FRESENIUS KABI

caring for life

Ambix nova

Ambulatory Infusion Pump

Version V1.0

Instructions For Use

Symbol descriptions

MD Medical Device	UDI Unique Device Identifier
Refer to the Instructions For Use	CE 0123 CE mark
Protection against electric shock: class II	Medical electrical system weight (kg)
REF Product reference / part number	SN Product serial number
Name and address of the manufacturer	Name and address of the manufacturing facility
Battery specification	Protection against leakage current; defibrillation-proof type CF applied part
Direct Current (DC)	Alternating Current (AC)
Output terminal - connector	Input terminal - connector
Fragile, handle with care	This way up
Keep away from rain	Temperature limitation
Humidity limitation	Atmospheric pressure limitation
General symbol for recyclable material	Part included in a recycling process
Accompanying documents	

UDI
(01)04086000851794
(21)12345678
(11)190730
(240)N044590

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

IP32 **Smart Holder Power**: 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.

Information: recommendations to be followed.

INFORMATION

- Please refer to the Use environment section for additional information on temperature, pressure and humidity limitations.
- These Instructions For Use (IFU) are also available online. For further information, check IFU for Ambix nova (ref.: DHF-0279) on *https://key2.fresenius-kabi.com*.

Table of contents

1 Introduction

1.1 Scope

These Instructions for Use (IFU) are applicable to the Ambix nova ambulatory infusion pump referred to as pump with software version V1.0.

WARNING

- Check that these IFU are applicable to the current Ambix nova software version. The software version of the pump is displayed in pump's information menu (check *Information* on page 72 for acccess).
- Failure to adhere to the instructions specified in this document may result in damage to the equipment, injury to patients, or injury to users.

INFORMATION

The screenshots in this document are for illustrative purposes only. Screen contents may vary based on individual configurations; therefore, not all screenshots may correspond to what you see on a specific device.

1.2 Principle of operation

Ambix nova is an ambulatory programmable electronic medical system dedicated to administering a pre-determined volume of infusion product at a programmed rate. This peristaltic pump ensures fluid delivery using pumping and clamping fingers to advance the liquid to the patient through an administration set.

Ambix nova is a transportable and reusable device that can be used daily.

Ambix nova can be used in:

- flow rate only mode

- ramp mode

- continuous mode

- intermittent mode

Ambix nova is intended for use on only one patient at a time. It can be reused indefinitely on multiple patients throughout its lifetime.

1.3 Intended purpose

Ambulatory infusion pump and accessories for IV administration of specific fluids.

1.4 Intended use

1.4.1 Indications

The Ambix nova is indicated for intravenous (IV) administration of parenteral nutrition, neutral solutions and antibiotic therapy.

1.4.2 Contraindications

DO NOT USE:

- with life-sustaining critical application drugs, or drugs with short half-life;
- for enteral administration;
- if parenteral nutrition is contraindicated;
- for infusion of insulin;
- with neonates.

1.4.3 Intended user profile

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

Patient and patient relatives must only use the pump under the responsibility of a qualified and trained healthcare professional.

It is recommended that user attend an at least 60 minutes initial training session. It is recommended that users attend a refresher training session every year. For training, contact your Fresenius Kabi sales representative.

INFORMATION
Product specialists are in charge of configuration and maintenance of pumps according to the technical manual.

1.4.4 Intended patient population

The pump is intended for use on adults and children. It cannot be used on neonates.

The pump is intended for use in accordance with healthcare facilities and healthcare providers protocols. All pump settings must be made according to the medical prescription.

1.4.5 Use environment

WARNING

- Keep the pump, sets and cables away from unsupervised children.
- Keep the pump, sets and cables away from pest, animals and pets.
- Keep away from heat sources, dust, fluff, direct and prolonged light exposure.
- The pump should be used under specified operational conditions listed below to ensure pump performance.

Ambix nova is an ambulatory infusion system intended to be used in a home environment (homecare and nursing home) and in ambulatory care environment.

The pump should be used in the following operational conditions to ensure proper performance:

- Operating temperature range: 5°C to 40°C
- Operating humidity range: 20% ~ 85%, no condensation

- Operating pressure range: 700 hPa to 1060 hPa
- Operating altitude range: Less than 3000 m

DO NOT USE IN:

- MRI (Magnetic resonance imaging)
- Nuclear imaging including PET scanner
- Internal or external radiotherapy
- Curietherapy with implantable radio sources
- Proximity with electrosurgical unit, cables and electrodes
- Hyperbaric chambers

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

When the pump is stored at a temperature outside the operating range, wait for 2 hours to allow the product to reach the operating temperature range before using the pump. An alarm can be triggered if the pump / set temperature is too low or too high.

For storage and transport use condition, see *Storage and transport conditions* on page 95.

