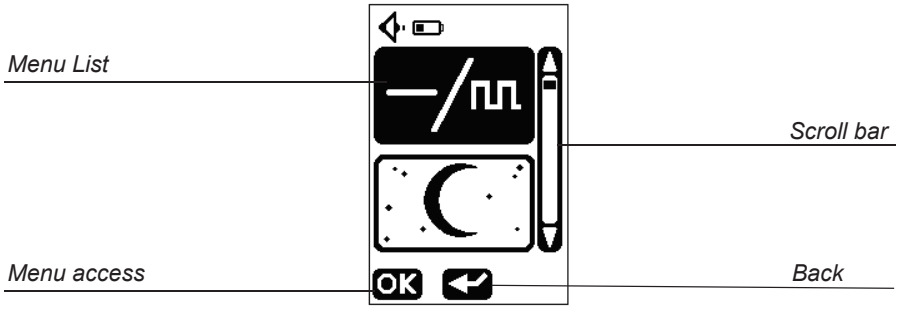
Continuous mode setting screen layout



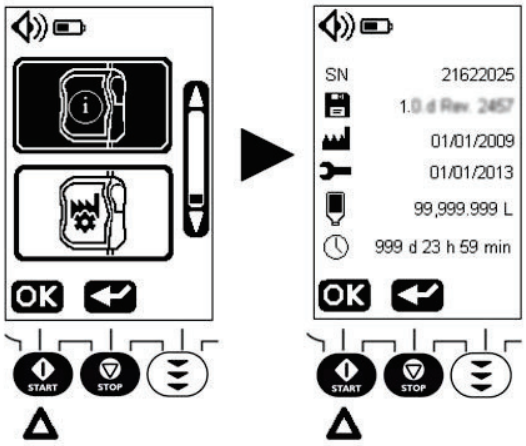
From the previous screen, press MENU then press , to scroll up / down between submenus.

Press START to enter the submenu.

Menu display layout



Technical information



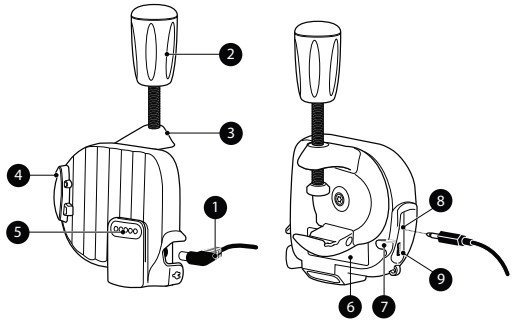
Press START to access the technical information.

INFORMATION

The technical information menu displays:

- SN Pump serial number
- Software version
- Production date (mm/dd/yyyy)
- Last maintenance date (mm/dd/yyyy)
- Total delivered volume
- Total delivered volume

1.6 Holder COM description



Legend:

1. AC/DC adapter's connector
2. Clamp handle
3. Pole clamp
4. Grey locking lever
5. Contact pins for pump to holder connection (Power supply)
6. Holder identification labels
7. Slot for cable
8. Jack 3.5 mm Nurse Call port
9. Mini USB port

Near the power cable inlet of the holder

1.7 Scope

Refer to the relevant section in the Amika+ IFU.

This document is applicable to the Amika+ pump with software version 1.0.

WARNING

The user must follow the instructions specified in this document. 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 "Description of symbols", page 7.

INFORMATION

- *Check that this document is applicable to the current Amika+ software version.*
- *The software version of the pump is displayed in the technical information menu described in "Technical information", page 10.*

1.8 Intended use

Amika+ enteral feeding pump is intended for use on adults and pediatrics to deliver nutrition and hydration fluids to the patient through an enteral route of administration using a feeding tube.

It is intended for use by both qualified and trained healthcare professionals in clinical healthcare facilities, in ambulatory use with an Amika Backpack and in pre-hospital medical ground transportation and home users in homecare.

1.8.1 Intended user population

Refer to the relevant section in the Amika+ IFU.

The service and maintenance technicians belong to the intended user population.

1.8.2 Intended patient population

Refer to the relevant section in the Amika+ IFU.

1.8.3 Principles of Operation

Refer to the relevant section in the Amika+ IFU.

1.9 Contraindications

DO NOT USE:

- for the intravenous administration of infusion fluids;
- if enteral feeding is contraindicated by medical prescription;
- with premature (born < 37 weeks of pregnancy) and neonates (<1 month);
- in Magnetic Resonance Imaging (MRI) environments;
- in ambulances, helicopters, aircrafts and hyperbaric chambers;
- in areas where there is a risk of explosion.

1.10 Use environment

The Amika+ AC/DC adapter is not meant to be used outdoor (such as in the garden, on the patio).

WARNING

- *Keep away from heat sources, dust, fluff, direct and prolonged light exposure.*
- *The pump should be used under specified storage and transport conditions listed in "Storage and transport conditions", page 21 as well as under operational conditions listed below to ensure the Amika+ pump performance and to avoid pump malfunction.*
- *At the limit of the operating temperature range, physical properties of set's tube may change; in such condition, alarms are more likely to happen.*

- Temperature operating range: 10°C to 40°C
- Pressure operating range: 700hPa to 1060hPa
- Humidity operating range: 30% to 85%, no condensation
- Altitude: maximum 3000m

For further information, refer to the relevant section in the Amika+ IFU.

In case of refrigerated products, allow the product to reach the operating temperature range before use.

When the pump is stored at extreme temperature (-20°C and +45°C), wait for 2 hours to allow the product to reach the operating temperature range before using the pump. An intempestive alarm can be triggered if the pump/giving set temperature is too low or too high.

1.11 Specificities for Homecare Environments

The responsibility of using the pump is shared between the healthcare professional and the patient. All pump settings must be performed according to the medical prescription.

If any doubt, patient or patient relatives should call healthcare professional to confirm correct handling of the device.

1.12 Warranty

1.12.1 General conditions of warranty

Fresenius Kabi guarantees that this product is free from defects in material and workmanship during the period defined by the accepted sales conditions, except for the batteries and the accessories.

1.12.2 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 the IFU 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 internal battery of the device must not have been replaced by a battery other than that specified by the manufacturer.

- The serial number (ID/N°) 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 a repair of the device are required, contact your Fresenius Kabi sales representative.*

1.12.3 Warranty conditions for battery and accessories

Batteries and accessories may have specific conditions of warranty.

Contact your Fresenius Kabi sales representative for additional information.

2 Description

For the system definition, packaging content, general description, detailed description, display description, refer to the relevant sections in the Amika+ IFU.

3 Safety and precautions

3.1 Safety recommendations

■ Fresenius Kabi will not be liable for any damages or claims, medical or otherwise, of any nature whatsoever, whether direct or consequential, caused by improper use of this device.

■ In order to ensure that all the safety features of the device are activated, the pump should be powered ON prior to being connected to the patient.

■ Special attention must be paid to the stability of the device. Use the device in horizontal position, with the incorporated holder for use on a pole or a rail, or on a table.

■ The Amika+ may only be connected to the power supply with the AC/DC adapter supplied by the manufacturer. Check that the power supply voltage corresponds with the value indicated on the label placed on the rear of the device housing. Do not exceed the permitted voltage on the different external connections.

■ The pump should ONLY be used with accessories listed in “Ordering information”, page 82.

■ Excessive lowering of in-line pressure may create free flow.

WARNING

■ *No modification of this device is allowed.*

■ *Audible alarm signals from medical devices may be masked by environmental noise. Make sure to set the alarm volume high enough so that you can hear the alarm signal above environmental noise.*

3.2 Warnings and precautions to be taken

WARNING

■ *The pump does not detect air bubbles when priming. When priming, do not connect the giving set to the patient.*

■ *Do not use this feeding pump in the shower, bath, or high humidity environments.*

■ *The device can be affected by pressure or pressure variations, mechanical shocks, heat ignition sources, etc. If you wish to use the device in specific conditions, contact your sales representative.*

■ *Excessive lowering of pressure in the giving set may create free flow.*

■ *Only use the Amika+ for the feeding of fluids that are intended for administration using a feeding pump.*

■ *Sets are supplied sterile and are indicated for single use. Do not reuse a giving set on a new patient. Do not use a giving set if its packaging appears to be damaged or opened.*

■ *Only use Amika+ giving sets with the Amika+. Use of any other giving sets and accessories with the Amika+ could affect the accuracy of the feeding and may result in injury to the patient and damage to the pump.*

■ *Properly dispose of the used giving sets.*

WARNING

In case of mechanical damage of the Holder COM locking/unlocking system, it must not be used and it has to be sent to maintenance.

3.3 Means to protect the patient

For a full description of means to protect the patient and of alarms and warnings, refer to the Alarms and safety features section in the Amika+ IFU.

3.4 Operation safety

As soon as it is in operation, the device ensures continuous surveillance of its functions. Any internal fault or any procedural anomaly is immediately detected. Nevertheless, abnormal functioning of the device, without a defined cause, must always be brought to the attention of the qualified staff in your establishment or our Technical Service.

Amika+ pump is equipped with an internal battery that ensures normal functioning during a power failure.

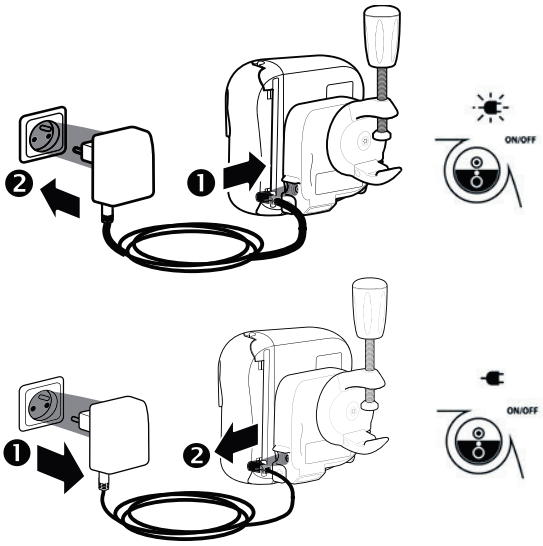
3.5 Power management

Ensure the AC/DC adapter is not damaged and is compatible with local voltage range.

3.5.1 Electrical connection

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

1. Connect AC/DC adapter to the holder.
2. Plug the AC/DC adapter to the mains socket.
   - ☐ When connecting to the mains, ensure that the AC/DC adapter and the power socket are easily accessible.
   - ☐ The mains power supply is indicated by a green light on the pump front panel (keypad).



3.5.2 Electrical disconnection

1. Remove AC/DC adapter from the power socket.
2. Remove AC/DC adapter from the holder.

INFORMATION

A beep is emitted by the pump when the AC/DC adapter is disconnected.

3.5.3 Battery precautions

Before using the Amika+ on battery for the first time, charge the battery until it is fully charged (approximately 6 hours).

Keeping the pump connected to mains when not in use is recommended in order to maintain battery charge. The battery is charging continuously ensuring its maximum capacity

It is recommended to set the pump to the highest sound level when using the pump on battery.

3.5.4 Battery operating mode

The icon is always displayed in the status bar.

The Amika+ can be used while battery is charging.

Symbols	Description
Battery life	24 hours ± 5% until 125 mL/h and a minimum of 8 hours for flow rates above 125 mL/h (in standard feeding conditions, at 22.5°C ± 2.5°C)
(green)	■ When the pump is connected to the mains, ☐ Battery charges automatically, also during operation.
	■ When the pump is disconnected from the mains, ☐ Pump switches to Battery Mode automatically.
	The battery is fully charged.
	The battery is partially charged.
(flashing)	The battery is nearly empty. ☐ A visual information is triggered. When battery is empty (less than 10 minutes left), an alarm is triggered.

INFORMATION

- *To optimize battery life, set the flow rate at 125 mL/h maximum and use the pump in battery mode several times until battery is discharged  (flashing).*
- *If battery is failing, do not use the device. Return the device to Fresenius Kabi sales representative as soon as possible.*
- *Battery replacement must be performed by a qualified and trained technical personnel in compliance with this document and procedures.*

Before using the Amika+, proceed to the Quick Check Protocol available in the IFU.

4 Cleaning and disinfection

Refer to the relevant section in the Amika+ IFU.

4.1 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.

4.2 Precautions for cleaning

Clean pump and pump holder as soon as they become contaminated with tube feed or drugs, and at least once a week.

After cleaning, the pump should be left to dry for approximately 5 minutes before being started or reconnected to the mains.

The pump must be cleaned after each patient usage by a trained nurse or nurse assistant and before any maintenance operation.

Follow the disinfecting and cleaning best practices to limit risks of pump damage and to protect patient and staff.

WARNING

- *The Amika+ pump is not intended to be sterilized. Sterilization may result in damages to the device. The Amika+ is a non-sterile medical device.*
- *The Amika backpack must be cleaned before inserting the pump. Please refer to its specific accompanying documents.*
- *Make sure to use the original door when replacing it on the pump (check the serial number on the pump is the same as on the door). A door switch between pumps can lead to major pumping errors.*

4.3 Recommended cleaning and disinfection agents

For cleaning and disinfection, the following agent is recommended:
Didecyldimethylammonium chloride (example: Wip'Anios Excel by Anios).

Contact the appropriate service, responsible for cleaning and disinfecting products, in your establishment for further details.

4.4 Cleaning and disinfection guidelines and protocol

INFORMATION

- *Do not immerse pump and pump holder in liquids or let liquids enter device's housing.*

- *Pump and pump holder are resistant to recommended cleaning agents (see "Recommended cleaning and disinfection agents", page 18).*

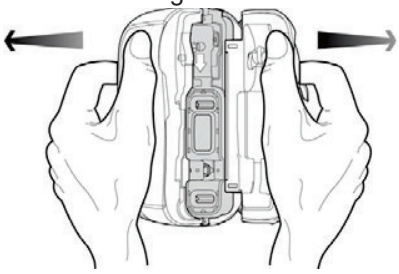
4.4.1 Cleaning Instructions

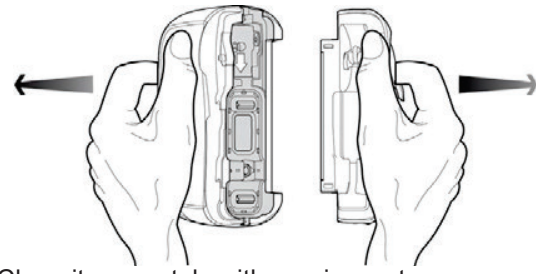
Prerequisites

- The pump is switched off.
- The power cord and all other cables are unplugged.
- The pump is disconnected from the holder.
- The air is at room temperature (20 to 25 ℃).
- The operator is wearing suitable protective equipment.

Protocol

1. Place the pump and the holder on a cleaned surface or disposable underlay. The door can be removed from the pump to facilitate the cleaning.

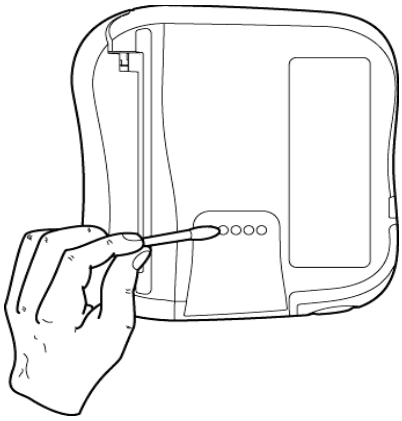




NOTE: The door can be immersed. Clean it separately with running water.

2. During cleaning, do not turn the pump over to avoid liquid leak in the battery door.
3. Use a ready-to-use wipe to remove any major grime.
4. Thoroughly wipe down all exposed surfaces (housing, keypad, screw area, holder connection area, etc.) of the pump, from top to bottom. Gently wipe down the pump exposed mechanism and sensor area (tube guide, purple insert).

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 pump housing. Use cotton wool to clean the contact pins.



5. Repeat step 4 with the pump door (housing, lever, counter door) and holder (pole clamp screw, housing, etc.)
6. 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.
7. Wipe down the power cord.
8. Allow the device to dry completely at room temperature.
9. Make sure to use the original door when replacing it on the pump (check the serial number on the pump is the same as on the door).

4.4.2 Disinfection instructions

Prerequisites

- The cleaning protocol has been performed.
- The pump is switched off.
- The power cord and all other cables are unplugged.
- The pump is disconnected from the holder.
- The air is at room temperature (20 to 25 ℃).
- The operator is wearing suitable protective equipment.

Protocol

1. Place the previously cleaned pump and holder on a cleaned surface or disposable underlay. The door can be removed from the pump to facilitate the disinfection.
2. During disinfection, do not turn the pump over to avoid liquid leak in the battery door.
3. Use a ready-to-use wipe to wipe down all exposed surfaces of the pump, holder and pump door (as described in cleaning protocol), making sure to cover all cracks, crevices, and hard-to-reach areas. Do not allow liquids to run, leak, or drip into the pump 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 cord.

6. Allow the pump to dry completely at room temperature.

7. Make sure to use the original door when replacing it on the pump (check the serial number on the pump is the same as on the door).

5 Transport, storage and recycling conditions

5.1 Storage and transport conditions

During transport, the Amika+ pump shall not be removed from its pole or rail when carrying feeding devices, especially when feeding is running.

Check that the AC/DC adapter is connected and operational after transport of the Amika+ pump.

The Amika+ pump should be used under the specified storage and transport conditions listed below to ensure its performance.

- Storage and transport temperature: -20°C to +45°C.
- Storage and transport pressure: 500hPa to 1060hPa.
- Storage and transport humidity: 10% to 90%, no condensation.
- Altitude: maximum 3000 m.

5.2 Storage

Make sure the Amika+ pump is stored in an appropriate manner so as to avoid its malfunctioning.

INFORMATION

- *The Amika+ must be cleaned and disinfected prior to storage.*
- *The storage area must be clean, organized and compliant with the storing conditions mentioned above.*
- *The Amika+ pump must be handled with care during storage.*

INFORMATION

- *If the Amika+ is not used for longer than 2 months, remove the battery and store it as per storage conditions above.*
- *If the Amika+ is stored without removing the battery, charge it at least once a month by connecting it to the mains for at least 6 hours.*

5.2.1 Prepare the device for storage

Refer to the relevant section in the Amika+ IFU.

5.2.2 Install the device after storage

Refer to the relevant section in the Amika+ IFU.

5.3 Recycling and disposal

Refer to the relevant section in the Amika+ IFU.

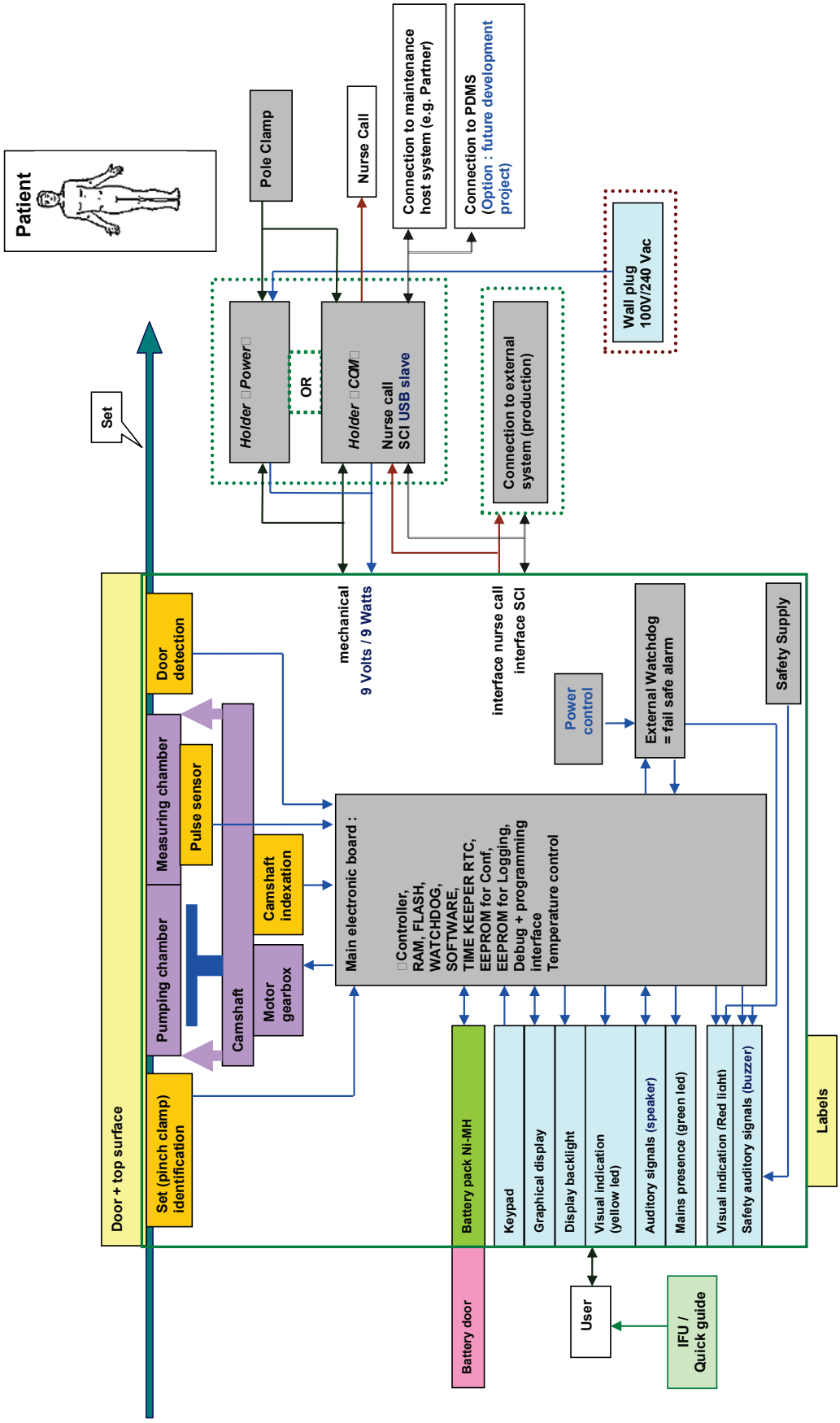
6 Technical characteristics

6.1 Compliance with standards

General requirements for basic safety and essential performance for Medical electrical equipment	Conform to IEC 60601-1
Electromagnetic compatibility- Requirements and tests for Medical electrical equipment	Conform to IEC 60601-1-2
Particular requirements for the basic safety and essential performance of infusion pumps and controllers	Conform to IEC 60601-2-24
General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems	Conform to IEC 60601-1-8
Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment	Conform to IEC 60601-1-11
CE 0123	Conform to the 93/42/EEC Medical directive 0123 : Notified body number (TÜV SÜD Product Service GmbH, Ridlerstrasse. 65, 80339 München, Germany)

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

6.2 Operation diagram



6.3 Technical data

6.3.1 Power supply

AC/DC adapter power supply main features:

- AC input voltage: 100-240VAC ± 10%
- AC input frequency: 50-60Hz
- Output voltage: 9Vdc ± 5%
- Output current: 1.0A
- AC input current: 110 mA-205 mA
- Cable length: approx. 2.5m
- Proofness: IP41
- Protection against electric shocks: class II

6.3.2 Battery

Disconnect the battery and discharge boost capacitor before opening the Amika+. Avoid short circuit and excessive temperature.

If the device is not used over an extended period, all of its parameters are stored permanently.

Battery main features:

- Chemistry: NiMH (Nickel-Metal Hydride)
- Voltage/cell: 1.2V
- Type: Cylindrical - AA
- Number of cells: 4 / serial assembly / 4.8V
- Capacity: 2.2 Ah
- Fast charge current: 400mA
- Maximum charging time: 6 hours

6.3.3 USB connector specifications

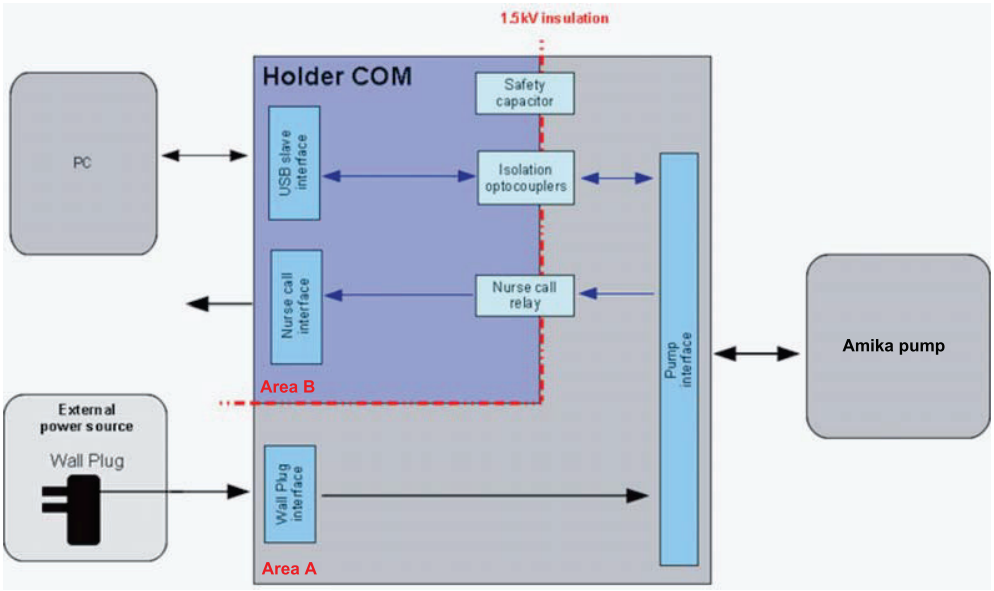
- Input/output: 5Vdc / 0.5 A
- Electrical insulation: 1.5 kV insulation

6.3.4 Nurse Call connector specifications

- Holder COM ouput:
  - 24 Vdc SELV (Safety Extra Low Voltage) / 0.5 A
  - 24 Vac / 0.5 A
- Electrical insulation: 1.5 kV insulation

6.3.5 Holder COM

Holder COM Board Architecture Overview



Holder COM - Communication port connector

Pin n°	Signal	Description
1	VBUS	5V voltage
2	DM	D-
3	DP	D+
4	ID	Not connected
5	IGND	Ground voltage

USB type mini B right angle connector

Holder COM - Nurse call connector

Pin n°	Signal	Description
1	COMMON_NURSECALL	COMMON
2	CLOSED_NURSECALL	
3	OPEN_NURSECALL	

3.5 mm audio jack connector for connection of a nurse call.

Holder COM adapter connector

Pin n°	Signal	Description
1	NC	Not connected
2	VHI	Holder input voltage
3	GNDWP	Wall Plug ground
4	GNDWP	Wall Plug ground
5	NC	Not connected

DC jack connector for connection of external wall plug.

Pump interface (power and communication)

Pin n°	Signal	Description
1	GND	Ground
2	NURSECALL	Nurse call
3	TX	Transmit data
4	RX	Receive data
5	VHO	Holder output voltage

- Serial communication interface characteristics:
  - RS232 connection (transmit data, receive data, and ground).
  - Baudrate: 9600 to 115200 Kbps.

5 metallic holes to ensure connection with the golden contacts inside the Holder COM housing.

6.3.6 Connection to the Nurse Call System and Removal

INFORMATION

- *Use ONLY cable recommended by Fresenius Kabi. Refer to "Ordering information", page 82.*
- *All connections and disconnections must be performed by qualified and appropriately trained staff.*

The Amika Holder COM and Nurse Call cable allow the connection of an Amika pump to an external Nurse Call system to transmit an Amika pump alarm state.

The Nurse Call connection is functional only if:

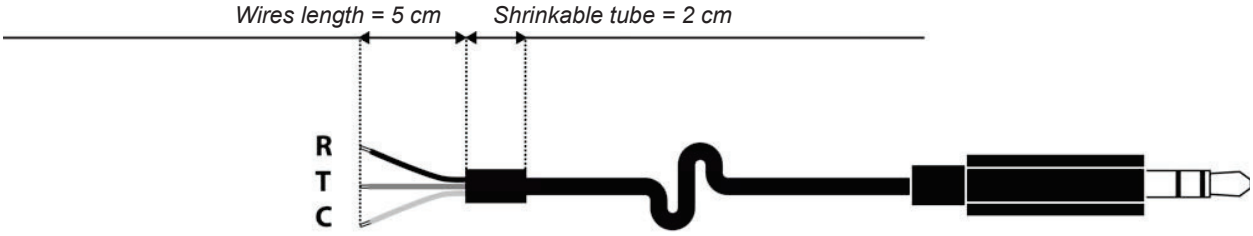
- the Amika+ pump is correctly installed on the Holder COM,
- the Holder COM is connected to the power supply,
- the Nurse Call cable is correctly plugged.

