FRESENIUS KABI

caring for life

Amika

Enteral feeding pump

Version 2.3 / i

Instructions For Use

Symbol descriptions

MD — Medical Device	UDI — Unique Device Identifier
Refer to the Instructions For Use	CE 0123 — CE marking
Class II equipment	Mass; weight
REF — Product reference	SN — Product serial number
Manufacturer	Name and address of the manufacturing facility
Battery characteristics	Defibrillation-proof type CF applied part
Direct Current (DC)	Alternating Current (AC)
Electrical output	Electrical input
Fragile, handle with care	This way up
Keep away from rain	Temperature limitation
Humidity limitation	Atmospheric pressure limitation
Batteries, accumulators and battery packs for separate collection	Forest Stewardship Council symbol
OF:320029999 — Production order	REF/SN:Z044130/12345678 — Product reference and product serial number

(01)04086000852142
(21)12345678
(11)190730
(240)Z044130

(01) Product identifier GTIN
(21) Product serial number
(11) Date of manufacture under form YYMMDD
(240) Product Reference

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

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 power 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

The Instructions for Use (IFU) is applicable to the Amika pump referred to as pump with software and hardware versions 2.3 / i.

WARNING

- Check that the IFU is applicable to the current Amika software version.
- The software and hardware versions of the pump are displayed in the technical information menu described in *Technical information* on page 38.
- 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 Principles of operations

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.

1.3 Intended purpose

Enteral feeding pump and accessories for administration through an enteral route (using a feeding tube) of nutrition and hydration fluids.

1.4 Intended use

1.4.1 Indications

The pump is indicated to administer products through clinically accepted routes. These products include: water, tea, soda and ready-to-use nutrition bags.

Administration routes:

The pump allows administration via the following tubes and associated access routes:

- Trans-nasal tubes
- Percutaneous feeding tubes

1.4.2 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.

1.4.3 Intended users

WARNING
Keep the pump, sets and power cable away from unsupervised children (and animals).

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

It is recommended that users attend a single training session of about 40 minutes (For training, contact your Fresenius Kabi sales representative).

INFORMATION
For Thailand, Amika pump is dedicated for qualified and trained healthcare professionals use.

1.4.4 Intended patients

The pump is intended for use on adults and pediatrics.

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.

1.4.5 Use environment

It is intended to be used in clinical healthcare facilities, in ambulatory use with an Amika Backpack, in pre-hospital medical ground transportation and in homecare.

INFORMATION
For Thailand, homecare is not the claimed use environment for Amika pump.

The Amika power cable 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: less than 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.

1.5 Clinical benefits

The therapeutic benefit of Amika enteral feeding pump for the patient is enabling controlled and safe enteral feeding in a clinical and outpatient setting as well as mobile. The objective of enteral nutrition is prevention and treatment of malnutrition to improve outcome.

1.6 Side-effects

There is no side-effect directly associated to the use of Amika.

1.7 Risks for patients

Failure to follow all instructions described in this document or loss or degradation of essential performance (see *Essential performance* on page 50) may result in: underfeeding, overfeeding, delay of therapy, air embolism, trauma, incorrect therapy, electric shock, toxicity or infection.

2 Description

2.1 System definition

The Amika system is composed of the following components:

- Amika pump: enteral feeding pump with pump holder and power cable.
- Amika disposable (applied part): giving sets.
- Amika accessories.

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

2.2 Packaging content

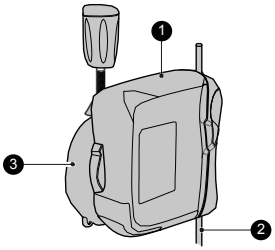
The Amika packaging contains the following elements:

- 1 Amika pump
- 1 pump holder
- 1 power 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

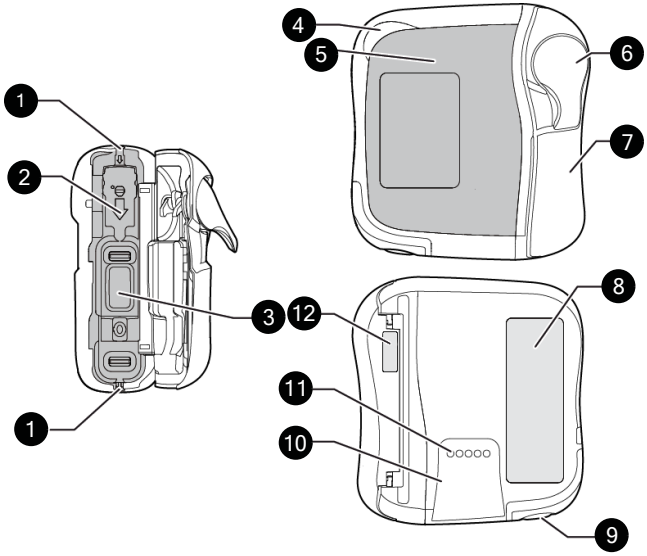


Legend

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

2.4 Detailed description

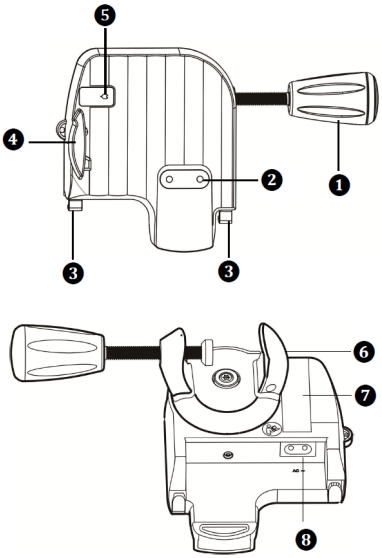
Pump description



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

Pump holder description



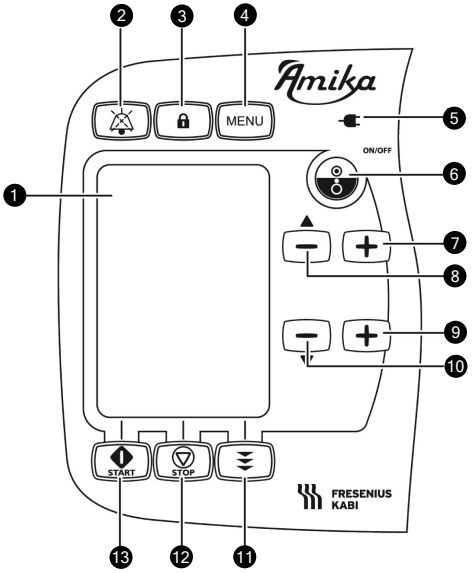
Legend

1. Clamp handle
2. Contact pins for pump to holder connection
3. Slot
4. Grey locking lever
5. Mains supply light indicator
6. Pole clamp
7. Holder identification labels
8. Power cable inlet

Mains supply light indicator, on the front panel of the holder

AC~ Near the power cable inlet of the holder, description in *Power supply specifications* on page 52

Front panel (keypad) description



Legend

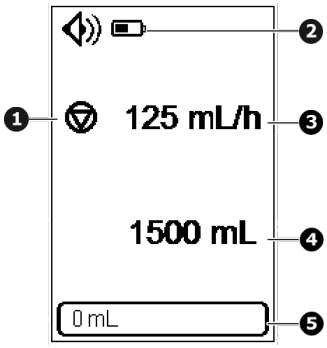
1. Display
2. Mute (alarm silence) key
3. Keypad lock key
4. Menu key
5. Mains supply light indicator
6. Power ON/OFF key
7. Flow rate Up
8. Flow rate Down / Scroll up in Menu
9. Target volume Up
10. Target volume Down / Scroll down in Menu
11. Priming function key
12. Stop / Cancel / Back key
13. Start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

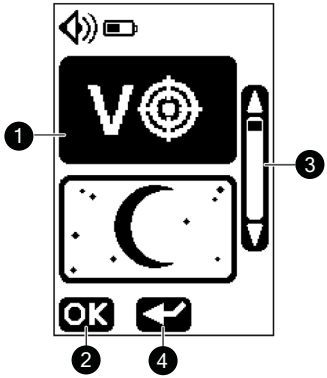
Setting screen layout



Legend

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

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.