1.5 Clinical benefits

Clinical benefits are achieved through the functions provided to the intended users, which has a positive impact on patient management.

Clinical benefits of Ambix nova ambulatory pump are the following:

- Provide a controlled and reliable system for the infusion of parenteral nutrition, neutral solutions and antibiotics (volume delivery accuracy of the pump is ±5% above 10mL/h and flow rate is adjustable from 1 to 600 mL/h).
- Provide an easy-to-use interface and design to facilitate programming, monitoring and handling.
- Provide infusion functions adapted to the needs of patients and healthcare professionals (several infusion modes: flow rate only, continuous, ramp and intermittent modes; keep vein open function, delayed start function, history menu, infusion monitoring screen, adaptable flow rate, night mode).
- Provide users with safety features and relevant alarms that improve infusion safety and prevent unexpected infusion discontinuation (adjustable occlusion pressure threshold, adjustable bubble volume detection, nurse settings lock, alarm system compliant with EN/IEC 60601-1-8).

1.6 Side-effects

There is no side-effect directly related to the use of Ambix nova.

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 88) may result in: delay of therapy, underdose, overdose, incorrect therapy, exsanguination, infection, air embolism, trauma or electric shock.

2 Ambix nova infusion system

Ambix nova range		Description
Pump	**Ambix nova**	**Ambulatory Volumetric Infusion Pump** Ambulatory pump designed to deliver the contents of an infusion container (bag or bottle) through an intravenous (IV) line connected to a patient.
Software	**Amika and Ambix nova Partner**	**Maintenance Software** Software designed to maintain, configure, test and calibrate the Ambix nova and Amika pumps.
Accessories	**Smart Holder Power**	**Holder** The holder can be positioned on authorized support such as a pole, rail, bed, wheelchair, table and table stand. It allows the pump to be attached to it to ensure the pump is securely positioned. It is intended to supply the operating power and to charge the battery for the pump installed on it when it is connected to the mains power supply. For ordering information, check *Accessories* on page 102.
	Smart Holder COM	**Holder** The holder can be positioned on authorized support such as a pole, rail, bed, wheelchair, table and table stand. It allows the pump to be attached to it to ensure the pump is securely positioned. It is intended to supply the operating power and to charge the battery for the pump installed on it when it is connected to the mains power supply. It is intended to connect a pump to an external Nurse Call system to transmit a pump alarm state. It is intended to connect a pump to a PC for service activities via Partner software. For ordering information, check *Accessories* on page 102.
	USB Partner Cable	**USB cable** Communication cable for USB connection. This accessory allows the communication between a pump and a computer on the USB port. For ordering information, check *Accessories* on page 102.

Ambix nova range		Description
Equipment (backpack)	**activ Rucksack**	**Backpack for adults** Backpack with 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. For ordering information, check *Accessories* on page 102.
	activ Rucksack mini	**Backpack for children** Backpack with 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. For ordering information, check *Accessories* on page 102.
Disposables	**Ambix nova Sets**	**Administration sets** Administration sets dedicated to Ambix nova pump. For ordering information, check *Administration sets* on page 102.

3 Description

3.1 Packaging content

The Ambix nova packaging contains the following elements:

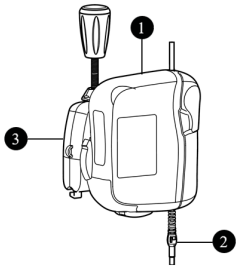
- 1 Ambix nova pump
- 1 Smart Holder Power (referred to as pump holder)
- 1 Power cable
- User documents

Packaging consists of: recycled cardboard.

Check the integrity of the content before use.

Symbols used on Ambix nova packaging are described in *Symbol descriptions* on page 2.

