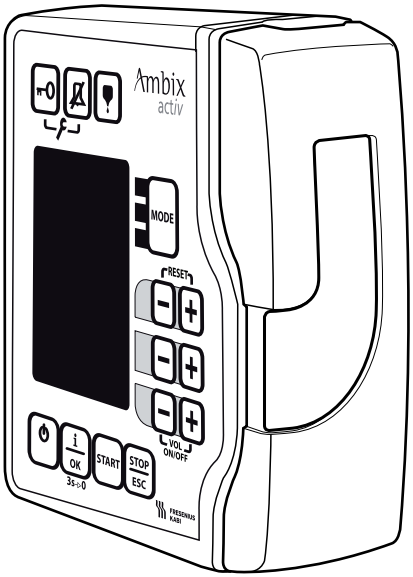
MEDICAL DEVICES

Ambix activ

Applicable to software version 2.3



INSTRUCTIONS FOR USE

FRESENIUS KABI
caring for life

Description of the symbols used on the device and its packaging

Warning
(Refer to the Instructions for Use)

Refer to the Instructions for Use

REF/SN — Product reference / part number

Input terminal - connector

Output terminal - connector

Alternating Current (AC)

Direct Current (DC)

Protection against electric shock: class II

IP34
IP33 — Splash-protected

Part included in a recycling process

Degree of protection against electric shock: type CF applied part

Nurse call

Battery

Power plug-in connector

Serial interface

CE 0123 — CE marking

E-Code — Features Code of equipment

Name and address of the manufacturer / Date of manufacture

Name and address of the manufacturing facility

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

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

Recommendations to be followed.

Local Contacts for Servicing

Write your contact here:

Table of contents

1 Introduction

1.1 Intended use

The **Ambix *activ*** is designed for parenteral nutrition and antibiotic therapy in homecare environment. **Ambix *activ*** is not designed for infusion of Insulin and critical life-sustaining drugs.

The **Ambix *activ*** is intended for children and adults. It is not suitable for neonatal use. Operators must be nurses or trained adults (patients or relatives) able to read the on-screen instructions and able to hear auditory alarms signals.

The **Ambix *activ*** is made for long term use as well as over-night use.

1.2 Indications

Suitable for parenteral nutrition and antibiotic therapy.

The **Ambix *activ*** pump is a mobile, portable, stationary, reusable device. the pump ensures fluid delivery in:

- Continuous
- Volume over time
- Intermittent mode
- Ramp mode

It uses a pumping and clamping fingers mechanism for advancing the liquid to the patient through a dedicated set.

1.3 Intended patient population

Ambix *activ* is intended for children and adults that require parenteral nutrition. It is not suitable for neonatal (< 1 month) use.

1.4 Intended user profile

Operators must be nurses or trained adults (patients or relatives) able to read the on-screen instructions and pumps alarms.

Warning

- *The pump must only be used by trained users both on using and cleaning the pump and able to understand and solve the pump alarm conditions.*

Typical initial training duration: 1 hour.

It is recommended that users attend a refresher training session of about 20 minutes every year.

For training, contact your **Fresenius Kabi** sales representative.

1.5 Intended conditions of use

The **Ambix *activ*** is an ambulatory infusion system intended to be used in a home environment (homecare, nursing home).

The **Ambix *activ*** is made for long term use as well as over-night use.

The **Ambix *activ*** is intented to be used in a backpack as an option (See Section 11, page 55).

The nurse call function is available through the use of Ambix holder as an option.

Outdoor use is not prohibited but temperature and humidity conditions of use to be respected are defined:

- Temperature: Operating: +13 to +40°C
- Relative humidity: Operating: 20 to 85%, no condensation
- Atmospheric pressure: Operating: 700 to 1060 hPa
- Altitude maximum: 3000 m

1.6 Administration Routes

The pumps administers products through intravenous (IV) access.

1.7 Contraindications

- Not for use with life-sustaining critical application drugs, or drugs with short half-life.
- Not designed for infusion of insulin.
- Not for use at flow rates below 10 ml/h.
- Not suitable for neonates.

1.8 Environment Considerations

Warning

Keep the pump, sets, holder and cables away from unsupervised children (and animals).

Consider the following operational conditions to ensure proper device performance:

- Do not expose to sun light, keep in dry place, at room temperature, normal pressure.
- Keep in clean environment.
- Keep away from objects which can potentially damage the device.
- Keep away from any noise disturbance which could prevent patient or relatives from hearing the pump alarms.
- Keep away from heat source, dust, fluff, direct and prolonged light exposure
- Keep away from animals, pests or children.

Do not share an outlet with another electrical device.

1.9 Important notes

Warning

- *Before using the **Ambix activ**, read the operating conditions carefully and check the good condition of the pump according to Section 6, page 40*.
- Do not use the **Ambix *activ*** without a timely and regular surveillance of patient and system, especially when an interruption of the nutrition delivery may lead to a patient hazard (e.g. comatose situation).
- Before using the **Ambix *activ***, check the battery level indicator. Full charge of the battery is obtained after 6 hours.
- The pump and holder shall be cleaned/disinfected before operation with a new patient.
- Give particular attention to the risk of strangulation with cables and sets, and with the small parts that could be swallowed or inhaled.
- In stationary mode, pump and holder shall be installed as close as possible to the patient with cable and set arranged so to minimize the risk of accidental disconnection by the operator or a person in vicinity of patient. The operator should be located in a position to be able to see the pump display and have access to pump keypad for alarm condition clearance.
- In order to ensure that all safety features are activated, switch pump ON before being connected with a patient.

Warning

- *The pump is designed to operate only with the appropriate **Fresenius Kabi activ** sets.*
- *The activ sets are single use only with a maximum set replacement interval of 24 hours, to avoid risk of underdose.*
- The physiological effects of drugs can be influenced by the characteristics of the device and the associated disposables. Please check the compatibility with prescriptions, the characteristics of trumpet curves and occlusion alarm settings in relation to the programmed flow rate.

Warning

- *Do not operate the **Ambix activ** in areas with a risk of explosion.*

- In case of refrigerated products, allow the product to reach the operating temperature range before use.
- When the device is stored at the minimum temperature of -20°C, wait for 2 hours to allow the product to reach the operating temperature range before using the pump. False occlusion alarm can be triggered if the pump/set temperature is too low.
- When the device is stored at the maximum temperature of +45°C, it is ready to be used at ambient temperature.

Warning

- *This device can be affected by environmental pressure or pressure variations, mechanical shocks, heat ignition sources, radio-frequency interference (RFI) or electromagnetic radiation.*
- The pump should only be connected to the wall outlet with the power cord supplied by the manufacturer.
- Check that the line power voltage corresponds with the value indicated on the device label.
- Do not exceed the permitted voltage on the external connections.
- A non-medical electric device connected to the device must conform to the suitable IEC/EN standard (e.g. IEC/EN 60950 and IEC/EN 60601-1).
- **Fresenius Kabi** accepts no liability for use of any interface communication between the **Ambix *activ*** and computer systems.
- The pump should be used under specified operational, storage and transport conditions, see Section 7.2, page 43.
- Use of ASV (Anti Siphoning Valve):
  - **Ambix *activ*** may be used with any ASV with a triggering pressure lower or equal than 0.2 bar.
  - ASV will affect the flow rate with a negative bias ≤ 3%.

2 Overview

The Ambix *activ* infusion pump provides the following four programmable modes:

- *Continuous:*

Fluid is administered continuously at the selected rate. Setting of target volume is optional.

- *Volume over time:*

Fluid is administered continuously at the calculated rate. The rate is calculated by the pump from the values for target volume and the required administration time. These parameters are input by the user. The calculated rate is shown in the display.

- *Intermittent mode*:

A defined dose of fluid (volume over time) is administered continuously at a calculated rate. After the dose is administered the pump returns to the KVO rate for a defined period. The dose is administered as often as defined. All parameters are input by the user. The calculated rate will be displayed by pressing the i button.

- *Ramp mode:*

Fluid is administered continuously, but with an increasing flow rate at the beginning and a decreasing flow rate at the end. Programmable ramping up and down times are entered by the user.