If the Nurse Call is not functional, Amika+ pump alarm state is not transmitted.

The Nurse Call system availability and technical compliance are the responsibility of the hospital.

The Nurse Call cable is delivered with an unterminated side, which will require customization to the hospital-specific nurse call system by a trained technician, following specific requirements and installation as described below. Also see the Amika Holder COM Nurse Call IFU.

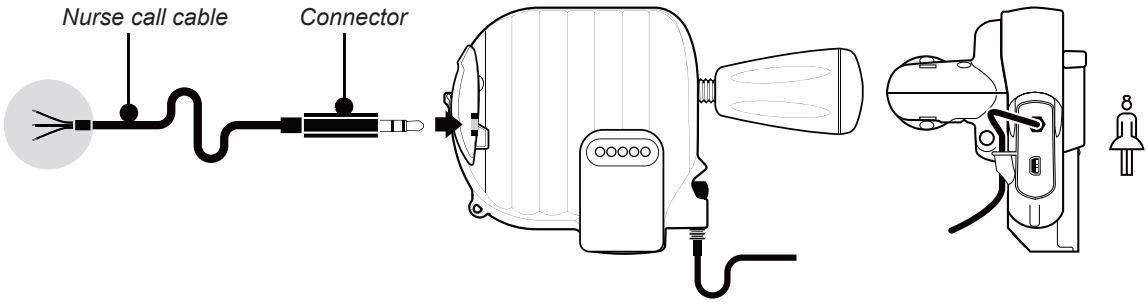
Nurse Call cable specification



The unterminated side is composed of 3 wires, connected to Nurse Call signalling system:

- R: Stand off contact
- T: Working contact
- C: Common contact

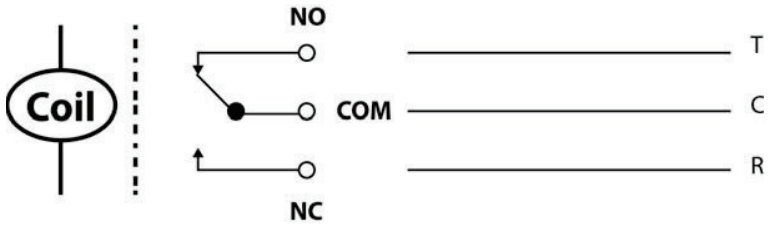
Connection to the Holder COM



- Connect the Holder COM to the mains. Ensure that the AC/DC adapter and the power socket are easily accessible.
- Connect the terminated Nurse Call cable to the Holder COM Nurse Call connector.
- Pinch the cable into the slot provided for this purpose.
- Connect the Nurse Call cable unterminated side to the hospital Nurse Call system as described below.
- Check that the nurse call system is functional by generating an alarm (eg: start the pump with no giving set installed). Ensure the pump alarm is transmitted on the connected Nurse Call system.
- To disconnect, unplug the Nurse Call cable.

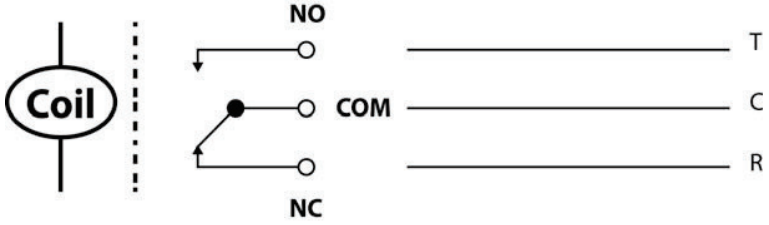
Nurse Call system electrical schematics

Without pump alarms:



System operation	Contact	Electrical continuity
Pump is running without any alarm Pump is OFF No pump is installed on the holder Pump is booting	C-T	C-COM-NO-T

With pump alarms:

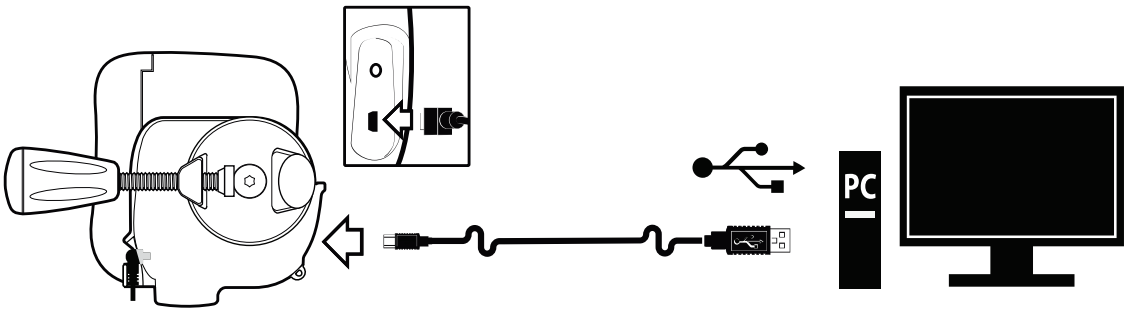


System operation	Contact	Electrical continuity
Pump is running with alarm Pump is running with prior information to alarm	C-R	C-COM-NC-R

6.3.7 USB connection and removal

INFORMATION

- *Use ONLY cable recommended by Fresenius Kabi. Refer to "Ordering information", page 82.*
- *All connections and disconnections must be performed by qualified and appropriately trained staff.*
- All IT devices (including computers, hubs and switches) inside the patient area (< 1.5 m) must comply with IEC/EN 60601-1 (leakage current).
- IT devices connected outside the patient area (> 1.5 m) must be at least IEC/EN 60950 compliant.
- Do not disconnect communication cables while data is being transferred.



- Connect the terminated USB cable to the Holder COM mini USB connector.
- Connect the other side of the USB cable to the third party system.
- Check communication status.
- To disconnect, unplug the USB PC cable.

6.3.8 Data communication overview

INFORMATION

- *Ensure that all hospital information systems have been approved by Fresenius Kabi. For more information, contact your technical services representative.*
- *Before connecting the pump to a hospital information system, please contact your IT or biomedical department.*

Amika+ data communication feature allows:

- Communication between a hospital information system server and one pump for the following purposes: State of the pump view, Pump history retrieval.
- Connection of one pump to a PC for maintenance purposes through Amika Partner maintenance software.

For further information, refer to the Amika+ and Amika Partner IFUs.

6.3.9 Approx. dimensions and weight

- Amika+ pump
  - Dimensions (H x W x D): 138 x 128 x 48 mm
  - Weight: 610 g
  - Screen size: 63 x 51 mm
- Amika Holder COM and cables
  - Dimensions (H x W x D): 200 x 110 x 90 mm
  - Weight: 600 g
  - Cable length: 2 m
- AC/DC adapter
  - Weight: 200 g

6.3.10 Electronic boards

The Amika+ pump contains 4 electronic boards:

- CPU board.
- Display board.
- Pinch clamp identification (not described here).
- Speaker board (not described here).

6.3.11 Material characteristics

Component	Material
6x4 neoflux magnet	Nd-Fe-B
force sensor honeywell	
id protect sticker 90x30	
id protect sticker 25x10	Polyester Clear Gloss
silver label 25x10	Polyester platinium
silver label 90x30 hub 40mm	
quicklock 1.5 dia washer	Steel
large pan head screw m2.5 x 8 t8	Steel
pan head screw 2.5x 8 t8	Steel
large pan head screw m2.5x8 t8	Steel
AA battery pack	
extension spring	Stainless steel

Component	Material
silent block	Elastomer Rubber Base BUTYL
door cover	ABS
counter door	PAMXD6
smart lever door	PBT
door axle lever	Stainless steel
clamp cam	POM
overmoulded clamp lock	POM
locking part for the door	CuZn36
door lock compression spring	
top surface	ABS
purple insert for Amika+ top surface	N.A
door pin	Stainless steel
insert s-m2-5 borgne simaf	Brass
gasket for Amika+ housing	SI
membrane clamp head	PP
membrane frame	PP
clamp pin	Stainless steel
moulded membrane	SEBS
membrane contact	PP
geared motor Amika+	
camshaft	
camshaft pulley	POM
pumping bearing shaft	
optical disk	POM
pump body	PC
clamping fingers	POM
pumping fingers	POM
bearing b de19 di10 w7	Steel
bearing b de13 di4 w5	Steel
bearing d4 d9 b4	Steel
overmoulded light indicator	PA
overmoulded transparent window	PA
main housing	ABS
overmoulded battery door	SEBS
Amika+ keyboard	
battery door lever	N.A
compression spring	Stainless steel
magnet gss21h-4x1-5	Neodymiu
camshaft with bearings	
force sensor flexible ic	
top surface generic insert	PBT
battery door	ABS
wire awg24	
uc board Amika+	
optical cs	
contact red wire	
contact orange wire	
contact white wire	

Component	Material
contact gray wire	
contact black wire	
sleeve yellow 1.75 mm helevia	
electric connector	
flounder 4 wires PCB-trappind	
front speaker part	ABS
fastlock spring	
battery door flexible ic	
jst connector 5 pins 2mm	
capacitor retainer	POM
battery door assembly	N.A
silent bloc spacer	Brass
pump sealing label	
iso-7010-m002 label	Polyester
silver label 31x20	Polyester platinium
id protect sticker 31x20	Polyester Clear Gloss
clamp screw tip	POM
nylstop nut m5	Steel
washer 2.5*7 mm .5 thick	Steel
pan head screw 2.5x 8 t8	Steel
pan head screw m5x25 t25	Steel
pole clamp screw	N.A
screw	Brass
pole clamp handle	PP
pole clamp handle cap	PP
pole clamp	
shoulder hollow shaft	Stainless steel
indexer	POM
upper holder housing	ABS
holder housing welded	N.A
cover	ABS
hook	ABS
wire spring for holder hook	Stainless steel wire 302
bolt	POM
two pin connector	ABS
plastic washer 15od*8id*1.5 thick	Iglidur G
bushing guide	POM
wall plug ac/dc	
adapter wall plug uk	
adapter wall plug eu	
pinch clamp Amika+	PC
id protection label 70 x 52	
packaging label 72 x120	UPM Raflatac Vellum paper
packaging Amika+	

6.3.12 Empty bag / air detection threshold

Empty bag / air detection threshold: 3.0 mL ± 1.0 mL.
This threshold is the same for the entire range of flow rates.

6.4 Essential performances

Pump essential performances are defined as follows in standard operating conditions.

6.4.1 Flow rate accuracy

±7% at 50mL/h with medical water.

WARNING

Flow rate accuracy can be influenced by giving set configuration, tube stretching, fluid viscosity, fluid temperature, container height and feeding settings.

6.4.2 Occlusion alarm response time

Occlusion detection time <6min at 50mL/h, with medical water.

6.4.3 Management of medium and high priority alarms

Refer to the "Different types of information signal or alarm" section in the Amika+ IFU.

For further information on essential performances, refer to the relevant section in the Amika+ IFU.

6.5 Guidance and manufacturer's declaration on Electromagnetic Compatibility (EMC)

The Amika+ pump is intended to be used in the electromagnetic environment specified below.

The customer or the user of the Amika+ pump should ensure that it is used in such an environment.

Excluding the cases described in this document, the pump operation must systematically be checked by a qualified operator, should the pump be installed in the vicinity of other electrical devices.

WARNING

Prolonged exposure to X-ray environments can damage the electronic components of the device and influence the flow rate accuracy. For a safe usage, we recommend to:

- *always put the device at the maximum distance from the patient and the source;*
- *limit the presence of the device in such environments.*

6.5.1 Electromagnetic compatibility and interference guidance

The Amika+ has been tested in accordance with the electromagnetic compatibility standards applicable to medical devices. Its immunity is designed to ensure correct operation. Limitation of the emitted radiation avoids undesirable interference with other equipment.

The Amika+ is classified as a Class B device according to CISPR 11 emitted radiation. The user might be required to take mitigation measures, such as relocating or re-orienting the equipment.

Use of accessories and cables other than those recommended by Fresenius Kabi, could result in increased emissions and / or decreased immunity of the Amika+ system.

If the Amika+ is placed near devices such as HF surgical device, X-ray equipment, NMR, cell phones, DECT phones or wireless access points, portable RFID reader, large scale RFID reader and RFID Tags, it is essential to observe a minimum distance between the Amika+ and this equipment (refer to "Table 6 - Recommended Separation Distances Between Portable and Mobile RF Communication Equipment and Amika+", page 34). If the Amika+ causes harmful interference or if it is itself disrupted, the user is encouraged to try to correct the interference by one of the following actions:

- Reorient or relocate the Amika+ or patient or disruptive equipment.
- Change the routing of cables.
- Connect Amika+ mains plug on protected / backed-up / filtered supply or directly on UPS circuit (Uninterruptible Power Supply).
- Increase the separation between the Amika+ and patient or disruptive equipment.
- Connect the Amika+ into an outlet on a circuit different from that to which the patient or disruptive device is connected.
- In any case, whatever the context, the user should conduct interoperability testing in a real situation to find the right setup and good location.

6.5.2 EMC and essential performances

WARNING

In the case of electromagnetic disturbances, if the essential performances, Section 6.4, page 32., are lost or degraded, the consequences for the patient can be: overfeeding, underfeeding, delay of therapy, trauma.

Table 1 - Guidance and Manufacturer's Declaration - Electromagnetic Emissions

The Amika+ pump and its accessories are intended to be used in the electromagnetic environments specified below. The customer or the user of the Amika+ should ensure that it is used in such environments.

Emission Test	Compliance Obtained by the Device	Electromagnetic Environment - Guidance
RF emissions CISPR 11	Group 1	Amika+ pump only uses RF energy for its internal operation. Its RF emissions are therefore very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	Amika+ pump is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC61000-3-2	Class A	
Voltage fluctuations Flicker emissions IEC 61000-3-3	N/A	

Table 2 - Guidance and Manufacturer's Declaration - Electromagnetic Immunity

The Amika+ pump and its accessories are intended to be used in the electromagnetic environments specified below. The customer or the user of the Amika+ should ensure that it is used in such environments.

Immunity Test	IEC 60601-1-2 --- IEC 60601-2-24 and ANSI/AAMI ID26 Test Level	Compliance Level Obtained by the Device	Electromagnetic Environment - Guidance
Electrostatic Discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air --- ± 8 kV contact ± 15 kV air	± 8 kV contact ± 15 kV air	Floor coverings made from wood, tiles and concrete, with relative humidity level at least 30 %, make it possible to guarantee the necessary level of conformity. If it is not possible to guarantee this environment, additional precautions must be taken, such as: use of anti-static equipment, preliminary user discharge and the wearing of antistatic clothing.
Electrical fast Transient / burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input output lines	± 2 kV for power supply lines ± 1 kV for input output lines	AC power quality should be that of a typical commercial or healthcare facility environment.
Surge IEC 61000-4-5	± 1 kV differential mode ± 2 kV common mode	± 1 kV differential mode ± 2 kV common mode	AC power quality should be that of a typical commercial or healthcare facility environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	< 5% Ut (> 95% dip in Ut) for 0.5 cycles	< 5% Ut (> 95% dip in Ut) for 0.5 cycles	AC power quality should be that of a typical commercial or healthcare facility environment. For short and long interruptions (< than battery life) of AC power, the internal battery provides continuity of service.
	40% Ut (60% dip in Ut) for 5 cycles	40% Ut (60% dip in Ut) for 5 cycles	
	70% Ut (30% dip in Ut) for 25 cycles	70% Ut (30% dip in Ut) for 25 cycles	
	< 5% Ut (> 95% dip in Ut) for 5 s	< 5% Ut (> 95% dip in Ut) for 5 s	

Immunity Test	IEC 60601-1-2 - - - - - - - - - - - - - - IEC 60601-2-24 and ANSI/AAMI ID26 Test Level	Compliance Level Obtained by the Device	Electromagnetic Environment - Guidance
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m - - - - - - - - - - - - - - 400 A/m	400 A/m	If necessary, the power of the magnetic field should be measured in the intended installation location to ensure that it is lower than compliance level. If the measured field in the location where Amika+ is used exceeds the applicable magnetic field compliance level above, observe Amika+ to verify that it is operating normally. If you notice abnormal performance, additional measures may be necessary, such as reorienting or relocating Amika+, or installing magnetic shielding.

Note: "Ut" is the AC Power voltage prior to applying the test level.

Table 4 - Guidance and Manufacturer's Declaration - Electromagnetic Immunity

The **Amika+** pump and its accessories are intended to be used in the electromagnetic environments specified below. The customer or the user of the **Amika+** should ensure that it is used in such environments.

Immunity Test	IEC 60601-1-2 - - - - - - - - - - - - - - IEC 60601-2-24 and ANSI/AAMI ID26 Test Level	Compliance Level Obtained by the Device	Electromagnetic Environment - Guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz - - - - - - - - - - - - - - Not applicable	10 Vrms	Portable and mobile RF communication equipment should be used no closer to any part of Amika+ (including cables), than the recommended separation distance calculated from the transmitter frequency equation. Recommended separation distance: D = 0.35 √ P, for a frequency of 150 kHz to 80 MHz
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz - - - - - - - - - - - - - - 10 V/m 80 MHz to 2.5 GHz	10 V/m	D = 0.35 √ P, for a frequency of 80 MHz to 800 MHz D = 0.7 √ P, for a frequency of 800 MHz to 2.5 GHz P is the maximum output power rating of the transmitter in Watts (W) according to the transmitter manufacturer, and D is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey (a), should be less than compliance level (b). Interference may occur in the vicinity of equipment marked with the following symbol:

Notes:

- At 80 MHz and 800 MHz, the highest frequency range applies.
- These guidelines may not apply to all situations. Absorption and reflection from structures, objects and people may affect the electromagnetic propagation.
- (a) Field strengths from fixed transmitters, such as base stations for radio (cell / cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcasts and TV broadcast cannot be predicted theoretically with accuracy. To access the electromagnetic environment due to the fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location where Amika+ is used exceeds the applicable RF compliance level above, Amika+ should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating Amika+, or installing magnetic shielding.
- (b) Over the frequency range of 150 kHz to 80 MHz, field strengths should be less than 10 V/m.

Table 6 - Recommended Separation Distances Between Portable and Mobile RF Communication Equipment and Amika+

The Amika+ and its accessories are intended for use in electromagnetic environments in which radiated RF disturbances are controlled.
Users of Amika+ may prevent electromagnetic interference by maintaining a minimum distance between portable and

mobile RF communication equipment (transmitters) and Amika+ as recommended below, and according to the maximum output power of the communication equipment (transmitters).

Rated Maximum Output Power of Transmitter (W)	Separation Distance According to Transmitter Frequency in Meters (m)		
	150 kHz to 80 MHz $D = 0.35 \sqrt{P}$	80 MHz to 800 MHz $D = 0.35 \sqrt{P}$	800 MHz to 2.5 GHz $D = 0.7 \sqrt{P}$
0.01	0.04	0.04	0.07
0.1	0.11	0.11	0.22
1	0.3	0.3	0.7
10	1.1	1.1	2.2
100	3.5	3.5	7

For transmitters rated at a maximum output power not listed above, the recommended separation distance D in meters (m) can be estimated using the equation applicable to the transmitter frequency, where P is the maximum output power rating of the transmitter in watts (W) as designated by the transmitter manufacturer.

WARNING

- *At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.*
- *These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.*
- *The Amika+ should not be used next to other equipment. If adjacent use is necessary, observe the device to verify that it operates normally in the configuration in which it will be used (Amika+ pump with a AC/DC adapter, a USB cable and a nurse call cable).*

6.5.3 EMC test deviations and supplementary tests

To ensure compatibility with the new EMC standard IEC / EN 60601-1-2 Ed4 and special environments, specific, additional or deviating tests are listed below with respect to the basic tests, in accordance to manufacturer risk analysis.

Immunity test	IEC 60601-1-2 IEC 60601-2-24 Test level	Compliance level obtained by the device	Electromagnetic environment – guidance
Discharge (ESD) IEC 61000-4-2	± 8 kV contact ± 15 kV air	± 8 kV contact ± 15 kV air	Wooden, tiled or concrete flooring, with a relative humidity level at least 30%, makes it possible to guarantee the level of necessary conformity. If it is not possible to guarantee this environment, the additional precautions must be taken, such as: use of anti-static material, preliminary user discharge and wearing anti-static clothing.
Radiated RF IEC 61000-4-3	10 V/m, 80 MHz à 2,7 GHz	10 V/m, 80 MHz à 2,7 GHz	Portable and mobile RF communications equipment should be used no closer to any part of the Amika+, including cables, than the recommended separation distance calculated from the equation applicable to the frequency and power of transmitter For standard communication services and equipment, the specific frequencies were tested for a minimum approach distance of 30 cm and 10 cm (see below)
Near field radiated RF IEC 61000-4-3 test method	385 MHz, PM 18Hz, 27 V/m 450 Mhz, 1 KHz, 28 V/m 710 MHz, PM 217 Hz, 9 V/m 745 MHz, PM 217 Hz, 9 V/m 780 MHz, PM 217 Hz, 9 V/m 810 MHz, PM 18 Hz, 28 V/m 870 MHz, PM 18 Hz, 28 V/m 930 MHz, PM217 18 Hz, 28V/m 1720 MHz, PM 217 Hz, 28 V/m 1845 MHz, PM 217 Hz, 28 V/m 1970 MHz, PM 217 Hz, 28 V/m 2450 MHz, PM 217 Hz, 28 V/m 5240 MHz, PM 217 Hz, 9 V/m 5500 MHz, PM 217 Hz, 9 V/m 5785 MHz, PM 217 Hz, 9 V/m	Not tested Not tested Not tested Not tested Not tested Not tested Not tested Not tested Not tested Not tested Not tested 2450 MHz, PM 217 Hz, 28 V/m 5240 MHz, PM 217 Hz, 9 V/m 5500 MHz, PM 217 Hz, 9 V/m 5785 MHz, PM 217 Hz, 9 V/m	For minimal distance approach 30 cm (12 inches) "Not tested" frequencies are replaced by IEC 61000-4-39 test method and reduced minimal distance approach (see below) Portable and mobile RF communications equipment should be used no closer to any part of the Amika+, including cables, than the recommended minimal separation distance (30 cm) for these frequencies

Immunity test	IEC 60601-1-2 IEC 60601-2-24 Test level	Compliance level obtained by the device	Electromagnetic environment – guidance
Near field radiated RF - special test IEC 61000-4-39 test method	450 MHz, PM 217 Hz, 28 V/m 710 MHz, PM 217 Hz, 28 V/m 787 MHz, PM 217 Hz, 28 V/m 810 MHz, PM 217 Hz, 44 V/m 830 MHz, PM 217 Hz, 44 V/m 870 MHz, PM 217 Hz, 44 V/m 1750 MHz, PM 217 Hz, 28 V/m 1875 MHz, PM 217 Hz, 28 V/m 1970 MHz, PM 217 Hz, 28 V/m 2560 MHz, PM 217 Hz, 28 V/m 2655 MHz, PM 217 Hz, 28 V/m	450 MHz, PM 217 Hz, 28 V/m 710 MHz, PM 217 Hz, 28 V/m 787 MHz, PM 217 Hz, 28 V/m 810 MHz, PM 217 Hz, 44 V/m 830 MHz, PM 217 Hz, 44 V/m 870 MHz, PM 217 Hz, 44 V/m 1750 MHz, PM 217 Hz, 28 V/m 1875 MHz, PM 217 Hz, 28 V/m 1970 MHz, PM 217 Hz, 28 V/m 2560 MHz, PM 217 Hz, 28 V/m 2655 MHz, PM 217 Hz, 28 V/m	For minimal distance approach 10 cm 250 mW average power for 28 V/m test level 600 mW average power for 44 V/m test level Portable and mobile RF communications equipment should be used no closer to any part of the Amika+, including cables, than the recommended minimal separation distance (10 cm) for these frequencies
Electrical Fast transient / Burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input output lines 100 KHz repetition	± 2 kV for power supply lines ± 1 kV for input output lines 100 KHz repetition	Electricity power quality should be that of a typical domestic, commercial or hospital environment
Surge IEC 61000-4-5	± 1 kV differential mode ± 2 kV common mode	± 1 kV differential mode Does not apply	Electricity power quality should be that of a typical domestic, commercial or hospital environment. For very exposed establishments or buildings with the lightning, a protection must be installed on electricity power. Class II product and no earth connexion.
Conducted RF IEC 61000-4-6	3 Vrms 150 KHz to 80 MHz And 6 Vrms in the ISM and amateur radio bands	10 Vrms 150 KHz to 80 MHz And 10 Vrms in the ISM and amateur radio bands	Portable and mobile RF communications equipment should be used no closer to any part of the Amika+ including cables, than the recommended separation distance calculated from the equation applicable to the frequency and power of transmitter (see table 6).
Power frequency (50 / 60 Hz) magnetic field IEC 61000-4-8	30 A / m	400 A / m	If necessary, the power magnetic field should be measured in the intended installation location to make sure it is lower than the compliance level. If the measured field in the location where the Amika+ is used exceeds the applicable magnetic field compliance level above, the Amika+ should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Amika+, or installing magnetic shielding.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0 % Ut (100% dip in Ut) for 0,5 cycle at 0°, 45°, 90°, 135°,180°, 225°, 270°,and 315° 0% Ut (100% dip in Ut) for 1 cycle 70% Ut (30% dip in Ut) for 25 cycles at 50 Hz for 30 cycles at 60 Hz at 0°	0 % Ut (100% dip in Ut) for 0,5 cycle at 0°, 45°, 90°, 135°,180°, 225°, 270°,and 315° 0% Ut (100% dip in Ut) for 1 cycle 70% Ut (30% dip in Ut) for 25 cycles at 50 Hz for 30 cycles at 60 Hz at 0°	Electricity power quality should be that of a typical domestic, commercial or hospital environment. For short and long interruptions (< than battery life) of electricity power supply, the internal battery provides the continuity of service. For very long (> than battery life) interruptions of electricity power supply, the Amika+ must be powered from an external Uninterruptible Power Supply (UPS). Note: Ut is the a/c mains voltage prior to application of the test level.

7 Physical description

The Amika+ pump is made up of 2 main parts, the top surface and the housing.

- The top surface supports:
  - The door.
  - The membrane.
  - The pressure sensor and the clamp sensor.
  - The main body, support gearmotor, camshaft and battery.
  - The CPU board.

- The housing supports:
  - The battery door (speaker and micro-phone).
  - The keyboard.

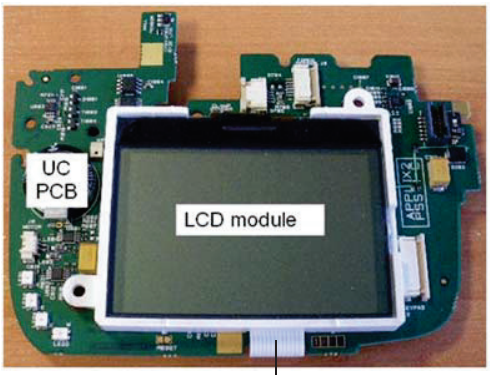
7.1 The display board

The display board is screwed on the main body and drives the LCD.
The description of the pins of the connector is available in “The CPU board and LCD module”, page 38 / connector J7.