Check that the Amika pump, holder and power cable are not damaged in any way at the beginning of installation and at the end of removal.

WARNING
If the Amika pump, holder or power cable is damaged, please do not use and contact the appropriate department or Fresenius Kabi sales representative for maintenance.

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.

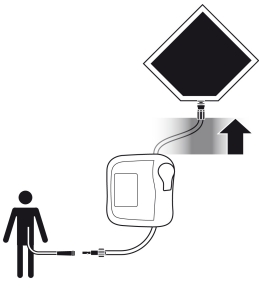


Figure 1: Recommended installation

Place the container above the pump

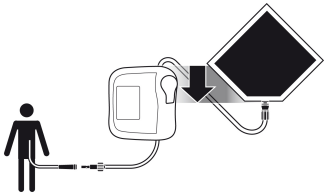


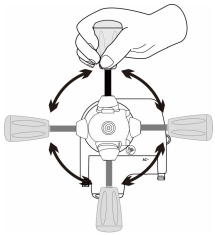
Figure 2: Possible installation

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.

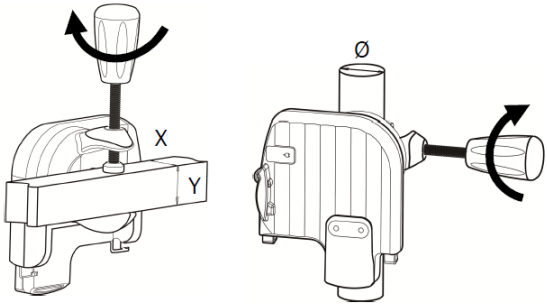
3.1.2 Using the pole clamp

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).

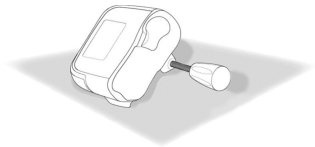


X, Y minimum = 10 mm
X, Y maximum = 35 mm
Ø minimum = 8 mm
Ø maximum = 40 mm

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.

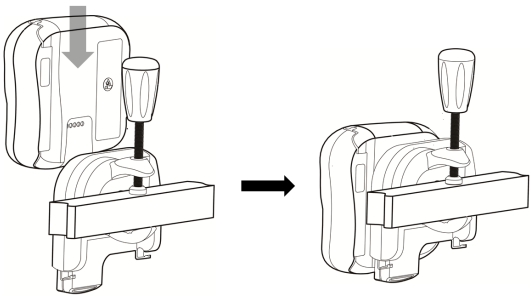
3.1.4 Positioning the holder on a table

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

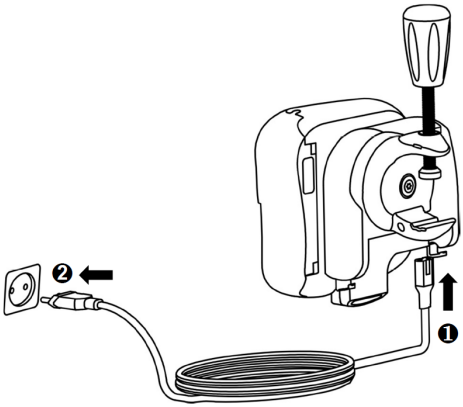
Slide the pump down until the grey locking lever locks the position.

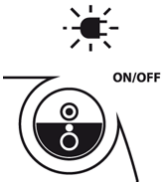


3.1.6 Electrical connection

Ensure power cable is not damaged.

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



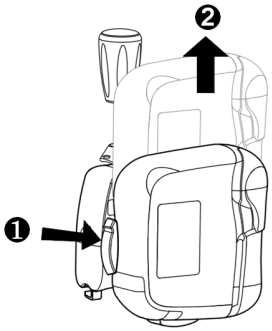


1. Connect power cable to the holder.
2. Plug the power cable to the mains socket.
   When connecting to the mains, ensure that the power cable and the power socket are easily accessible.
   The mains power supply is indicated by a green light on the pump's front panel (keypad).

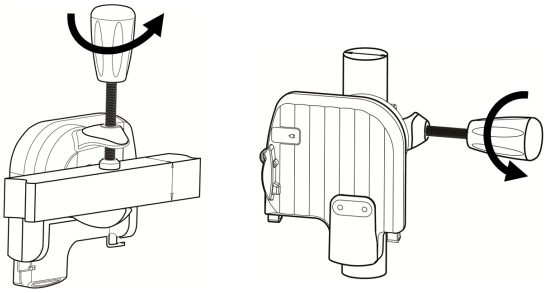
3.2 Removal

3.2.1 Removing the pump from the pump holder

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

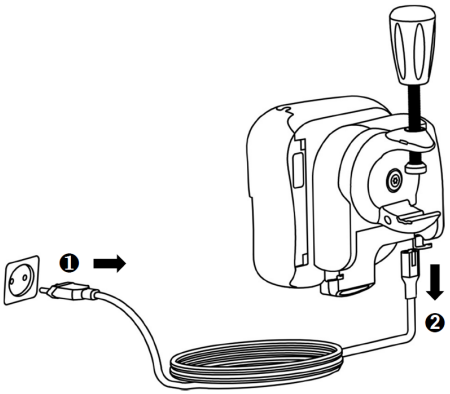


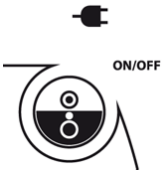
3.2.2 Removing the pump holder



3.2.3 Electrical disconnection

1. Remove power cable from power socket.
   - A beep is emitted by the pump with mains supply light indicator turned off when the power cable is disconnected.
   - To store the pump, see *Storage* on page 59.

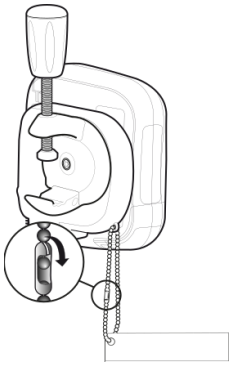




2. Remove power cable from holder.

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	Minimum 24 hours 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 16) ► 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 43). When battery is empty (less than 10 minutes left), an alarm is triggered (see *Alarms / Actions* on page 43.)

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.
- Under normal condition of use, battery life might be reduced from 24 hours to 20 hours by the end of the third year of use.

4.2 Basic operations

Before using the pump, please check it is not damaged in any way to ensure the integrity of the pump appearance.

WARNING
If there is any damage found with the pump, please do not use it and contact the appropriate department or Fresenius Kabi sales representative for maintenance.

4.2.1 Switch-on

When using a pump on patient requiring special attention, ensure that a backup pump or giving 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 14.