Information

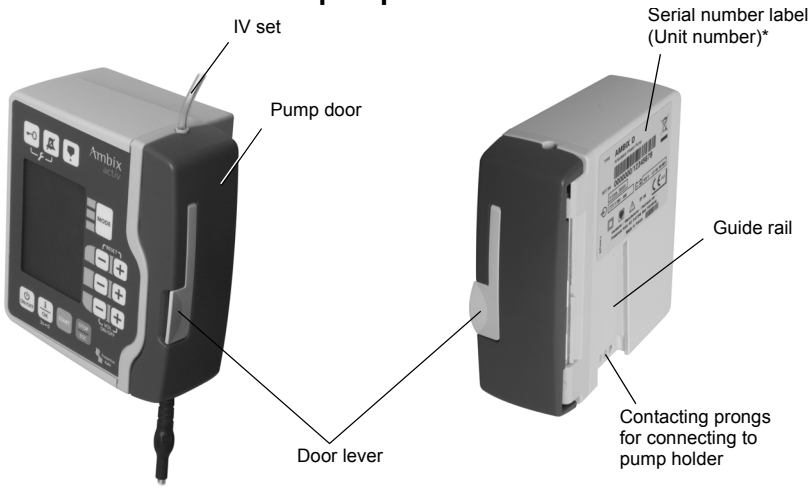
Calculation rule: When a Volume over time mode is programmed, the rate is calculated according to the following rule: R=V/T
R: Rate; V: Volume to Be Infused; T: AdministrationTime

Features:

- Rate range: 10 to 600 ml/h
- Increments of 1ml/h from 10 to 100 ml/h
- Increments of 5 ml/h from 100 to 600 ml/h.
- Volume to be infused range: 1 to 9999 ml
- Increments of 1 ml from 1 to 200 ml,
- Increments of 10 ml from 200 to 9999 ml.
- Typical Accuracy of ± 5% at 22.5°C ± 2.5°C, pressure < 0.1 bar.
- Dedicated pumping segment with integral anti-free-flow ***activ*** clamp and bend protection.
- Upstream and downstream occlusion detection when infusing.
- Small, light and compact:
- H/W/D 132 x 120 x 45 mm, 550 g (pump).
- H/W/D 146 x 162 x 115 mm, 500 g (holder).
- Dedicated ***activ*** sets with built-in safety features (anti-free-flow clamp, flow stop cap, bend protection, DEHP free, ...).
- Virtually silent operation.
- 40 h battery life (at 125 ml/h), 15h battery life (at maximum rate of 600 ml/h).
- Dedicated ***activ*** Rucksack.

2.1 The Ambix act*iv* - illustrations

2.1.1 View of the pump

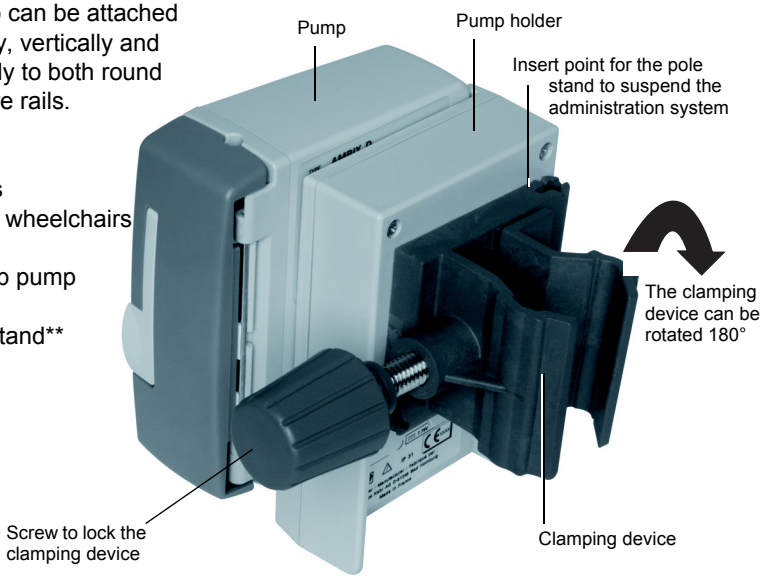


* The identification labels on the **AMBIX *Activ*** pump and on the ***Activ*** holder are readable at a distance of 20 cm.

2.1.2 Pump holder and pump

The pump can be attached universally, vertically and horizontally to both round and square rails.

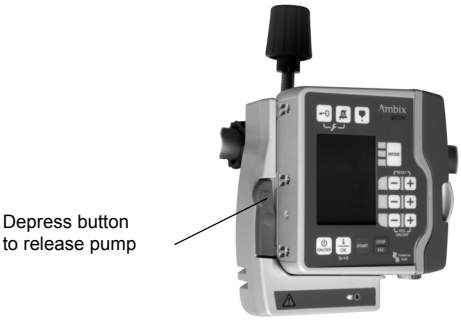
E.g.:
- IV poles
- medical wheelchairs
- beds
- table-top pump stand
- rolling stand**



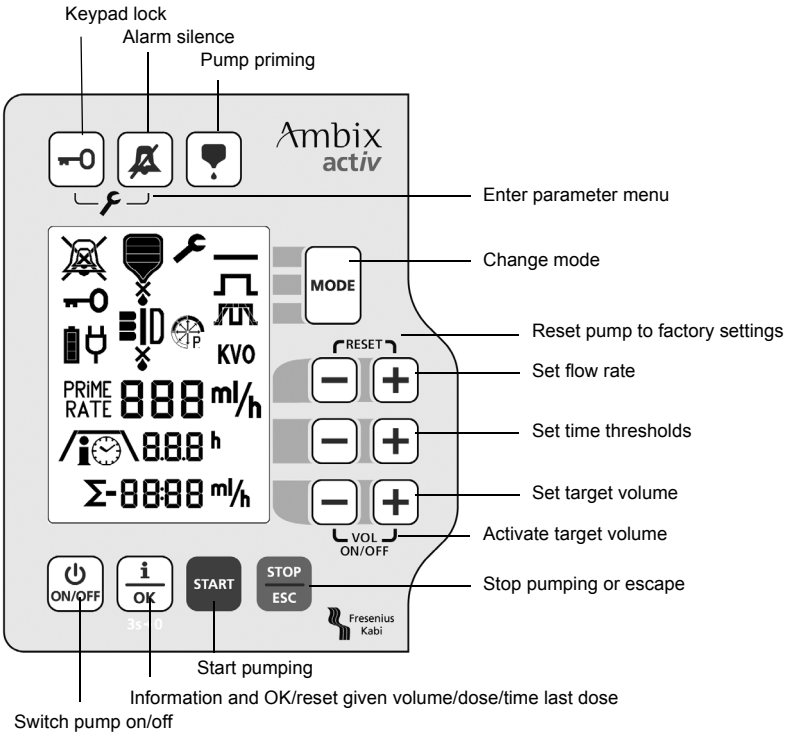
** The **AMBIX *Activ*** pump shall be installed at a height between 50cm and 150cm on the rolling stand.

2.1.3 Nurse call and data interface

2.1.4 Attaching the pump to the pump holder



2.1.5 User interface



Display Symbol	Meaning	Further details
	Auditory alarm volume level	Indicates the volume of the alarm silent, low, medium, high (see parameter setting menu Section 3.6.1, page 28).
	Keypad locked	Keypad lock is active.
	Wrench flashing: Maintenance requested	Pumped volume > 1000 litres.
KVO	Keep Vein Open mode	KVO function is activated and target volume selected; if this symbol is flashing, KVO is running (see parameter setting menu Section 3.6.1, page 28).
	Continuous mode	Continuous mode is active.
	Volume/Time mode	Volume/Time mode is active.
	Ramp mode	Ramp mode is active.
	Intermittent mode	Intermittent mode is active.
	Active ramping phase	Active phase of the ramping procedure will flash.
PRIME	Priming mode	Pump is priming.
	Battery charging status	Charging status of the internal battery pack (empty battery, nearly empty battery, partially charged battery, fully charged battery).
	Information mode	Mode-dependent information will be displayed.
	Volume remaining to infuse	Remaining volume will be displayed.
	Time threshold	Time thresholds should be programmed.
	Pressure indication	Current pressure. If the arrow reaches the black area of the circle, occlusion alarm will be triggered.

Display Symbol	Meaning	Further details
	Power indication	***Activ*** holder is connected to mains.
	Volume remaining to be administered	Volume remaining to be administered 75%, 50%, 25%, 0%.
	Run indicator	The movement of drops and bars indicates that the pump is running.

2.2 Data interface and Nurse call connection

The pump holder includes a data interface and nurse call connection port.

This port enables the pump to be connected either to a computer or to a nurse call system.

The type of cable connected to this port determines the function used.

Data interface:

- Only used for maintenance.
- The pump must not be connected to a patient.

This feature is available when the pump is properly engaged in the holder and the holder is connected to the AC wall outlet.

Further information about connectivity is available from the technical service department. Cable references are accessible on the Technical Manual.

Warning

- *Use only original Fresenius Kabi cables.*

For additional information about Data communication, please refer to Data communication, page 34.

Use of the Nurse call does not replace permanent patient observation.

2.3 Ambix *activ* pump sets

The ***activ*** sets are specially designed for the **Ambix *activ***. Every set includes a sophisticated particle/air filter which, in conjunction with the air alarm sensor of the **Ambix *activ***, prevents air administration. Downstream kink protection is also integrated to reduce the risk of kink especially in ambulatory use. Free flow protection is provided by the ***activ*** clamp, an advanced second generation pinch clamp. This clamp automatically closes when the pump door is opened, thereby preventing free-flow. An integrated flow cap facilitates priming proceedings.