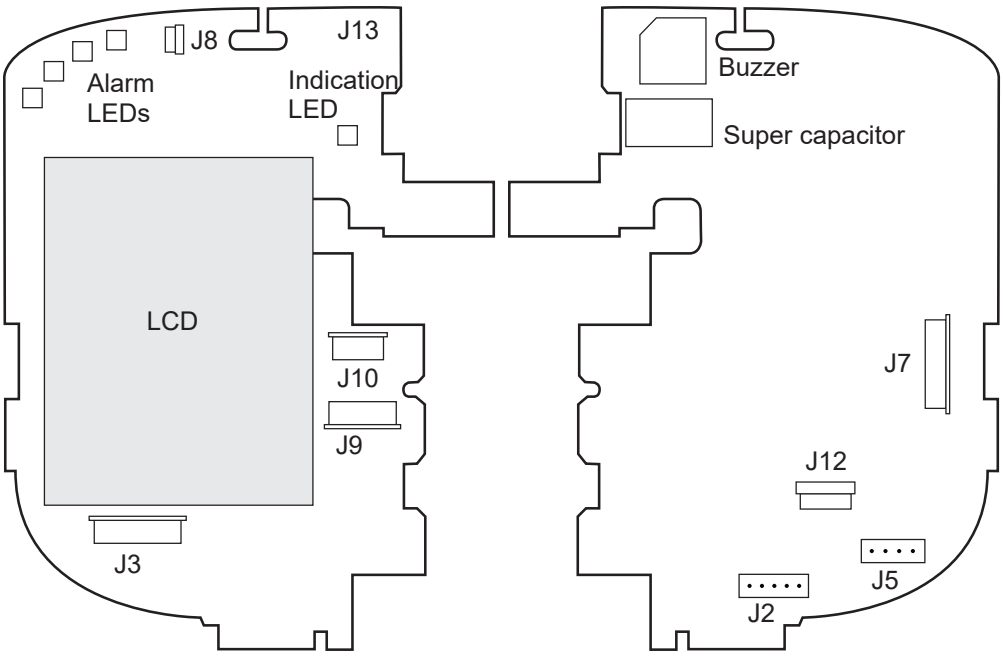
7.2 The CPU board and LCD module

The CPU board includes the micro controller, FLASH and RAM memory, and a watchdog to manage:

- A power switching system (battery or AC/DC adapter).
- A serial communication interface.
- The nurse call.
- A battery management interface.
- The pumping system.
- The sensors (force, temperature, door, clamp, temperature).
- The human-machine interface (LCD, LEDs, keyboard, speaker, buzzer).



Cable to connect LCD module with CPU PCB



Display board

Connector J2, to Holder

Pin	Signal name	Signal description
1	VHOLDER	Holder power supply 9V
2	NURSE_CALL	Nurse call (Open drain output)
3	TX_LVTTL	RS232 Transmitted Data
4	RX_LVTTL	RS232 Received Data
5	GND	GND

Connector J5, to Battery

Pin	Signal name	Signal description
1	VBATTERY	Battery power supply
2	ANA_CTN	Battery Thermistor
3	GND	GND
4	GND	GND

Connector J3, to Keypad

Pin	Signal name	Signal description
1	SW_ON1	ON/OFF key terminal 1
2	GND	GND
3	KPD_COL3	Keypad Matrix Column 3
4	KPD_COL2	Keypad Matrix Column 2
5	KPD_COL1	Keypad Matrix Column 1
6	KPD_COL0	Keypad Matrix Column 0
7	KPD_LIN2	Keypad Matrix Line 2
8	KPD_LIN1	Keypad Matrix Line 1
9	KPD_LIN0	Keypad Matrix Line 0
10	SW_ON2	ON/OFF key terminal 2

Connector J7, to LCD module

Pin	Signal name	Signal description
1	VSS	Logic power supply GND
2	XCS_N	Chip Select (active low)
3	RST_N	Reset (active low)
4	A0	Display/Control data (High<=>Display, Low<=>Control)
5	VDD	Logic power supply 3V3
6	MOSI	Serial data input
7	CLK	Serial clock
8	VSS	Logic power supply GND
9	VLCD33	Buffered VLCD voltage
10	VSS	Logic power supply GND
11	LED_A	Backlight anode
12	LED_K	Backlight cathode

Connector J8, to Pumping motor

Pin	Signal name	Signal description
1	MOTP	Motor positive terminal
2	MOTN	Motor negative terminal

Connector J9, to Force sensor

Pin	Signal name	Signal description
1	GND	Logic power supply GND
2	V-	Negative sensor output - Wheatstone bridge
3	GND	Logic power supply GND
4	V+	Positive sensor output - Wheatstone bridge
5	VDD	Logic power supply 3V3
6	GND	Logic power supply GND

Connector J10, to Clamp sensor

Pin	Signal name	Signal description
1	GND	Logic power supply GND
2	V_{clamp_tx}	Clamp Infrared emitter - Diode Cathode
3	VDD	Logic power supply 3V3
4	V_{clamp_rx}	Clamp Infrared receiver output

Connector J12, to Speaker and microphone

Pin	Signal name	Signal description
1	SPKP	Speaker positive terminal
2	SPKN	Speaker negative terminal
3	MICP	Microphone positive terminal
4	MICN	Microphone negative terminal

Connector J14, to JTAG

Pin	Signal name	Signal description
1	GND	Logic power supply GND
2	VDD	Logic power supply 3V3
3	TRST-N	Test Reset
4	TDO	Test Data Output
5	TDI	Test Data Input
6	RESET_N	
7	TMS	Test Mode Selet
8	DBGRQ	
9	TCK	Test Clock
10	DBGACK	
11	RTCK	
12	GND	Logic power supply GND

8 Operations

8.1 Use of the internal battery

To use the Amika+ pump on internal battery, refer to the corresponding section in the Amika+ IFU.

8.2 Basic operations

To switch the Amika+ pump ON and OFF; to install, prime, remove, change the giving set; start and stop the feeding; to lock the keypad; to mute the alarm, refer to the corresponding sections in the Amika+ IFU.

8.3 Amika+ pump menu

To access menus such as target volume mode, night mode, sound, settings lock, cumulative feeding volume counter, alarm history, feeding history, contrast / Brightness, set time between two alarm sounds, set time for target volume almost reached message, technical information, refer to the corresponding sections in the Amika+ IFU.

9 Maintenance

9.1 Service policy and rules

For warranty conditions, see Warranty section.

For further information concerning the Amika+ servicing or use, contact our Technical Service or our Customer service.

Fresenius Kabi provides, on demand, the electronical diagram of the pump.

If the device must be sent for servicing, contact Fresenius Kabi to have packaging shipped to your facility. Clean and disinfect it, because of potential harm or risks to staff health. Then pack it in the provided packaging and ship to Fresenius Kabi.

INFORMATION

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

9.2 Maintenance requirements

WARNING

- *Maintenance:*

When using the device on a patient, no maintenance action must be performed.
Maintenance is requested to ensure that all sensors and measurements are within the expected range after maintenance and that backup capacitor and watchdogs are checked.

- *Metrology: any instrument or device used for maintenance must be regularly checked or re-calibrated according to its specifications and local regulations.*
- *Accessories and spare parts: use ONLY recommended accessories and options delivered with the device.*

NO PART IS REPAIRABLE.
When replacing components, only use Fresenius Kabi spare parts. Refer to the "Amika+ Spare parts catalogue" for ordering.

- *Upgrade: if an upgrade of the pump is required, Fresenius Kabi or its representative will provide relevant instructions. The hospital is responsible to proceed as per Fresenius Kabi's recommendations.*
- *Procedures applications: failure to comply with these maintenance procedures could damage the device and lead to a functional failure. Internal inspection of the device involves compliance with special procedures to avoid damage to the device.*
- *Technician qualification: maintenance should be performed by a qualified and trained technical personnel in compliance with the Technical manual and procedures.*
- *Amika+ malfunctions: the qualified personnel must be informed if the device is dropped or if any malfunctions occur. In this case, the device must not be used. Contact your biomedical department or Fresenius Kabi.*

INFORMATION

It is possible to restore Amika+ pump factory settings:

- *using Amika Partner maintenance software. Refer to the Amika Partner IFU for further information.*
- *manually through the Menu key of the Amika+ pump. Then, select the relevant submenu. Refer to the Amika+ IFU for further information.*

This operation must be performed, when necessary (e.g. before use of the Amika+ pump on a new patient and/or in another ward), by authorized and trained personnel only.
This can be biomedical technicians and engineers or any personnel involved into the configuration and the maintenance of the Amika+ pumps.

To reset default parameters:

- Switch on the Amika+ pump.
- Access to pump menu to set parameters as below: see details in the Amika+ IFU
  - Target volume mode = **Activated**
  - Night mode = **Deactivated**
  - Sound:
    - Sound level = **High**
    - Key beep = **Activated**
  - Cumulative volume feeding counter = **Cleared** (0mL)
  - Contrast / Brightness:
    - Contrast = **60%** corresponding to **3 blocks** in the pictogram
    - Brightness = **60%** corresponding to **3 blocks** in the pictogram
  - Time between two alarm sounds = **2.5s**
  - Time for target volume almost reached message = **5min**
- Quit pump menu and adjust feeding settings: see details in the Amika+ IFU.
  - Feeding rate to **50 mL/h**
  - Target volume to **500 mL**

9.3 Technical training

For training, contact Fresenius Kabi.

The Training levels, listed below, outline the specifics needed to maintain and preserve the device. They are defined below:

Level 1	Is intended to the user for on-site maintenance, using the technical documentation of the device and specific tools. This degree of maintenance does not need an extensive inventory. ■ Mechanical and electrical knowledge. ■ Biomedical structures knowledge.
Level 2	Is intended to a technician specialised in maintenance performed through specific tools and procedures. ■ Good mechanical and electronics knowledge. ■ Two years experience minimum in a biomedical department.
Level 3	Is intended to a technician specialised in repair performed in the maintenance department using specific tools, procedures as well as measurement and adjustment instruments. Complete check-up according to the Technical Manual of the device. ■ Good mechanical, electrical and electronics knowledge. ■ More than two years experience minimum in a biomedical department.

9.4 Maintenance schedule

9.4.1 Preventive maintenance

WARNING

In order to maintain the pump's performance, perform Preventive Maintenance at least once every 2 years. This procedure, which includes changing the battery and the membrane, should be carried out by a qualified technician.

Any abnormal functioning or failure must be reported to the qualified technical staff in your organisation or to your Fresenius Kabi representative. In these instances, the pump should not be used.

9.4.2 Quality control

INFORMATION

At the request of the health organisation, a quality control will be carried out on the Amika+ every 12 months.

A quality control (not included in the guarantee) consists of different inspection procedures. Only a qualified technician

may perform the quality control that is not covered by any contract or agreement provided by Fresenius Kabi.
For more information, contact your Fresenius Kabi representative.

9.5 Configuration, software update, calibrations and controls

All the service tests (except the electrical, flow rate, downstream occlusion, battery life, watchdog tests that are to be performed without using Amika Partner maintenance software but for which the results need to be registered in Amika Partner), the calibration of the Amika+ pump, the configuration of the Amika+ pump, the software update and a quality control certificate are available through Amika Partner.

Refer to the Amika Partner IFU for further information.

WARNING

- *A quality control must be performed after a software upgrade.*
- *It is necessary to control the embedded sofware version which is displayed in the quality control certificate and in the "Technical information" menu.*
- *The clinical software version must be checked on the pump after a connection with Amika Partner in order to avoid pump malfunctioning.*
- *The occlusivity of the pump shall be checked, with Amika Partner, after the membrane replacement, for each preventive maintenance and for each quality control.*

Pump sensors are calibrated during manufacturing.

WARNING

- *Calibration should only be performed if a sensor test fails during a Quality control or during a Preventive maintenance.*
- *It must be done if a new sensor is installed to replace a faulty sensor or if a part is changed.*
- *When changing the CPU board, all calibrations must be performed.*

.

INFORMATION

The following calibrations are performed using Amika Partner and are detailed in the IFU of this maintenance software: door sensor calibration, clamp optical sensor calibration, pressure calibration, motor rotation calibration, flow rate calibration (V0 calibration).

Refer to the Amika Partner IFU for further information.

WARNING

- *After calibrations, it is mandatory to perform a full quality control using Amika Partner.*

The following controls are performed using Amika Partner and are detailed in the IFU of this maintenance software: battery: temperature, voltage, and capacity control ; CPU board: temperature control ; pressure sensor: measured pressure control ; door sensor: door closed control ; clamp optical sensor: value measured control ; motor camshaft synchronization control ; motor rotation control ; air alarm control ; communication control ; general appearance control ; LCD control ; backlighting control ; LED control ; keypad control ; door open control ; clamp absence control ; door alarm control ; mains presence control ; flow rate control (V0 control) ; downstream occlusion control ; occlusivity control ; upstream occlusion control ; speaker and microphone control ; buzzer control.

The following controls are to be performed offline and then registered in Amika Partner to end a Preventive Control:

9.5.1 Electrical control

Carry out the electrical control according to IEC 60601-1 or IEC 62353 standard.
For further information, contact your Technical Service.

9.5.2 Battery life control

When the test is carried out in normal functioning mode (22.5°C ± 2.5°C), the battery life must be an average of 24 hours ± 5% for a flow rate of 125 mL/h.
To perform this test:

- Make sure Amika+ battery is fully charged (Symbol = ).
- Start a feeding at 125 mL/h with the Amika+ pump used **on battery only**.
- Check that the feeding could be performed during 24 hours ± 5%.

If the Amika+ pump is OFF the day after this test, it is recommended to check the last volume is a minimum of 3000 mL ± 5% in the Feeding history menu.
This value, displayed by the Amika+ pump, is valid only if the flow rate is properly calibrated.

9.5.3 Downstream occlusion alarm control

- Switch the Amika+ pump ON in clinical mode.
- Install a giving set filled with water into the Amika+ pump.
- Close the door of the Amika+ pump.
  - ☐ Check that there is no air bubble in the giving set.
- Create an occlusion 20cm downstream from the Amika+ pump.
- Program a feeding at 600ml/h.
- Start the feeding.
  - ☐ Check that a downstream occlusion alarm is triggered within 30 seconds.

9.5.4 Watchdog control

The Amika+ pump must be used on battery, mains power cord disconnected.

- Switch the Amika+ pump ON.
- Disconnect the battery.
  - ☐ Check that the red LED is lighting and that the buzzer sounds.
- Reconnect the battery.

9.5.5 Flow rate control with a scale

A new giving set must be used for this procedure. The recommended giving set is the following: Amika Pump Set VarioLine, ENFit univ. referenced 7751909.

Recommended temperature for flow rate accuracy shall be:

- Giving set temperature: 20°C ± 2°C (68°F ± 4°F).
- Temperature of the fluid in the set: 20°C ± 2°C (68°F ± 4°F).

Do not recycle medical water.

Keep the container clean by changing it as often as necessary.

Equipment needed

- Bag.
- Scale (Requested accuracy depending on flow rate, see table below). For a Quality control using Amika Partner, the flow rate is of 50 mL/h during 30 minutes.

Flow rate value	Scale accuracy
1 mL/h ≤ flow rate ≤ 30 mL/h	1 mg
flow rate > 30 mL/h	10 mg

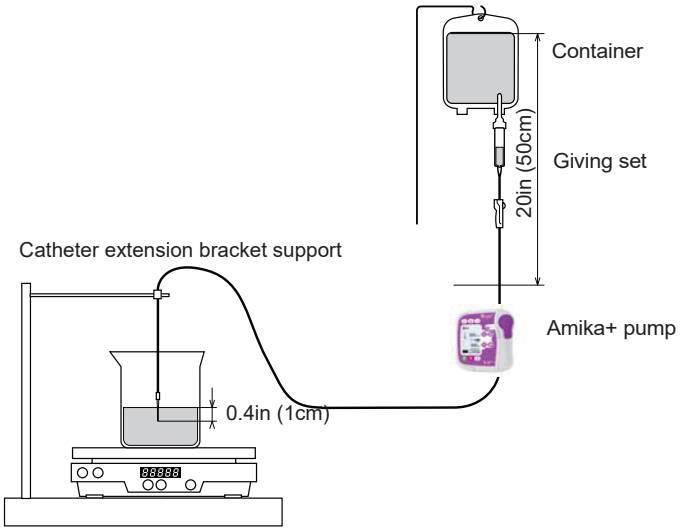
- Beaker.
- Liquid: distilled water (for flow rate controls lasting more than 2 hours, add some drops of oil to create a thin greasy film over water to prevent evaporation).
- Needle:

Flow rate value	Type of needle
1 mL/h ≤ flow rate ≤ 30 mL/h	G26 (or equivalent with same internal diameter)
flow rate > 30 mL/h	G18 or G21 (or equivalent with same internal diameter)

- Stopwatch.

Installation

- Install the bag, pump, giving set, needle, beaker and scale referring to the diagram below:



INFORMATION

Observe the equipment's horizontal installation plan and make sure that no vibrations occur during the flow rate control.

- Fill the bag with distilled water. Check that the water volume is sufficient for the duration of the test.
- Connect the giving set to the bag.
- Connect the needle to the giving set.

Procedure

- Half fill the drip chamber.
- Press "ON" (device on mains)  .
  - ☐ Prime the feeding line using the "PRIMING" function key  .
  - ☐ Check that there are no air bubbles in the giving set.
- Carry out an initial "feeding" of 25 mL at 600 mL/h to warm up the giving set.
- At end of this period, fill the beaker with some water.
- Carry out a flow rate selection with no target volume.
- Place the needle at the centre of the beaker.
- Immerse the needle by more than 1 cm. Make sure the giving set does not rest on the scale.
- Weight the mass of the beaker with initial volume of water or tare the scale.
- Press "START"  to run the feeding, and start the stopwatch.
- When the flow rate measurement period has elapsed, press "STOP"  .
- Weight the mass of the beaker with final volume of water.

The mass difference in grams gives the volume in mL (at 20°C, 1 mL of distilled water has a mass of 1.00 g).

The error percentage is calculated according to the following formula:

$$\text{Flow rate error (\%)} = \frac{\text{Measured volume} - (\text{Programmed Flow rate} \times \text{Time})}{\text{Programmed Flow rate} \times \text{Time}} \times 100$$

For a Quality control (50 mL/h during 30 minutes), the flow rate error corresponds to:

$$\text{Flow rate error (\%)} = \frac{\text{Measured volume} - 25\ \text{mL}}{25\ \text{mL}} \times 100$$

Other controls:

9.5.6 Mains/battery operation test

- To carry out this procedure, switch off the Amika+  .
- Connect the AC/DC adapter to the AC power supply.
  - ☐ Check the LED on the fonctioning panel (plug-shaped indicator)  .
- Disconnect the AC/DC adapter from the AC power supply.
  - ☐ Check that the power source indicator is switching off  .

9.5.7 Membrane and pumping finger test

If the membrane is worn on its periphery, check the guidance and the lubrification of the pumping finger.

10 Alarms and safety features

10.1 Alarms / Actions

Refer to the relevant sections in the Amika+ IFU to identify the alarms, understand their meanings and conduct the appropriate action.

WARNING

A technical alarm is an alarm which needs the Amika+ pump and its holder COM to be returned to maintenance service.

10.2 Troubleshooting

Issue description	Recommended action
Pump is not stable when mounted.	■ Check that the clamp handle is fastened.
Pump or Holder COM is damaged, noisy, smoking or with an abnormally hot part. Pump screen is damaged.	■ Remove the AC/DC adapter. ■ Do not use the device. ■ Immediately contact your biomedical department or **Fresenius Kabi** Technical Service.
Pump has been dropped.	■ Do not use the device. ■ Contact your biomedical department or **Fresenius Kabi** Technical Service.
Pump does not start after switched ON.	■ Connect pump to the mains supply in case the battery is fully discharged. ■ Contact your biomedical department or **Fresenius Kabi** Technical Service if problem remains.
Flow rate variance is higher than flow rate accuracy.	■ Check giving set configuration. ■ Check fluid viscosity. ■ Check the fluid is within normal temperature conditions. ■ Contact your biomedical department or Fresenius Kabi Technical Service if problem remains.
Front panel problem (keys, LEDs).	■ Check the general state of the front panel. ■ Check the contrast. ■ Contact your biomedical department or Fresenius Kabi Technical Service if problem remains.
The mains connection LED does not light up.	■ Connect pump to the mains supply. ■ Check that the LED on the AC/DC adapter lights. If not, unplug and plug it again in the mains socket. ■ Contact your biomedical department or Fresenius Kabi Technical Service if problem remains.
The device switches off on its own.	■ Connect pump to the mains supply. ■ Contact your biomedical department or Fresenius Kabi Technical Service if problem remains.
Battery alarm when pump has been correctly charged.	■ Check mains supply voltage. ■ Contact your biomedical department or Fresenius Kabi Technical Service if problem remains.

Issue description	Recommended action
The device switches off when it is disconnected from the mains.	■ Battery is completely discharged: Charge the battery. ■ Contact your biomedical department or Fresenius Kabi Technical Service if problem remains.
In bolus mode, the bolus volume and flow rate are blinking and the feeding cannot start.	■ Check bolus feeding parameters. Refer to the relevant section in the Amika+ IFU.
The Nurse Call system does not replicate pump alarms. USB connection is not functional.	■ Check Nurse Call cable installation. ■ Check Holder COM is connected to the power supply. ■ Contact your biomedical department or Fresenius Kabi sales representative if problem remains.

10.3 Technical error messages

Code	Description
Persistency	
0.1.1	Persistency CRC error
0.1.2	Persistency blank eeprom
0.1.3	Persistency version not compatible
0.1.4	Persistency CRC error on the component LastTechErrorReminder
Door	
1.1.1	The hall effect sensor signal is too low
1.1.2	The hall effect sensor signal is too high
1.1.3	The Door SW component is not calibrated
Camshaft	
2.1.2	The camshaft is blocked
2.1.3	Regulation error
2.1.4	The camshaft is not calibrated (Kp/Ki coefficients)
2.1.5	The camshaft has wrong coefficient for the control loop (Kp/Ki coefficients)
2.1.6	The camshaft is requested to perform a tour out of the range 510ms < duration_tour < 450000ms
2.1.7	The camshaft detect an error when turning in pulsed mode
Tube Middleware	
4.1.9	Requested flow rate is > 600ml/h
4.1.11	V0 is not calibrated
Food administration protocol	
9.1.1	ConstantProtocolSettings flow rate corrupted
13.1.1	BoundedConstantProtocolSettings flow rate out of range
13.1.2	BoundedConstantProtocolSettings target volume out of range
13.1.3	BoundedConstantProtocolSettings infused volume out of range
16.1.1	Protocol selector index out of range
Sound level	
10.1.1	Sound level out of range
Force sensor	
11.1.1	Force sensor signal too low
11.1.2	Force sensor signal too high

Code	Description
11.1.3	Force sensor not calibrated
Pinchclamp	
14.1.1	The sensor signal too low
14.1.2	The sensor signal too high
14.1.3	The signal is received but the emitter was off
14.1.4	The pinchclamp SW component is not calibrated
Tube	
15.1.1	The cumulative volume is corrupted
Motor	
17.1.3	Motor over current
Battery	
18.1.1	Battery over voltage
18.1.2	Invalid loading current
18.1.3	Pre-charge timeout
18.1.4	If battery temperature > threshold and battery voltage too low then battery cellul failure
18.1.5	If end of charge because of delta battery temperature > threshold and battery voltage too low
18.1.7	Fast charge time out and battery voltage too low then battery cellul failure
18.1.8	Invalid battery temperature measurement
18.1.9	Difference between battery temperature and cpu board temperature > 25°C
18.1.10	Invalid board temperature measurement
27.1.1	Battery pack defect
Power sources	
19.1.1	HMI power source error
19.2.1	AUX power source error
19.3.1	5V power source error
19.4.1	ANA power source error
19.6.1	Motor power source error
Key beep setting	
20.1.0	KeyBeep setting out of range
Keypad	
21.1.0	Keypad pressed more than 3 minutes (BP01 - Lock)
21.3.0	Keypad pressed more than 3 minutes (BP03 - Vol dec.)
21.4.0	Keypad pressed more than 3 minutes (BP10 - Vol inc.)
21.5.0	Keypad pressed more than 3 minutes (BP11 - Mute)
21.6.0	Keypad pressed more than 3 minutes (BP12 - Rate inc.)
21.7.0	Keypad pressed more than 3 minutes (BP13 - Rate dec.)
21.8.0	Keypad pressed more than 3 minutes (BP20 - Stop)
21.9.0	Keypad pressed more than 3 minutes (BP21 - Prime)
21.10.0	Keypad pressed more than 3 minutes (BP22 - Start)
21.11.0	Keypad pressed more than 3 minutes (BP23 - Menu)
21.12.0	Keypad pressed more than 3 minutes (ON/OFF)
LCD setting	

Code	Description
24.1.1	LCD Contrast setting out of range
24.1.2	LCD brightness setting out of range
24.1.3	LCD autotest failed
Speaker	
25.1.2	Speaker failure
CPU Oscillator	
28.1.1	Drift of the CPU quartz oscillator
Alarm History	
29.1.1	Alarm history persist data error
29.1.2	Alarm history retrieve data error
29.1.3	Alarm history event CRC data error
29.1.4	Alarm history navigation data CRC error
System	
32.1.1	The system has reset (software assert)
Supercapacitor	
33.1.1	Super capacitor charge time out
Time between alarm	
36.1.1	The retrieved period is out of range
Prior information	
37.1.1	The retrieved period is out of range
Nurse lock	
38.1.0	Error on the retrieved nurse lock status
Delivery History	
40.1.1	Delivery history persist data error
40.1.2	Delivery history retrieve data error
40.1.3	Delivery history event CRC data error
40.1.4	Delivery history navigation data CRC error
Device History	
41.1.1	Device history persist data error
41.1.2	Device history retrieve data error
41.1.3	Device history event CRC data error
41.1.4	Device history navigation data CRC error
Optical disk	
43.1.3	Incorrect synchronisation (unconsistent positions)
44.1.1	Optical disk position time algorithm unsynchronized
44.1.2	Optical disk position time algorithm is lost too many times (more 5 times since the start of the motor)
45.1.1	Optical disk position intensity algorithm unsynchronized
Bolus mode	
82.1.1	Bolus flow rate out of range
82.1.2	Bolus volume out of range
82.1.3	Bolus Infused volume out of range

Code	Description
82.1.4	Bolus current bolus number out of range
82.1.5	Bolus total number out of range
82.1.6	Bolus interval time out of range
82.1.7	Bolus current dose infused volume out of range
82.1.8	Bolus flushing information out of range
82.1.9	Bolus remaining hold time out of range

11 Intervention procedures

This chapter lists all of the procedures of disassembly and reassembly.

Service shall be done by approved and qualified technicians who have been trained.

WARNING

■ *Use ONLY recommended accessories and options delivered with the device.*

NO PART IS REPAIRABLE.

When replacing components, only use Fresenius Kabi spare parts. Refer to the Amika+ Spare parts catalogue for ordering.

■ *Any instrument or device used for maintenance must be regularly checked or re-calibrated according to its specifications and local regulations.*

INFORMATION

Any maintenance which requires a partial (battery change for example) or complete (pump body) disassembling of the Amika+ must be followed by a measure of the leakage current according to EN/IEC 60 601-1: 2006 (ed. 3).

INFORMATION

Each part calibration can impact the flow rate. Carry out a Quality control using Amika Partner maintenance software.

WARNING

When touching the boost capacitor, there is a risk of electrisation.

Disconnect the battery and discharge the boost capacitor before opening the device.

Intervention Procedure N°1: Battery and battery door / Boost capacitor discharge

Safety recommendations:

WARNING

For safety reasons, the technician should not intervene when the device is connected to the mains.

Disconnect the power supply cord from the power source.

Switch off the device.

WARNING

When touching the boost capacitor, there is a risk of electrisation.

Disconnect the battery and discharge the boost capacitor before opening the device according to this intervention procedure.

WARNING

When working with electronic components, we recommend wearing an anti-static wrist strap connected to earth and working on a anti-static mat.

Material needed:

- 1 Torx T-8 screwdriver or electric screwdriver with a torque of 0.4Nm.
- 1 anti-static bracelet.