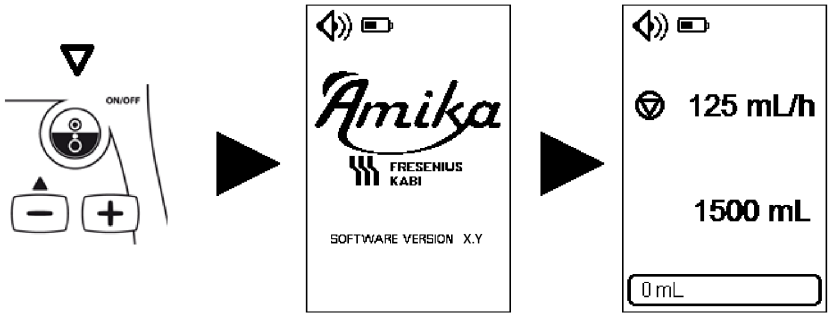


Figure 3: Auto test

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

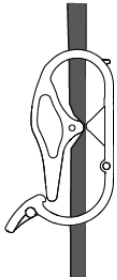
- Only Fresenius Kabi giving sets can guarantee pump reliability. Please refer to the compatible giving sets (see *Giving sets* on page 66) and compatible nutrition fluids (see *Intended use* on page 7). The use of unsuitable giving sets may cause patient harm such as overfeeding, underfeeding.

- 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°C to +40°C.

4.2.2.2 Description of the pinch clamp

Pinch clamp is open



Pinch clamp is closed

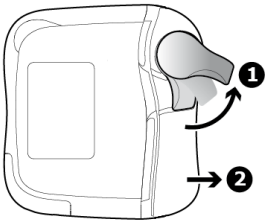
INFORMATION
Patient must not be connected to the set when the pinch clamp is open.

4.2.2.3 Installing the giving set in the pump

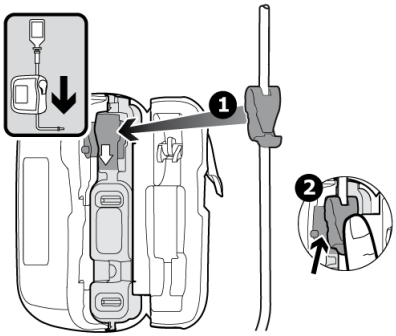
To connect / disconnect / change the container and feeding tube to the set, refer to the giving set "Instructions for use" on primary packaging.

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

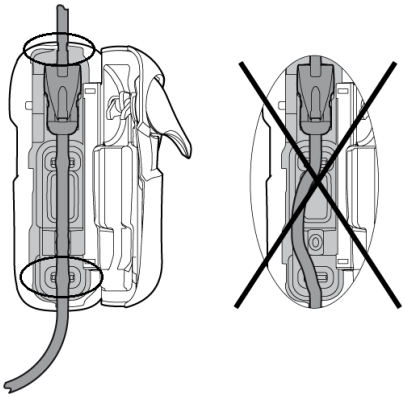
1. Push up the lever to unlock the door ❶. Open the door ❷.



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.

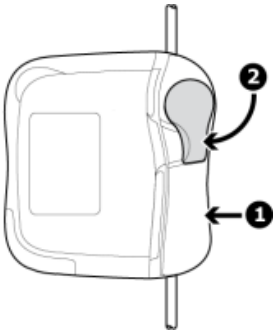


3. On the sides of the pump, place the tube straight inside tube guides.



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 

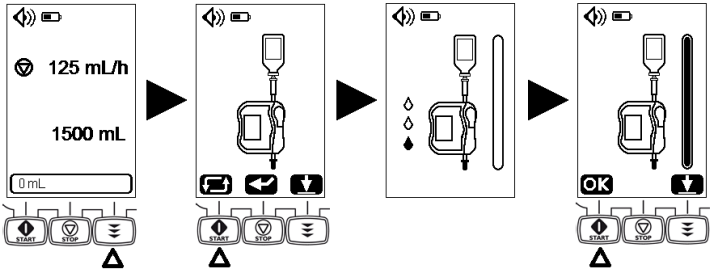
;
- semi-automatic priming: Amika pump fills in the giving set at maximum rate as long as the semi-automatic priming key  is kept depressed.

INFORMATION

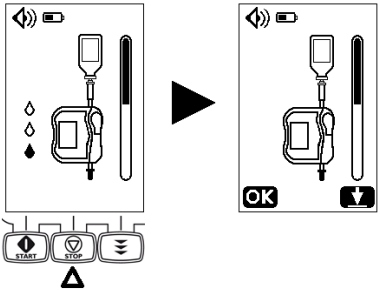
- Automatic and semi-automatic priming fill the giving set at a rate of 600 mL/h and are stopped after 17.6 ± 10% mL (factory settings).
- During priming, the air in line alarm is disabled.

Make sure that priming is correctly completed before starting feeding.

Automatic priming

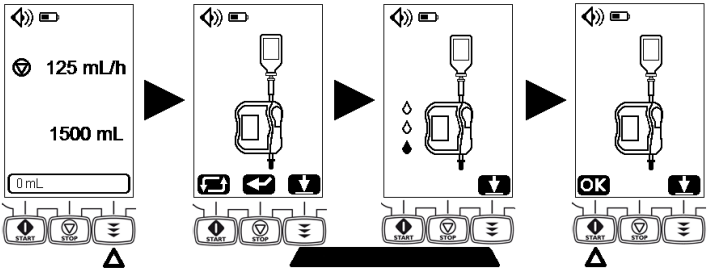


Auto priming can be stopped at any time:



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.

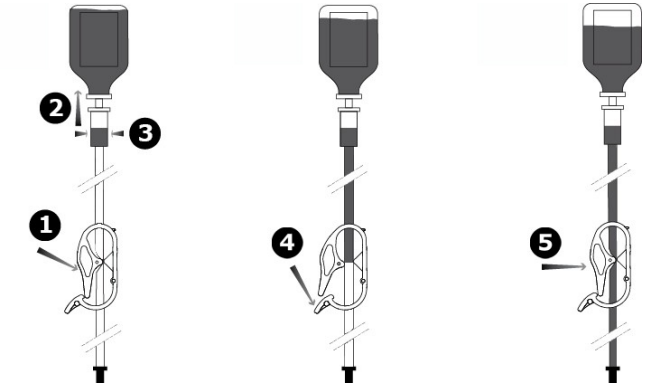
WARNING
At the end of priming, check that the set is correctly primed.

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).

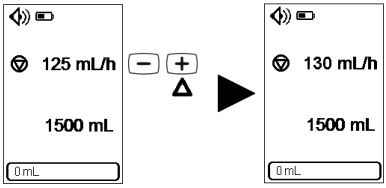


4.2.4 Change feeding setting

INFORMATION

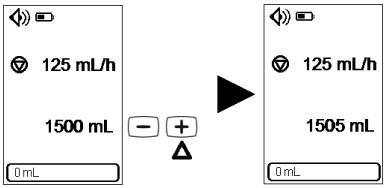
- A longer keypress provides faster scrolling.
- The flow rate of delivery must be adapted individually to the patient. Regular checks are required.

- Adjust feeding rate (mL/h)



Press + or − key to set the feeding rate.

- Adjust target volume (mL)

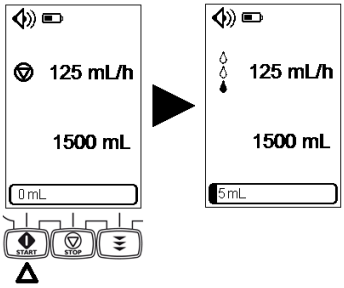


Press + or − key to set the target volume.