3.2 General description

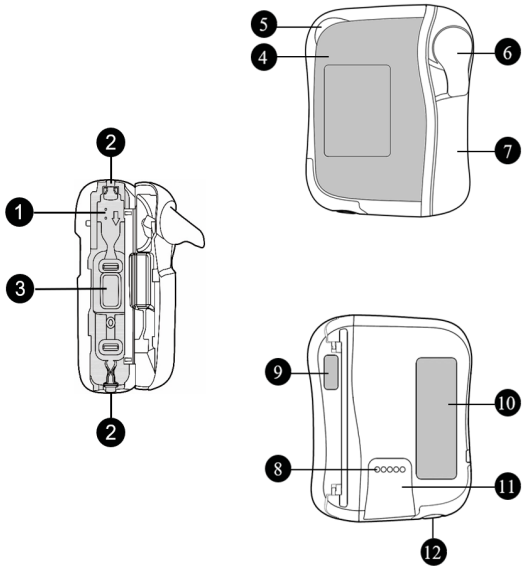


Legend

1. Pump
2. Infusion set (sold separately)
3. Smart Holder Power

3.3 Detailed description

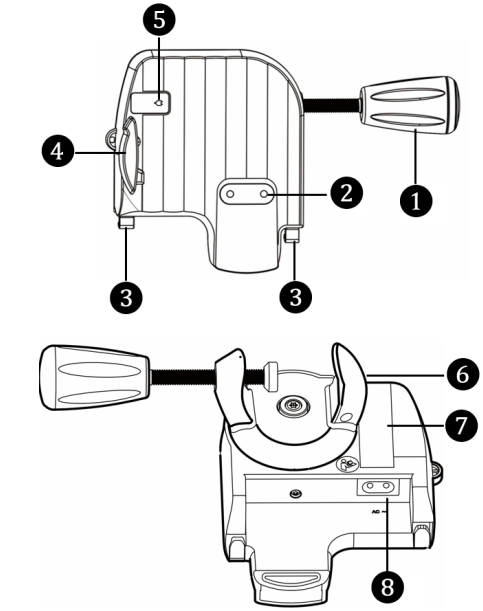
3.3.1 Pump



Legend

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

3.3.2 Smart Holder Power (Pump holder)

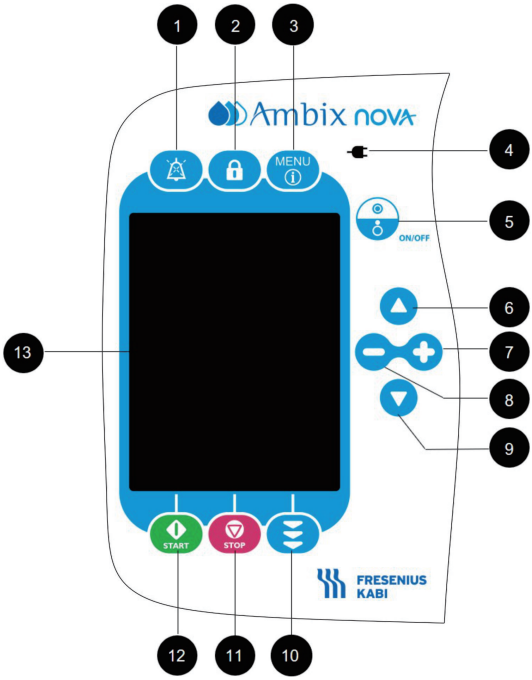


Legend

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

AC~ Near the power cable inlet of the holder, description in *Power supply specifications* on page 90

3.3.3 Front panel (keypad)



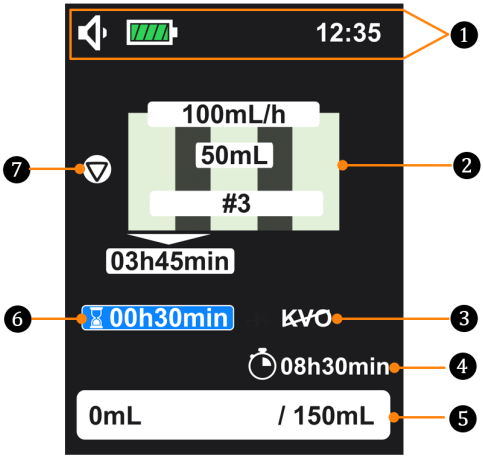
Legend

1. Alarm beep mute
2. Keypad lock / unlock
3. Menu & Information
4. Mains supply light indicator
5. ON / OFF key
6. Scroll up in Menu / Select previous field
7. Increase value / Active function
8. Decrease value / Deactive function
9. Scroll down in Menu / Select next field
10. Prime
11. Stop / Cancel
12. Start / Validate
13. Display (described below)

3.4 Display description

3.4.1 Infusion screens

Infusion programming screen layout



Legend

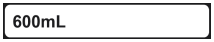
1. Status bar
2. Infusion parameters
3. KVO (keep vein open) status indicator
   Detailed information are described in *KVO (Keep Vein Open)* on page 66
4. Remaining time
5. Progress bar
6. Delayed start
   Detailed information are described in *Delayed start* on page 55
7. Pumping status indicator

To program the infusion parameters, see *Programming the infusion settings* on page 32.

Infusion monitoring screen layout

Legend

1. Infusion mode symbol
2. Ongoing flow rate
3. Remaining time
4. Progress bar
5. Pumping status indicator

Pumping status indicator			
	Pumping is in progress		Infusion start but no pumping (pause status during intermittent mode with KVO deactivated)
	Infusion is stopped		Infusion start but in delayed start period (no pumping if KVO is deactivated)
Progress bar			
 or  in flow rate only mode		On the left side of the progress bar "**75 mL**" indicate **infused volume** and on the right side "**150 mL**" indicate **total volume to be infused**. In **flow rate only mode**, there is no total volume to be infused, therefore, only the **infused volume** "**600 mL**" is displayed on the left.	
Infusion mode symbols			
	Flow rate only mode		Continuous mode
	Ramp mode		Intermittent mode

For infusion screens on each mode, see *Infusion mode* on page 44.