Information

- ***Fresenius Kabi*** *recommends placing the container 50 cm (± 10 cm) above the pump.*
- *For further information about* ***activ*** *sets, please refer to the related labelling on the* ***activ*** *sets.*

Warning

- *In case of use of ASV (Anti syphoning valve), the pressure level may be changed, see warning Section 1.9, page 8.*
- *When set is out of the pump, ensure that the clamp is closed especially when the container is placed above the injection site or that the set is disconnected from the patient.*
- *The* ***Ambix activ*** *is designed to operate exclusively with the appropriate* ***Fresenius Kabi activ*** *sets including the patented* ***activ*** *clamp (see ordering information Section 11, page 55). The use of other sets is prohibited and may endanger patient safety either through the risk of air infusion, reduced flow rate accuracy or free-flow conditions. For ordering information see Section 11, page 55.*

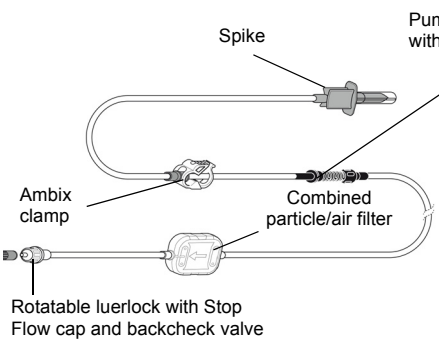


Figure: ***activ*** set ambulatory SF

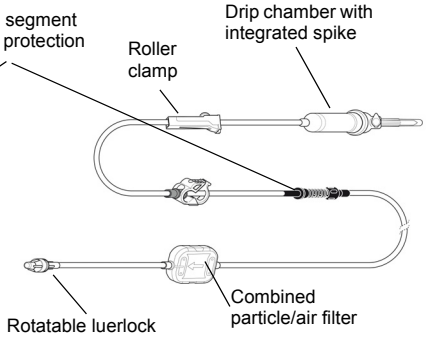
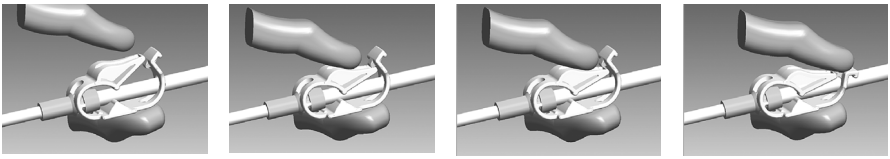


Figure: ***activ*** set stationary SF



opened | closing | being opened 1 | being opened 2

2.4 Backpack for adults and for children

Both backpacks have a main compartment incorporating a universal fastening system for infusion bags and the pump. A second large compartment at the front is provided for accessories and personal items.

- The ***activ*** Rucksack for adults is suitable for carrying up to 5 litres of infusion fluids along with the pump.
- The **Ambix *activ*** pump is located in the main compartment and for easy access. It can be operated from outside through the front window.
- The ***activ*** Rucksack can be carried using the top handle, the shoulder straps, or worn on the back.
- The ***activ*** Rucksack mini is suitable for carrying up to 1.5 litres with the pump.
- The ***activ*** Rucksack mini can be carried using the top handle or the shoulder straps. It also has a hanging strap from hang from a baby carriage.
- When the ***activ*** Rucksack is used, the pump display and keypad are not immediately accessible for alarm condition clearance. In such a use, the auditory alarm level shall be set to high.

Detailed instructions for use are available for the ***activ*** Rucksack. For ordering information see Section 11, page 55.

activ Rucksack

activ Rucksack mini

3 Operating instructions

3.1 Packaging

Content:

Ambix *activ*
act*iv* holder
Power cord
Instructions for use

Packaging weight: Approximately 1600 g.
Packaging consists of: Recycling cardboard.

3.2 Power supply

Warning

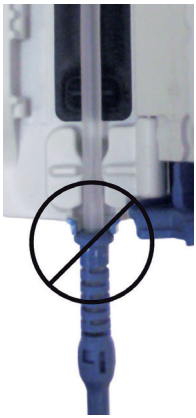
- *Before using the pump, the internal battery should be charged for at least 6 hours. The battery is charged during operation when the pump is mounted on the **activ** holder and connected to the wall outlet. When the pump is disconnected from the outlet, it automatically switches to battery mode. The maximum battery life is achieved after several charge/discharge cycles.*

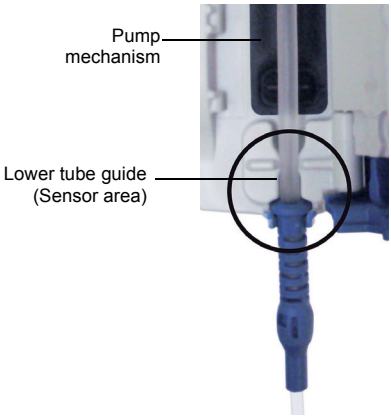
- *When the pump is used in stationary, connect the pump/holder to the mains supply.*
- *The battery should be fully charged before every ambulatory use and check the battery is fully charged.*
- *The power outlet on **activ** holder is the disconnecting device from mains and must remain accessible at anytimes to allow emergency disconnection. For switching OFF the pump, please refer to Section 3.4.2, page 19.*

3.3 Loading the set (patient not connected)

3.3.1 Installing the set in the pump

1. Open the door with the lever.
2. Insert the ***activ*** clamp into the intended cavity of the pump. Position and lock the green section of the set into the green slot in the pump.
3. Place the upper ring of the blue kink protector in the blue coloured notch. Take care that the pumping segment of the tubing is in front of the pump mechanism.
4. Close the pump door and push the lever down. The ***activ*** clamp will open automatically. Flow will be prevented by the pumping mechanism until administration is started.
5. If applicable, open roller clamp after set installation, before starting infusion.





3.3.2 Removing the set

If the pump is running, stop the infusion by pressing the STOP/ESC button.

1. Switch the pump OFF by holding the On/Off button down for more than 3 seconds.
2. Ensure that backflow from the patient access system is prevented, if present, close the roller clamp, and disconnect the set from the patient.
3. Open the pump door – the ***activ*** clamp will be automatically closed. Remove the set starting with the green adapter.
4. Dispose of the set following appropriate legislation and local procedures.
5. If it is required to restart the pump, repeat the installation procedure described above in Section 3.3.1, page 18.

3.4 Operating the Ambix *activ*

3.4.1 Switch pump on

Press the On/Off button for more than one second to switch the pump on. The pump will boot and will perform a self test. The most recent parameters and program will be shown in the display.

3.4.2 Switch pump off

Press the On/Off button for more than three seconds to switch the pump off. The display will count down, 3-2-1-off, and the pump will then shut down. Parameters from the most recent infusion will be retained in the pump's memory. This information is saved for 1 month following the last switch-off, provided the battery was fully charged at switch off.

This operation is possible when the pump is not running (for example, after the end of infusion programmed or at stopping of the infusion by pressing the STOP/ESC button).

3.4.3 Priming the set using the pump (recommended)

- Close the ***activ*** clamp.
- Connect the container to the set and hang up. Do not remove the stop flow cap at this stage.
- After having installed the set in the pump (see Section 3.3.1, page 18), press and hold the prime button.
- For the correct priming procedure, refer to the Instructions for Use included in each set box or on each individual set package.
- Release the priming button when the set is fully primed.

Warning

- *The container should be placed 50 cm±10cm above the pump or place the container in its dedicated location of the* ***activ*** *rucksack.*

The pump primes the line at 600 ml/h. During priming the empty bag alarm is deactivated and a short beep sounds every 2 seconds.

Warning

- *Never prime the set with a patient connected.*

Information

- *Check the integrity of the set prior to connecting the patient.*
- *The empty bag alarm is disabled while the pump is priming.*

Warning

- *When priming stationary sets, do not forget to open the roller clamp.*
- *After priming, make sure there is no air in the infusion line*.

3.4.4 Select application mode

Pressing the Mode button changes the mode of delivery. There are 4 modes: continuous, volume over time, intermittent and ramp mode.

3.4.5 Change parameters

Displayed parameters are changed using the +/– buttons in the adjacent row. The + button will increase the value whereas the – button decreases it. All buttons have an auto acceleration push button mode. If the button is kept depressed, the rate of change of the value accelerates.

3.4.6 Start pumping

Press the Start button to start administration.

Warning

For sets with a drip chamber, please check that the roller clamp is opened and that liquid is flowing into the drip chamber.

3.4.7 Stop pumping

Press the Stop/Esc button to stop administration.

Information

- *The Stop/Esc button is also used to clear alarms. In some screens, the Stop/Esc button will also function as an escape button to escape from an unwanted display or parameter setting procedure.*

3.4.8 Stop a program

Once a program is started, it is impossible to change values. To abort a program, the pump has to be switched off. After switching the pump on again, a new program can be set and started.

3.4.9 Information button

By pressing the i/OK button the total volume infused since the last reset will be displayed for 5 seconds (∑ will be shown in the display). If the pump is running and the target volume is activated, the remaining volume will then be displayed (∑- will be shown in the display).

When the pump is not pumping, pressing the i/OK button for more than 3 seconds resets the display of the administered volume to zero.

Information

- *Further functions of the info button are described in the relevant sections below*.

3.4.10 Silence an alarm

Alarms can be silenced for 2 minutes by pressing the Alarm silence button ( ). During this period the alarm reminder will only be indicated by flashing of the display. It is possible to re-start administration by pressing the Start button.

3.4.11 Keypad lock

Lock the keypad of the pump prevents unintentional change of infusion settings of the pump.

Press the Lock button once. A key symbol will flash in the display for 5 seconds. If the OK button is pressed during this time, the keypad will be locked and the key symbol will remain in the display. The locked keypad will be indicated by a beep if one of the locked buttons is pressed.

To unlock the keypad press the Lock button and then within 5 seconds press the OK button.