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

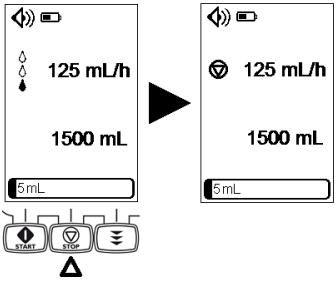
1. Connect the giving set to the patient's enteral feeding tube.
2. Make sure that priming is correctly completed before starting feeding.
3. Check power supply before starting feeding.
   - Green light indicator if supplied by mains, or
   - Battery icon filled up if supplied by the battery.
4. Start feeding.



WARNING
The keyboard shall be locked during feeding to avoid misusage.

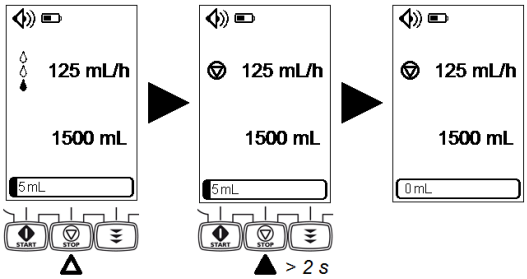
4.2.6 Terminate feeding

- Stop feeding



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

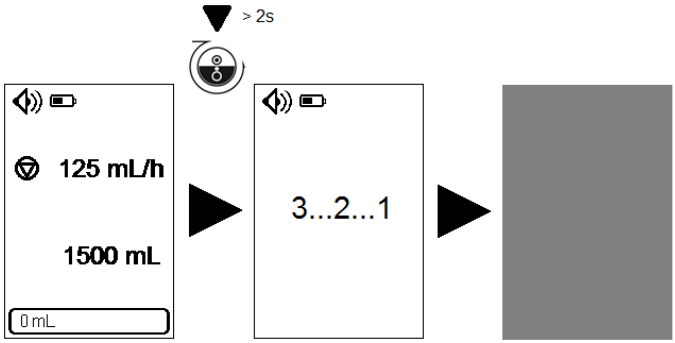
- Reset the progress bar.



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;
  - feeding 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.
- In the case of disconnected with mains supply and battery, the time of existing history event is not retained.

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 5000 mL or a 24-hour period.

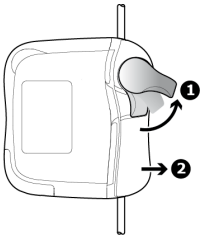
Replace the administration set according to your healthcare facility's protocol or CDC guidelines.

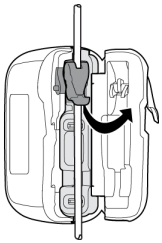
Administration sets are supplied sterile and are indicated for single use.

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.

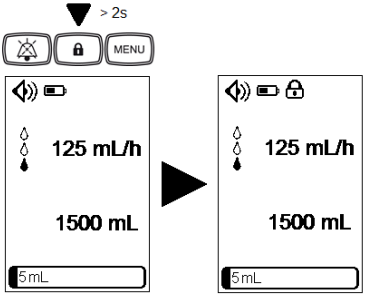




Install a new giving set in the pump (see *Installing the giving set* on page 20).

4.2.9 Keypad lock

Keypad lock prevents from unintentional tampering of pump settings.



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

When keypad is locked:

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

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

4.2.10 Mute alarm

To temporarily turn off 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 43.

5 Pump menu

INFORMATION

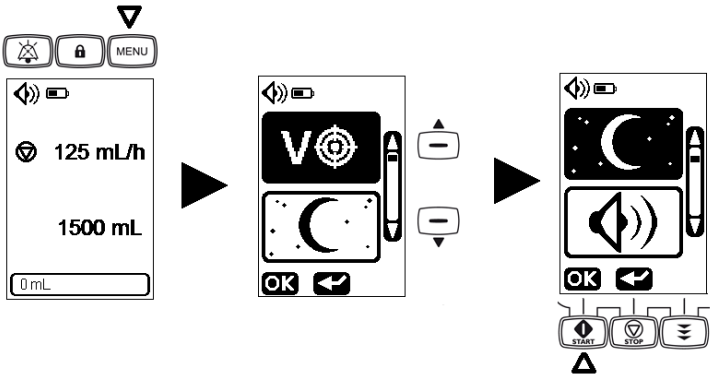
- The menu is accessible when feeding is stopped.
- A beep sound is triggered when a forbidden key (not active in specific screens) is depressed.
- During a procedure, press START (OK) to validate the choice and go back to the setting screen.
- Press STOP (↩) to go back to the previous screen (without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

5.1 Access menus

Menu descriptions

Menus	Description
Feeding mode	Deactivate / activate target volume (the access code is required, if the settings lock 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 150 alarm events
Feeding history	Consult the last 200 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)
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 settings	Set pump to factory settings (the access code is required)

Menu navigation

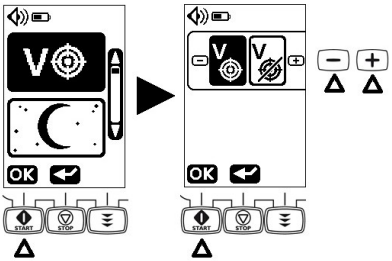


Press MENU then press ▲, ▼ to scroll up / down between submenus.

Press START to enter the submenu.

5.2 Feeding mode

On this screen, target volume 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.



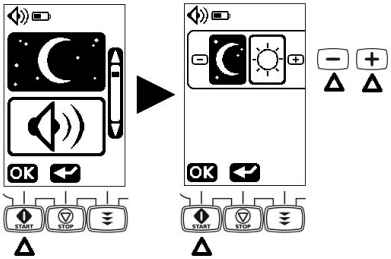
Press START to select feeding mode. Press − or + to activate / deactivate target volume (default setting activated). Press START to validate.

INFORMATION

- When target volume 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.

5.3 Night mode

On this screen, night mode is activated .



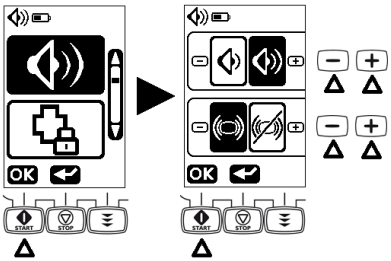
Press to select Night or Day Mode. Press to activate Day Mode or to activate Night Mode. Press to validate Night or Day Mode.

INFORMATION

- When night mode is activated, the brightness of mains supply light and screen will be decreased.
- In case of alarm, the brightness 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 .



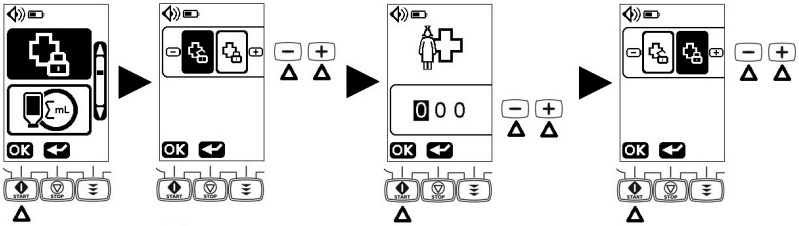
Press to select the sound level and key beep sound.

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

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

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 key to configure Settings lock. Press and key to enter the access code interface.

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 or to deactivate / activate settings lock function. Press to validate.

When settings lock is activated:

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

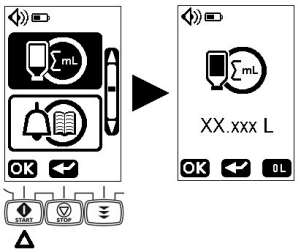
, with restrictions.

INFORMATION
- To get the access code, contact your Fresenius Kabi sales representative.