3.4.2 Menu screen

Menu screen layout

Legend

1. Status bar
2. Menu list
3. Soft key bar

Status bar			
	Sound level icons		Alarm icons
	Battery icons (check details in *Battery operating mode* on page 24)		Muted alarm icon
	Keypad locked icon		Nurse settings lock icon
Soft key bar			
	Semi-automatic Prime		Automatic Prime
	Validate the setting / Confirm the result		Back to previous screen / Back to infusion programming screen

Menu list is detailed in *Menus description* on page 41.

4 Installation and removal

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

4.1 Installation

4.1.1 Recommended installation

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

WARNING

- Do not place the pump more than 1.3 meter above or below the patient.
- Do not vary the pump height while a patient is connected to it. This may lead to patient harm.
- Give particular attention to the risk of strangulation with cables and sets, and with the small parts that could be swallowed or inhaled.

INFORMATION

- It is recommended not to remove the pump from its pole or rail when it is connected to the patient.
- Check that the power cable is connected and the device is operational after movement of the pump.

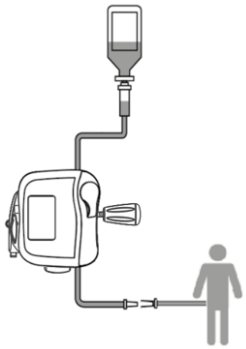
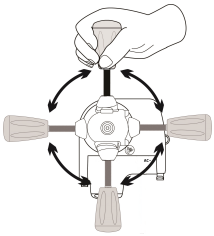


Figure 1: Recommended installation

Fresenius Kabi recommends placing the container 50 cm (± 5 cm) above the pump

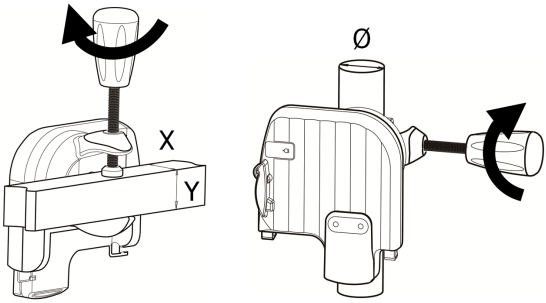
4.1.2 Using the pole clamp

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



4.1.3 Positioning the holder on a rail, pole, bed or wheelchair

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

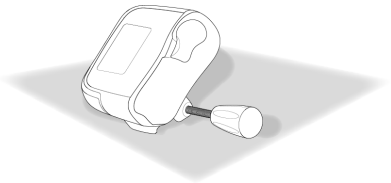


X, Y min = 10 mm
X, Y max = 35 mm
Ø min = 8 mm
Ø max = 40 mm

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

4.1.4 Positioning the holder on a table

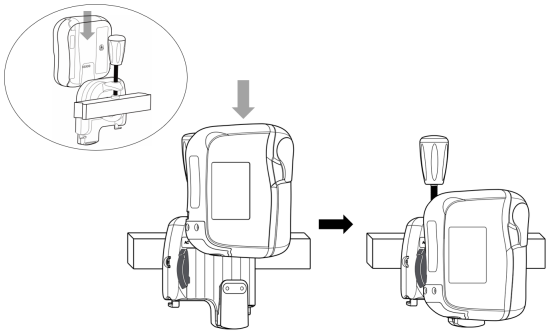
The holder can be placed on a flat and horizontal table as indicated in the figure.
Ensure the pump is positioned away from table edges to avoid being accidentally pushed off the table.



4.1.5 Positioning the pump

WARNING
Do not use the holder and send to maintenance service in case of mechanical damage of the holder locking/unlocking system.

Slide the pump down until the grey locking lever locks the position (be sure to hear the "Click" sound).



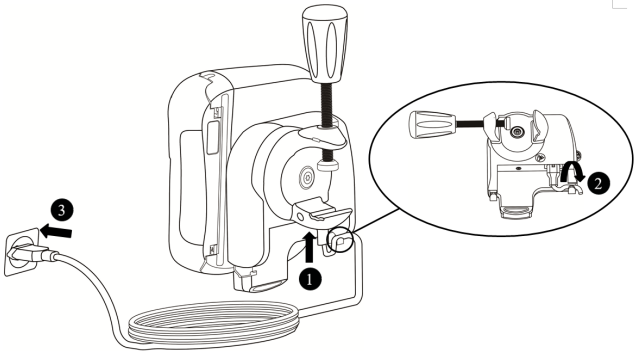
4.1.6 Electrical connection

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. Pinch the cable into the slot provided for this purpose.
3. Plug the power cable to the mains socket.
4. When the pump is powered by mains power supply, check the pump front panel to confirm that the mains supply light indicator is on.