Information

Once the keypad lock is activated, only the following buttons are active:

- On/Off button:
  Switches pump on and off.
- Start button:
  Continues the infusion after an alarm without unlocking the keypad.
- Stop/Esc button:
  Stops administration when pump is running (an alarm will appear).
- Stop/Esc button:
  Clears the alarm permanently.
- Alarm silence button:
  Silences alarms for two minutes.
- Info button:
  Accesses info function. To exit the info function, wait for 5 seconds.

3.4.12 Pump reset

Press the upper + and – buttons simultaneously for more than 3 seconds to reset the pump and set all values to the factory default settings.

3.4.13 Target volume

In continuous mode, the target volume feature can be activated/deactivated by pressing the lower + and – buttons simultaneously.

Please make sure to program a target volume 5% lower than the volume in the container.

3.4.14 Parameter menu

Press the Lock button and the Alarm silence button simultaneously to enter the parameter menu, see Section 3.6, page 28. Exit the menu by pressing the Lock button and the Alarm silence button simultaneously again.

3.4.15 Mode lock

Press the Lock button and the Alarm silence button simultaneously to enter the parameter menu. The wrench and the current mode symbol flash in the display. Press the Mode button once and the mode symbol will stop flashing.

To enable lock mode, press the Lock button and the Alarm silence button simultaneously to leave the parameter menu. To disable Lock mode enter the parameter menu by pressing the Lock button and the Alarm silence button simultaneously and press the Mode button once and the mode symbol will flash again. Press the Lock button and the Alarm silence button simultaneously to leave the parameter menu.

Information

- *A beep sounds if the Mode button is pressed while the mode lock is enabled.*

3.4.16 Resets

Press the upper +/– buttons for more than 3 seconds until a beep sounds to reset all values to the default factory settings.

Press the Info button for more than 3 seconds until a beep sounds to reset the administered volume.

3.5 Programming the Ambix *activ*

3.5.1 Continuous Mode

Button	Action
ON/OFF	Switch pump on
MODE	Change to continuous mode
+/–	Set rate
START	Start pumping

Information

- *Press the + and – buttons in the lowest row simultaneously to activate the target volume.*
- *To abort the program, switch pump off.*

3.5.2 Volume/Time Mode

Button	Action
ON/OFF	Switch pump on
MODE	Change to volume/time mode
Middle row +/–	Set application time
Lower row +/–	Set target volume
START	Start pumping

Information

- *The flow rate will be calculated and displayed automatically. If the configured limit of the flow rate is reached, other parameters are also limited.*
- *To abort the program, switch pump off.*

3.5.3 Intermittent Mode

Button	Action
ON/OFF	Switch pump on
MODE	Change to intermittent mode
Upper row +/–	Switch between the screens: dose setting (doS), interval setting (int) and delay start (dS)

Button	Action
Middle row +/–	Set dose time, interval time and delay start
Lower row +/–	Set dose volume and number of intervals
START	Start pumping

Information

- *To abort the program, switch pump off.*
- *By pressing the i-button the flow rate, the total volume and the total time of the programmed protocol will be shown in the display.*

  The KVO volume administered between the dose administrations will be included in the total volume. All displayed values will be calculated automatically. If the configured limit of the flow rate is reached, other parameters are also limited.

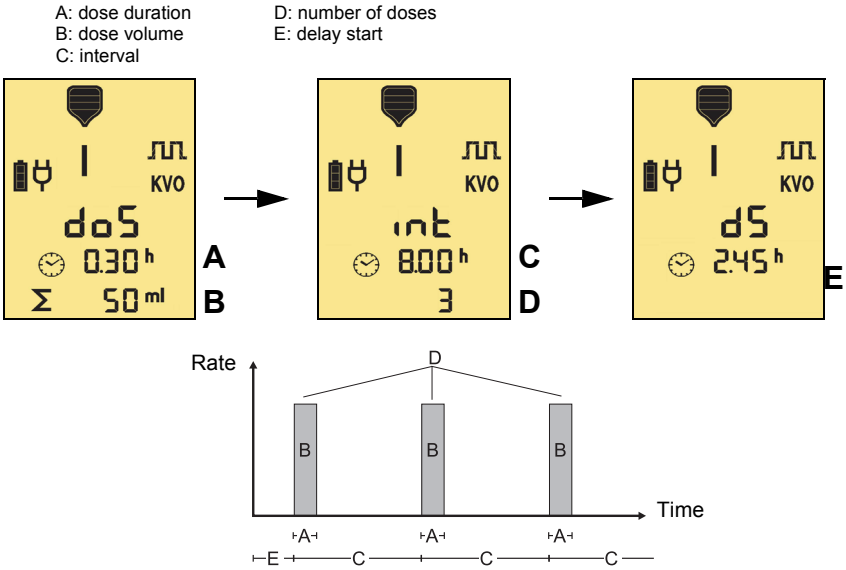
  To display the time elapsed since the last infused dose and the volume administered since the beginning of the first dose, press and hold the stop and i/OK buttons when the pump is stopped.

  The time and the volume will be counted regardless of whether the pump was turned off.

  If the infusion duration exceeds 24h, the display shows: -- : --

- *If the infusion is stopped during the dose, the infusion will resume by pressing the START button. All other doses will be delayed for the same amount of time. To abort the program, switch off or reset the pump.*
- *By pressing the i-button, the total programmed cycle information appears. The pump will show the total cycle duration taking into account the last pause using a 24h cycle representation.*

  Example below: the total time shown on the display for a programmed cycle of 3 doses with 8 hours interval is 16h30+2h45 (delay start)=19h15 if KVO is deactivated, otherwise 24h+2h45 (delay start)=26h45. The time elapsed will be counted even if the pump has been turned off.



3.5.4 Ramp Mode

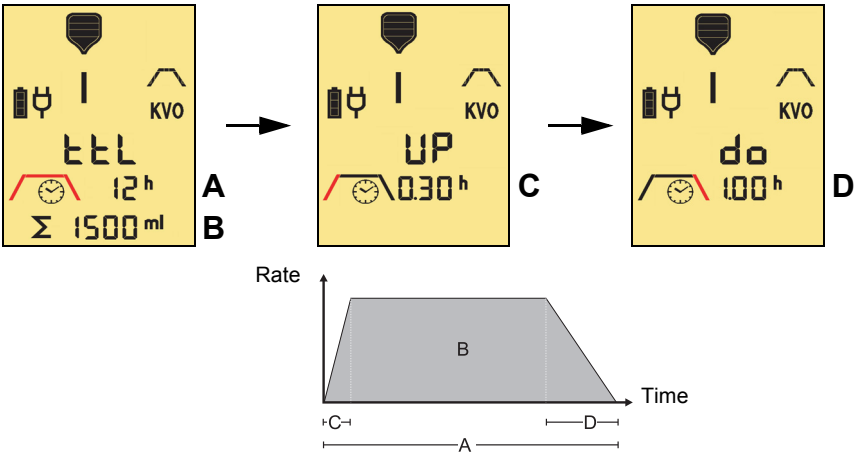
Button	Action
ON/OFF	Switch pump on
MODE	Change to Ramp mode
Upper row +/–	Switch between the screens: total time and volume (ttl), up ramp (UP), down ramp (do)
Middle row +/–	Set total time*, ramp up time or ramp down time
Lower row +/–	Set target volume
START	Start pumping

Information

- *To abort the program, switch pump off.*
- *The current rate, the remaining time and the remaining volume to be administered will be calculated automatically and displayed.*
- *Press the STOP button once during the ramp program to stop the infusion. Stop will be shown for 3 seconds in the lower line of the display. Press Start to resume the program. For immediate ramp down, the Mode and Start button have to be pressed simultaneously - the ramp down symbol will start flashing. To abort the program, the pump has to be switched off or reset.*

Warning

Taking into account the accuracy range of ± 5%, in order to prevent an interruption of the ramp down, please make sure to program a target volume 5% lower than the volume in the container or to have 5% more nutrition in the container than the programmed target volume.



The standard display of time over 10h is in full hours, except if the option "steps of 5 minutes" is activated.

Note: For an infusion time greater than 10 hours, minutes can be programmed in increment of 5 minutes by pressing simultaneously the + and – keys. The minutes appear on the display for 5 seconds “00h”, then use + and – keys to adjust. To confirm minutes, press the i/OK button.

3.6 Advanced functions

3.6.1 The parameter setting menu

See Section 3.4.14, page 23.

The parameter setting menu allows the following parameters to be modified:

No.	Function
0	Button Mode locking
1	Password
2	KVO rate
3	Pressure sensitivity
4	Sound volume level
5	Backlight status
8	End volume pre-alarm
15	Alarm, interval time (for alarm level medium or low)
17	Max. programmable flow rate
25	Change password

The alteration of parameters always follows the same logic. First, select the parameter that is to be altered, using the upper row of +/– buttons. Then alter the value of that parameter, using the lower row of +/– buttons. The change should be confirmed with the i/OK button (or cancelled with the STOP/ESC button).

Information

The alterable value flashes.

Button	Action
Upper +/–	Select numeric code from parameter menu above
Lower +/–	Change required parameter to the desired value
i/OK or	Confirm the adjusted value
STOP/ESC	Cancel the change and return to the previous value

Information

Pressing either the i/OK or STOP/ESC button returns the user to the parameter menu and the number of the function that has been selected flashes in the display.