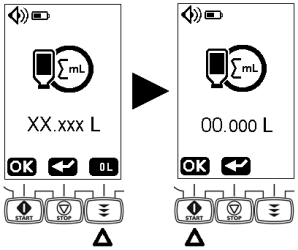
- Settings lock activation / deactivation isn't modified after switching OFF the pump.
- When settings lock is activated, keypad lock can still be activated / deactivated.

5.6 Cumulative feeding volume counter

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

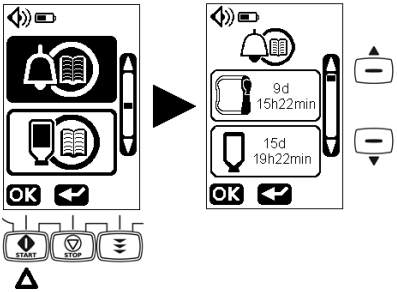


If needed, press ⏬ to clear the cumulative feeding volume (default setting) then press START to enter feeding setting screen.



5.7 Alarm history

Alarm events are automatically saved in the pump memory.

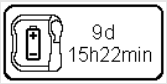


Press START to display the alarm events.

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

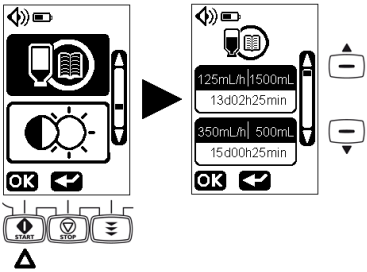
INFORMATION

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

  Example: 

  a battery empty alarm occurred 9 days, 15 hours and 22 minutes ago.
- When the history is full, the system overwrites the oldest event with any new event.

5.8 Feeding history



Press START to display the feeding events.

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

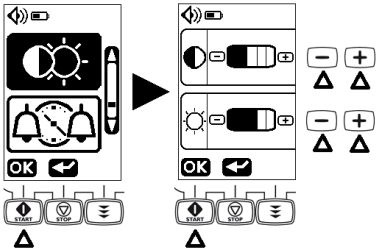
INFORMATION

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

  Example: 

  a volume of 1500 mL was administered at a flow rate of 125 mL/h, 13 days, 2 hours and 25 minutes ago.
- When the history is full, the system overwrites the oldest event with any new event.

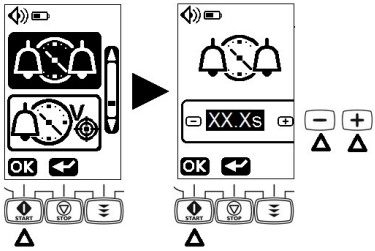
5.9 Contrast / Brightness



Press START key to configure contrast or brightness. Press − / + to set the contrast or the brightness.

Press START to validate.

5.10 Set time between two alarm sounds



Press START key to set the time between two alarm sounds. Press − / + to set the time between two alarm sounds. Press START to validate.

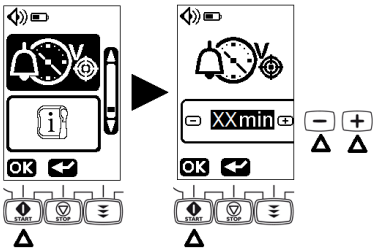
INFORMATION

- The setting is not applicable to low priority alarm.

- 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



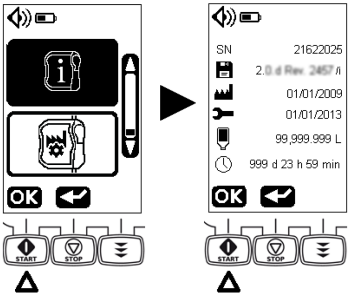
Press START key to set the time for target volume almost reached message. Press − or + to set the time for target volume almost reached message.

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 0 min).
- Access code is required to set time for target volume almost reached message.

5.12 Technical information



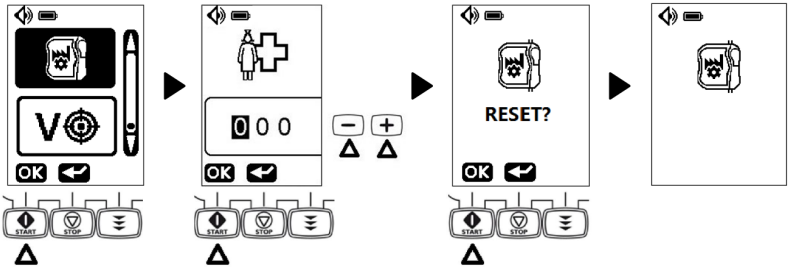
Press START to access the technical information menu.

NOTE: the technical information menu displays:

- SN Pump serial number
- Software version/ Hardware 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 enter the access code interface.

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

Press START 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 change 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 40).

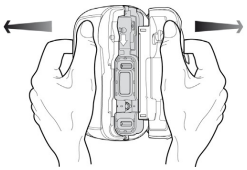
6.4.1 Cleaning Instructions

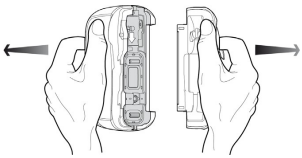
Prerequisites

- The pump is switched off.
- The power cable 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.

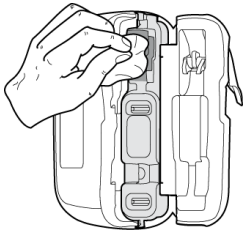


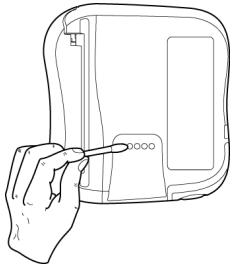


   NOTE: The whole pump can be cleaned under running water if necessary. The door can be immersed and cleaned separately with running water.

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, inner 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 cable.
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 cable 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 cable.
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 Alarms and safety features

7.1 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.

All alarms' sound levels are within the range of 45 dB(A) to 85 dB(A).

Two different alarm sound levels are available to choose: low and high. To set the alarm sound level, please go to *Sound* on page 33.

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

7.1.1 The different types of information signal or alarm

Information signal sound (2 beeps)		Information signal	Feeding continues / stops
Information signal sound (1 beep)		Information signal	Feeding continues
Flashing yellow LED and alarm sound (sequences of 2 beeps)		Information signal	No feeding, continue to be idle
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

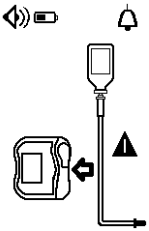
When a functional alarm or prior information to alarm occurs:

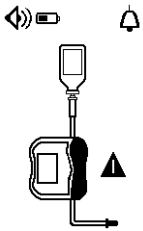
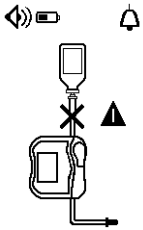
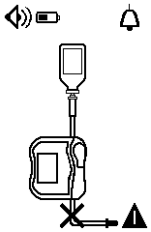
- to mute alarm sound, press  , see *Mute alarm* on page 29;
- detect the specific problem causing the alarm or prior information to alarm condition, by looking at the drawing displayed on the pump;
- to release alarm (except battery alarm), press  ;
- make a corrective action (see table below);
- restart feeding using the  key.

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

7.1.2 Alarm descriptions

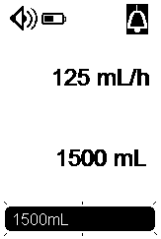
Line control

Symbol	Meanings	Actions
Medium priority - Yellow LEDs are flashing		
Giving set 	Missing giving set or giving set not properly installed or wrong set 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 42.