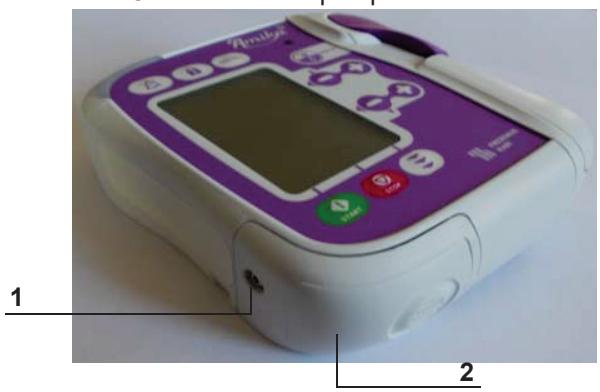
Maintenance level:

Level 2, specialist technician (see “Technical training”, page 43).

Procedure:

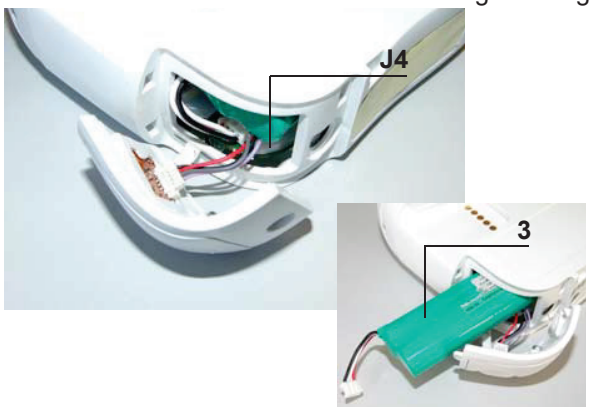
Access

- Unscrew the Torx screw (marker 1) holding the battery door in place.
- Remove the battery door (marker 2).
- Switch "ON" the Amika+ pump.



Dismantling

- Disconnect the J4 connector and remove the battery (marker 3).
  - The boost capacitor starts to discharge.
  - The buzzer sounds and red LEDs light during this discharge (5 minutes approximately).



Re-assembling

- Carry out the dismantling procedure in reverse order to re-assemble the unit.
- Respect the battery mounting direction.

- Carry out the regular servicing tests.

INFORMATION

At the end of this procedure, carry out a Quality control using Amika Partner maintenance software.

Intervention Procedure N°2: Housing

Safety recommendations::

WARNING

For safety reasons, the technician should not intervene when the device is connected to the mains.

Disconnect the power supply cord from the power source.

Switch off the device.

WARNING

When touching the boost capacitor, there is a risk of electrisation.

Disconnect the battery and discharge the boost capacitor before opening the device (refer to the Intervention procedure N°1).

WARNING

When working with electronic components, we recommend wearing an anti-static wrist strap connected to earth and working on a anti-static mat.

Required tools:

- 1 Torx T-8 screwdriver or electric screwdriver with a torque of 0.4Nm.
- 1 flat screwdriver (small).
- 1 antistatic band.

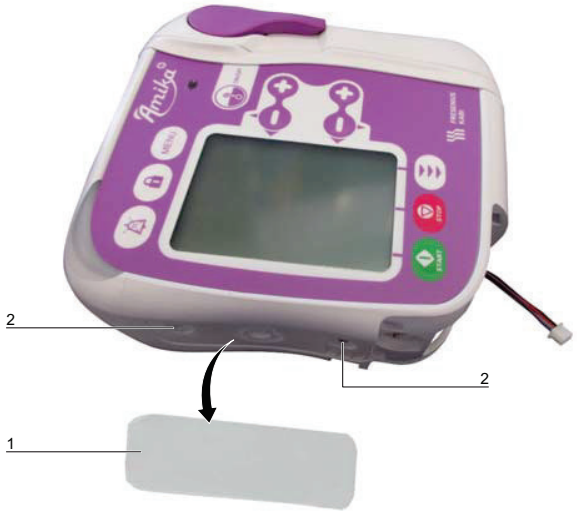
Maintenance level:

Level 2, specialised technician (see “Technical training”, page 43).

Procedure:

Access

- Battery and battery door - Boost capacitor discharge (refer to the Intervention procedure N°1).
- Remove the Amika+ pump from its Holder.
- Remove the label (marker 1).
- Unscrew the 2 Torx screws (marker 2) located at the left of the housing.



INFORMATION

Do not put hands on the electronic boards (especially the LCD).

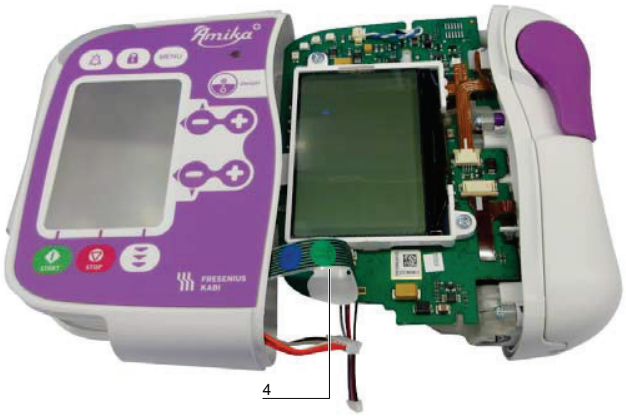
Disassembly

- Gently uncouple the front face/housing assembly, bending it to prevent LCD to scrape on the housing windows. Do not entirely remove the housing.
(During this operation, it is normal to get a resistance when separating the two parts).

- Return it on the "keyboard" face (housing to the right).

- Finish uncoupling the assembly, until seeing the white connector (marker 3). Disconnect the connector (marker 3).

- Maintain the Amika+ pump in this position and return it on the "contact" face (housing to the left).
- Remove the housing and take care of not tearing out the keyboard flat cable (marker 4).
- With a small flat screwdriver, loosen the connector (marker 4).
  - Remove the flat cable, the housing is free.



Re-assembly

- Carry out the reverse operations of disassembly taking care of correctly positioning the keyboard flat cable and the strands.

INFORMATION

Stick the Amika+ pump identification label at the rear of the housing, in the dedicated slot.
This sticker is to be ordered to Fresenius Kabi Spare parts department (Refer to the Useful adresses section in this document) indicating the pump reference and serial number.

INFORMATION

At the end of this procedure, carry out a Quality control using Amika Partner maintenance software.

Intervention Procedure N°3: Board

Safety recommendations::

WARNING

For safety reasons, the technician should not intervene when the device is connected to the mains.

Disconnect the power supply cord from the power source.

Switch off the device.

WARNING

When touching the boost capacitor, there is a risk of electrisation.

Disconnect the battery and discharge the boost capacitor before opening the device (refer to the Intervention procedure N°1).

WARNING

When working with electronic components, we recommend wearing an anti-static wrist strap connected to earth and working on a anti-static mat.

Required tools:

- 1 Torx T-8 screwdriver or electric screwdriver with a torque of 0.4Nm.
- 1 flat screwdriver (small).
- 1 antistatic band.

Maintenance level:

Level 3, specialised technician (see “Technical training”, page 43).

Procedure:

Access

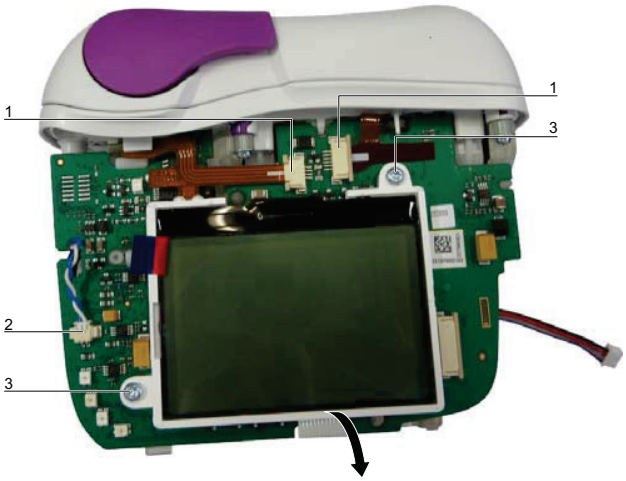
- Battery and battery door - Boost capacitor discharge (refer to the Intervention procedure N°1).
- Open the housing (refer to the Intervention procedure N°2).

Disassembly

INFORMATION

Disconnect all the connectors from the board.

- With a small flat screwdriver, loosen the 2 connectors and remove the flat cables (marker 1).
- Disconnect all the connectors from the board (marker 2).
- Unscrew the 2 Torx T8 Torx screws (marker 3), that connect the board with the pumping unit.
  - Remove the board, uncliping the board and pulling at the clips level.
  - Pull gently on the board and extract it from the top surface.
- When replacing the CPU board, carry out a complete configuration of the board.



- Do not use a CPU board from a device to another, since specific information are programmed.

WARNING

Amika Partner maintenance software is necessary to configure a blank CPU board.

Re-assembly

INFORMATION

When fixing the board, it is important to gently tighten slightly the plastic inserts to avoid to damaging them.

- To reassemble, carry out the reverse procedure.
  - When reassembling insert carrefully the board into the top surface and into the clips.
  - Ensure the keyboard flat cable and the strands are correctly positioned.

INFORMATION

At the end of this procedure, carry out calibrations linked with the parts changed and a Quality control using Amika Partner maintenance software.

Intervention Procedure N°4: Main body

Safety recommendations:

WARNING

For safety reasons, the technician should not intervene when the device is connected to the mains.

Disconnect the power supply cord from the power source.

Switch off the device.

WARNING

When touching the boost capacitor, there is a risk of electrisation.

Disconnect the battery and discharge the boost capacitor before opening the device (refer to the Intervention procedure N°1).

WARNING

When working with electronic components, we recommend wearing an anti-static wrist strap connected to earth and working on a anti-static mat.

Required tools:

- 1 Torx T-8 screwdriver or electric screwdriver with a torque of 0.4Nm.
- 1 flat screwdriver (small).
- 1 antistatic band.

Maintenance level:

Level 3, specialised technician (see “Technical training”, page 43).

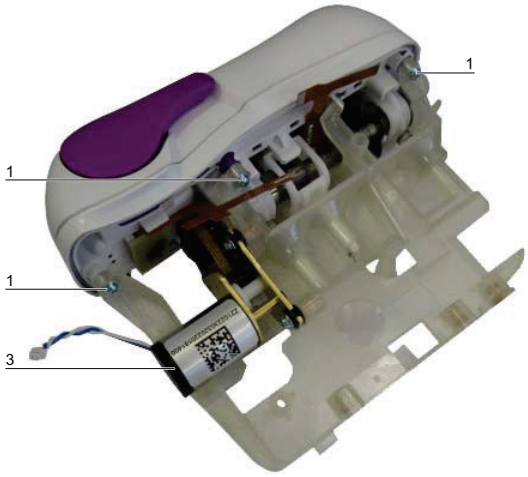
Procedure:

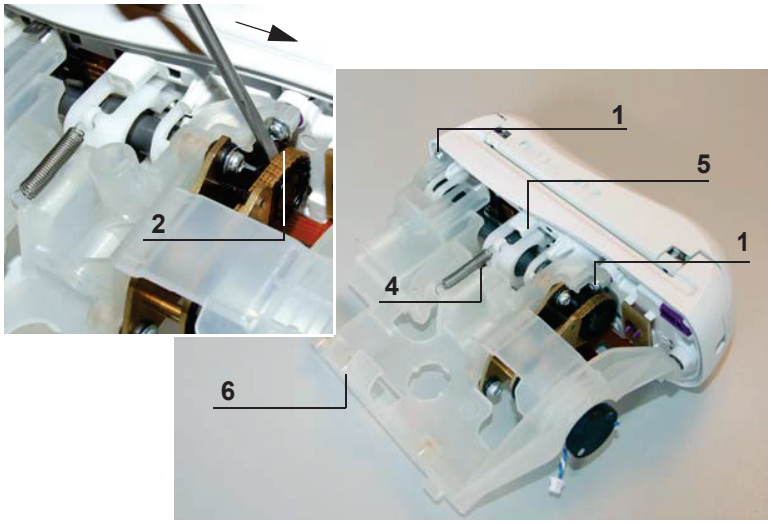
Access

- Battery and battery door - Boost capacitor discharge (refer to the Intervention procedure N°1).
- Open the housing (refer to the Intervention procedure N°2).
- Remove the board (refer to the Intervention procedure N°3).

Disassembly

- Using a small flat screwdriver, remove the motor belt (marker 2).
- Remove the spring (marker 4) between the pushing finger (marker 5) and the main body (marker 6).
- Unscrew the 5 Torx T8 screws (marker 1) from the pump body.
- Remove the main body from the top surface.





Re-assembly

- Carry out to the reverse operations of disassembly taking care of correctly positioning the keyboard flat cable and the strands.
- Make sure the pumping finger is in down position.
- Care must be taken with the membrane.

INFORMATION

At the end of this procedure, carry out calibrations linked with the parts changed and a Quality control using Amika Partner maintenance software.

Intervention Procedure N°5: Membrane

Safety recommendations:

WARNING

For safety reasons, the technician should not intervene when the device is connected to the mains.

Disconnect the power supply cord from the power source.

Switch off the device.

WARNING

When touching the boost capacitor, there is a risk of electrisation.

Disconnect the battery and discharge the boost capacitor before opening the device (refer to the Intervention procedure N°1).

WARNING

When working with electronic components, we recommend wearing an anti-static wrist strap connected to earth and working on a anti-static mat.

Required tools:

- Facom 187.18 CPE combination plier.

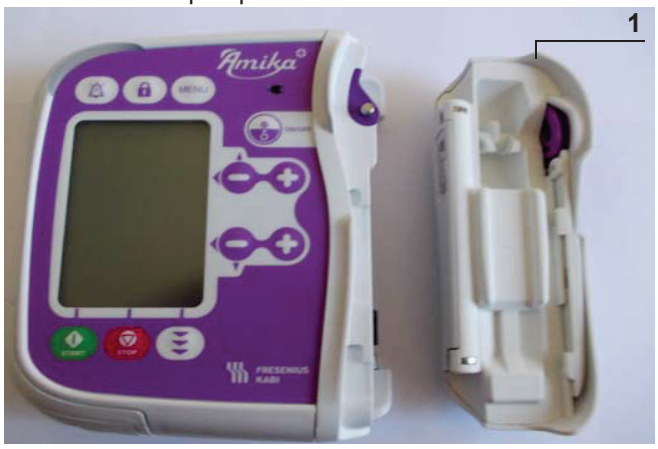
Maintenance level:

Level 2, specialised technician (see “Technical training”, page 43).

Procedure:

Access

- Battery and battery door - Boost capacitor discharge (refer to the Intervention procedure N°1).
- Remove the pump door.



Disassembly

- Press the first clamp head with the combination plier (marker 1).
- Turn the clamp head with the combination plier (marker 1).
- Pull on the combination plier (marker 1) to extract the head from the first clamp finger (marker 2).
- Do the same with the second clamp finger (marker 3).

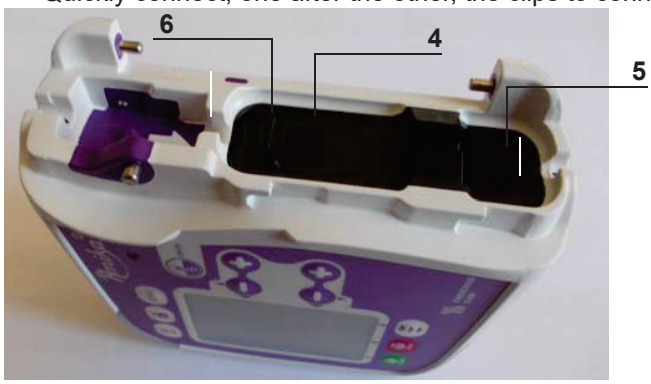
INFORMATION

The membrane must NOT be reassembled. It must be disposed of according to local regulations.

For further information regarding waste processing regulations, contact your local Fresenius Kabi organisation or the local distributor.

Re-assembly

- Position the new membrane (marker 4).
- Place the membrane clips (markers 5 and 6) above each push button.
- Quickly connect, one after the other, the clips to connect the new membrane.



- Clip the door back on the top surface.

INFORMATION

At the end of this procedure, carry out a Quality control (which includes a control of the occlusivity of the pump) using Amika Partner maintenance software.

Intervention Procedure N°6: Gearbox/motor

Safety recommendations:

WARNING

For safety reasons, the technician should not intervene when the device is connected to the mains.

Disconnect the power supply cord from the power source.

Switch off the device.

WARNING

When touching the boost capacitor, there is a risk of electrisation.

Disconnect the battery and discharge the boost capacitor before opening the device (refer to the Intervention procedure N°1).

WARNING

When working with electronic components, we recommend wearing an anti-static wrist strap connected to earth and working on a anti-static mat.

Required tools:

- 1 Torx T-8 screwdriver or electric screwdriver with a torque of 0.4Nm.
- 1 flat screwdriver (small).
- 1 antistatic band.

Maintenance level:

Level 3, specialised technician (see “Technical training”, page 43).

Procedure:

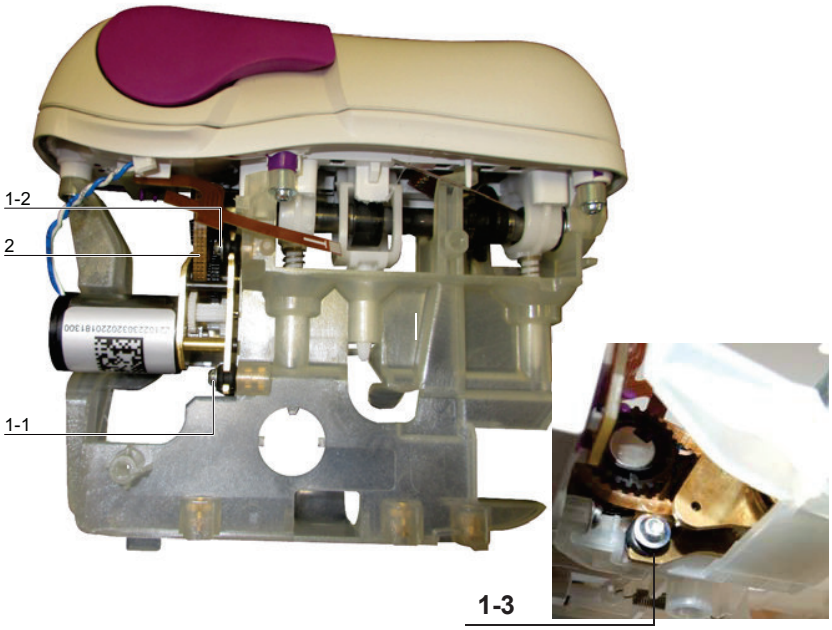
Access

- Battery and battery door - Boost capacitor discharge (refer to the Intervention procedure N°1).
- Open the housing (refer to the Intervention procedure N°2).
- Remove the board (refer to the Intervention procedure N°3).

Disassembly

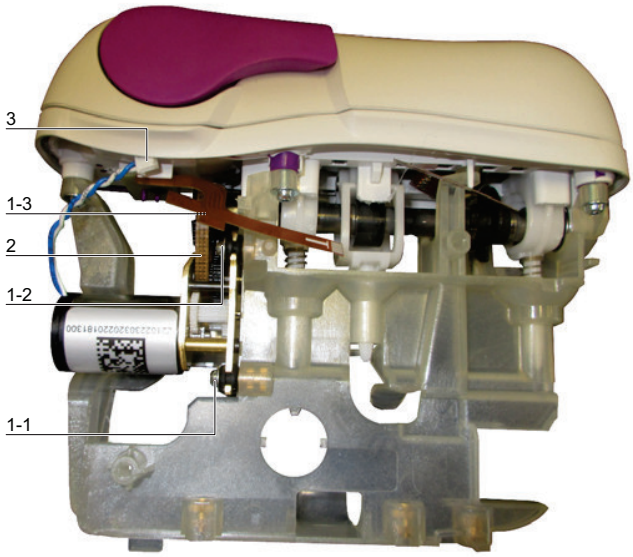
- Unscrew the 3 Torx T8 screws (marker 1) taking care of not losing the captive nuts.

- Remove the gear motor by disengaging carefully the belt (marker 2).



Re-assembly

- Place the gear motor engaging the belt (marker 2) carefully on the gear of the pumping assembly.
- Screw the 3 Torx T8 screws in that order (markers 1-1, 1-2 and 1-3) ensuring the correct positioning of each screw, the silent block and the captive nut.
- Connect the connector (marker 3).



Carry out to the reverse operations of disassembly taking care of correctly positioning the keyboard flat cable and the strands.

INFORMATION

At the end of this procedure, carry out calibrations linked with the parts changed and a Quality control using Amika Partner maintenance software.

Intervention Procedure N°7: Pressure sensor

Safety recommendations::

WARNING

For safety reasons, the technician should not intervene when the device is connected to the mains.

Disconnect the power supply cord from the power source.

Switch off the device.

WARNING

When touching the boost capacitor, there is a risk of electrisation.

Disconnect the battery and discharge the boost capacitor before opening the device (refer to the Intervention procedure N°1).

WARNING

When working with electronic components, we recommend wearing an anti-static wrist strap connected to earth and working on a anti-static mat.

Required tools:

- 1 Torx T-8 screwdriver or electric screwdriver with a torque of 0.4Nm.
- 1 flat screwdriver (small).
- 1 antistatic band.

Maintenance level:

Level 3, specialised technician (see “Technical training”, page 43).

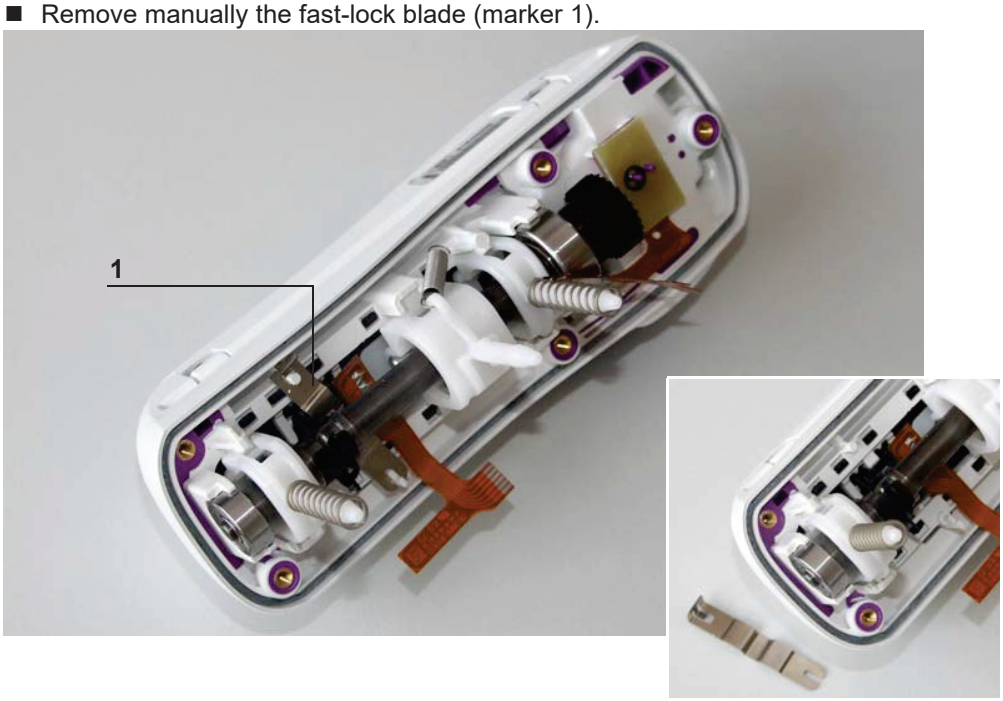
Procedure:

Access

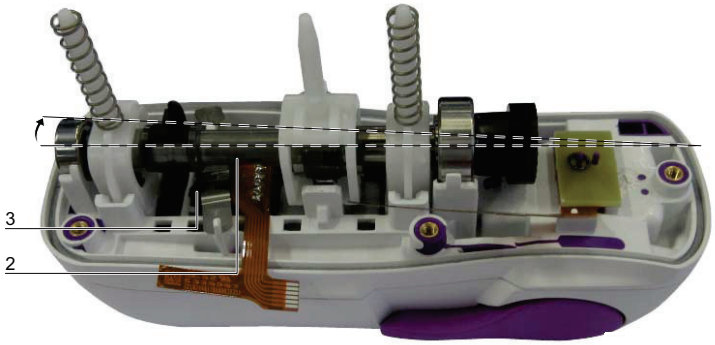
- Battery and battery door - Boost capacitor discharge (refer to the Intervention procedure N°1).
- Open the housing (refer to the Intervention procedure N°2).
- Remove the main body (refer to the Intervention procedure N°4).

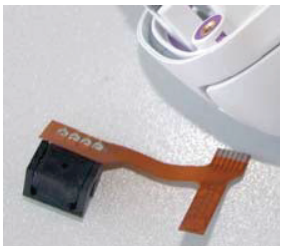
Disassembly

- Remove manually the fast-lock blade (marker 1).



- Pull out slightly the camshaft (marker 2) to release the pressure sensor (marker 3)
- Remove manually the pressure sensor (marker 3).





Re-assembly

- To reassemble, carry out the reverse procedure.

INFORMATION

At the end of this procedure, carry out calibrations linked with the parts changed and a Quality control using Amika Partner maintenance software.

Intervention Procedure N°8: Pinch clamp optical sensor

Safety recommendations:

WARNING

For safety reasons, the technician should not intervene when the device is connected to the mains.

Disconnect the power supply cord from the power source.

Switch off the device.

WARNING

When touching the boost capacitor, there is a risk of electrisation.

Disconnect the battery and discharge the boost capacitor before opening the device (refer to the Intervention procedure N°1).

WARNING

When working with electronic components, we recommend wearing an anti-static wrist strap connected to earth and working on a anti-static mat.

Required tools:

- 1 Torx T-8 screwdriver or electric screwdriver with a torque of 0.4Nm.
- 1 flat screwdriver (small).
- 1 antistatic band.

Maintenance level:

Level 3, specialised technician (see “Technical training”, page 43).

Procedure:

Access

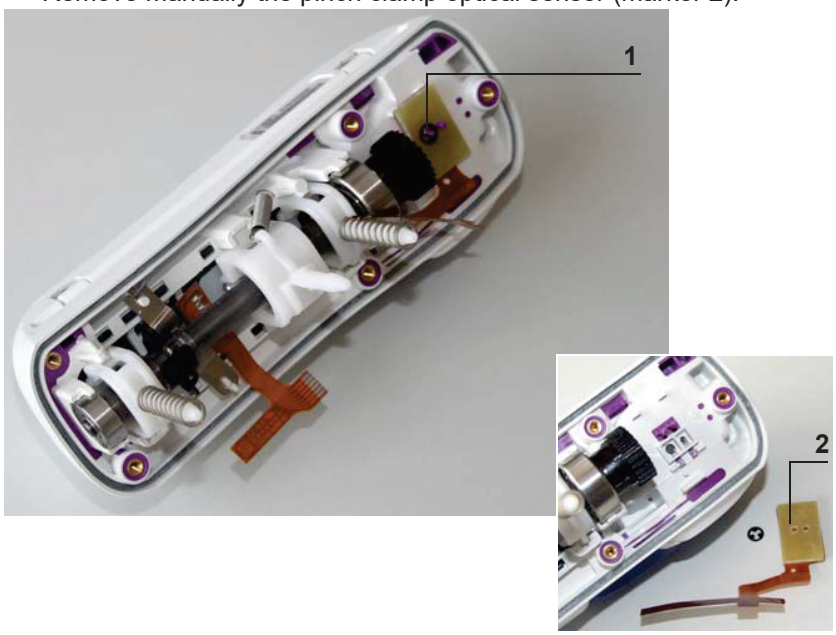
- Battery and battery door - Boost capacitor discharge (refer to the Intervention procedure N°1).
- Open the housing (refer to the Intervention procedure N°2).
- Remove the main body (refer to the Intervention procedure N°4).

Disassembly

INFORMATION

Disconnect all the connectors from the board.

- Remove with the flat screwdriver (small) the quicklock ring (marker 1).
- Remove manually the pinch clamp optical sensor (marker 2).