3.6.2 Enter the parameter setting menu

Press the Lock button (🔒0) and the Alarm silence button (🔕) simultaneously to enter the parameter menu.

3.6.3 Password for the parameter setting menu

Before changing any parameter, the password has to be entered by selecting option 1 from the menu. If the password is not entered, it is only possible to review the parameter values. The preset of the password is 3. The password can be altered, see Section 3.6, page 28.

Button	Action
Upper +/–	Select 1 from the menu to enter the password (see list in Section 3.6.1, page 28).
Lower +/–	Enter password (can be set between 0 and 250, preset is 3)
i/OK	Confirm the password

3.6.4 KVO rate

The **Ambix *activ*** can perform a Keep Vein Open (KVO) function. This function will continue the infusion at a low rate after the target volume is reached in order to keep the vascular access device and vein open. The KVO function is available in all modes except continuous mode with deactivated target volume. The setting of the KVO is between 0 (deactivated) and 10 ml/h in increments of 1 ml/h. The preset KVO rate is 2 ml/h. The KVO rate will not exceed the set flow rate for the infusion, irrespective of the configured default value for KVO.

When the KVO function is activated and the target volume selected, KVO will be displayed in the display. During KVO application, KVO will flash in the display and the KVO flow rate will be displayed in the upper row.

Information

- *In case of KVO interruption, the function will be deactivated.*
- *In case of KVO change, the parameters values are reset to the factory initial settings.*

Button	Action
Upper +/–	Select 2 from the menu to enable KVO rate change
Lower +/–	Change to the desired value (between 0 and 10 ml/h, increments of 1 ml/h, preset 2 ml/h)
i/OK	Confirm the adjusted value

Information

- *A setting of 0 will deactivate the KVO*
- *KVO rate must be appropriate for the patient.*

3.6.5 Pressure sensitivity for downstream occlusion detection

Pressure sensitivity settings are HI and LO. This corresponds with a pressure level of approx. 0.8 bar and 0.5 bar, respectively.

The HI level is from 0.7 bar to 1.8 bar.

Information

- *During pumping, a display graphic will indicate the pressure (See page 12).*

Button	Action
Upper +/–	Select 3 from the menu to enable pressure sensitivity change
Lower +/–	Change to the desired value (HI - LO, preset HI)
i/OK	Confirm the adjusted value

3.6.6 Alarm sound level

Alarm sound level settings are HI (High); ME (Medium) and LO (Low). When an alarm is triggered, the configured value will be indicated as a pictogram in the display. High [🔔], medium [🔔], low [🔔].

Information

- *The time between two sound sequences can only be adjusted for the medium and low levels (see Section 3.6.9, page 32).*

Button	Action
Upper +/–	Select 4 from the menu to enable alarm volume level change
Lower +/–	Change to the desired value (HI, ME, LO). Preset is HI.

Button	Action
i/OK	Confirm the adjusted value

Information

- *Ensure that the selected alarm sound level is audible by the user, taking into account the environment.*

The alarm sound level measured according to ISO3744 are:

a - Alarm sound level setting Hi

High priority alarms > 60 dB(A)

Low priority alarms > 40 dB(A)

b - Alarm sound level setting LO

High priority alarms > 50 dB(A)

Low priority alarms > 40 dB(A)

3.6.7 Backlight status

The backlight function of the **Ambix *activ*** depends on whether the pump is running on battery or connected to the wall outlet. If the pump is running on battery, the backlight is off. Only when a key is pressed will the backlight come on for 10 seconds. In case of alarm, the backlight will flash. If the pump is connected to a wall outlet, there are 3 possible settings:

Off: Same as in battery mode

On: The backlight is always on. Alarms will be indicated by flashing of the backlight

Temp: Same as in the ON setting, but when unplugged, stays on for 10 seconds only.

Button	Action
Upper +/–	Select 5 from the menu to enable backlight status change
Lower +/–	Change to the desired value (Off, On, Temp). Preset is On.
i/OK	Confirm the adjusted value

3.6.8 Target volume pre-alarm

If the target volume feature is on at the start of an infusion, the **Ambix *activ*** will provide a pre-alarm just prior to the end of the infusion. The trigger for the pre-alarm is selected as a percentage of the target volume. The time is therefore dependent on flow rate. Available settings are between 0 and 100% of the target volume in increments of 10%.

Information

- *The volume for the pre-alarm is silent without any further reminder by pressing the Alarm silence button.*
- *In Volume over Time, Intermittent and Ramp modes, the target volume feature is automatically switched on.*
- *The alarm will sound 30 minutes before the end of the target volume even if the programmed percentage threshold is not reached.*
- *The alarm is deactivated when the value is 0.*
- *Ensure that the setting is appropriate for the patient.*

Button	Action
Upper +/–	Select 8 from the menu to enable change to percentage of volume for end alarm
Lower +/–	Change to desired value (0 - 100%). Preset is 10%.
i/OK	Confirm the adjusted value

3.6.9 Interval time of the alarm

The time between alarms can be adjusted to between 5 and 300 seconds in increments of 5 seconds.

Button	Action
Upper +/–	Select 15 from the menu to enable change to alarm interval time
Lower +/–	Change to desired value (between 5 and 300 s). Preset is 30s.
i/OK	Confirm the adjusted value

3.6.10 Maximum flow rate

The physical maximum flow rate of the **Ambix *activ*** is 600 ml/h. To avoid harm to the patient, this maximum flow rate can be limited to a value between 100 and 600 ml/h in increments of 5 ml/h.

Button	Action
Upper +/–	Select 17 from the menu to enable change to maximum flow rate
Lower +/–	Change to desired value (between 100 and 600 ml/h). Preset is 600 ml/h
i/OK	Confirm the adjusted value

3.6.11 Change password for parameter menu

The password for entering the parameter menu can be set between 0 and 250 to prevent access by unauthorized persons. This menu is only visible if the password is entered correctly in menu 1.

Button	Action
Upper +/–	Select 25 from the menu to change the password for the parameter menu
Lower +/–	Change to the desired value (between 0 and 250). The preset is 3.
i/OK	Confirm the adjusted value

4 Data communication

4.1 Internal data management

The **Ambix *activ*** includes an internal time keeper. Every event (command, alarm etc.) is recorded with the time and date in the pump's memory. The date of the internal time keeper of the **Ambix *activ*** will be retained for 3 months following the last switch-off, provided the battery was fully charged at switch-off. For more details see the technical manual.

4.2 History file

Every event will be stored in the history file. The history file has a maximum capacity of approximately 500 events. The events are stored using a FIFO (first in, first out) procedure for 5 years. This means that after the maximum capacity is reached the first stored event will be deleted for the next event.

The technical manual provides details of how to read events from the history file.

5 Alarms & safety features

Ambix *activ* has an intelligent alarm management system (with auditory and visual alarms). This system can discriminate different level of alarm in the aim to show to the operator the most important one to be solved.

5.1 Alarms

Blinking Symbols	Alarm Priority	Meanings	Pumping stop	Type	Operating conditions/Actions
	-	***Visual Alarm***	**Not applica-ble**	**Alarm/ pre-alarm**	Activated by the alarm types listed below, and is accompanied by the specific symbol for each alarm type. Take action described under specific alarm below.
	High	***Set insertion*** Set inserted incorrectly, except when blue portion of set is seated below intended area. Wrong set inserted. Contamination of ***activ*** clamp or recess for the clamp.	**yes**	**alarm**	Check position of ***activ*** Set above and below the pump mechanism and insert correctly if necessary. Use recommended ***activ*** sets. Clean the clamp and wipe using a lint-free cloth lightly dampened with warm water and a mild detergent or disinfectant or follow the recommended local procedure. Allow the pump to dry. For cleaning procedures see page 53.
	**High**	***Pump mechanism blocked***	**yes**	**alarm**	Tubing set may be too hard (temperature of liquid too low/high or liquid with high viscosity). If alarm persist after set verification, please contact your **Fresenius Kabi** sales representative or the local distributor.*
	**High**	***Downstream occlusion*** Flow obstruction below the pump. Tube is bent between pump and patient. Patient access system is blocked. Particle/air filter is clogged. Downstream pressure alarm level is configured too low.	**yes**	**alarm**	Remove kink Check patient access system Check Particle/air filter Change pressure sensitivity (see page 30).*

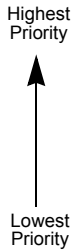
Blinking Symbols	Alarm Priority	Meanings	Pumping stop	Type	Operating conditions/Actions
	**High**	***Upstream occlusion , detection when infusing only*** Flow obstruction above the pump Tube is bent between container and pump If applicable, roller clamp closed Blockage in bag or spike	**yes**	**alarm**	Remove kink Open roller clamp Check bag and spike Note: the upstream occlusion alarm becomes active only after 2 ml of infusion solution is pumped successfully. A set that is occluded when loaded in the pump will not trigger this alarm.*
	**High**	***Line empty*** Container empty after 0.75 ml of continuous air infusion Set not fully primed Air sensor area contaminated Set inserted incorrectly	**yes**	**alarm**	Stop infusion or change container and set Prime set Clean the air sensor area using a lint-free cloth lightly dampened with warm water and a mild detergent or disinfectant or follow the recommended procedure. Allow the pump to dry. For cleaning procedures see Cleaning and Disinfecting, page 53. Check the position of the set and insert correctly.
	**High**	***Batteries are defective*** (not charging correctly) Pump is plugged in at the wall outlet	**no**	**alarm**	Contact service *
	**Low**	***Battery pre-alarm***	**no**	**warning**	Battery will be depleted in 30 minutes. Plug pump into the wall outlet
	**High**	***Battery depleted*** No electrical power	**yes**	**alarm**	No external power available. Check proper installation in the holder. Check contact pins of holder and pump. Check cable and connection to the wall outlet. Battery is nearly depleted. Plug into the wall outlet to continue infusion or stop infusion.*
	**High**	***Door open*** Pump door or lever open Pump door installed incorrectly Door mechanism defective	**yes**	**alarm**	Close pump door and lever Remove door and reinstall Contact service*