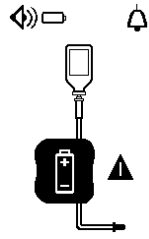
Symbol	Meanings	Actions
Door open 	Pump door not properly closed at start.	■ Close pump door. ▹ See *Installing the giving set* on page 20.
	Pump door opened after start.	■ Close pump door. ▹ See *Installing the giving set* on page 20.
	Pump door removed from its anchoring.	■ Re-hang door.
	Door mechanism 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.

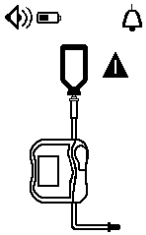
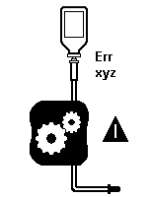
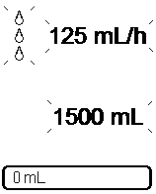
Feeding control

Symbol	Meanings	Actions
Low priority - Yellow LEDs are fixed		

Symbol	Meanings	Actions
Target volume almost reached 	Target volume will be reached.	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 38. ■ End feeding or continue feeding.
Medium priority - Yellow LEDs are flashing		
Target volume reached 	The target volume is reached. (Complete progress bar)	■ End feeding or proceed to the next step.

Function control

Symbol	Meanings	Actions
Low priority - Yellow LEDs are fixed		
Empty Battery Pre-alarm **flashing**	Battery voltage is nearly empty. Appears at least 30 min before the empty battery alarm.	■ Connect the pump to the mains via the pump holder. Recharge battery to continue pump operation.
Medium priority - Yellow LEDs are flashing		
Empty battery  **flashing**	Minimum battery voltage is not available. Appears at least 10 min before battery is fully discharged.	■ Connect the pump to the mains via the pump holder. Recharge battery to resume pump operation.

Symbol	Meanings	Actions
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 40). 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.
Fail safe technical alarm	Power supply failure. Software activity (watchdog) failure. RAM / ROM failure.	■ Contact your biomedical department.
Information signal - Yellow LEDs are flashing		
Start reminder 	Pump is switched on but not operated for 2 minutes (2 beeps)	■ Proceed to next step or switch pump off.
Reminder		

Symbol	Meanings	Actions
Last technical alarm reminder  	The last specific 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.

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

7.1.3 Maximum alarm raising delay

Time between alarm condition and alarm generation are more than 5 seconds like Giving set, Upstream and Downstream occlusions and Empty bag / Air in Line alarms (see *Performance* on page 50).

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

7.2 Troubleshooting

Issue description	Recommended action
Pump is not stable when mounted	■ Check that the clamp handle is fastened
Pump is damaged, noisy, smoking or with an abnormally hot part. Pump screen, Holder power or Holder COM are damaged	■ Remove power cable ■ 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

Issue description	Recommended action
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 supply light indicator does not light up	■ Connect pump to the mains supply ■ Check that the LED on the front panel of the pump holder 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 is triggered 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

8 Technical information

8.1 Performance

8.1.1 Essential performance

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

- flow rate accuracy (± 5% at 125 mL/h*);
- 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 43.

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

8.1.2 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 100 mL/h 5 mL/h from 100 mL/h to 600 mL/h
Accuracy	± 5% at 125 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 and medical water. * Probability ≥ 80%.

Container height: 50 cm.

8.1.3 Volume range

Range	From 1 mL to 5000 mL (default setting 500 mL)
Increments	1 mL from 1 mL to 100 mL 5 mL from 100 mL to 5000 mL

8.1.4 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.

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

NOTE: Maximum occlusion pressure for the pump is 1050.1 mmHg.

8.1.5 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 before occlusion release.

8.1.6 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 h 30 min maximum
25 mL/h	10 min maximum
100 mL/h	3 min maximum

8.1.7 Giving set alarm response time at different flow rates

Flow rate	Giving set alarm detection time
1 mL/h	15 min 30 s maximum
25 mL/h	45 s maximum
100 mL/h	15 s maximum

8.2 Technical characteristics

8.2.1 Operation mode

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

8.2.2 Power supply specifications

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

Protection against electric shocks: class II.

Holder input	AC input voltage: 100-240 Vac ± 10 % AC input frequency: 50/60 Hz ± 1 Hz AC input current: 110 mA-205 mA
Holder output	9 Vdc ± 5 % / 9 W (maximum load)
Power cable length	Approximately 2 m (except plug type M is approximately 3 m)

8.2.3 Battery specifications

Characteristics	NiMH (Nickel-Metal Hydride) 4.8V, 2.2 Ah Ni-MH
Weight	Approximately 110 g
Maximum charging time	6 hours

8.2.4 Power consumption

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

8.2.5 Dimensions - Weight

	Weight	Dimensions (H x W x D)
Pump	Approximately 610 g	Approximately 138 x 128 x 48 mm
Holder	Approximately 400 g	Approximately 132 x 118 x 46 mm (without pole clamp)
Power cable	-	Cable length: approximately 2 m (except plug type M is approximately 3 m)
Packaging	Less than 400 g	Approximately 272 x 230 x 112 mm

8.2.6 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.

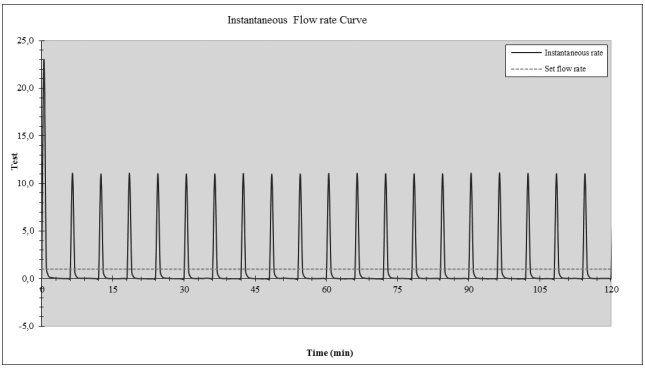
The curves can be helpful in determining the suitability of feeding parameters for specific nutrition programmes.

Giving set used: Amika Varioline

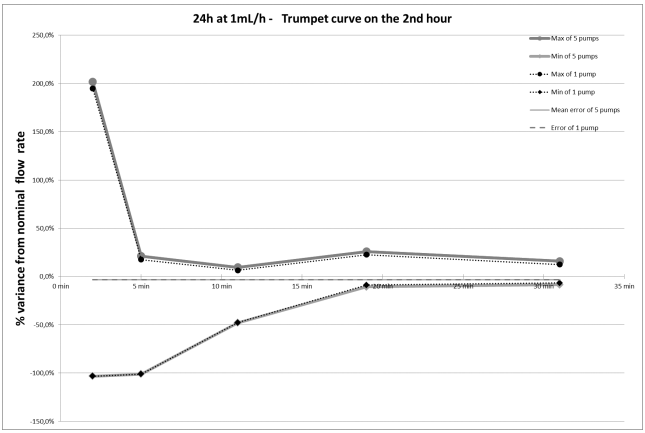
Fluid used: distilled water, and Fresubin energy drink (1 mL/h only)