Re-assembly

To reassemble, carry out the reverse procedure.

INFORMATION

At the end of this procedure, carry out calibrations linked with the parts changed and a Quality control using Amika Partner maintenance software.

Intervention Procedure N°9: Door kit

Safety recommendations:

WARNING

For safety reasons, the technician should not intervene when the device is connected to the mains.

Disconnect the power supply cord from the power source.

Switch off the device.

WARNING

When touching the boost capacitor, there is a risk of electrisation.

Disconnect the battery and discharge the boost capacitor before opening the device (refer to the Intervention procedure N°1).

WARNING

When working with electronic components, we recommend wearing an anti-static wrist strap connected to earth and working on a anti-static mat.

Required tools:

No specific tool is required

Maintenance level:

Level 2, specialised technician (see “Technical training”, page 43).

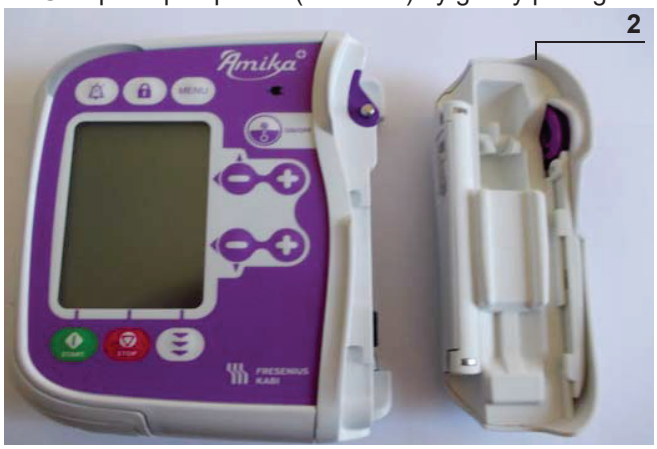
Procedure:

Access

- Turn the lever (marker 1) and open the pump door (marker 2).

Disassembly

- Unclip the pump door (marker 2) by gently pulling the door towards the right.



Re-assembly

- Clip the new door (marker 2) on the top surface (marker 3).

- Close the pump door (marker 2) and turn the lever (marker 4) .

WARNING

Do not forget to stick, on the Amika+ pump, the additional label containing the new door serial number as well as the corresponding barcode and that is delivered with the new door kit. It is your responsability to ensure the traceability between the Amika+ pump serial number and the new door serial number.

INFORMATION

At the end of this procedure, carry out calibrations linked with the parts changed and a Quality control using Amika Partner maintenance software.

Intervention Procedure N°10: Top surface kit

Safety recommendations:

WARNING

For safety reasons, the technician should not intervene when the device is connected to the mains.

Disconnect the power supply cord from the power source.

Switch off the device.

WARNING

When touching the boost capacitor, there is a risk of electrisation.

Disconnect the battery and discharge the boost capacitor before opening the device (refer to the Intervention procedure N°1).

WARNING

When working with electronic components, we recommend wearing an anti-static wrist strap connected to earth and working on a anti-static mat.

Required tools:

- 1 Torx T-8 screwdriver or electric screwdriver with a torque of 0.4Nm.
- 1 flat screwdriver (small).
- 1 antistatic band.

Maintenance level:

Level 3, specialised technician (see “Technical training”, page 43).

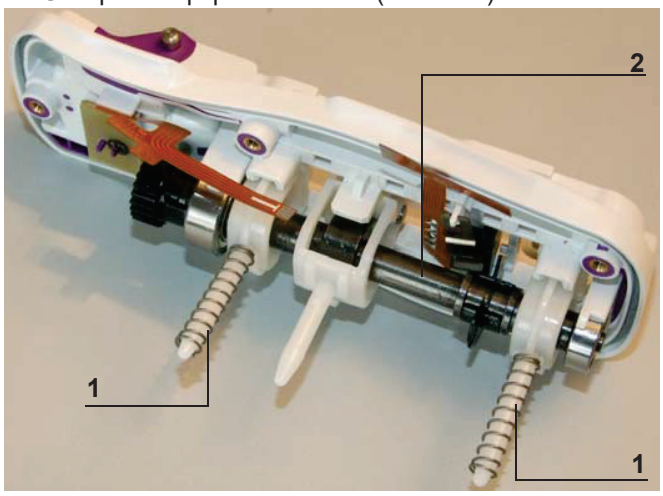
Procedure:

Access

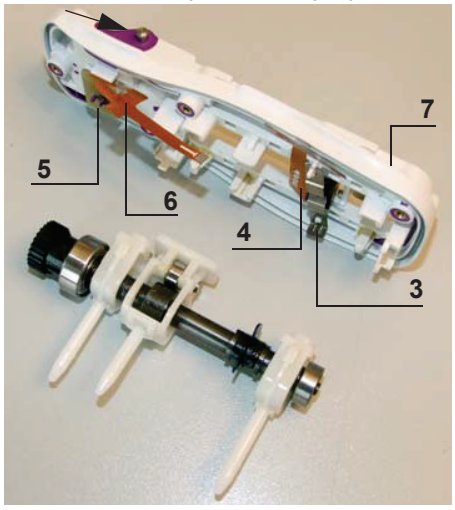
- Battery and battery door - Boost capacitor discharge (refer to the Intervention procedure N°1).
- Open the housing (refer to the Intervention procedure N°2).
- Remove the main body (refer to the Intervention procedure N°4).
- Remove the membrane (refer to the Intervention procedure N°5).

Disassembly

- Remove the springs (marker 1).
- Unclip the equiped camshaft (marker 2).



- Remove the fast-lock (marker 3) and the pressure sensor (marker 4).
- With the small flat screwdriver, remove the quick lock ring (marker 5).
- Remove the pinch clamp optical sensor (marker 6) from the top surface kit (marker 7).



Re-assembly

Carry out to the reverse operations of disassembly taking care of correctly positioning the keyboard flat cable and the strands.

Make sure the **s**prings are in position and the pumping finger is in down position.

Care must be taken with the membrane.

INFORMATION

At the end of this procedure, carry out calibrations linked with the parts changed and a Quality control using Amika Partner maintenance software.

Intervention Procedure N°11: Camshaft / Bearing kit

Safety recommendations:

WARNING

For safety reasons, the technician should not intervene when the device is connected to the mains.

Disconnect the power supply cord from the power source.

Switch off the device.

WARNING

When touching the boost capacitor, there is a risk of electrisation.

Disconnect the battery and discharge the boost capacitor before opening the device (refer to the Intervention procedure N°1).

WARNING

When working with electronic components, we recommend wearing an anti-static wrist strap connected to earth and working on a anti-static mat.

Required tools:

- 1 Torx T-8 screwdriver or electric screwdriver with a torque of 0.4Nm.
- 1 flat screwdriver (small).
- 1 antistatic band.

Maintenance level:

Level 3, specialised technician (see “Technical training”, page 43).

Procedure:

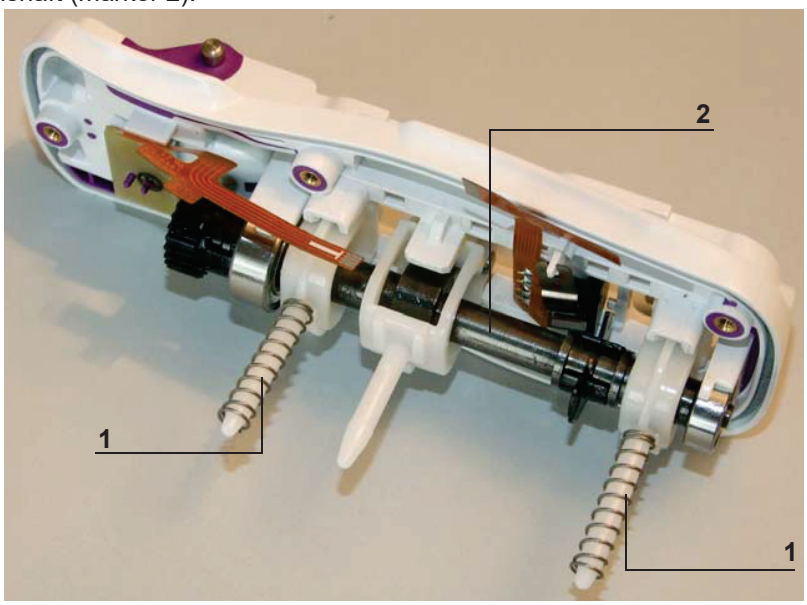
Access

- Battery and battery door - Boost capacitor discharge (refer to the Intervention procedure N°1).
- Open the housing (refer to the Intervention procedure N°2).
- Remove the main body (refer to the Intervention procedure N°4).
- Remove the membrane (refer to the Intervention procedure N°5).

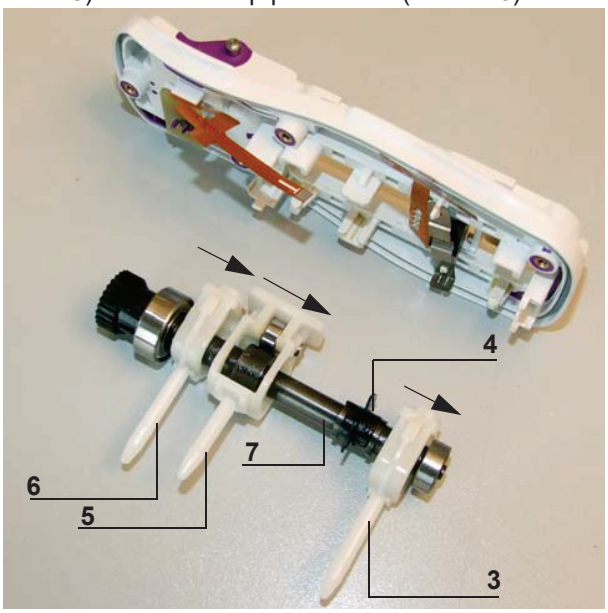
Disassembly

- Remove the springs (marker 1).

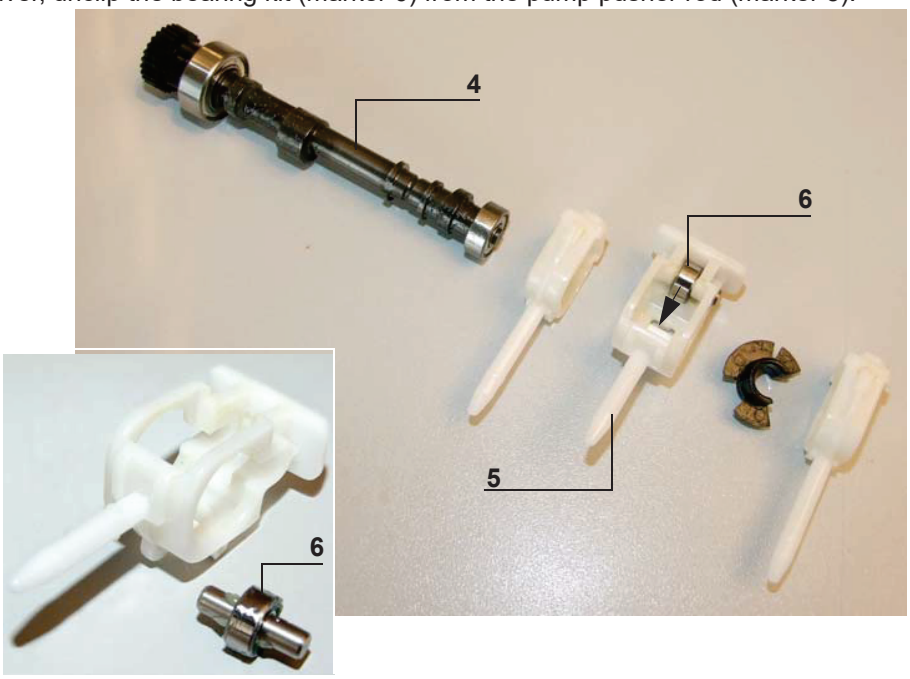
- Unclip the equiped camshaft (marker 2).



- Remove the clamp pusher rod (marker 3).
- Unclip the optical disk (marker 4).
- Remove the pumping fingers (marker 5) and the clamp pusher rod (marker 6) from the camshaft (marker 7).



- With a flat screwdriver, unclip the bearing kit (marker 6) from the pump pusher rod (marker 5).



Re-assembly

- Carry out to the reverse operations of disassembly taking care of correctly positioning the keyboard flat cable and the strands.
- Prior to the assembly of the new camshaft, it is necessary to grease it with Kluber GLY151 grease referenced Z171423.
- Make sure:
  - the optical disk is in good position.
  - Pump and clamps pusher rod are in position.
  - Springs are in position.
  - Pumping finger is in down position.
  - Care must be taken with the membrane.

INFORMATION

At the end of this procedure, carry out calibrations linked with the parts changed and a Quality control using Amika Partner maintenance software.

Intervention Procedure N°12: Holder COM

Safety recommendations:

WARNING

For safety reasons, the technician should not intervene when the device is connected to the mains.

Disconnect the power supply cord from the power source.

Switch off the device.

WARNING

When touching the boost capacitor, there is a risk of electrisation.

Disconnect the battery and discharge the boost capacitor before opening the device (refer to the Intervention procedure N°1).

WARNING

When working with electronic components, we recommend wearing an anti-static wrist strap connected to earth and working on a anti-static mat.

Required tools:

- 1 Torx T-25 screwdriver and 1 Torx T-8 screwdriver.

Maintenance level:

Level 1, specialised technician (see “Technical training”, page 43).

Procedure:

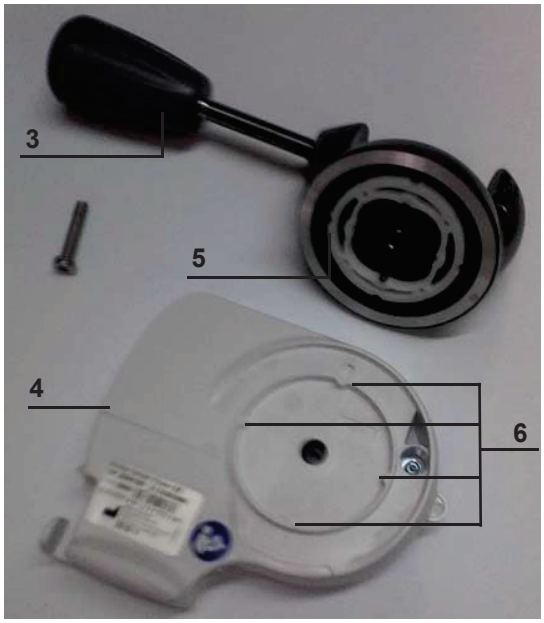
Access

- Separate the housing from its Holder (marker 1).

Disassembly

- Unscrew the torx T25 screw (marker 2).

- Remove the pole clamp kit (marker 3) from the kit upper case Holder (marker 4).



- Remove the indexer (marker 5) from the pole clamp kit (marker 3).

INFORMATION

Even if the indexing pins (marker 6) are damaged, only the indexer (marker 5) needs to be changed.

Re-assembly

Carry out to the reverse operations of disassembly.

INFORMATION

At the end of this procedure, carry out a Quality control using Amika Partner maintenance software.

12 Ordering information

Contact your local Fresenius Kabi organisation or the local distributor for ordering.

12.1 Giving Sets

Refer to the "Ordering information - Giving sets" section of the Amika+ IFU.

12.2 Data management cable

Amika+ mini 2 USB shielded cable (ref. Z044905).

12.3 Maintenance kit

Amika Maintenance Kit Essentials (ref. Z210991).
(Refer to the Amika Partner maintenance software IFU for a complete description).

12.4 Accessories

WARNING

Use ONLY recommended accessories delivered with the device.
(Refer to the "Ordering information - Accessories" section of the Amika+ IFU).

12.5 AC/DC Adapter

The Amika+ AC/DC Adapter exists in two versions:

- Amika+ AC/DC Adapter EUR (ref. Z044904) - Includes a type C plug adapter (Europe).
- Amika+ AC/DC Adapter INT (ref Z044907) - Includes type A, C, G, I, M plug adapters.

13 Spare parts catalogue

Refer to the Amika+ spare parts catalogue to order spare parts and kits.

14 Glossary of terms

Term	Description
°C	Celsius Degree
A	Amper
AC	Alternating Current
Ah	Amper hours
Amika+	Enteral feeding and hydratation pump manufactured by Fresenius Kabi
CE mark	European Conformity Mark
CISPR	Special International Committee on Radio Interference
cm	Centimeters
DC	Direct Current
DECT	Digital Enhanced Cordless Telecommunications
ECG	Electrocardiogram
EEG	Electroencephalogram
EMC	Electromagnetic compatibility
g	Gram
h	Hours
H x W x D	Height / Width / Depth
HF	High Frequency
HIS	Hospital Information System
ID/N°	Serial number
IEC	International Electrotechnical Commission
IFU	Instructions For Use
LED	Light Emitting Diode
m	Meters
mL	Milliliter
mL/h	Milliliter per hour
NiMH	Nickel-Metal Hydride
NMR	Nuclear Magnetic Resonance
RF	Radio Frequency
RFID	Radio Frequency Identification
UPS	Uninterruptable Power Supply
V	Volt
Vac	Volt Alternating Current
W	Watt

15 Release notes

Date	Software version	Description
January 2018	1.0	Creation.

Useful addresses

TRAINING DEPARTMENT / TECHNICAL SERVICE

Fresenius Kabi
Le Grand Chemin,
38590 Brézins
France

Tel.: + 33 (0)4 76 67 10 10
Fax: + 33 (0)4 76 67 11 22

SPARE PARTS DEPARTMENT

Fresenius Kabi
Le Grand Chemin,
F - 38590 Brézins

Tel.: + 33 (0)4 76 67 10 34
Fax: + 33 (0)4 76 67 11 88

Made in France

Revision date: May 2018

www.fresenius-kabi.com

CE 0123

First CE Mark: 2018

Local Contacts for Servicing

FRESENIUS KABI
caring for life

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FRESENIUS KABI

caring for life

Amika+

Enteral feeding pump

Software version 1.0

Instructions For Use

Symbol descriptions

 Warning (Refer to the Instructions For Use)

CE 0123 CE mark

 Refer to the Instructions For Use

 Medical electrical system weight (kg)

REF Product reference / part number

SN Product serial number

 Name and address of the manufacturer / Date of manufacture

 Name and address of the manufacturing facility

 Battery specification

 Protection against leakage current; defibrillation-proof type CF applied part

 Direct Current (DC)

 Alternating Current (AC)

 Output terminal - connector

 Input terminal - connector

 Fragile, handle with care

 This way up

 Keep away from rain

 Temperature limitation

 Humidity limitation

 Atmospheric pressure limitation

 General symbol for recyclable material

 Eco packaging symbol

IP32 **Holder**: IP32-Index of protection against solid foreign objects (> 2.5 mm) and dripping liquids

IP35 **Pump**: IP35-Index of protection against solid foreign objects (> 2.5 mm) and water jets from any direction

IP41 **AC/DC Adapter**: IP41-Index of protection against solid foreign objects (> 1 mm) and dripping liquids

 Protection against electric shock: class II

 Part included in a recycling process

 **Warning**: warning of a potential hazard that could result in serious personal injury and/or product damage if the written instructions are not followed.

 **Caution**: warning of a potential hazard that could result in minor personal injury and/or product damage if the written instructions are not followed.

 **Information**: recommendations to be followed.

INFORMATION
Please refer to the Use environment section for additional information on temperature, pressure and humidity limitations.

Table of contents

1 Introduction

Amika+ is an enteral feeding pump with a holder and disposables dedicated to enteral feeding and hydration. The intended use of Amika+ pump and sets is to deliver nutrition and hydration fluids to the patient through a feeding tube, in a safe, instinctive and convenient manner.

1.1 Scope

These Instructions for Use (IFU) are applicable to the Amika+ pump referred to as pump with software version 1.0.

WARNING

- Check that these IFU are applicable to the current Amika+ software version.
- The software version of the pump is displayed in the technical information menu described in *Technical information* on page 40.
- 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 descriptions* on page 2.

1.2 Intended use

Amika+ enteral feeding pump is intended for use on adults and pediatrics to deliver nutrition and hydration fluids to the patient through an enteral route of administration using a feeding tube.

It is intended for use by both qualified and trained healthcare professionals in clinical healthcare facilities, in ambulatory use with an Amika Backpack and in pre-hospital medical ground transportation and home users in homecare.

1.3 Intended user population

WARNING
Keep the pump, sets and AC/DC adapter away from unsupervised children (and animals).

The pump must only be used and cleaned by trained healthcare professionals, patients or patient relatives.

It is recommended that users attend a single training session of about 60 minutes (For training, contact your Fresenius Kabi sales representative).

1.4 Intended patient population

The pump can be used on one patient at a time and on multiple patients during its lifetime.

The pump can be used on patients requiring enteral feeding and enteral hydration.

The intended patient population includes patients who get enteral nutrition parallel to IV insulin administration. Those patients require special attention during the feeding process.

1.5 Principles of Operation

The device is a peristaltic pump dedicated to enteral feeding.

The pump is used to administer to patient (humans only) a volume of nutrition at a programmed flow rate.

The feeding can be administered continuously (Continuous mode) or sequentially (Bolus mode).

The pump is designed to administer fluids through trans-nasal or percutaneous feeding tube.

The pump is designed to administer any kind of enteral nutrition fluids, including drinking water (still and sparkling), tea, soda, fresh water and the whole product range of ready nutrition from Fresenius Kabi.

1.6 Contraindications

DO NOT USE:

- for the intravenous administration of infusion fluids;
- if enteral feeding is contraindicated by medical prescription;
- with premature (born < 37 weeks of pregnancy) and neonates (<1 month);
- in Magnetic Resonance Imaging (MRI) environments;
- in ambulances, helicopters, aircrafts and hyperbaric chambers;
- in areas where there is a risk of explosion.

1.7 Use environment

The Amika+ AC/DC adapter is not meant to be used outdoors (such as in the garden, on the patio).

WARNING

- Keep away from heat sources, dust, fluff, direct and prolonged light exposure.
- The pump should be used under specified operational, storage and transport conditions listed below to ensure pump performance.
- At the limit of the operating temperature range, physical properties of set's tube may change; in such condition, alarms are more likely to happen.

- Temperature operating range: 10°C to 40°C
- Storage and transport temperature: -20°C to +45°C
- Pressure operating range: 700 hPa to 1060 hPa
- Storage and transport pressure: 500 hPa to 1060 hPa
- Humidity operating range: 30% to 85%, no condensation
- Storage and transport humidity: 10% to 90%, no condensation

- Altitude: maximum 3000 m.

In case of refrigerated products, allow the product to reach the operating temperature range before use.

When the pump is stored at extreme temperature (-20°C and +45°C), wait for 2 hours to allow the product to reach the operating temperature range before using the pump. An intempestive alarm can be triggered if the pump/giving set temperature is too low or too high.

1.8 Specificities for Homecare Environments

The responsibility of using the pump is shared between the healthcare professional and the patient. All pump settings must be performed according to the medical prescription.

If any doubt, patient or patient relatives should call healthcare professional to confirm correct handling of the device.

2 Description

2.1 System definition

The Amika+ system is composed of the following components:

- Amika+ pump: enteral feeding pump with pump holder and AC/DC adapter.
- Amika+ disposable (applied part): giving sets.
- Amika+ accessories.

For more information on accessories, refer to their respective accompanying documents.

2.2 Packaging content

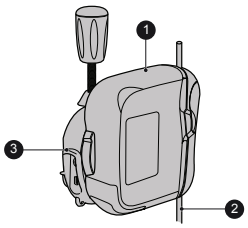
The Amika+ packaging contains the following elements:

- 1 Amika+ pump
- 1 pump holder COM
- 1 AC/DC adapter
- 1 Amika Nurse call Cable
- User documents

Packaging consists of: recycled cardboard.

Symbols used on Amika+ packaging are described in *Symbol descriptions* on page 2.

2.3 General description

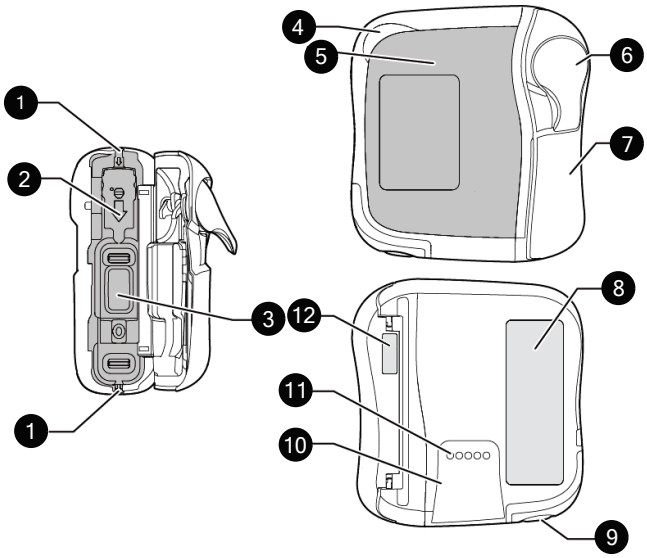


Legend

1. Pump
2. Giving set (sold separately)
3. Pump holder

2.4 Detailed description

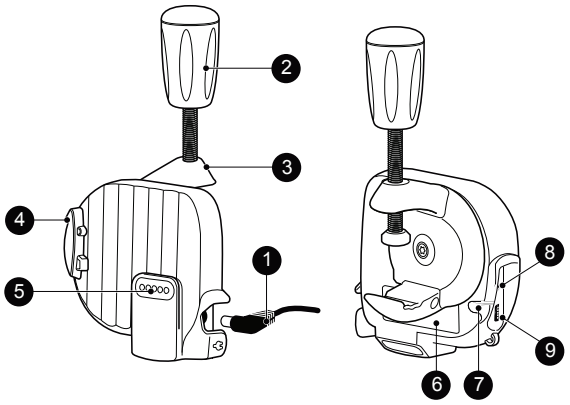
Pump description



Legend

1. Tube guides
2. Pinch clamp slot
3. Pumping mechanism
4. Status light indicator
5. Front panel (keypad)
6. Door lever
7. Pump door
8. Pump identification label
9. Speaker
10. Rails for installation on pump holder
11. Contact pins for pump to holder connection
12. Pump door identification label

Holder COM description

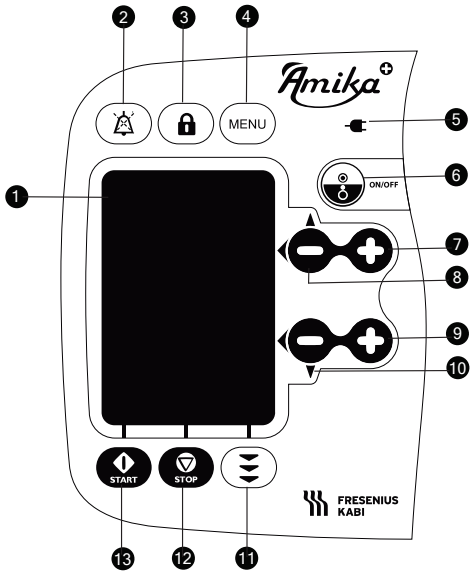


Legend

1. AC/DC adapter's connector
2. Clamp handle
3. Pole clamp
4. Grey locking lever
5. Contact pins for pump to holder connection (Power supply)
6. Holder identification labels
7. Slot for cable
8. Jack 3.5 mm Nurse Call port
9. Mini USB port

Near the power cable inlet of the holder, description in *Power supply specifications* on page 55

Front panel (keypad) description



Legend

1. Display (description next page)
2. Mute key
3. Keypad lock key
4. Menu key
5. Mains supply light indicator
6. Power ON/OFF key
7. Flow rate Up
8. Flow rate Down / Scroll up in Menu
9. Target volume Up
10. Target volume Down / Scroll down in Menu
11. Priming function key
12. Stop / Cancel / Back key
13. Start / Enter / OK key

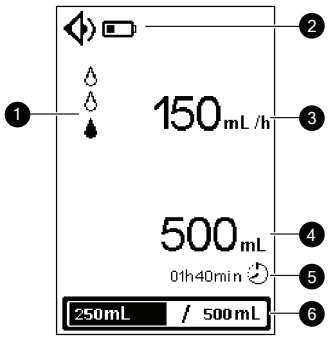
2.5 Display description

Status Bar icons

	Sound level icons		Alarm icon

	Battery icon		Muted alarm icon
	Keypad locked icon		Settings lock icon

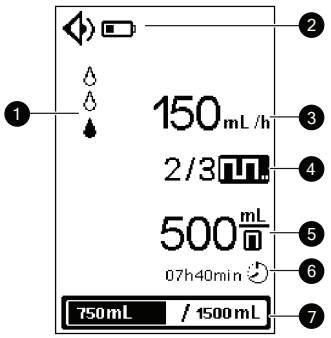
Continuous mode setting screen layout



Legend

1. Pumping status indicator:
   - Pumping is stopped
   - Pumping is in progress
2. Status bar
3. Flow rate
4. Target volume
5. Remaining feeding time
6. Progress bar showing volume delivered / total volume

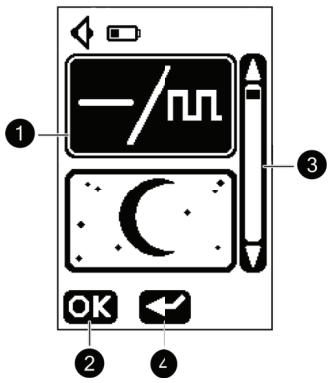
Bolus mode setting screen layout



Legend

1. Pumping status indicator:
   - Pumping is stopped
   - Pumping is in progress
2. Status bar
3. Flow rate
4. Current bolus / Bolus number
   - Bolus mode is activated.
5. Volume per bolus
6. Remaining feeding time of all boluses
7. Progress bar showing volume delivered / total volume

Menu display layout



Legend

1. Menu list
2. Menu access
3. Scroll bar
4. Back

3 Installation and removal

Installation and removal must only be done when the patient is not connected.