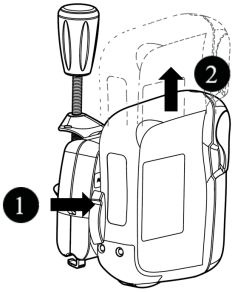
- The mains power supply is indicated by a green light on the holder's front panel as well as on the pump's front panel (keypad).
- A beep is emitted by the pump when the pump is connected to the mains.



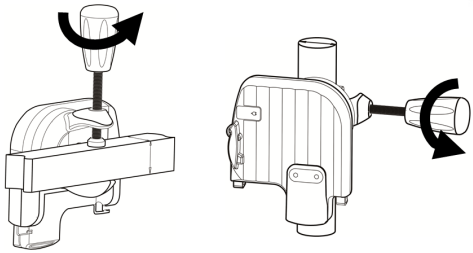
4.2 Removal

4.2.1 Removing the pump from the pump holder

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

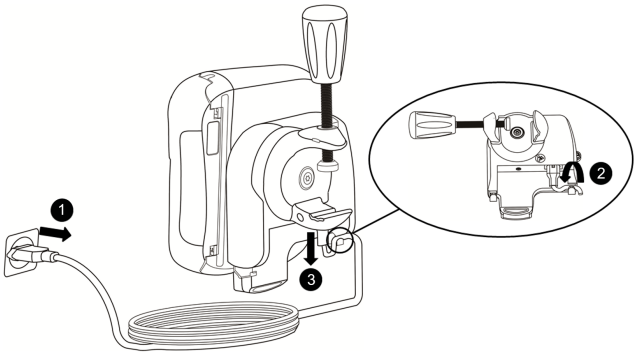


4.2.2 Removing the pump holder



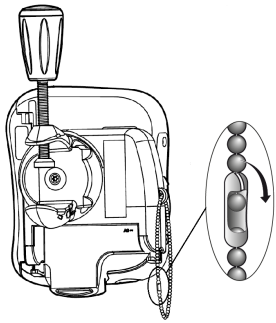
4.2.3 Electrical disconnection

1. Remove power cable from the mains socket.
   - A beep is emitted by the pump when the power cable is disconnected.
   - To store the pump, see *Storage* on page 95.
2. Remove power cable from the slot.
3. Remove power cable from the holder.



4.2.4 Attaching / Removing the Quick Guide

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



5 Operations

5.1 Power management

5.1.1 Connect to the mains

Before connecting to the mains power supply, check that the mains power supply voltage corresponds to the value indicated on the label on the back of the pump holder. Do not exceed the permitted voltage.

WARNING

- The power outlet must remain accessible at all times to allow emergency power supply disconnection.
- The pump and its accessories can only be connected to the mains power supply with the power cable supplied by Fresenius Kabi.

For connection, described in *Electrical connection* on page 21.

5.1.2 Battery operating mode

The device is provided with an internal battery that automatically provides power to the device in case of power failure or disconnection from the mains power supply. The battery charges when the pump is connected to mains power supply.

Before starting for the first time, charge the battery for at least 6 hours by plugging in the power supply cable with the pump powered off.

INFORMATION
During operation, leave the device connected to the power supply to maintain the battery's charge and maximum capacity, and to maximize battery lifetime and performance.

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

Battery life	A minimum of 24 hours at 25 mL/h and a minimum of 14 hours for flow rate at 600 mL/h in the following conditions: ■ after battery maximum charge ■ with minimum backlight ■ temperature at 22.5°C ± 2.5°C ■ new battery with maximum 5 cycles of charging and discharging
 (green)	When the pump is connected to the mains (see *Electrical connection* on page 21) ► Battery charges automatically, also during operation
	When the pump is disconnected from the mains (see *Electrical disconnection* on page 22) ► Pump switches to Battery Mode automatically

	The battery is fully charged
	The battery is 80% charged
	The battery is 60% charged
	The battery is 40% charged
	The battery is 20% charged
 (in yellow)	The battery is nearly empty Battery life is at least 30 minutes remaining ►A pre-alarm is triggered (see *Alarm description* on page 80)
 (in red)	The battery is empty (approx. 10 minutes left), an alarm is triggered (see *Alarm description* on page 80)

INFORMATION

- 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.

5.1.3 Battery precautions

The device uses a Lithium-ion rechargeable battery.

The following actions may cause leakage, overheating, smoke, explosion or fire, which could result in deterioration of performance, failure, damage to the equipment or injury to the user:

- Incorrect handling of a Lithium-ion battery.
- Replacement of the battery by inadequately trained personnel.

INFORMATION

- Do not replace with a battery other than the one provided by **Fresenius Kabi**.
- Do not use the pump without the battery connected.
- Do not disconnect the battery when the device is operating on mains power supply or battery power. Disconnect the power cable and power off the device before disconnecting the battery.
- Do not incinerate or place near a flame.
- Do not drop, crush, puncture, modify or disassemble the battery.