Blinking Symbols	Alarm Priority	Meanings	Pumping stop	Type	Operating conditions/Actions
	**Low**	***Target volume pre-alarm*** Only available if target volume is active	**no**	**warning**	The specified percentage of the target volume defined in the parameter menu is achieved. Minimum warning before achieving the target volume is 30 minutes.
	**High**	***Target volume achieved*** Only available if target volume is active	**yes**	**alarm**	Target volume is achieved.
 **(blinky)**	**Low**	***Infusion has been stopped*** No action on pump	**yes**	**alarm**	Check programming parameters and press Start to infuse.
KVO	**Low**	***Pump is infusing at KVO*** (keep vein opened)	**no**	**alarm**	The volume to be infused is completed. Press Stop to select a new infusion setting (if required).
	**-**	***Wrench: Preventive maintenance***	**no**	**Informa-tion signal**	Perform for maintenance
EXX	**High**	***Technical error***	**yes**	**alarm**	Contact your **Fresenius Kabi** sales representative or the local distributor.

*If alarm persist, please contact your Fresenius Kabi sales representative or the local distributor.

Ambix *activ* Pump intelligent alarm management system uses the following prioritization rules:

Priority 1	Technical Error - Batteries are defective
Priority 2	Door Open - Set insertion - Pump mechanism blocked - Downstream occlusion - Upstream occlusion - Line empty
Priority 3	Target volume pre alarm - Battery pre-alarm - KVO
Priority 4	Target volume achieved
Priority 5	Wrench -Preventive maintenance



5.2 Troubleshooting

Issue description	Recommended action
Pump is not stable when mounted	▪ Check that the clamp handle of the holder is fastened
Pump is damaged, noisy, smoking or with an abnormally hot part	▪ Remove the holder power cord ▪ Do not use the device ▪ Contact your biomedical department or **Fresenius Kabi** After-Sales Service immediately
Pump has been dropped	▪ Do not use the device ▪ Contact your biomedical department or **Fresenius Kabi** After-Sales 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** After-Sales Service if problem remains
Flow rate variance is higher than flow rate accuracy	▪ Check set configuration ▪ Check fluid viscosity and temperature ▪ Check the fluid is within normal temperature conditions ▪ Contact your biomedical department or **Fresenius Kabi** After-Sales Service if problem remains
Front panel problem (keys, backlight)	▪ Check the general state of the front panel ▪ Plug the pump to mains and check lightning of backlight ▪ Contact your biomedical department or **Fresenius Kabi** After-Sales Service if problem remains
The Power Indicator LED does not light up	▪ Connect the holder to the mains supply ▪ Contact your biomedical department or **Fresenius Kabi** After-Sales Service if problem remains
The device switches off on its own	▪ Connect pump to the mains supply ▪ Contact your biomedical department or **Fresenius Kabi** After-Sales Service if problem remains
Battery alarm when pump has been correctly charged	▪ Check mains supply voltage ▪ Contact your biomedical department or **Fresenius Kabi** After-Sales Service 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** After-Sales Service if problem remains
Technical error ERXX	▪ Contact service (homecare provider)

5.3 Safety features

5.3.1 Air infusion

The **Ambix *activ*** has an integrated air sensor that stops the infusion if an air bubble higher than 0.75 ml is detected.

In addition every ***activ*** set has a particulate and air filter.

Warning

High-lipid-containing solutions could impair the air removal function of the filter!

5.3.2 Maximum infused volume under single fault conditions

The **Ambix *activ*** administers a maximum of 10 ml under single fault conditions.

5.3.3 Temperature of applied parts to patient

The ***Activ*** set is a Type CF applied part. It can be in contact with the patient without time limitation during the operating life of the ***Activ*** set.

Warning

*The outer enclosure of **AMBIX Activ** pump and HOLDER are also considered to be applied parts. When operating at max ambient temperature as defined in Section 7.1, page 42, accessible parts of outer enclosure will be below 60°C and contact limited to 1min.*

6 User Test and Alarms checking

The following tests allow the user to check if the device is functioning correctly. **Fresenius Kabi** recommends that these tests are performed before attaching the **Ambix *activ*** to a patient. Auditory alarm can be checked during Downstream Occlusion detection function test.

Function	Action	Symbol	Passed
General aspect	Check the external appearance of the pump/holder for the absence of cracks or other visible damage. Check that any parts seem to move freely inside the pump/holder. Check for the absence of visible damage on the power cord inlet and the power cord. Switch ON the pump, check if all display segments are correctly displayed and check the device visually for damage and listen for abnormal sounds.		
Nurse call cable	Check the nurse call cable is not altered or damaged (housing and connectors). To check the proper operation of the nurse call, create specific alarms on the pump and check that they are replicated on the nurse call system.		
Power indication	Connect the holder with attached pump to the wall outlet. Verify that the two-prongs plug symbol appears in the display and the green LED on the holder lights up.		
Battery Charge	After complete charging, check the battery level indicator.		
Incorrectly installed set	Start infusion without installed set. Check that the alarm is set off.		
Empty bag detection	Install an empty set. Start infusion and check for empty bag alarm.		
Free-flow	Check ***activ*** clamp visually for damage. Connect the set to the container, open the ***activ*** clamp and check flow is stopped when the clamp is closed.		
Air infusion	Check the particulate/air removal filter visually for damage. Check the proper operation of the particulate/air removal filter of the set during priming.		
Downstream Occlusion detection	Fill the set with the infusion solution and prime. Occlude the downstream tubing e.g. by pinching or bending the tubing. Start the infusion. Check the pressure level in the display. The pressure should increase to within the alarm zone and auditory and visual alarms should be activated.		

Function	Action	Symbol	Passed
Upstream Occlusion detection	Administer at least 25 ml at a flow rate of 150 ml/h. Bend the upstream tubing 2 cm above the pump. Check if the upstream occlusion alarm is activated.		
Door opened	Open the door during infusion. Check that open door alarm is activated.		
Air alarm active	Check that the symbol is not displayed. Reset pump if the symbol is displayed.		

Warning

- *In case of test failure or any doubt regarding the integrity of the pump, please do not use the device.*
- *If one or more checks do not comply with the right pump behaviour, please contact the appropriate department or* ***Fresenius Kabi*** *After-Sales Service for additional verification.*

7 Technical information

7.1 Performance

Weight
Pump: 550 g
Pump holder: 500 g

Dimensions
Pump: 132 x 120 x 45 mm
Holder: 146 x 162 x 115 mm

Disposal
For appropriate disposal, at the end of the device life, please contact your local **Fresenius Kabi** organisation or your local distributor.The life cycle of the pump is 5 years provided that the maintenance is properly performed as described on Section 9.2, page 51.

Protection against electric shock
Protection class II
Type CF applied part
- the ***activ*** set
- the **Ambix *activ*** pump
- the ***activ*** Holder

Electromagnetic interference
This device can be disturbed by large electromagnetic fields, external electrical influences and electrostatic discharges above the limits stipulated by EN 60601-1-2 and EN 60601-2-24. If you wish to use the device in special conditions, please contact your local Fresenius Kabi branch.
This mobile RF communication equipment can affect medical electrical equipment.

Safety of ElectroMedicalEquipment
Conforms to EN/IEC 60601-1 & EN/IEC 60601-2-24

Protection against moisture
Pump IP34 and Holder IP33 (splash-protected)

Electrical supply
Power supply:
100-230 V ±10% / 50-60 Hz 14 VA
Pump holder output: 7.75 V/800 mA
Battery type: NiMH 4.8 V 1.8 Ah (Nickel-Metal Hydride)
Battery life: 40 hours at 125 ml/h
The maximum battery life could only be achieved after several charge/discharge cycles.
Avoid short circuit and excessive temperature.