3.1 Installation

3.1.1 Global installation

Ensure that the appropriate positions between patient, pump, giving set and container are maintained.

WARNING

- Do not vary the pump height while a patient is connected to it. This may lead to false alarms and will alter flow rate accuracy.
- Check the stability of the whole system. If the container is positioned lower than 0.5 m beneath the pump, this can lead to flow rate deviation.
- Give particular attention to the risk of strangulation with cables and sets, and with the small parts that could be swallowed or inhaled.

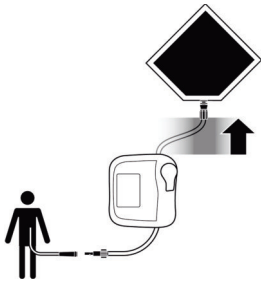


Figure 1: Recommended installation

Place the container above the pump

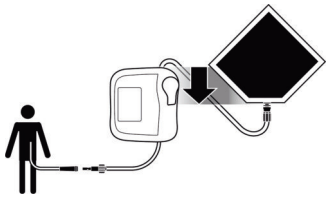


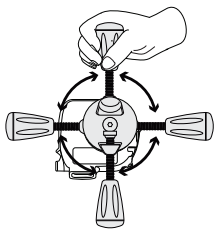
Figure 2: Possible installation

The container can be placed down to 0.5 m beneath the pump

Do not place the pump below the patient or more than 1.3 meter above the patient.

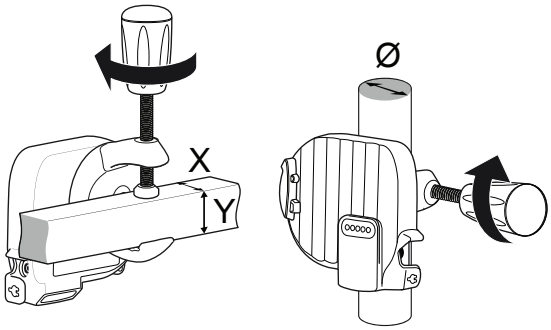
3.1.2 Using the pole clamp

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



3.1.3 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).

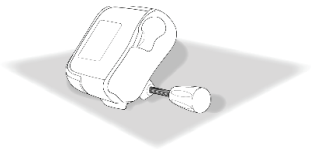


X, Y min = 10 mm
X, Y max = 35 mm
Ø min = 8 mm
Ø max = 40 mm

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

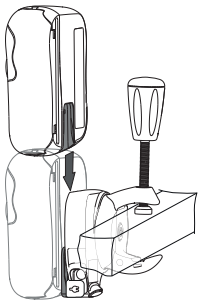
3.1.4 Positioning the holder on a table

The holder can be placed on a flat and horizontal table as indicated in the figure.
Ensure the pump is positioned away from table edges to avoid being accidentally pushed off the table.



3.1.5 Positioning the pump

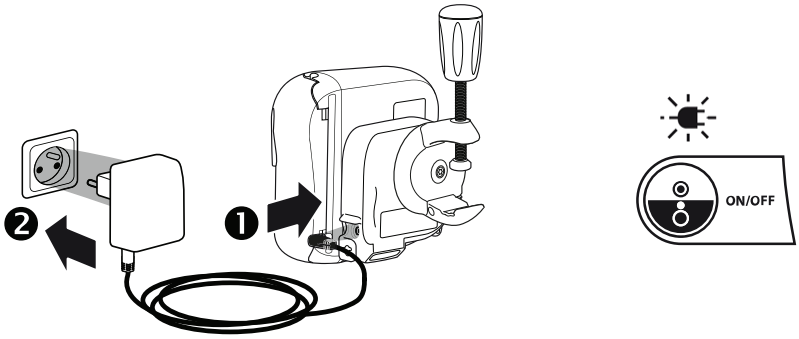
Slide the pump down until the grey locking lever locks the position.



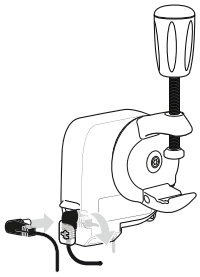
3.1.6 Electrical connection

Ensure AC/DC adapter is not damaged and is compatible with local voltage range.

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



1. Connect AC/DC adapter to the holder.
2. Plug the AC/DC adapter to the mains socket.
   When connecting to the mains, ensure that the AC/DC adapter and the power socket are easily accessible.
   The mains power supply is indicated by a green light on the pump's front panel (keypad).



3.1.7 Connection to the Nurse Call System and Removal

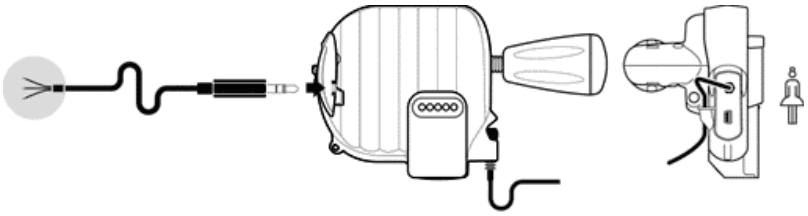
The Amika Holder COM and Nurse Call cable allow the connection of an Amika+ pump to an external Nurse Call system to transmit an Amika+ pump alarm state.

The Nurse Call connection is functional only if:

- the pump is correctly installed on the holder.
- the holder is connected to the power supply.
- the Nurse Call cable is correctly plugged.

If the Nurse Call is not functional, Amika+ pump alarm state is not transmitted.

The Nurse Call system availability and technical compliance are the responsibility of the hospital.



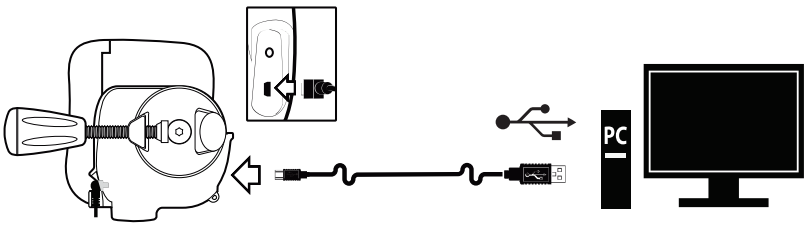
1. Connect the terminated Nurse Call cable to the holder Nurse Call connector.
2. Pinch the cable into the slot provided for this purpose.
3. Check that the nurse call system is functional by generating an alarm (eg: start the pump with no giving set installed). Ensure the pump alarm is transmitted on the connected Nurse Call system.
4. To disconnect, unplug the Nurse Call cable.

INFORMATION The nurse call cable is delivered with an unterminated side, which will require customization to the hospital-specific nurse call system by a trained technician. See Amika Holder COM Nurse Call IFU or Amika+ technical manual for further information.

3.1.8 USB connection and removal

INFORMATION

- Use ONLY cables recommended by Fresenius Kabi. Refer to *Ordering information* on page 69.
- All connections and disconnections must be performed by qualified and appropriately trained staff.
- All IT devices (including computers, hubs and switches) inside the patient area (< 1.5 m) must comply with IEC/EN 60601-1 (leakage current).
- IT devices connected outside the patient area (> 1.5 m) must be at least IEC/EN 60950 compliant.
- Do not disconnect communication cables while data is being transferred.



1. Connect the terminated USB cable to the holder mini USB connector.
2. Connect the other side of the USB cable to the third party system.
3. Check communication status.
4. To disconnect, unplug the USB PC cable.

3.1.9 Data communication overview

INFORMATION

- Ensure that all hospital information systems have been approved by Fresenius Kabi. For more information, contact your technical services representative.
- Before connecting the pump to a hospital information system, please contact your IT or biomedical department.

Amika+ data communication feature allows:

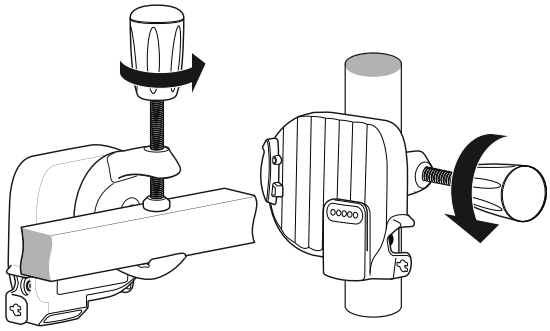
- Communication between a hospital information system server and 1 pump.
- Connection of 1 pump to a PC for the following purposes: Maintenance (via Amika Partner software).

3.2 Removal

3.2.1 Removing the pump from the pump holder

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

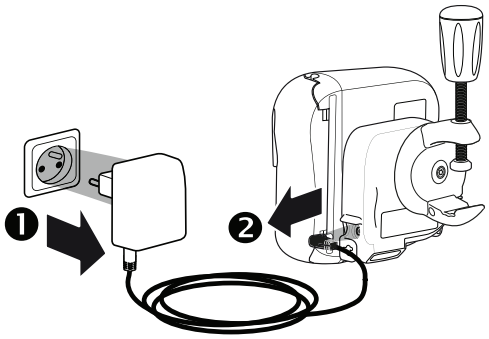
3.2.2 Removing the pump holder

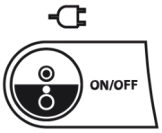


3.2.3 Electrical disconnection

1. Remove AC/DC adapter from power socket.

- A beep is emitted by the pump when the AC/DC adapter is disconnected.
- To store the pump, see *Storage* on page 63.

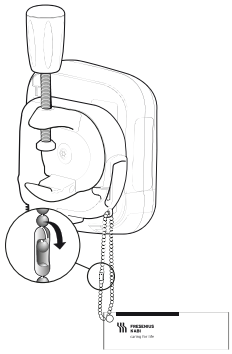




2. Remove AC/DC adapter from holder.

3.2.4 Attaching / Removing the Quick Guide

A quick guide can be easily attached and removed from the pump holder.



4 Operations

4.1 Use of internal battery

4.1.1 Battery precautions

Before using the pump on battery for the first time, charge the battery until it is fully charged (approximately 6 hours).

Keeping the pump connected to mains when not in use is recommended in order to maintain battery charge. The battery is charging continuously ensuring its maximum capacity.

4.1.2 Battery operating mode

The icon is always displayed in the status bar. The device can be used while battery is charging.

Battery life	24 hours ± 5% until 125 mL/h and a minimum of 8 hours for flow rates above 125 mL/h (in standard feeding conditions, at 22.5°C ± 2.5°C)
(green)	When the pump is connected to the mains (see *Electrical connection* on page 14) ► Battery charges automatically, also during operation
	When the pump is disconnected from the mains (see *Electrical disconnection* on page 17) ► Pump switches to Battery Mode automatically
	The battery is fully charged
	The battery is partially charged
(flashing)	The battery is nearly empty. ►A visual information is triggered (see *Alarms / Actions* on page 47). When battery is empty (less than 10 minutes left), an alarm is triggered (see *Alarms / Actions* on page 47.)

INFORMATION

- To optimize battery life, set the flow rate at 125 mL/h maximum and use the pump in battery mode several times until battery is discharged (flashing).
- If battery is failing, do not use the device. Return device to Fresenius Kabi sales representative as soon as possible.
- Battery replacement must be performed by qualified and trained technical personnel in compliance with the technical manual and procedures.

4.2 Basic operations

Before using the pump, proceed to Quick Check Protocol (see *Quick check protocol* on page 45).

4.2.1 Switch-on

When using a pump on patient requiring special attention, ensure that a backup pump or gravity set are available for immediate use.

When switching on the pump, check that the auto test sequence is as described below.

Before switching on the pump, install holder and pump, see *Installation* on page 13.

Figure 3: Auto test

During the 2-second autotest:

- red, yellow and green LEDs blink;
- beep sounds (if sound level is low, melody is playing on low, if sound level is high, melody is on high).

4.2.2 Installing the giving set

4.2.2.1 Preparing the giving set

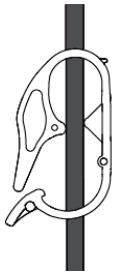
In order to protect user health, please follow clean aseptic handling procedures for container, set or feeding tube disposal.

WARNING

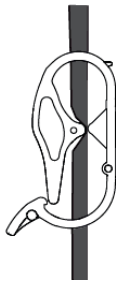
- Only Fresenius Kabi giving sets can guarantee pump reliability. Please refer to the compatible giving sets (see *Giving sets* on page 69) and compatible nutrition fluids (see *Intended use* on page 5).
- Check the giving set's intended use regarding the feeding protocol, especially for patients requiring special attention.
- Check giving set and patient connection integrity before use.

CAUTION
The fluid in the giving set and the bag/bottle must be within normal temperature conditions: +10°/+40°C.

4.2.2.2 Description of the pinch clamp



Pinch clamp is open



Pinch clamp is closed

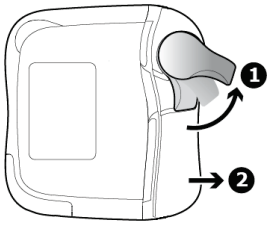
INFORMATION
Patient must not be connected to the set when the pinch clamp is open.

4.2.2.3 Installing the giving set in the pump

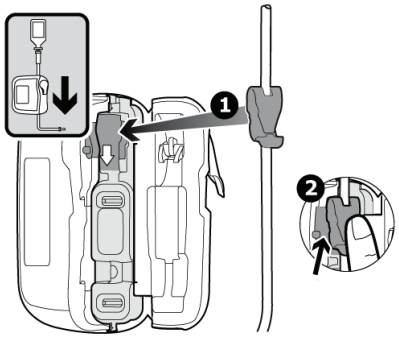
To connect / disconnect / change the container and feeding tube to the set, refer to the giving set "Instructions for use" on primary packaging.

WARNING
For patients requiring special attention, another giving set must always be available.

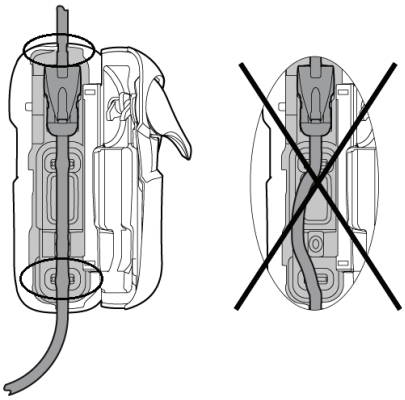
1. Push up the lever to unlock the door ❶. Open the door ❷.



2. Position the pinch clamp using the arrow marks indicating the direction of the flow ❶.
Insert the pinch clamp until you hear the ‘CLIC’ ❷.

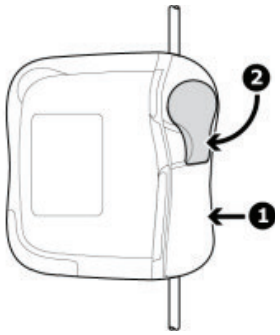


3. On the sides of the pump, place the tube straight inside tube guides.



WARNING
Check that the giving set is correctly installed to avoid patient harm such as overfeeding, underfeeding.

4. Close the door ❶. Push down the lever to lock the door ❷.



INFORMATION
When opening the pump door, the tube clamp is automatically closed (free-flow prevention system).

4.2.3 Priming the giving set

WARNING
Patient must not be connected to the pump when priming is performed.

INFORMATION

- To proceed to giving set priming, fill drip chamber half full by pressing gently.
- Ensure that liquid is flowing in the drip chamber after starting the pump.
- For giving sets without drip chamber, use only automatic priming.
- A beep sound will be heard every 30 seconds during priming.

4.2.3.1 Priming with the pump

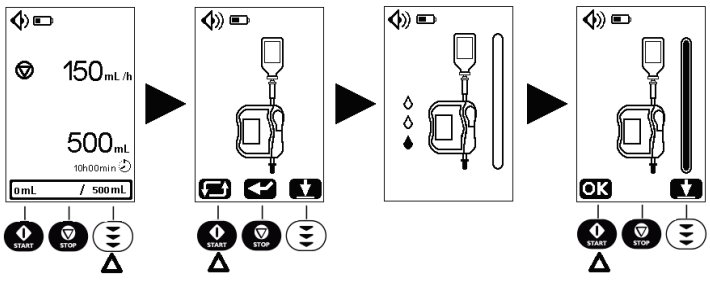
Amika+ pump allows two priming modes:

- automatic priming: Amika+ pump automatically fills in the giving set at maximum rate by depressing the automatic priming key START;
- semi-automatic priming: Amika+ pump fills in the giving set at maximum rate as long as the semi-automatic priming key is kept depressed.

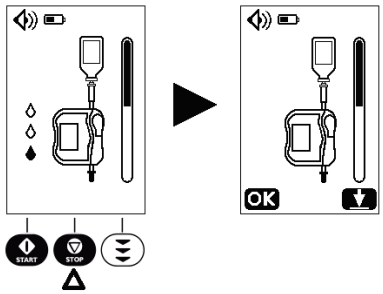
INFORMATION
Automatic and semi-automatic priming fill the giving set at a rate of 600 mL/h and are stopped after 17 mL (factory settings).

Make sure that priming is correctly completed before starting feeding.

Automatic priming

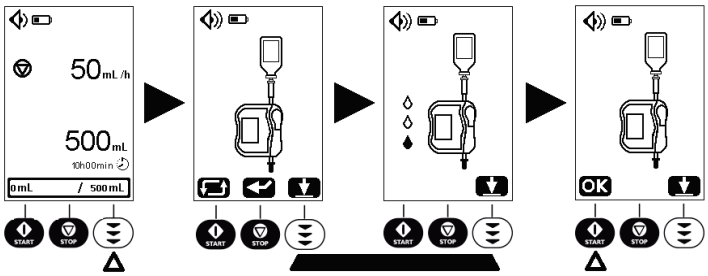


Auto priming can be stopped at any time:



At the end of automatic priming, it is possible to continue the priming using the semi-automatic priming function as defined below.

Semi-automatic priming



Press key to access to the priming modes. Press key to launch the priming. Keep it depressed during priming. Release it once priming is complete.

Press START to go back to setting screen.

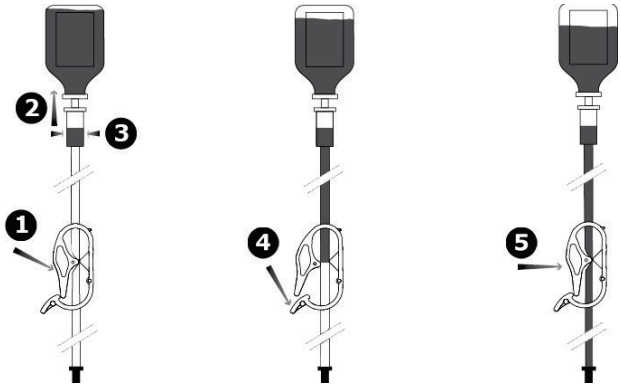
WARNING
At the end of priming, check that the set is correctly primed.

4.2.3.2 Priming without the pump (Manual priming)

Remove the giving set from the pump (see *Removing/Changing the giving set from the pump* on page 28).

1. Close pinch clamp.
2. Connect food container to giving set and hang up.
3. Fill drip chamber half full by pressing gently.
4. Open pinch clamp and prime to the end of the giving set.
5. Close pinch clamp.

Install the set in the pump to start feeding (see *Installing the giving set* on page 20).

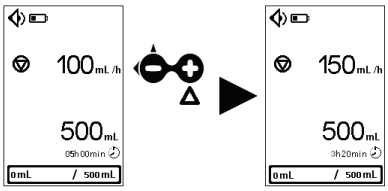


4.2.4 Change feeding setting

INFORMATION

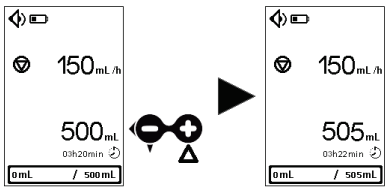
- A longer keypress provides faster scrolling.
- The flow rate of delivery must be adapted individually to the patient. Regular checks are required.

- Adjust feeding rate (mL/h)



Press + or − key to set the feeding rate.

- Adjust target volume (mL)



Press + or − key to set the target volume.

INFORMATION
In bolus mode, the target volume is adjusted per bolus.

- Solve incompatible values (for bolus feeding)

If the feeding is impossible due to incompatible values with the Bolus parameters programming (Flow rate and Volume values are not possible with the time interval between boluses programmed in the bolus menu):

– The bolus volume and the flow rate are blinking
– The start key is inactive and the forbidden key beep is triggered
– The remaining time is not displayed

In homecare, prescription values can be confirmed by calling healthcare provider or healthcare professional.
Modify bolus feeding parameters. To modify bolus settings, see *Bolus mode settings* on page 33.

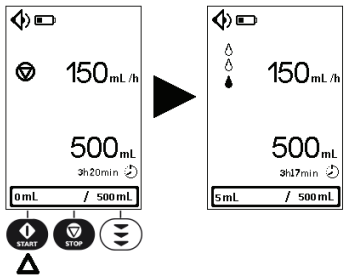
When the setting is OK for running with the correct values according to the prescription:

– Start key is functional
– Remaining time is displayed
– Feeding can be started

WARNING
Make sure feeding parameters are checked before starting feeding (programming error can lead to overfeeding, underfeeding or delay of therapy).

4.2.5 Start feeding

1. Connect the giving set to the patient's enteral feeding tube. Ensure that the giving set is not stucked in any way.
2. Make sure that priming is correctly completed before starting feeding.

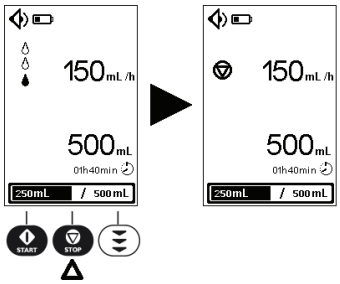


3. Check power supply before starting feeding.
   - Green light indicator if supplied by mains, or
   - Battery icon filled up if supplied by the battery.

   Keypad lock is recommended for bolus feeding in order to avoid misusage.

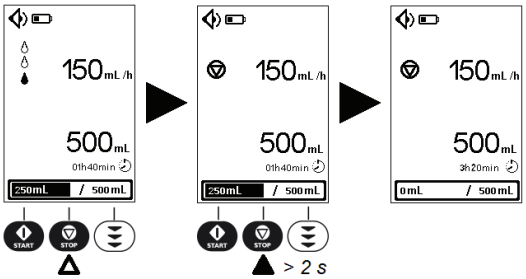
4.2.6 Terminate feeding

- Stop feeding



When feeding is stopped, flow rate and target volume parameters can be adjusted. Then, feeding can resume.

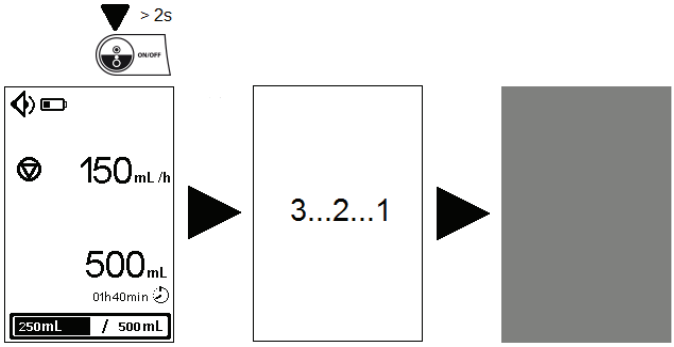
- Reset the progress bar.



When the pump is stopped, progress bar can be reset by depressing the STOP key for 2 seconds.

4.2.7 Switch off pump

Feeding shall be stopped before switching off the pump.



INFORMATION

- When feeding is on-going, the key is inactive: the forbidden key beep is triggered but feeding continues.
- When switched off, the pump retains the following information:
  - flow rate, volume and progress bar on the setting screen;
  - cumulative feeding volume;
  - bolus settings;
  - remaining time;
  - target volume mode;
  - sound level, key beep activation / deactivation;
  - contrast and brightness;
  - feeding and Alarm history;
  - settings lock activation / deactivation;
  - time between 2 alarm sounds;
  - time for target volume almost reached message;
  - technical information.
- This information is saved even if the battery is disconnected with no time limit.
- Feeding history and Alarm history allow the record of the 250 latest events for each history.
- In the case of a powering down, the time of powering down is not retained in the history.

4.2.8 Removing/Changing the giving set from the pump

The mechanical properties of the administration set in association with the pump are designed to maintain pumping performance for a maximum of 5 L or a 24-hour period.

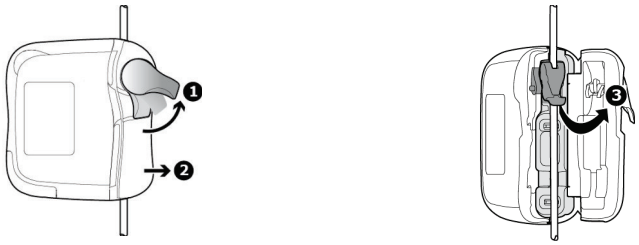
Replace the administration set according to your healthcare facility's protocol or CDC guidelines.

Administration sets are supplied sterile and are indicated for single use.

WARNING

- The use of the same set for more than 24 hours can lead to therapeutic issues, such as infection, and uncontrolled flow.
- For patients requiring special attention, another giving set must always be available.

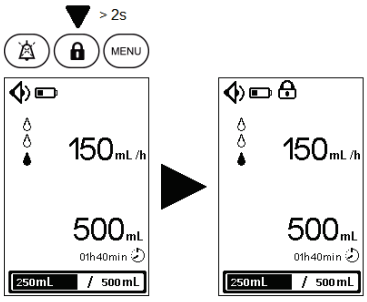
1. Push up the lever to unlock the door ❶.
2. Open the door ❷.
3. Remove giving set ❸.



Install a new giving set in the pump (see *Installing the giving set* on page 20).

4.2.9 Keypad lock

Keypad lock prevents from unintentional tampering of pump settings.



When keypad is locked:

- is displayed in the status bar;
- is the only active key. If other keys are depressed, the forbidden key beep (2 beeps) is triggered, no action is undertaken and feeding continues.

Keypad can be unlocked by depressing the keypad lock key for 2 seconds.

Unlocking the keypad is required to stop feeding, change feeding settings and enter the menu.

4.2.10 Mute alarm

To temporarily release alarm sound, press  .