- Do not use a battery that is severely scratched or damaged.
- Do not short the terminals.
- Do not expose to high temperatures or very low temperatures:

  refer to the operating conditions for use, and the storage and transport conditions.
- Do not try to charge or discharge the battery outside the device.
- For more information on replacing the battery, refer to the technical manual.

5.2 Switch on

INFORMATION

- Before using the pump, proceed to *Quick check protocol* on page 77.
- When using a pump on patient requiring special attention, ensure that a backup pump is available for immediate use especial in homecare environment.
- Before switching on the pump, install holder and pump, see *Installation* on page 19.
- The pump can operate using the battery, however, we recommend that the pump be connected to a power supply as often as possible during use to ensure that the battery remains charged.
- When the pump is connected to the power supply, check that the power supply indicator lights up green , and that the power cable and the wall plug are accessible.

To switch on the pump, press the ON/OFF key until the screen light up.
At start-up, the device displays the product name and logo, the version number of the pump's software. An auto-test checks the functionality of the module.

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 medium, melody is on medium, if sound level is high, melody is on high).

NOTE: When display switches from switch on screen to main screen, the main screen displays the last validated infusion settings.

5.3 Preparing the set

In order to protect user health from infection, please follow aseptic handling procedures for container, set and infusion tube.

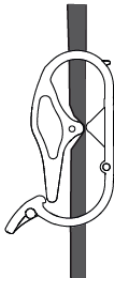
Only Fresenius Kabi infusion sets can guarantee pump reliability (*Ordering information* on page 102)

WARNING

- Do not use incompatible sets, it can lead to patient harm.
- Check the infusion set and patient connection integrity before use to protect the patient from underdose, trauma and infection.
- Change the set after 24 hours of use to avoid therapeutic issues.

5.3.1 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.

5.4 Loading the set

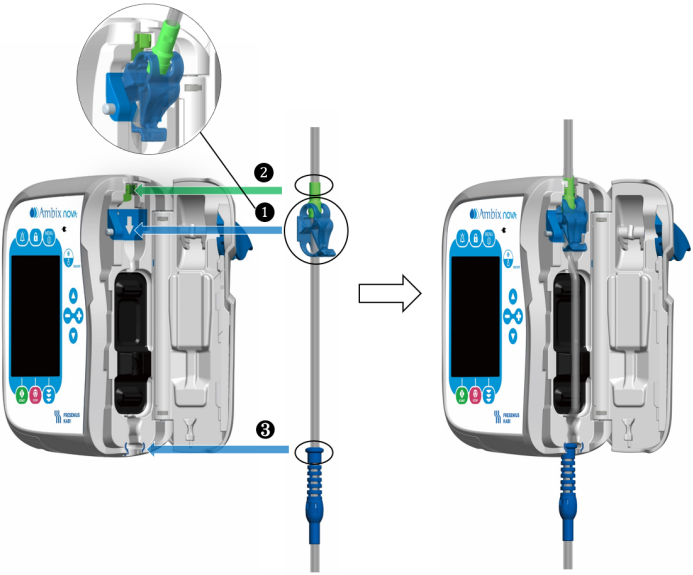
To connect / disconnect or change the container and set, please refer to the Instructions for Use of the administration set.

When using the pump on a patient requiring special attention, ensure that a backup gravity set is available for immediate use specially in homecare environment.

When the set is load in the pump, it must not be connected to the patient.

1. Open the pump door by lifting the door lever ;

2. Align the set along with the tube guide of the pump with the right flow direction (the arrow mark on the pump indicates the direction of the flow).
3. Insert the blue pinch clamp ❶ into the blue cavity of the pump with 45 ° angle, then push the green connector ❷ towards the green area to secure the position.
4. Keep the tube straight without any twist and knot, and push the upper ring of the blue antikink ❸ into the coordinated pump notch (circled with blue colour).



5. Close the pump door by pushing the door lever down .

5.5 Priming the set with the pump (recommended)

WARNING

- Patient must not be connected to the set when priming is performed.
- Check the air absence in the infusion set at the end of priming.

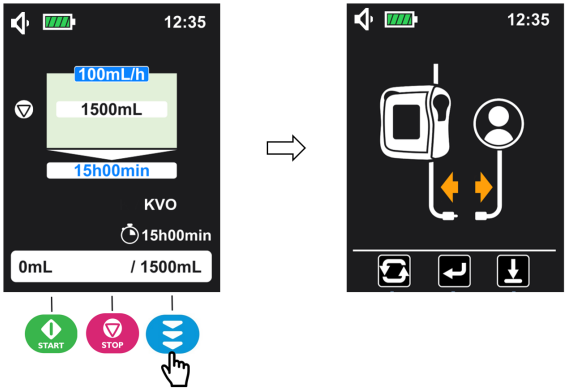
INFORMATION

- To proceed to infusion set priming, fill drip chamber 2/3 full by pressing gently if applicable.
- Automatic and semi-automatic priming fill the infusion set at a rate of 600 mL/h and are stopped after 24 mL ± 10%.
- During priming, the air in line alarm is disabled.