8.2.6.1 Minimum flow rate: 1 mL/h

Sampling time: 30 seconds

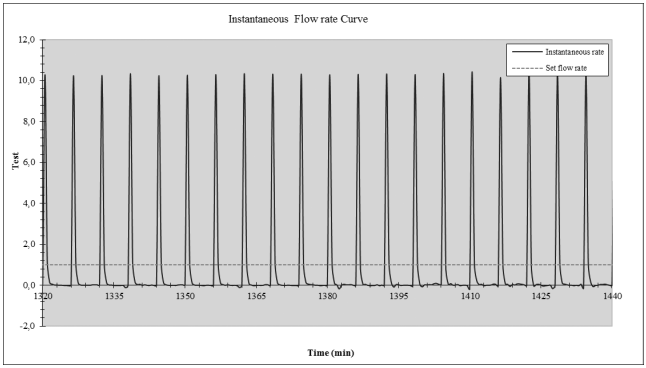


Start up and instantaneous flow rate (1 mL/h, over first 2h of the test period)

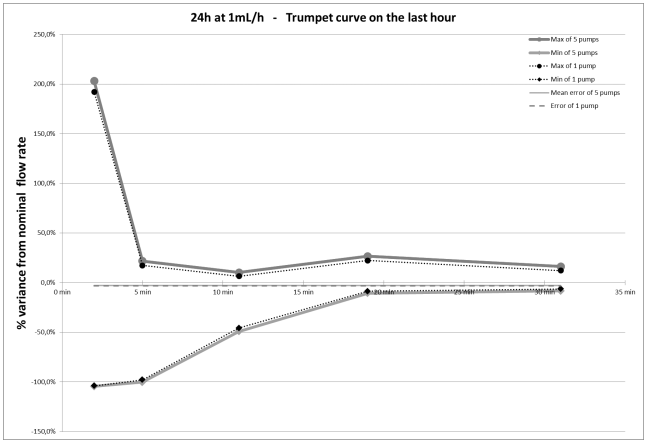


Trumpet curves for 2, 5, 11, 19, 31 minute observation windows (1 ml/h over second hour of the test period)

Sampling time: 30 seconds

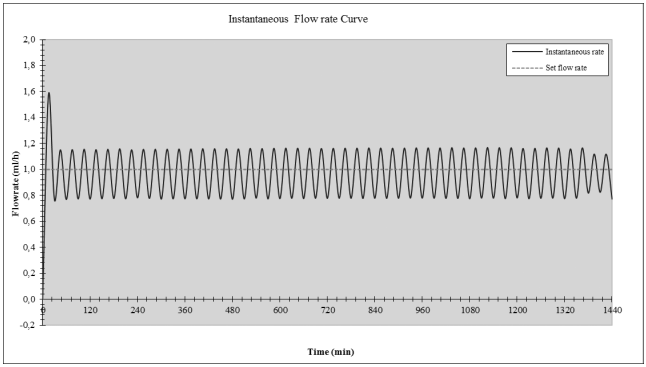


Instantaneous rate (1 mL/h, over last 2 hours of set change interval, 24 hours)

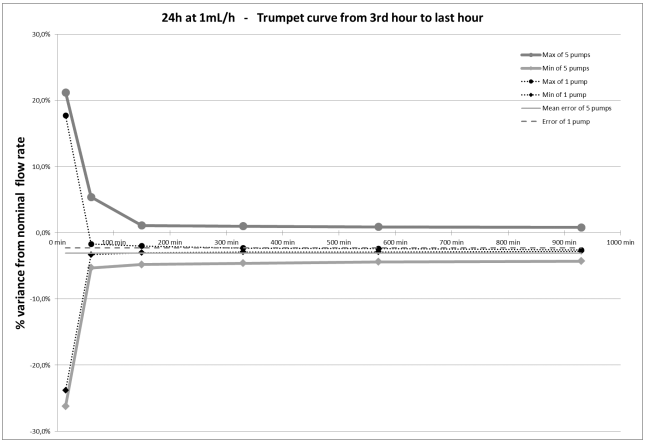


Trumpet curves for 2, 5, 11, 19, 31 minute observation windows (1 mL/h, over last hour of the set change interval, 24 hours)

Sampling time: 15 minutes



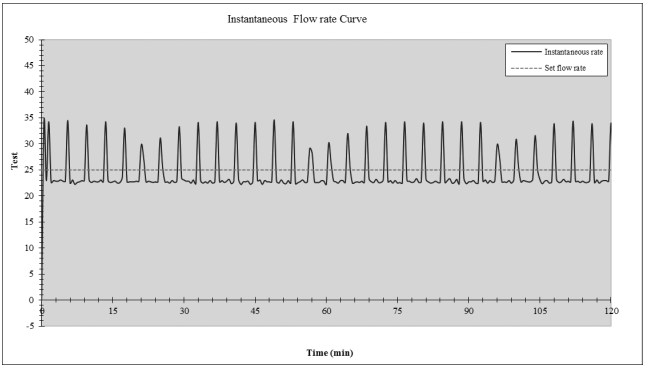
Instantaneous flow rate (1 mL/h, over set change interval 24 hours)



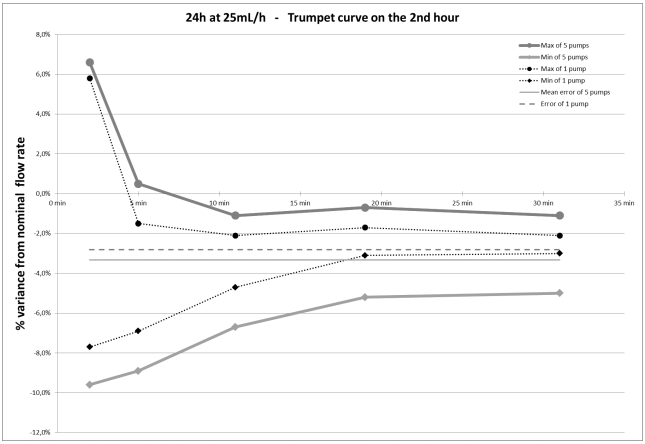
Trumpet curves for 15, 60, 150, 330, 570, 930 minute observation windows (1 mL/h, over set change interval, 24 hours)

8.2.6.2 Intermediate flow rate: 25 mL/h

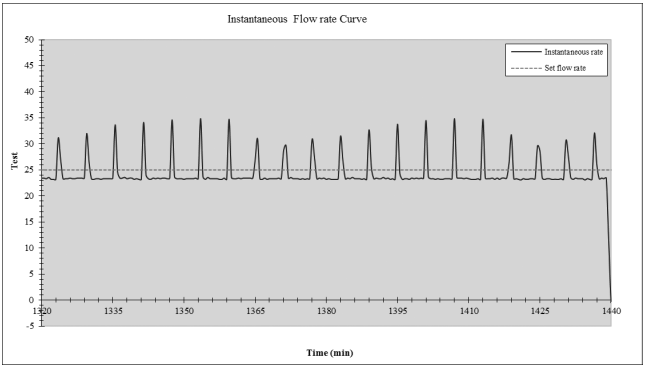
Sampling time: 30 seconds



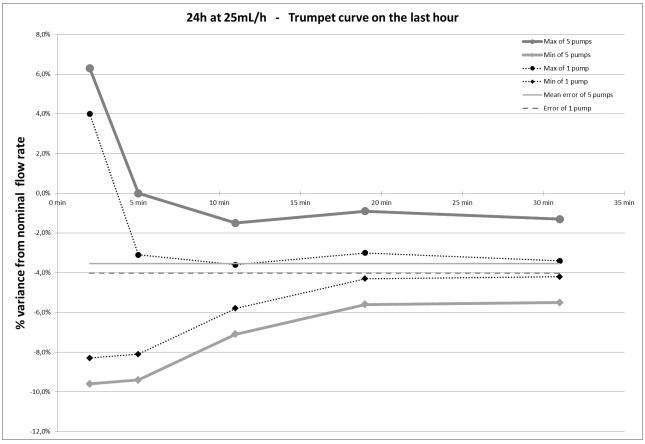
Start up and instantaneous at intermediate flow rate (25 mL/h, over first 2h of the test period)