When a medium priority alarm is muted:

- the mute icon  is displayed in the status bar;
- the alarm symbol is displayed and the yellow LED keeps flashing until a corrective action is performed;
- the alarm sound is off for 2 minutes.

When a low priority alarm is muted:

- the mute icon  is displayed in the status bar;
- the alarm symbol is displayed and the yellow LED is lit;
- the alarm sound is off and an information signal sound (2 beeps) is emitted every 30 minutes.

For further information about alarms, see *Alarms / Actions* on page 47.

5 Pump menu

INFORMATION

- The menu is accessible when feeding is stopped.
- A beep sound is triggered when a forbidden key (not active in specific screens) is depressed.
- During a procedure, press START (OK) to validate the choice and go back to the setting screen.
- Press STOP (↵) to go back to the previous screen (without validation).

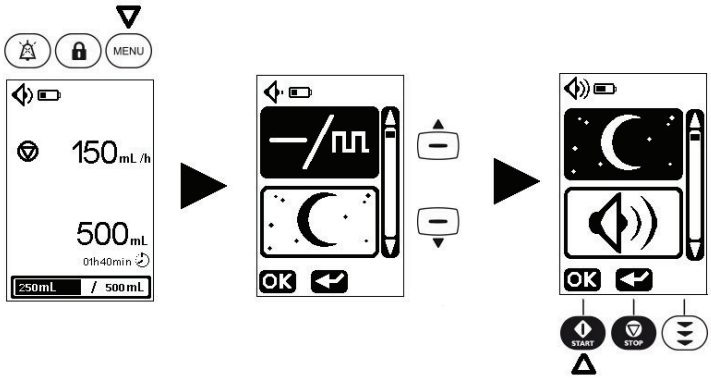
5.1 Access menus

Menu descriptions

Menus	Description
Select feeding mode and settings	Continuous mode activated: Deactivate / activate target volume mode (the access code is required, if the settings lock is activated)
	Bolus mode activated: Deactivate / activate flushing information Enter the bolus settings (number of bolus, time interval between boluses) (the access code is required, if the settings lock is activated)
Night mode	Night mode activation / deactivation
Sound	Adjust sound level
	Deactivate / activate key beep
Settings lock	Deactivate / activate settings lock
Cumulative feeding volume counter	Display cumulative feeding volume
	Clear cumulative feeding volume
Alarm history	Consult the last 250 alarm events
Feeding history	Consult the last 250 feeding events
Contrast / Brightness	Contrast setting
	Brightness setting
Time between 2 alarm sounds	Consult time between 2 alarm sounds
	Set time between 2 alarm sounds (the access code is required)

Menus	Description
Time for target volume almost reached message	Consult time for target volume almost reached message
	Set time for target volume almost reached message (the access code is required)
Technical information	Consult technical information of the pump
Reset manufacturing setting	Set pump to factory settings

Menu navigation



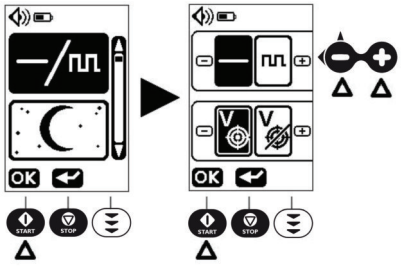
Press MENU then press , to scroll up / down between submenus.

Press START to enter the submenu.

5.2 Feeding mode and settings

5.2.1 Feeding mode selection

On this screen, continuous mode is activated .

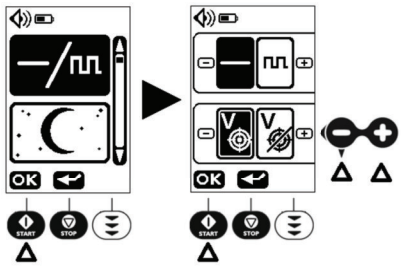


Press START to select Feeding mode and settings.

Press − to activate Continuous mode or + to activate Bolus mode.

5.2.2 Continuous mode settings

On this screen, target volume mode is activated . If you programme a feeding with no target volume and a feeding with target volume with respectively different flow rates, the respective flow rates are saved.



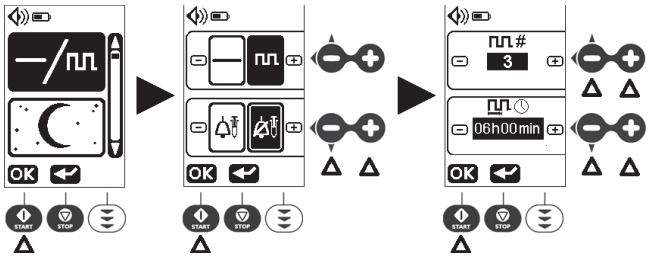
Press START to select target volume mode in the menu. Press + or − to deactivate / activate target volume mode (defaut setting: activated). Press START to validate.

INFORMATION

- When target volume mode is deactivated, the target volume and the progress bar disappear from the display.
- If the settings lock is activated, the access code is required to activate / deactivate target volume.

5.2.3 Bolus mode settings

On this bolus mode menu , flushing information is deactivated .



Press the upper ⊕ to activate Bolus mode in feeding mode menu. Press ⊕ or ⊖ to deactivate / activate flushing information (defaut setting: deactivated). Press START to validate.

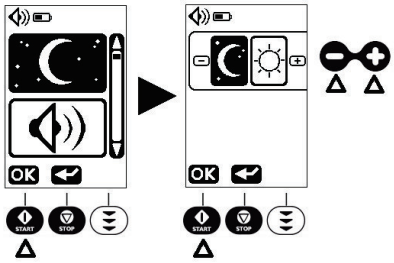
Press ⊖ or ⊕ to set the bolus number.

INFORMATION
The bolus number is adjustable from 1 to 24. If ∞ is selected, the pump performs boluses until the replacement of the container. In this case, if the pump is switched off during a bolus, the complete volume of bolus will be delivered when starting feeding again.

Press ⊖ or ⊕ to set the time interval between boluses. Press START to validate.

5.3 Night mode

On this screen, night mode is activated .

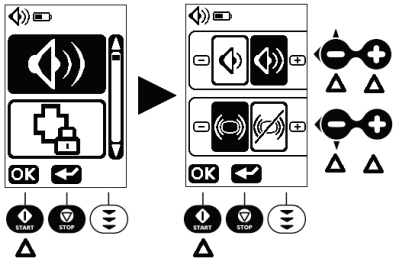


Press START to select Night or Day Mode. Press ⊕ to activate Day Mode or ⊖ to activate Night Mode. Press START to validate Night or Day Mode.

INFORMATION
- When night mode is activated, display backlight and power LED are set to minimum level.
- In case of alarm, the backlight turns back to normal.
- Night mode is automatically deactivated after switching OFF the pump.

5.4 Sound

The pump is set by default to the highest sound level . It can be reduced to a lower sound level .



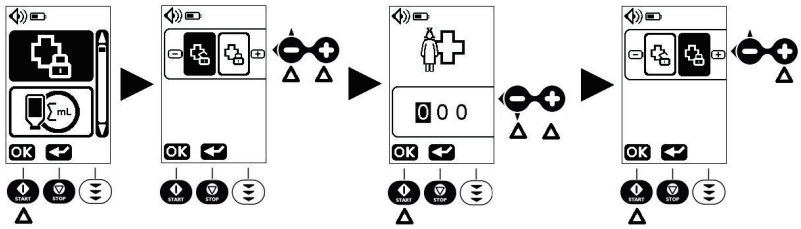
Press START to select the sound level and key beep sound.

Press − / + to select low or high sound level. Press + to deactivate key beep or press − to activate key beep.

Press START to validate the sound level and key beep sound ON or OFF (default setting ON).

WARNING
Audible alarm signal level is adjustable. However, please ensure the user can hear alarms, especially when the pump is used on battery.

5.5 Settings lock



Press START key to configure Settings lock. Press − key to enter the access code.

Enter the access code by adjusting each digit (0 to 9) using and keys and validate each digit by pressing . If you enter the wrong code, it is reset to 0 0 0.

Press to activate settings lock function.

When settings lock is activated:

- is displayed in the status bar;
- target volume and flow rate cannot be changed;
- Accessible keys are:

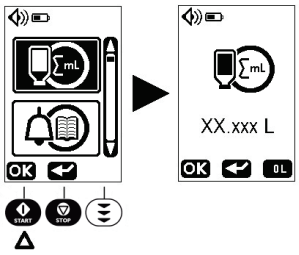
, with restrictions.

INFORMATION

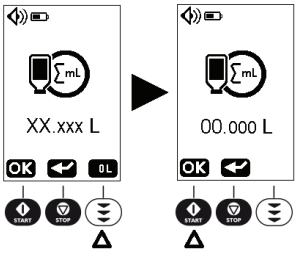
- To get the access code, contact your Fresenius Kabi sales representative.
- Settings lock activation / deactivation isn't modified after switching OFF the pump.
- When settings lock is activated, keypad lock can still be activated / deactivated.

5.6 Cumulative feeding volume counter

Press to display the cumulative feeding volume. The total feeding volume since last reset is displayed.

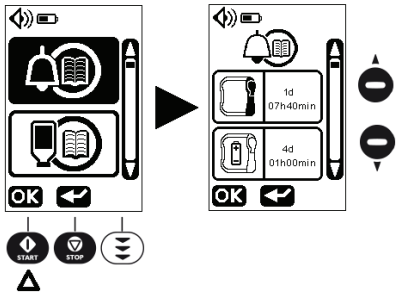


If needed, press then to clear the cumulative feeding volume (default setting).



5.7 Alarm history

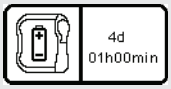
Alarm events are automatically saved in the pump memory.



Press START to display the alarm events.

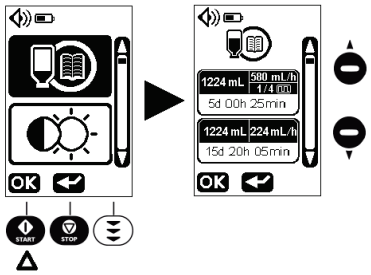
Press ▲, ▼ to switch from one alarm event to another.

INFORMATION
Alarm history indicates the type of alarm and the time elapsed since the event happened.

Example: 

a battery alarm occurred 4 days, 1 hour and 0 minute ago.

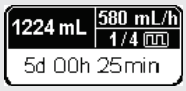
5.8 Feeding history



Press START to display the feeding events.

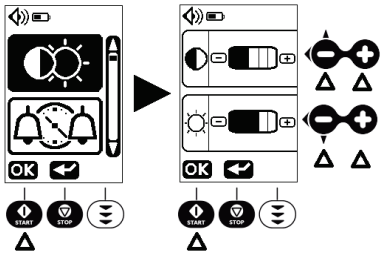
Press ▲, ▼ to switch from one feeding event to another.

INFORMATION
Feeding history indicates the delivered volumes, their associated flow rate and the time elapsed since their delivery.

Example: 

a volume of 1224 mL was administered at a flow rate of 580 mL/h split on 4 boluses, 5 days and 25 minutes ago.

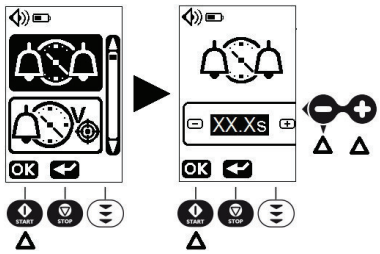
5.9 Contrast / Brightness



Press START. Press ◄► to set the contrast or the brightness.

Press START to validate.

5.10 Set time between two alarm sounds

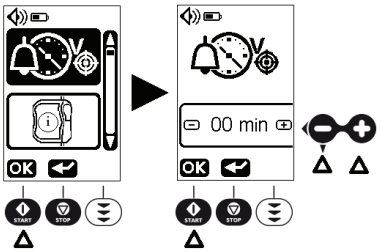


Press START. Press to set the time between two alarm sounds. Press START to validate.

INFORMATION
The access code is required to set time between two alarm sounds.

WARNING
Time between 2 alarms can be adjusted from 2.5 to 30 seconds with steps of 0.5 seconds. This adjustment can modify the perception of an alarm (Default value 2.5 seconds).

5.11 Set time for target volume almost reached message



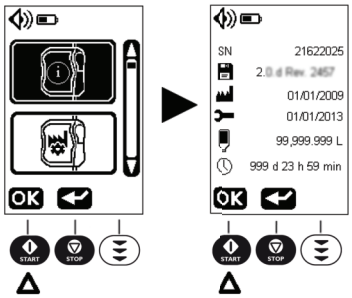
Press START. Press or to set the time for target volume almost reached message.

Press START to validate.

INFORMATION

- Time between target volume almost reached message and target volume reached alarm can be adjusted from 0 to 59 min., with steps of 1 min (default setting 5 min.).
- Access code is required to set time for target volume almost reached message.

5.12 Technical information



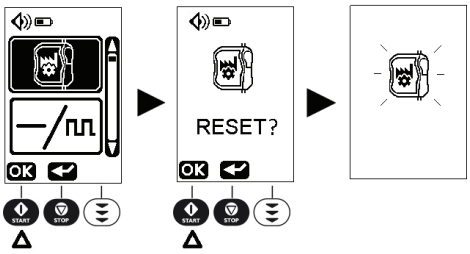
Press START to access the technical information.

NOTE : the technical information menu displays:

- SN Pump serial number
- Software version
- Production date (mm/dd/yyyy)
- Last maintenance date (mm/dd/yyyy)
- Total delivered volume
- Total functioning time

5.13 Reset manufacturing settings

Reset manufacturing settings is recommended to facilitate the transition from one patient to another.



Press START to access the reset menu.

Press START again to reset to manufactory settings. The Reset symbol is flashing for 2 seconds.

- All prior settings are erased

- All pump settings revert back to factory settings

INFORMATION
The access code is required to reset manufacturing settings.

6 Cleaning and disinfection

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 pump and pump holder as soon as they become contaminated with tube feed or drugs, and at least once a week.

After cleaning, the pump should be left to dry for approximately 5 minutes before being started or reconnected to the mains.

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

WARNING

- The pump is not intended to be sterilized, it may damage the pump. The Amika+ is a non-sterile medical device.
- The Amika backpack must be cleaned before inserting the pump. Please refer to its specific accompanying documents.
- Make sure to use the original door when replacing it on the pump (check the serial number on the pump is the same as on the door). A door switch between pumps can lead to major pumping errors.

6.3 Recommended cleaning and disinfection agents

Didecyldimethylammonium 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 pump and pump holder in liquids or let liquids enter device's housing. 
- Pump and pump holder are resistant to recommended cleaning agents (see *Recommended cleaning and disinfection agents* on page 42).

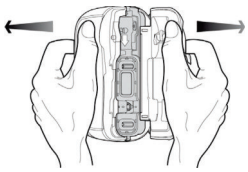
6.4.1 Cleaning Instructions

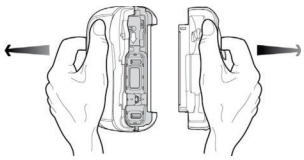
Prerequisites

- The pump is switched off.
- The power cord and all other cables are unplugged.
- The pump is disconnected from the holder.
- The air is at room temperature (20 to 25 °C).
- The operator is wearing suitable protective equipment.

Protocol

1. Place the pump and the holder on a cleaned surface or disposable underlay. The door can be removed from the pump to facilitate the cleaning.

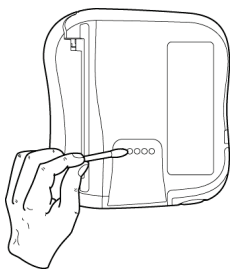




   NOTE : The door can be immersed. Clean it separately with running water.

2. During cleaning, do not turn the pump over to avoid liquid leak in the battery door.
3. Use a ready-to-use wipe to remove any major grime.
4. Thoroughly wipe down all exposed surfaces (housing, keypad, screw area, holder connection area, etc.) of the pump, from top to bottom. Gently wipe down the pump exposed mechanism and sensor area (tube guide, purple insert).

   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 pump housing. Use cotton wool to clean the contact peans.



5. Repeat step 4 with the pump door (housing, lever, counter door) and holder (pole clamp screw, housing, etc.)
6. 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.
7. Wipe down the power cord.
8. Allow the device to dry completely at room temperature.

9. Make sure to use the original door when replacing it on the pump (check the serial number on the pump is the same as on the door).

6.4.2 Disinfection instructions

Prerequisites

- The cleaning protocol has been performed.
- The pump is switched off.
- The power cord and all other cables are unplugged.
- The pump is disconnected from the holder.
- The air is at room temperature (20 to 25 °C).
- The operator is wearing suitable protective equipment.

Protocol

1. Place the previously cleaned pump and holder on a cleaned surface or disposable underlay. The door can be removed from the pump to facilitate the disinfection.
2. During disinfection, do not turn the pump over to avoid liquid leak in the battery door.
3. Use a ready-to-use wipe to wipe down all exposed surfaces of the pump, holder and pump door (as described in cleaning protocol), making sure to cover all cracks, crevices, and hard-to-reach areas. Do not allow liquids to run, leak, or drip into the pump 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 cord.
6. Allow the pump to dry completely at room temperature.
7. Make sure to use the original door when replacing it on the pump (check the serial number on the pump is the same as on the door).

7 Quick check protocol

WARNING

- The following checks allow users to confirm device behaviour according to these instructions for use. Fresenius Kabi recommends performing these tests before connecting Amika+ pump to patients.
- If one or more checks do not comply with the right pump behaviour, please contact the appropriate department or Fresenius Kabi sales representative for additional verification.

Action	Yes
Before use	
1 - Check if the Amika+ pump, holder and AC/DC adapter are not damaged in any way	☐
2 - Check the general status of the display	☐
3 - Install the Amika+ pump on the holder	☐
4 - Connect holder to the mains	☐
5 - Switch on the pump	☐
6 - Check the autotest sequence (LCD display intact, speaker, LED and the back light). Do not use with damaged screens.	☐
7 - Check the mains LED lights up	☐
8 - Remove the Amika+ from the holder and check the battery symbol on the display	☐
9 - Install the Amika+ pump on the holder	☐
10 - Check that the pump and its holder are securely attached or positionned	☐
11 - Check that all menu settings are adapted to the next patient	
12 - Connect a set to a filled container, install the set in the pump and close the door	☐
13 - Prime the set	☐
14 - Set at the prescribed flow rate and target volume	☐
15 - Start feeding	☐
16 - Check the feeding information (droplet animation)	☐
17 - Check that pumping is effective	☐
After use	
1 - Check if pump, holder and AC/DC adapter are not damaged in any way	☐

Action	Yes
2 - Clean the pump, holder and AC/DC adapter	☐
3 - Check the membrane of Amika+ pump is intact (no cracks, no wear)	☐
Once a year	
Check the following alarms and messages (symbol on the display, beep sound, blinking status light indicator)	
1 - Set installation alarm	☐
2 - Door alarm	☐
3 - Upstream occlusion alarm	☐
4 - Downstream occlusion alarm	☐
5 - Empty bag / Air in Line alarm	☐
6 - Target volume almost reached message	☐
7 - Battery nearly empty message	☐
8 - Check the flow rate by measuring the delivered volume	☐

8 Alarms and safety features

8.1 Alarms / Actions

The Amika+ pump has a continuous inspection system that operates as soon as it is in use.

It is recommended that the user should be in front of the Amika+ pump, for best visibility of alarm display.

Please make sure the appropriate reaction to alarm is undertaken. A wrong or delayed reaction leads to a delay in therapy.

WARNING
The pump emits audible alarm signals. Audible alarm signals from medical devices may be masked by environmental noise.
Ensure the alarm sound level is audible by the user, taking into account the environment.

The alarm sound level measures are:

	Settings	Pump on its holder	Pump inside a backpack
High, medium, low priority alarms	Low Level	> 50 dB(A)	> 45 dB(A)
	High Level	> 60 dB(A)	> 50 dB(A)

NOTE : dB(A) is the Level average pressure mesured following ISO 3744

8.1.1 The different types of information signal or alarm

Information signal sound (2 beeps)		Information signal	Feeding continues
Information signal sound (1 beep)		Information signal	Feeding continues
Flashing yellow LED and alarm sound (sequences of 2 beeps)		Information signal	Feeding continues
Fixed yellow LED and alarm sound (sequences of 3 beeps).		Prior information to alarm (Low priority alarm)	Feeding continues
Flashing yellow LED and alarm sound (sequences of 3 beeps)		Functional alarm (Medium priority alarm)	Feeding stops

Flashing red LED and alarm sound (sequences of 10 beeps)		Technical alarm (High priority alarm)	Feeding stops
Flashing red LED and buzzer sound		Fail safe technical alarm (High priority alarm)	Feeding stops

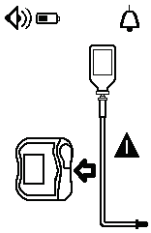
When a functional alarm or prior information to alarm occurs:

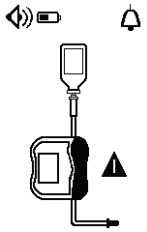
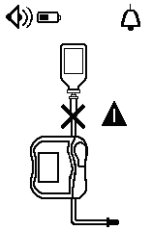
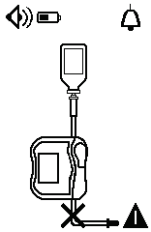
- to mute alarm sound, press  , see *Mute alarm* on page 30;
- detect the specific problem causing the alarm or prior information to alarm condition, by looking at the drawing displayed on the pump;
- to release alarm, press  ;
- make a corrective action (see table below);
- restart feeding using the  key.

WARNING
Identify displays, symbols and status in the table below, to understand the meaning and conduct the appropriate action.

8.1.2 Alarm descriptions

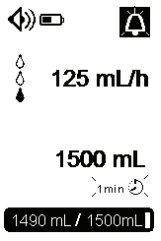
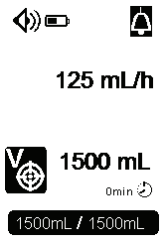
Line control

Symbol	Meanings	Actions
Medium priority - Yellow LEDs are flashing		
Giving set 	Missing giving set or giving set not properly installed.	■ Check position of giving set above and below the pump mechanism and insert correctly if necessary. ■ Check that the proper set is used (Amika+ giving sets only). ▹ See *Installing the giving set* on page 20.
	Area where pinch clamp is inserted is contaminated.	■ Remove dirt with cloth and soapy water or as directed by hospital policy. ■ Allow the pump to dry. ▹ See *Disinfection instructions* on page 44.

Symbol	Meanings	Actions
Door open 	Pump door not properly closed at start.	■ Close pump door. ▹ See *Installing the giving set* on page 20.
	Pump door opened after start.	■ Close pump door. ▹ See *Installing the giving set* on page 20.
	Pump door removed from its anchoring.	■ Re-hang door.
	Door mechanism is faulty.	■ Contact your biomedical department.
Upstream occlusion 	Upstream flowpath is blocked between the container and the pump.	■ Open the door, check set installation. ▹ See *Installing the giving set* on page 20. ■ Check that the set is not kinked. ■ Check that upstream clamp is open. ■ Flush tube if necessary. ■ Check the absence of upstream / downstream occlusion in the line.
Downstream occlusion 	Downstream flowpath is blocked after the pump, at the patient side.	■ Open the door, check the set installation, close the door. ▹ See *Installing the giving set* on page 20. ■ Check that the set is not kinked. ■ Re-position and verify that food flows freely after adjustment. ■ Check that the feeding tube is clear. ■ Flush tube if necessary. ■ Check the absence of upstream / downstream occlusion in the line.

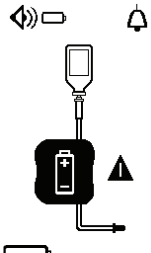
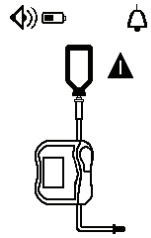
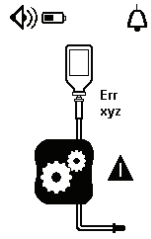
Feeding control

Symbol	Meanings	Actions
Low priority - Yellow LEDs are fixed		

Symbol	Meanings	Actions
End of bolus reached 	Displayed in feeding bolus mode only if the flushing information is activated. The flushing information will be displayed at the end of the pumping period of a bolus (except the last bolus).	The flushing information can be activated/deactivated in the menu. ▹ See *Bolus mode settings* on page 33. ■ To clear the flushing information, press .
Target volume almost reached 	Target volume will be reached. Remaining time is flashing.	The time of message before target volume is reached can be set in the menu. ▹ See *Set time for target volume almost reached message* on page 39. ■ End feeding or continue feeding.
Medium priority - Yellow LEDs are flashing		
Target volume reached 	**Alarm** The target volume is reached. (Complete progress bar)	■ End feeding or proceed to the next step.

Function control

Symbol	Meanings	Actions
Low priority - Symbol battery is fixed yellow		
Battery empty **fixed**	Minimum battery voltage is not available.	This message appears 30 min. before the empty battery alarm. ■ Connect the pump to the mains via the pump holder. Recharge battery to resume pump operation.
Medium priority - Symbol battery is flashing yellow		

Symbol	Meanings	Actions
Battery empty  **flashing**	**Alarm medium** Minimum battery voltage is not available.	This alarm appears 10 min. before battery is fully discharged. ■ Connect the pump to the mains via the pump holder. Recharge battery to resume pump operation.
Medium priority - Yellow LEDs are flashing		
Empty bag / Air in line 	Feed container is empty.	■ End feeding or connect to a filled feed container.
	Air is in the giving set.	■ Fill giving set to the end. ▹ See *Priming the giving set* on page 23.
	Dirt in sensor area (lower tube guide).	■ Open the door and remove dirt with cloth and soapy water or as directed by hospital policy (see *Cleaning and disinfection* on page 42). Allow the pump to dry.
	Giving set not properly connected to the container.	■ Check position of giving set and insert correctly if necessary. ▹ See *Installing the giving set* on page 20.
High priority - Red LEDs are flashing - Alarm sound		
Technical alarm 	A technical alarm code is displayed with the “Pump error alarm” drawing.	■ Note the technical Error code (Err xyz). ■ To release technical alarms, press STOP or  for 2 seconds. The pump will then switch off instantly (no count-down). ■ Contact your biomedical department.

Symbol	Meanings	Actions
Battery technical alarm 	The last battery technical alarm that occurred before switch OFF is reminded at the next switch ON.	■ Note the technical Error code (Err xyz). ■ Contact your biomedical department.
Fail safe technical alarm	Pump stops immediately.	■ Contact your biomedical department.
Information signal - Yellow LEDs are flashing		
Start reminder 	Pump is switched on but not operating for 2 minutes (2 beeps)	■ Proceed to next step or switch pump off.

NOTE : The maximum volume infused between the alarm condition and the technical alarms generation is 35 mL.

8.1.3 Maximum alarm raising delay

Time between alarm condition and alarm generation is less than 5 seconds, except for Giving set, Upstream and Downstream occlusions and Empty bag / Air in Line alarms (see *Performance* on page 54).

INFORMATION
When two alarms are raised at the same time, the pump software prioritizes the alarms.

8.2 Troubleshooting

Issue description	Recommended action
Pump is not stable when mounted	■ Check that the clamp handle is fastened

Issue description	Recommended action
Pump or holder is damaged, noisy, smoking or with an abnormally hot part. Pump screen is damaged	■ Remove AC/DC adapter ■ Do not use the device ■ Contact your biomedical department or Fresenius Kabi sales representative immediately
Pump has been dropped	■ Do not use the device ■ Contact your biomedical department or Fresenius Kabi sales representative
Pump does not start after switched ON	■ Connect pump to the mains supply in case the battery is fully discharged ■ Contact your biomedical department or Fresenius Kabi sales representative if problem remains
Flow rate variance is higher than flow rate accuracy	■ Check giving set configuration ■ Check fluid viscosity ■ Check the fluid is within normal temperature conditions ■ Contact your biomedical department or Fresenius Kabi sales representative if problem remains
Front panel problem (keys, LEDs)	■ Check the general state of the front panel (keypad) ■ Check the contrast ■ Contact your biomedical department or Fresenius Kabi sales representative if problem remains
The mains connection LED does not light up	■ Connect pump to the mains supply ■ Check that the LED on the AC/DC adapter lights. If not, unplug and plug it again in the mains socket. ■ Contact your biomedical department or Fresenius Kabi sales representative if problem remains
The device switches off on its own	■ Connect pump to the mains supply ■ Contact your biomedical department or Fresenius Kabi sales representative if problem remains
Battery alarm when pump has been correctly charged	■ Check mains supply voltage ■ Contact your biomedical department or Fresenius Kabi sales representative if problem remains
The device switches off when it is disconnected from the mains	■ Battery is completely discharged: Charge the battery ■ Contact your biomedical department or Fresenius Kabi sales representative if problem remains
Bolus volume and flow rate are blinking and feeding can not start in bolus mode.	■ Check bolus feeding parameters, see *Feeding mode and settings* on page 32.
The Nurse Call system does not replicate pump alarms. USB connection is not functional.	■ Check Nurse Call cable installation ■ Check holder is connected to the power supply ■ Contact your biomedical department or Fresenius Kabi sales representative if problem remains.