5.5.1 Access priming interface

Priming interface is only accessible when pump is on infusion program interface (the following screen illustrates these principles).

Press prime key to enter priming interface.



Under priming interface, Ambix nova pump enables two ways of priming:

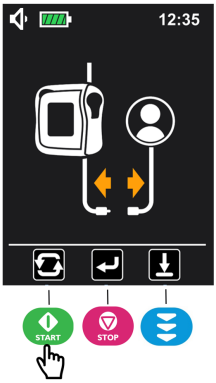
- **Automatic priming**: Pump automatically fills in the infusion set at maximum rate once (START) key is pressed;
- **Semi-automatic priming**: Pump fills in the infusion set at maximum rate while user press and **HOLD** the ( ) key.

NOTE: Before priming is launched, press (STOP) ( ) key can exist the priming interface and return to the programming screen.

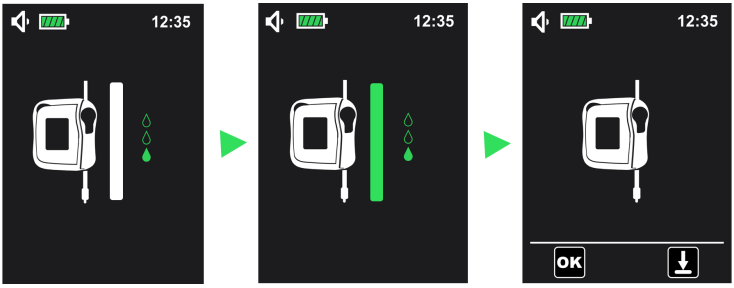
5.5.2 Automatic priming

Check the administration set to make sure it is not connected to the patient.

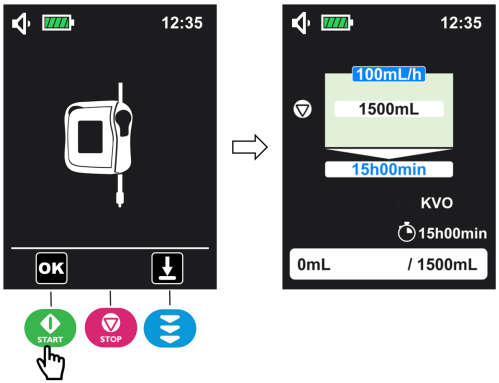
1. Under priming interface (see *Access priming interface* on page 29 to access), press (START) ( ) key to launch automatic priming.



2. **Wait** until the progress bar has filled up and the pump stops priming automatically.



3. Check the administration set to make sure there is no air in the line.
4. If necessary, press and hold (⏬) key to perform semi-automatic priming (see *Semi-automatic priming* on page 31) until no air can be found in the line.
5. Press START (OK) key to confirm. Pump automatically goes back to the infusion programming screen as illustrated below.

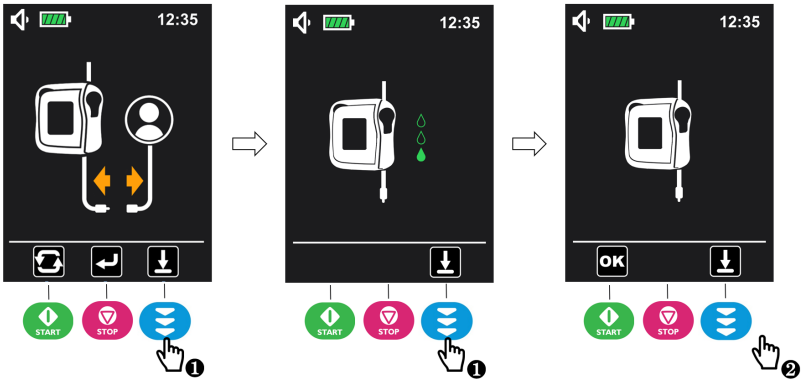


Note: Automatic priming can be stopped at any time by pressing the STOP key. Once it is stopped, it is possible to continue priming by using *Semi-automatic priming* on page 31.

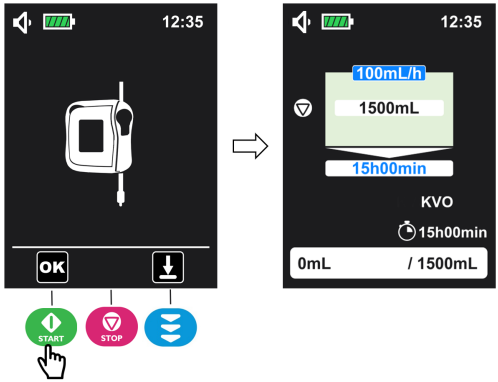
5.5.3 Semi-automatic priming

Check the administration set to make sure it is not connected to the patient.