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

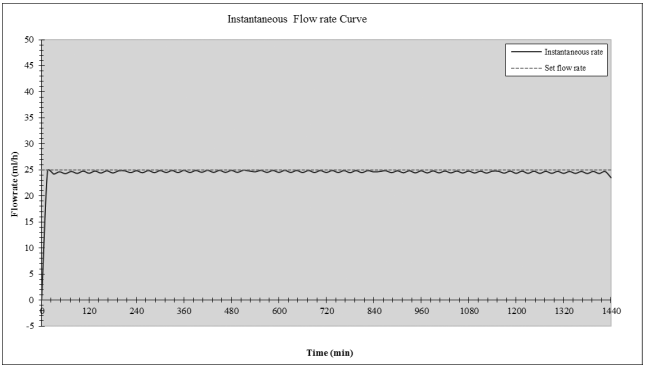


Instantaneous rate (25 mL/h, over last 2 hours of set change interval, 24 hours)

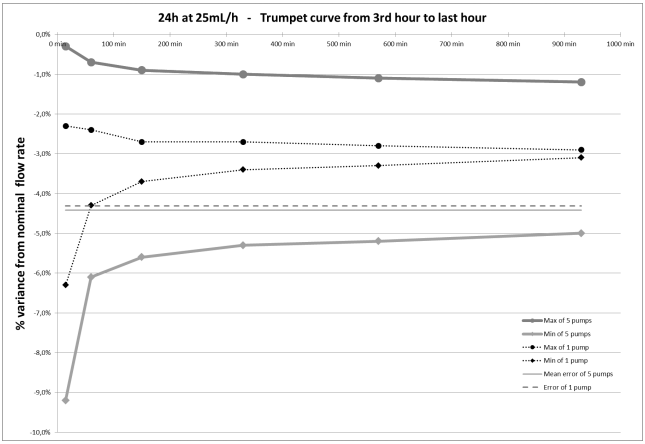


Trumpet curves for 2, 5, 11, 19, 31 minute observation windows (25 mL/h, over last hour of the set change interval, 24 hours)

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)

8.2.7 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 Medical Device Regulation (EU) 2017/745 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.

9 Transport, storage and recycling conditions

9.1 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 power cable 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 8.

9.2 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 40).

9.2.1 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 cable (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 40).
6. Handle the pump with care and store it in a compliant area.

9.2.2 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).

9.3 Recycling and disposal

Batteries, accessories and devices with this label must not be disposed of with general waste. They might contaminate environment and pose a health risk to the public and waste workers.
They must be collected separately and disposed of according to local regulations.
Before disposal, make sure that a qualified technician removes the battery from the device according to the procedure described in the Technical Manual.

For further information on waste processing regulations and dismantling, please contact your Fresenius Kabi sales representative.

10 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 50, are lost or degraded, the consequences for the patient can be: overfeeding, underfeeding, delay of therapy, trauma.

10.1 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.

WARNING
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 62). 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.

10.2 Guidance and manufacturer's declaration - Electromagnetic immunity

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

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

10.3 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

- Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should not be used no closer than 30 cm (12 inches) to any part of the Amika, including cables specified by the manufacturer. See the Technical Manual of this equipment for more information. Failure to respect these distances can degrade performance and lead to safety hazards.
- 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 power cable, a USB cable and a nurse call cable).

11 Services

11.1 Warranty

11.1.1 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.

11.1.2 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.

11.1.3 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.

11.2 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 (including the functionality check of alarm system) 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.

11.3 Maintenance requirements

WARNING

- Perform preventive maintenance at least once every **3 years**. This includes battery and membrane replacement. To avoid pumping performance deterioration, it is important to follow maintenance requirements.
- If the membrane is observed with any cracks or wear, the device must not be used. Please contact your biomedical department or Fresenius Kabi for membrane replacement.
- 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.

11.4 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.

11.5 Notification of serious incident

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

Contact information of the manufacturer:

Fresenius Kabi AG

Else-Kröner-Str. 1

61352 Bad Homburg

GERMANY

Tel.:+49 (0) 6172 / 686-0

http://www.fresenius-kabi.com

12 Ordering information

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

12.1 Instructions for use

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

12.2 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

12.3 Accessories

Do not use the device with damaged accessories.

WARNING
Use ONLY recommended accessories described below. 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
Smart Holder Power EU Accessory	CS1000428
Smart Holder COM EU Accessory	CS1000429

Please contact your Fresenius Kabi sales representative for orders.

13 Glossary of terms

Term	Description
°C	Celsius Degree
AC	Alternating Current
Ah	Ampere hours
Amika	Enteral feeding and hydratation pump manufactured by Fresenius Kabi
CE marking	European Conformity Marking
CISPR	International Special Committee on Radio Interference
cm	Centimeters
dB	Decibel
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
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
mA	Milliampere
MHz	MegaHertz
min	Minutes
mL	Milliliter

Term	Description
mL/h	Milliliter per hour
mm	Millimeters
MRI	Magnetic Resonance Imaging
NiMH	Nickel-Metal Hydride
NMR	Nuclear Magnetic Resonance
RAM	Random Access Memory
RF	Radio Frequency
RFID	Radio Frequency Identification
ROM	Read-Only Memory
s	Seconds
UPS	Uninterruptible Power Supply
V	Volt
Vac	Volt Alternating Current
Vdc	Volt Direct Current
W	Watt

Release notes

Date	Software version	Description (mainly changes)
February 2013	2.0	Creation
September 2013	2.1	This software version features a technical information menu.
October 2017	2.2	Alarm priority management modified to meet new standards.
July 2020	2.3	■ Addition of a new function "Reset manufacturing settings"; ■ Replace the related information and drawings of "Amika holder" in the whole IFU with "Smart holder power"; ■ Change the accuracy from "±7% at 50 mL/h" to "±5% at 125 mL/h" in chapter 9.1.1 and 9.1.2; ■ Maintenance period changes from 2 years to 3 years in chapter 12.3.
April 2021	2.3	■ Add chapters "Clinical benefits", "Side-effects" and "Risks for patients" and "Notification of serious incident" for Medical Device Regulation (EU) 2017/745 compliance; ■ Update compliance regulation to Medical Device Regulation (EU) 2017/745 in chapter 9.7; ■ Update the manufacturing address, add the contact information and website in the back cover page.
September 2022	2.3	■ Add the intended users and use environment information for Thailand in chapter 1.4.3 and 1.4.5; ■ Update the default setting of keypad beep to OFF in chapter 5.4; ■ Update the default setting of target volume almost reached message to 0 min in chapter 5.11; ■ Clarify that the whole pump can be cleaned under running water if necessary in chapter 6.4.1; ■ Remove previous chapter 7 Quick check protocol and add corresponding information in chapter 3, 4.2, 11.2 and 11.3.

This document may contain inaccuracies or typographical errors. Modifications may thus be made, and included in later editions. Due to the evolution of standards, and of legal texts and materials, the characteristics indicated in the text and images of this document are applicable only to the device with which it is included.

Made in China

Revision date: September 2022 (DHF-0569-07)

Reference: DD3030052-03 Amika IFU_ENG

CE 0123

Local contacts for servicing

DD3030052-03

DD3030052-03 Amika IFU_ENG

FRESENIUS KABI

caring for life

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