Equipment group
Class IIb
(Medical Devices Directive 93/42/EEC)
Class III
(Canadian Medical Devices Regulations SOR/98-282)

Environmental conditions of transport and storage between uses:
Temperature:-20°C to 45°C
Relative humidity: 10 to 85%, no condensation
Atmospheric pressure: 700 to 1060 hPa

Pump, pump holder operating conditions:
Temperature: +13 to +40°C
Relative humidity: 20 to 85%, no condensation
Atmospheric pressure: 700 to 1060 hPa
Altitude: max 3000m

Attachment size (vertical/horizontal)
cylinder shape: 18-36 mm
square shape: 10x25 mm

Deviation of rate
± 5% at 22.5°C ± 2.5°C, pressure < 0.1 bar, flow rates above 10 ml/h

Downstream occlusion detection

Occlusion pressure (downstream), 2 levels:
L. approx. 0.5 bar
H. approx. 0.8 bar

KVO:
0 - 10 ml/h
preset 2 ml/h

Infusion program:
Continuous, volume/time, ramp, intermittent

Nurse call
Potential-free switch, 4 KV, decoupling
Power output: 24 V / 100 mA to power Nurse Call*****

Serial communication
RS232 optical isolation 4 kV*****
Communication format: 9600 baud / Even parity / 7 data bits / 1 stop bit

*****Connected only to SELV circuits (<60VDC)

Warning

- *The internal battery should be changed every 2 years. In case of a prolonged storage period (more than 4 months), it is recommended that the battery is removed.*
- *Battery replacement must be performed by qualified and trained technical personnel in compliance with the technical manual and procedures.*

7.2 Occlusion alarm

Table 7.2 - 1: Maximum time for activation of occlusion alarm at different flow rates and Bolus volume generated when pump operating at 125 ml/h and reaching the minimum and maximum occlusion alarm threshold*:

	Occlusion alarm treshold			
	LO (Low)		**HI (High)**	
Flow rate	Time of detection	Volume after occlusion release	Time of detection	Volume after occlusion release
10 ml/h	< 10 min	< 2.0 ml	< 15 min	< 2.0 ml
125 ml/h	< 30 s	< 1.5 ml	< 1 min	< 1.5 ml

* Data as evaluated by the test methods of IEC 60601-2-24.
Note: the bolus volume after occlusion release (2 ml) is not considered as a hazardous situation when the device is used for its intended use.

7.3 Flow rate trumpet and start up curves

The trumpet curve shows the variation of the mean flow rate accuracy over specific observation periods. The variations are presented only as maximum and minimum deviations from the overall mean flow within the observation window.

Trumpet curves are presented below for a number of representative flow rates.

The test protocol used to obtain these results is described in IEC60601-2-24.

The curves can be helpful in determining the suitability of infusion parameters for specific drugs and concentrations.

Set used: ***activ*** Set ambulatory.

Fluid used: ISO class III water.

7.3.1 Minimum flow rate : 10 ml/h

Data as evaluated by the test methods of IEC 60601-2-24
Sampling time : 30 seconds

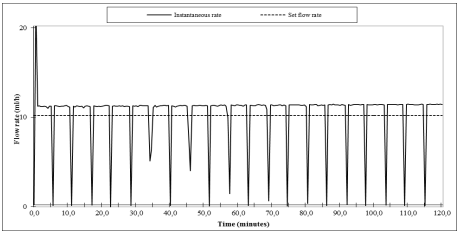


Figure 7.1: Start-up and instantenous flow rate (10ml/h, over first 2h of the test period)

Sampling time : 30 seconds

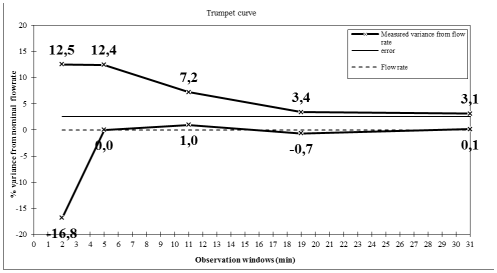


Figure 7.2: Trumpet curves For 2, 5, 11, 19, 31 minutes observation windows (10 ml/h over second hour of the test period)

Sampling time : 30 seconds

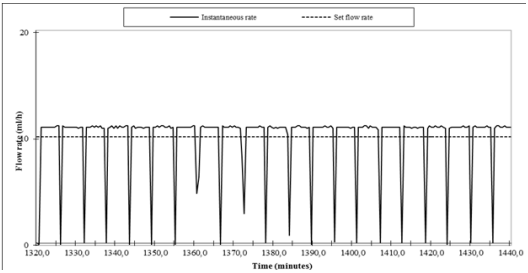


Figure 7.3: Instantenous rate (10 ml/h, over last 2h of set change interval,24h)

Sampling time : 30 seconds

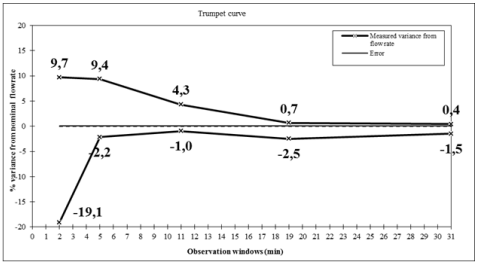


Figure 7.4: Trumpet curves For 2, 5, 11, 19, 31 minutes observation windows (10 ml/h, over last hour of the set change interval,24h)

Sampling time : 15 minutes

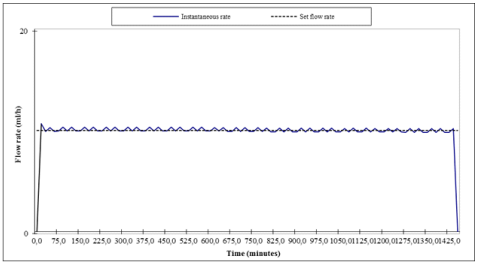


Figure 7.5: Instantenous flow rate (10ml/h, over set change interval 24h)

Sampling time : 15 mins

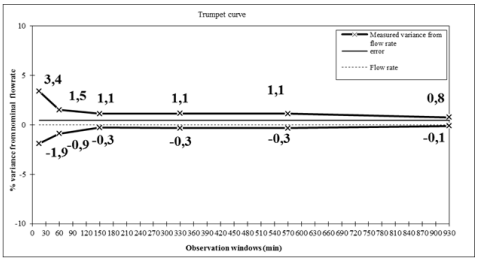


Figure 7.6: Trumpet curves For 15, 60,150, 330, 570, 930 minutes observation windows (10 ml/h over set change interval 24h)

7.3.2 Intermediate flow rate : 125 ml/h

Sampling time : 30 seconds

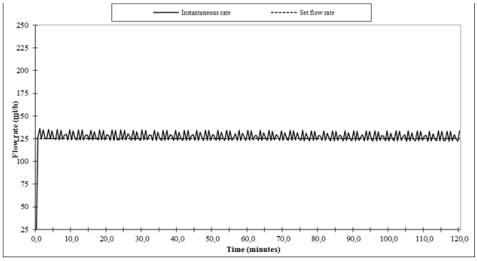


Figure 7.7: Start-up and instantenous at intermediate flow rate (125ml/h, over first 2h of the test period)

Sampling time : 30 seconds

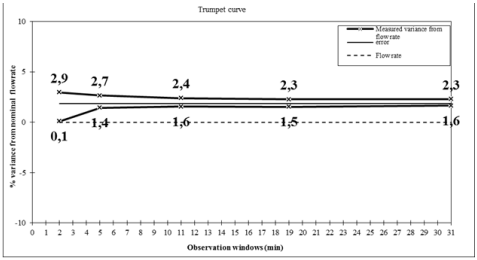


Figure 7.8: Trumpet curves For 2, 5, 11, 19, 31 minutes observation windows (125 ml/h over second hour of the test period)

Sampling time : 30 seconds

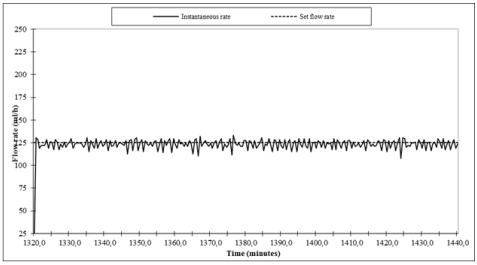


Figure 7.9: Instantenous rate (125 ml/h, over last 2h of set change interval,24h)

Sampling time : 30 seconds

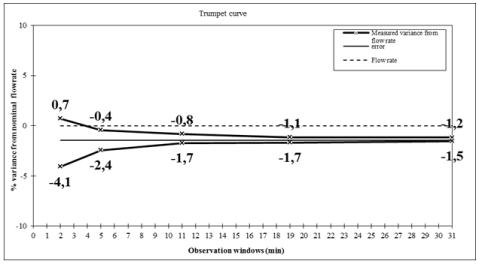


Figure 7.10: Trumpet curves For 2, 5, 11, 19, 31 minutes observation windows (125 ml/h, over last hour of the set change interval,24h)

Sampling time : 15 minutes

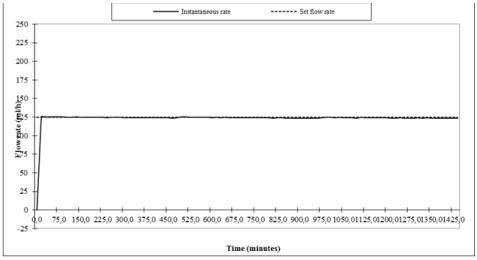


Figure 7.11: Instantenous flow rate (125ml/h, over set change interval 24h)

Sampling time : 15 minutes

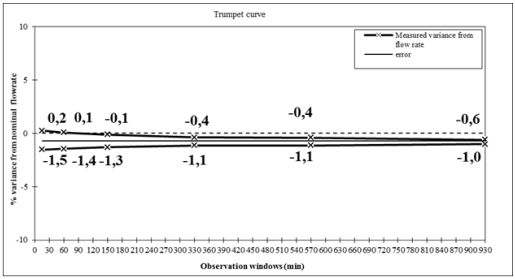


Figure 7.12: Trumpet curves For 15, 60, 150, 330, 570, 930 minutes observation windows (125 ml/h over set change interval 24h)

7.4 Accuracy

Warning

Accuracy (flow rate, volume infused, pressure) can be influenced by fluid viscosity, fluid temperature and TPN product that is not fully compatible with a 1.2 micron filter on the set.