9 Technical information

9.1 Performance

9.1.1 Essential performance

Essential pump performance is defined as follows in standard operating conditions:

- flow rate accuracy (± 7% at 50 mL/h with medical water);
- occlusion detection time (< 6 min at 50 mL/h with medical water);
- management of medium and high priority alarms, see *The different types of information signal or alarm* on page 47.

WARNING
Flow rate accuracy can be influenced by giving set configuration, tube stretching, fluid viscosity, fluid temperature, container height and feeding settings.

9.1.2 Flow Rate range

Range	From 1 mL/h to 600 mL/h (default setting 50 mL/h)
Increments	1 mL/h from 1 mL/h to 600 mL/h
Accuracy	± 7% at 50 mL/h, ± 10% for the whole range of flow rates

Test initial conditions following 60601-2-24. Cumulative volume measured on a two-hour period, with 25 mL minimum volume.

Container height: 50 cm.

9.1.3 Volume range

Range	From 1 mL to 5000 mL (default setting 500 mL)
Increments	1 mL from 1 mL to 5000 mL

9.1.4 Upstream and downstream occlusions

Occlusion alarm response time at different flow rates.

Threshold available for triggering downstream occlusion alarm:

- Occlusion will be detected for pressure 787.6 mmHg, ± 262.5 mmHg.

Occlusion detection time		
Flow rate	**Downstream occlusion (1 m after the pump)**	**Upstream occlusion (5 cm before the pump)**
1 mL/h	5 hours	1 hour 40 min.
25 mL/h	9 min.	4 min.

NOTE : Maximum occlusion pressure for the pump is 1875 mmHg, ± 225 mmHg.

9.1.5 Volume Accuracy

	Accuracy	
Limit to detect Upstream Occlusion*	≤ 25 mL	
Bolus volume at Occlusion Release*	Rate 25 mL/h	< 5 mL

*Test condition: Back pressure: 0 mmHg, Container height: 50 cm

NOTE : A bolus (± 5mL) may occur during pump movement from 0 to 1 m above the patient, and before occlusion release.

9.1.6 Empty bag / Air in Line alarm response time at different flow rates

Time mentioned is applicable only if the set has been previously filled.

Empty bag / Air in Line detection time	
Flow rate	**Air volume = 3.5 mL**
1 mL/h	3 hours 30 min. maximum
25 mL/h	10 min. maximum
100 mL/h	3 min. maximum

9.1.7 Giving set alarm response time at different flow rates

Flow rate	Giving set alarm detection time
1 mL/h	8 minutes maximum
25 mL/h	30 seconds maximum
100 mL/h	10 seconds maximum

9.2 Technical characteristics

9.2.1 Operation mode

The Amika+ pump is a reusable device. The pump ensures fluid delivery in a continuous and sequential feeding mode, using pumping and clamping fingers to push the liquid to the patient.

9.2.2 Power supply specifications

The AC/DC adapter must be connected directly to the mains power socket.

Protection against electric shocks: class II

AC/DC adapter input	AC input voltage: 100-240 Vac ± 10% AC input frequency: 50-60 Hz AC input current: 110 mA-205 mA
AC/DC adapter output	9 Vdc ± 5 % / 1.0 A
AC/DC adapter cord length	Approximately 2.5 m

9.2.3 Battery specifications

Characteristics	NiMH (Nickel-Metal Hydride) 4.8V 2.2 Ah Ni-MH
Weight	Approximately 100 g
Maximum charging time	6 hours

9.2.4 Power consumption

Consumption of the pump in standard operating conditions: maximum 9 W.

9.2.5 USB connector specifications

Input/output	5 Vdc / 0.5 A.
Electrical insulation	1.5 kV insulation.

9.2.6 Nurse call connector specifications

Holder COM output	24 Vdc SELV (Safety Extra Low Voltage) / 0.5 A 24 Vac / 0.5 A
Electrical insulation	1.5 kV insulation

9.2.7 Dimensions - Weight

	Weight	**Dimensions (H x W x D)**
Pump	610 g	138 x 128 x 48 mm
Holder COM and cables	600 g	200 x 110 x 90 mm Cable length: 2 m
AC/DC adapter	200 g	-
Packaging	500 g	-

9.2.8 Trumpet curves

The trumpet curves show the variations in the mean flow accuracy over specific observation periods. The variations are presented on the maximum and minimum deviations of 5 pumps and 1 pump from the overall mean flow within the observation window.

The test protocol used to obtain these results is described in 60601-2-24.

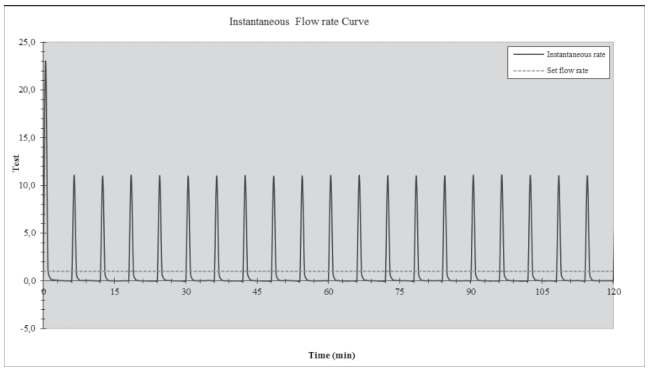
The curves can be helpful in determining the suitability of feeding parameters for specific nutrition programmes.

Giving set used: Amika Varioline

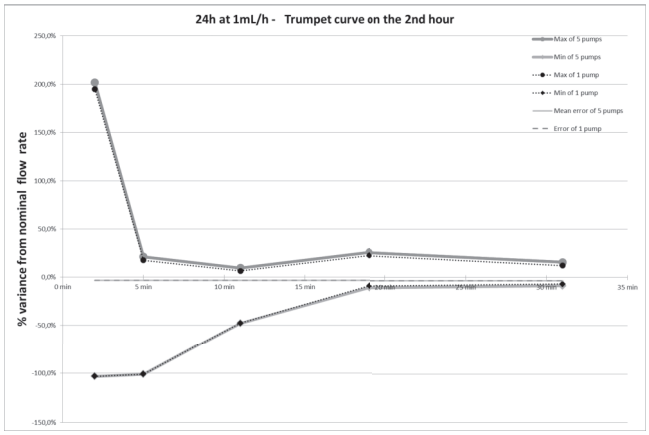
Fluid used: distilled water, and Fresubin energy drink (1 mL/h only)

9.2.8.1 Minimum flow rate: 1 mL/h

Sampling time: 30 seconds

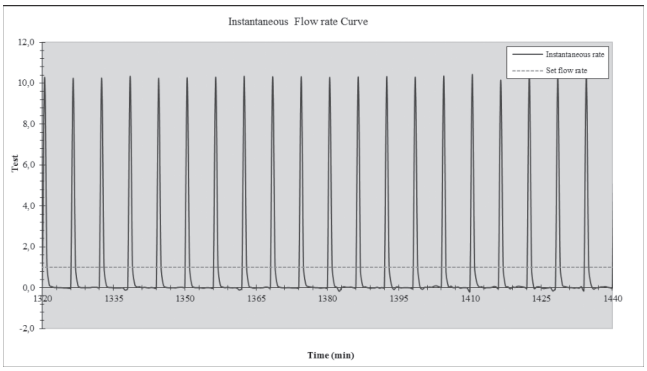


Start up and instantaneous flow rate (1 mL/h, over first 2h of the test period)

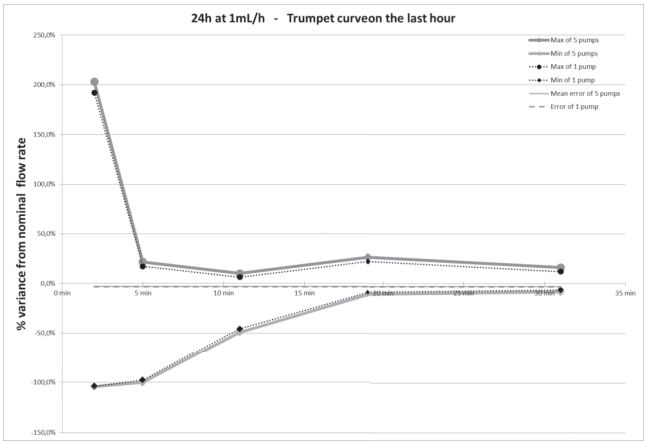


Trumpet curves for 2, 5, 11, 19, 31 minute observation windows (1 ml/h over second hour of the test period)

Sampling time: 30 seconds

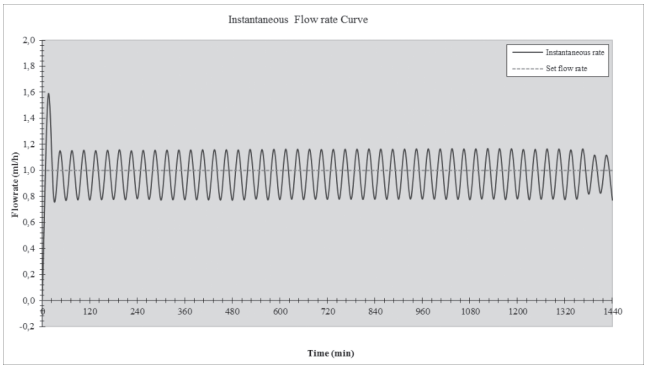


Instantaneous rate (1 mL/h, over last 2 hours of set change interval, 24 hours)

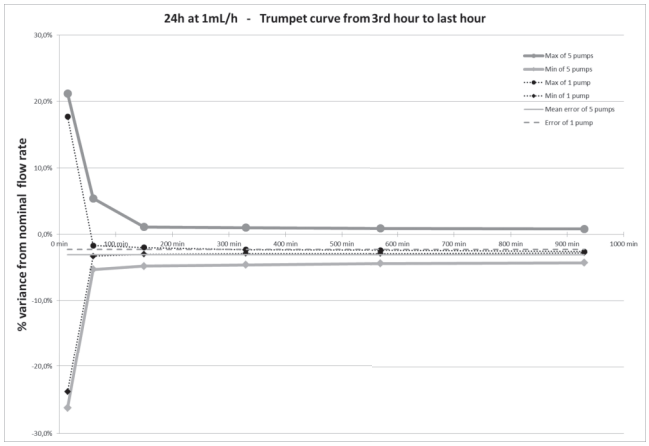


Trumpet curves for 2, 5, 11, 19, 31 minute observation windows (1 mL/h, over last hour of the set change interval, 24 hours)

Sampling time: 15 minutes



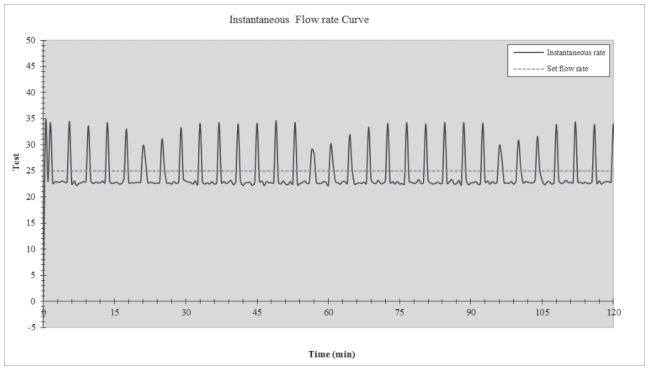
Instantaneous flow rate (1 mL/h, over set change interval 24 hours)



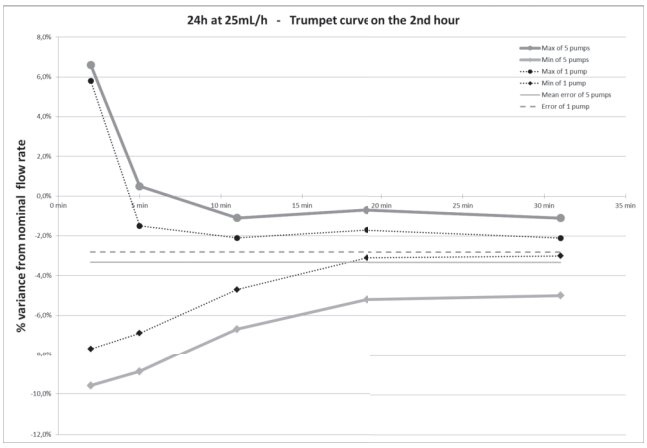
Trumpet curves for 15, 60, 150, 330, 570, 930 minute observation windows (1 mL/h, over set change interval, 24 hours)

9.2.8.2 Intermediate flow rate: 25 mL/h

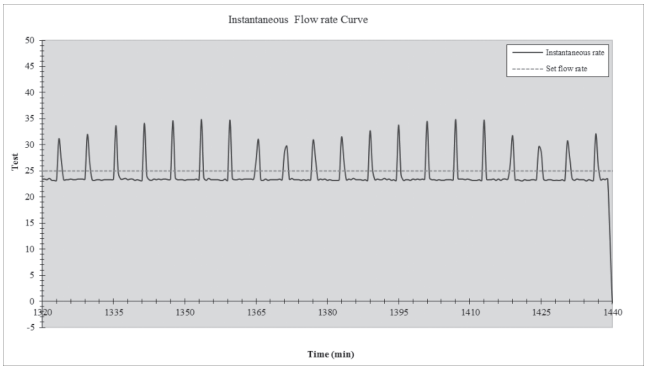
Sampling time: 30 seconds



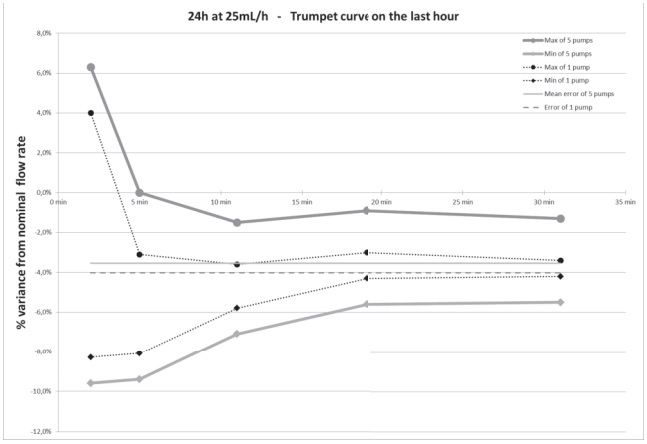
Start up and instantaneous at intermediate flow rate (25 mL/h, over first 2h of the test period)



Trumpet curves for 2, 5, 11, 19, 31 minute observation windows (25 mL/h over second hour of the test period)

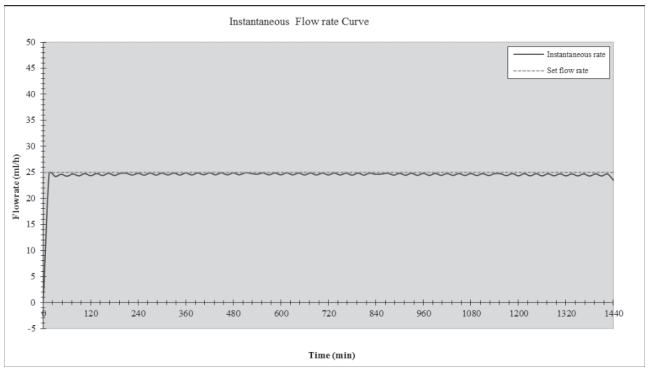


Instantaneous rate (25 mL/h, over last 2 hours of set change interval, 24 hours)

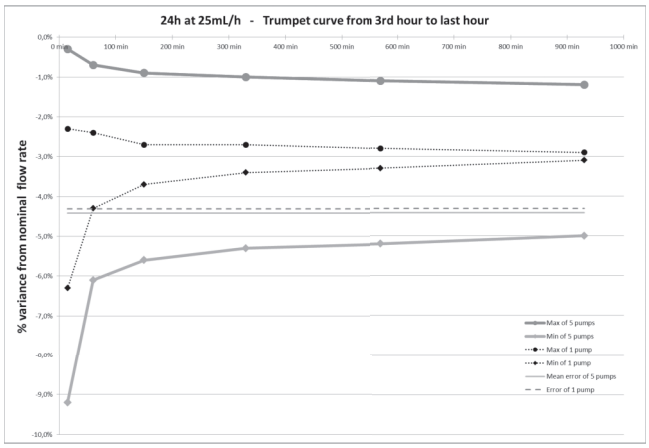


Trumpet curves for 2, 5, 11, 19, 31 minute observation windows (25 mL/h, over last hour of the set change interval, 24 hours)

Sampling time: 15 minutes



Instantaneous flow rate (25 mL/h, over set change interval 24 hours)



Trumpet curves for 15, 60, 150, 330, 570, 930 minute observation windows (25 mL/h, over set change interval, 24 hours)

9.2.9 Compliance with standards

General requirements for basic safety and essential performance for Medical electrical equipment	Conform to IEC 60601-1
Electromagnetic compatibility- Requirements and tests for Medical electrical equipment	Conform to IEC 60601-1-2
Particular requirements for the basic safety and essential performance of infusion pumps and controllers	Conform to IEC 60601-2-24

General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems	Conform to IEC 60601-1-8
Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment	Conform to IEC 60601-1-11
CE 0123	Conform to the 93/42/EEC Medical directive 0123 : Notified body number (TÜV SÜD Product Service GmbH, Ridlerstrasse. 65, 80339 München, Germany)

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

10 Transport, storage and recycling conditions

10.1 Storage and transport conditions

During transport, the Amika+ pump shall not be removed from its pole or rail when carrying feeding devices, especially when feeding is running.

Check that the AC/DC adapter is connected and operational after transport of the pump.

The pump should be used under specified storage and transport conditions listed below to ensure pump performance and to avoid pump malfunction.

For further information about storage and transport, see *Use environment* on page 6.

10.2 Storage

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

INFORMATION

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

WARNING

- If the device is not used for longer than 2 months, remove the battery and store it as per storage conditions above.
- If the device is stored without removing the battery, charge it at least once a month by connecting it to the mains for at least 6 hours.
- Amika+ must be cleaned and disinfected prior to storage (see *Cleaning and disinfection* on page 42).

10.2.1 Prepare the device for storage

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

1. Be sure the pump is not being used on a patient.
2. Switch pump OFF and remove installed giving set (see *Removing/Changing the giving set from the pump* on page 28).
3. Disconnect pump power cord (see *Electrical disconnection* on page 17).
4. Remove the pump and its holder from pole or rails (see *Removing the pump from the pump holder* on page 17).
5. Clean the pump (see *Cleaning and disinfection* on page 42).
6. Handle the pump with care and store it in a compliant area.

10.2.2 Install the device after storage

INFORMATION

- If the battery has been removed for storage, please contact your biomedical department in order to replace the battery into the device prior to using the pump.
- We recommend charging the battery, by leaving the device connected to the mains power supply for at least 6 hours. After prolonged storage, a few minutes may be required before using the pump (an hourglass will be displayed).
- We recommend that the "Amika+ Quick check protocol" is performed when the device is installed after transport, in case of prolonged storage, or before being used on a new patient.

10.3 Recycling and disposal

Before disposal, remove battery from the device. Batteries, accessories and 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 and dismantling, contact your local Fresenius Kabi sales representative.

11 Guidance and manufacturer's declaration on EMC

The Amika+ pump is intended to be used in the electromagnetic environment specified below.

The customer or the user of the Amika+ pump should ensure that it is used in such an environment.

Excluding the cases described in this manual, the pump operation must systematically be checked by a qualified operator, should the pump be installed in the vicinity of other electrical devices.

For further information on EMC compliance, please refer to the Amika+ Technical Manual.

WARNING

- Prolonged exposure to X-ray environments can damage the electronic components of the device and influence the flow rate accuracy. For a safe usage, we recommend to:
  - always put the device at the maximum distance from the patient and the source;
  - limit the presence of the device in such environments.
- In the case of electromagnetic disturbances, if the essential performances, see *Essential performance* on page 54, are lost or degraded, the consequences for the patient can be: overfeeding, underfeeding, delay of therapy, trauma.

11.1 Electromagnetic compatibility and interference guidance

The Amika+ has been tested in accordance with the electromagnetic compatibility standards applicable to medical devices. Its immunity is designed to ensure correct operation. Limitation of the emitted radiation avoids undesirable interference with other equipment.

The Amika+ is classified as a Class B device according to CISPR 11 emitted radiation. The user might be required to take mitigation measures, such as relocating or re-orienting the equipment.

Use of accessories and cables other than those recommended by Fresenius Kabi, could result in increased emissions and / or decreased immunity of the Amika+ system.

If the Amika+ is placed near devices such as HF surgical equipment, X-ray equipment, NMR, cell phones, DECT phones or wireless access points, portable RFID reader, large scale RFID reader and RFID Tags, it is essential to observe a minimum distance between the Amika+ and this equipment (see *Recommended separation distances between portable and mobile RF communication equipment and pump* on page 66). If the Amika+ causes harmful interference or if it is itself disrupted, the user is encouraged to try to correct the interference by one of the following actions:

- reorient or relocate the Amika+ or patient or disruptive equipment;

- change the routing of cables;
- connect the Amika+ mains plug on protected / backed-up / filtered supply or directly on UPS circuit (uninterruptible power supply);
- increase the separation between the Amika+ and patient or disruptive equipment;
- connect the Amika+ into an outlet on a different circuit from that to which the patient or disruptive equipment is connected;
- in any case, whatever the context, the user should conduct interoperability testing in a real situation to find the right setup and good location.

11.2 Guidance and manufacturer's declaration - Electromagnetic immunity

The Amika+ pump is intended to be used in the electromagnetic environment specified in the Technical Manual.

The customer or the user of the Amika+ pump should ensure that it is used in such an environment.

11.3 Recommended separation distances between portable and mobile RF communication equipment and pump

The Amika+ pump is intended to be used in an electromagnetic environment in which radiated RF disturbances are controlled.

Users of the Amika+ may prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Amika+ as recommended below and according to the maximum output power of the communication equipment (transmitters).

WARNING

- At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.
- These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.
- 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 (Amika pump with a AC/DC adapter, a USB cable and a nurse call cable).

12 Services

12.1 Warranty

12.1.1 General conditions of warranty

Fresenius Kabi guarantees that this product is free from defects in material and workmanship during the period defined by the accepted sales conditions, except for the batteries and the accessories.

12.1.2 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 internal battery of the device must not have been replaced by a battery other than that specified by the manufacturer;
- the serial number (ID/N°) 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 a repair of the device are required, please contact your Fresenius Kabi sales representative.

12.1.3 Warranty conditions for battery and accessories

Batteries and accessories may have specific conditions of warranty.

Please contact your Fresenius Kabi sales representative for additional information.

12.2 Quality control

Upon request by the hospital, a **quality control** check can be performed on the Amika+ **every 12 months**.

A regular quality control (not included in the guarantee) consists of various inspection operations listed in the technical manual. Please refer to the technical manual or contact your Fresenius Kabi sales representative.

INFORMATION

- These checks must be performed by trained technical personnel and are not covered by any contract or agreement provided by Fresenius Kabi.

- For more information, please contact our Fresenius Kabi sales representative.

12.3 Maintenance requirements

WARNING

- Perform preventive maintenance at least once every **2 years**. This includes battery and membrane replacement. To avoid pumping performance deterioration, it is important to follow maintenance requirements.
- Preventive maintenance must be performed by qualified and trained technical personnel in compliance with the technical manual and procedures.
- 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.
- When using the device on a patient, no maintenance action must be performed.

Life cycle of Amika+ pump: 10 years provided that the maintenance is properly performed as described above.

12.4 Service policy and rules

For further information concerning device servicing or use, please contact our sales representative or our Customer service.

If the device must be sent for servicing, contact Fresenius Kabi to have packaging shipped to your facility.

Clean and disinfect the device, because of potential harm or risks to staff health. Then pack it in the provided packaging and ship to Fresenius Kabi.

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

13 Ordering information

Amika+ pump is available in several countries, contact your Fresenius Kabi sales representative for orders.

13.1 Instructions for use

Several 'Instructions for use' documents translated into local languages are available. Please contact your Fresenius Kabi sales representative for orders.

13.2 Giving sets

Do not use Amika giving sets to deliver liquids using gravity method, except the Amika set Varioline Comfort that can be used either for feeding by pump or by gravity.

Giving sets are single use. Whatever the giving set, the performance of the pump is maintained.

	ENFit Transition Sets	ENFit Sets	ENFit Sets with cover
Amika EasyBag	7751907	7751900	7751917
Amika EasyBag Two Line	7751910	7751903	7751994
Amika EasyBag mobile	7751999	7751905	7751916
Amika Varioline	7751909	7751902	7751919
Amika Varioline Comfort	7751998	-	7751904
Amika Bag	7751908	7751956	7751914
Amika Bag mobile	7751913	7751906	7751915
Amika Easy Bag without Medication port	-	-	7751918

13.3 Accessories

Do not use the device with damaged accessories.

WARNING
Use ONLY recommended accessories described below or delivered with the device. Patient must not be connected to the set when installing the pump with accessories. Please refer to its specific instructions for use.

Accessories	Reference
Amika Backpack Large	7752323
Amika Backpack Small	7752343
Amika Universal Table Top Stand	7751082

Accessories	Reference
Amika AC Adapter / Charger	Z200651**
Amika USB Cable	Z044905

*Several country kits are available.

**Additional power cords, AC adapter/charger, wall plug must be ordered separately. Each Product reference includes its own appropriate wall plug, depending on the country.

Please contact your Fresenius Kabi sales representative for orders.

14 Glossary of terms

Term	Description
°C	Celsius Degree
A	Amper
AC	Alternating Current
Ah	Ampere hours
Amika+	Enteral feeding and hydratation pump manufactured by Fresenius Kabi
CE mark	European Conformity Mark
CISPR	Special International Committee on Radio Interference
cm	Centimeters
dB	Decibel
DECT	Digital Enhanced Cordless Telecommunications
ECG	Electrocardiogram
EEG	Electroencephalogram
EMC	Electromagnetic compatibility
EXX	Error message
g	Gram
h	Hours
H x W x D	Height / Width / Depth
HF	High Frequency
hPa	Hecto Pascal
Hz	Hertz
ID/N°	Serial number
IEC	International Electrotechnical Commission
IFU	Instructions for Use
IV	Intravenous
LED	Light Emitting Diode
m	Meters
MHz	MegaHertz
min	Minutes

Term	Description
mL	Milliliter
mL/h	Milliliter per hour
mm	Millimeters
MRI	Magnetic Resonance Imaging
NiMH	Nickel-Metal Hydride
NMR	Nuclear Magnetic Resonance
RF	Radio Frequency
RFID	Radio Frequency Identification
sec	Seconds
UPS	Uninterruptable Power Supply
V	Volt
Vac	Volt Alternating Current
Vdc	Volt Direct Current
W	Watt

Release notes

Date	Software version	Description
May 2018	1.0	Creation

Made in France

Revision date: May 2018

Reference: 13311-1_Master_ifu_Amikaplus_eng

http://www.fresenius-kabi.com CE 0123 First CE Mark: 2018

Local contacts for servicing

13311-1_Master_ifu_Amikaplus_eng

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