Note: All tests below are in accordance with the IEC 60601-2-24 standard and tested with ISO Class III water.

7.4.1 Flow Rate Accuracy

	Accuracy
Cumulative Flow Rate*	± 5 % for 24 hours

* Test condition: *Back pressure:* 0 mmHg, *Container height:* 50 cm, room temperature at 22°C. ± 5 % on the rate range 100-450 mL/h, additional maximum rate error of ± 4 % for other rate ranges.
Note: the flow rate accuracy varies by 0.35% per °C variation of the room temperature.

7.4.2 Effects of Pressure Variations on Accuracy

	Accuracy	
Effects of Pressure Variations on Flow Rate Accuracy*	**Back pressure**	**Accuracy (from mean values)**
	+ 13.33 kPa	~ - 2 %
	- 13.33 kPa	~ + 2 %
Effects of Negative Solution Container Heights on Flow Rate Acuracy**	**Container Height**	**Accuracy (from mean values)**
	-15 cm***	- 2 %
	0 ➔ 50 cm	+ 5 %

* Test condition: *Container height:* 50 cm

** Test condition: *Back pressure:* 0 mmHg

*** Due to set length the container cannot be placed below - 15 cm

8 Guidance and Manufacturer's Declaration on EMC

The **Ambix *activ*** pump is intended to be used in electromagnetic environments such as those specified below:

- Homecare
- Nursing home
- Ambulatory care department in hospital.

The customer or user of the **Ambix *activ*** pump must ensure that it is used in such environments.

The **Ambix *activ*** pump is used for parenteral nutrition or for antibiotic treatments.

Excluded medical and special electromagnetic environments:

- Pediatric, neonatal, adult intensive care units
- Emergency services
- Operating rooms, surgery
- MRI (magnetic resonance imaging)
- X-rays imaging including CT scanner and radioscopy
- Nuclear imaging including PET scanner
- Internal or external radiotherapy
- Curietherapy with implantable radio sources
- Air and ground ambulances
- Proximity with electrosurgical unit, cables and electrodes

The customer or user of the **Ambix *activ*** pump must ensure that it is not used in such environments.

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.

8.1 EMC and essential performance

In standard operating conditions (homecare, nursing home and ambulatory care department in hospital), the essential performance of the **Ambix *activ*** pump is defined as follows:

- Flow rate accuracy
- Occlusion detection
- High priority alarms (empty bag/air detection), door open detection.

In the event of electromagnetic disturbances above the limits defined in the applicable EMC standards, if the essential performance is lost or degraded, the consequences for the patient are under infusion.

It is the responsability of the customer or user to check the equipment before use as described in Section 6, page 40 and to consider the EMC guidance of Section 8.2, page 50.

8.2 Electromagnetic compatibility and interference guidance

Warning

- *Use of the **Ambix activ** pump adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.*
- *Use of accessories, transducers and cables other than those specified or provided by the manufacturer of the **Ambix activ** pump could result in increased electromagnetic emissions or decreased electromagnetic immunity of the pump and result in improper operation.*
- *Portable RF communication equipment (including peripherals such as antenna cables, internal and external antennas) should be used no closer than 10 cm for cell phones and 30 cm for other equipment, to any part of the **Ambix activ** pump, including cables specified by the manufacturer. Otherwise, degradation of the essential performance of **Ambix activ** pump could result.*

The user might be required to take mitigation measures, such as relocating or re-orienting the equipment.

If the **Ambix *activ*** pump is placed near RF communication equipment such as cell phones, DECT phones or wireless access points, RFID reader and tags, ... it is essential to observe a minimum distance between the **Ambix *activ*** pump and the equipment specified above. If the **Ambix *activ*** pump 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 **Ambix *activ*** pump, the patient, or the disruptive equipment.
- Change the routing of cables.
- Connect the **Ambix *activ*** pump mains plug to a protected, backed-up, or filtered supply, or directly to a UPS (uninterruptible power supply) circuit.
- Increase the separation between the **Ambix *activ*** pump and the disruptive equipment.
- Connect the **Ambix *activ*** pump into an outlet on a different circuit from that to which the patient or disruptive equipment is connected.

If the problem remains, the pump shall not be used in such environment.

For further information on EMC compliance, please refer to the **Ambix *activ*** Technical Manual.

9 Warranty, inspection and repair

9.1 Warranty

Please refer to the terms and conditions of the local **Fresenius Kabi** organisation or the local distributor for the duration of the warranty.

The warranty covers repair and replacement of components proven to be defective in material or workmanship. The warranty does not extend to units that have been altered, repaired or modified by unauthorised persons and malfunctions which are due to improper handling and wear.

The manufacturer is responsible for the safety, reliability and performances of the nutrition pump if:

- assembly, extensions, readjustments, modifications or repair have been performed by persons authorised by **Fresenius Kabi,**
- the electrical installation site where the pump is used complies with the requirements of the IEC regulations,
- the pump is used as specified in these Instructions for use, according to its intended use as defined in Section 1.1, page 6
- the pump is operated with the sets specified by the manufacturer (see Section 2.3, page 15).

9.2 Maintenance requirements

The recommended maintenance interval for the **Ambix *activ*** and the pump holder is two years or the application of 1,000 litres (equivalent to 8,000 hours at 125 ml/h). The **Ambix *activ*** indicates the application of 1,000 litres by showing the wrench symbol permanently in the display.

Pump performance over life cycle is ensured only if the recommended maintenance is performed.

Warning

- *Pump and pump holder may only be repaired by the manufacturer's Pump Maintenance Department or persons authorised by them. Failure to observe this leads to loss of warranty. In the event of a fault, always send in the complete system (pump, pump holder and set).*
- *If the device is modified (repaired), appropriate inspection and testing must be conducted to ensure continuated safe use of equipment.*

Pump maintenance: Contact the local **Fresenius Kabi** organisation or the local distributor.

Recycling of obsolete battery and devices:

Before disposal, remove battery from the device. Battery 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 pertaining to waste processing regulation, contact your local **Fresenius Kabi** organisation or the local distributor.

10 Cleaning and Disinfecting

Warning

- *Do not submerge the pump in water or any liquid!*
- *Not for use in the dishwasher.*

10.1 Cleaning Instructions

Didecyldimethylammonium chloride shall be used as the cleaning agent (example : WIP'ANIOS EXCEL by Anios).

Prerequisites:

- The pump is powered off.
- The power cord and all other cables are unplugged.
- The pump is disconnected from the holder.
- The room temperature is between 20 and 25 °C.
- The operator is wearing suitable protective equipment.

Protocol:

1. Place the pump and the holder on a clean surface or disposable underlay. The door can be removed from the pump to facilitate the cleaning.
2. During cleaning, do not turn the pump upside-down to avoid liquid leaking into the pump.
3. Use a ready-to-use wipe to remove any major grime.
4. Thoroughly wipe down all exposed surfaces (housing, keyboard, holder connection area, etc.) of the pump, from top to bottom.

   Gently wipe down the exposed mechanism of the pump and the sensor area (tube guide, clamp insert).

   A cleaning process of 1 minute minimum 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, and hard-to-reach areas.
5. Repeat step 4 with the pump door (housing, lever, counter door) and holder (pole clamp screw, housing, screw area, etc.)
6. Using a fresh ready-to-use wipe, thoroughly wipe down all exposed surfaces. A cleaning process of 1 minute minimum 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.

10.2 Disinfection instructions

Didecyldimethylammonium chloride shall be used as the disinfectant agent (example : WIP'ANIOS EXCEL by Anios).

Prerequisites:

- The cleaning protocol has been performed.
- The pump is powered 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 clean surface or disposable underlay. The door can be removed from the pump to facilitate the disinfection.
2. During disinfection, do not turn the pump upside-down to avoid liquid leaking into the pump.
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.

11 ORDER INFORMATION

Art.-No.	Description	OP
2892130*	**Ambix act*iv* GB**	**1**
2892191*	**Ambix act*iv* ZA**	**1**
Disposables		
2892095	**act*iv*** Set ambulatory	**15**
2892100	**act*iv*** Set ambulatory SF	**15**
2892098	**act*iv*** Set stationary SF	**15**
2892091	**act*iv*** Rucksack	**1**
2892101	**act*iv*** Rucksack mini	**1**
Accessories		
**	**Rolling stand**	**1**

* Contains **Ambix *activ*** (Art. - No. 2892000), ***activ*** holder, power cable, and Instructions for use.
** Contact **Fresenius Kabi** for appropriate Rolling stand

For any assistance, if needed, in setting up, using or reporting unexpected operation or events, please contact your homecare provider. **Fresenius Kabi** can be contacted at the following address.

Fresenius Kabi AG
61346 Bad Homburg
Germany

Fresenius Vial S.A.S
Le Grand Chemin
38590 Brézins
France

www.fresenius-kabi.com

CE 0123

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Software version: 2.3

First CE Mark: November 2007

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