1. Under priming interface (see *Access priming interface* on page 29 to access), ❶ press and **Hold** ⏬ (⬇) key to prime and ❷ release it when priming is complete.



2. Check the administration set to make sure there is no air in the line.
3. If necessary, repeat step 1 to restart priming to make sure no air can be found in the infusion line.
4. Press START (OK) key to confirm. Pump automatically goes back to the infusion programming screen.



5.6 Programming the infusion settings

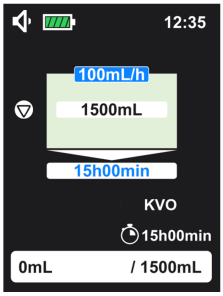
This section illustrates the programming of an infusion with the continuous mode (default infusion mode).

Check the infusion mode on current display:

For programming with different infusion mode, see *Infusion mode* on page 44.

For staying on the current infusion mode, following below steps:

1. Press  or  on the keypad to select the parameter needs to be adjusted and press  to adjust the value of the selected parameter (the selected parameter appears in a dark blue background).



2. Repeat step 1 until all parameters are set.

Incompatible values

When a new infusion is programmed with incompatible values:

- The selected parameter cannot be set to an incompatible value.
- The linked parameter to the parameter adjusted is out of setting range, the background changes to orange until the setting is compatible.

When infusion is stopped, and current parameters are changed:

- If the parameter adjusted is out of setting range, the selected and the linked values background flash in black.

Once all parameters are set, go to *Start infusion* on page 33.

INFORMATION

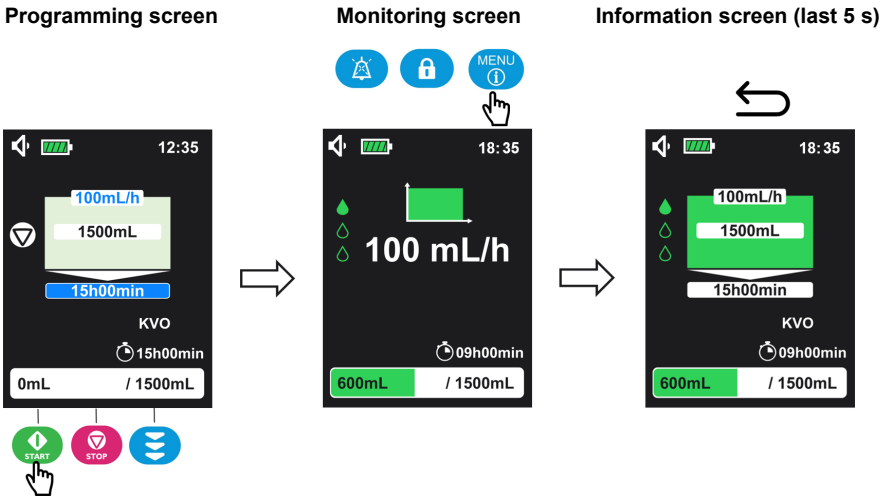
- A longer keypress provides faster scrolling.
- The flow rate of administration must be adapted individually to the patient. Regular checks are required.
- The selected parameter appears in a dark blue background and the linked parameter appears in a light blue.
- The linked parameter is calculated automatically when the other parameters are programed.
- For all modes, it is possible to change the infusion parameters when infusion is stopped.
- After switch on the pump, the pump stays on the last validated infusion programming screen.

5.7 Start infusion

1. Check the administration set integrity.
2. Check that no air remains in the administration set.

3. Confirm that the administration set is correctly installed in the pump.
4. Open the roller clamp (for stationary set only).
5. Connect the administration set to the patient's IV access device.
6. Check the infusion settings prior to start the infusion.
7. Press START to start infusion.

When the infusion starts, the pump displays the monitoring screen. To check the programmed values without stop infusion, press MENU to enter the information screen. The information screen will last 5 seconds then return to monitoring screen.



Infusion must be stopped to modify the current infusion parameters (more details, see *Stop infusion* on page 36).

INFORMATION
The infusion parameters cannot be programmed on the information screen and monitoring screen.

5.8 Keypad lock

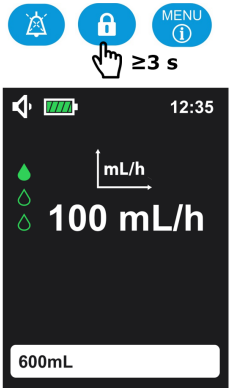
Keypad lock prevents from unintentional change of pump settings during infusion.

INFORMATION
Keypad lock cannot be activated under following condition:

- Priming is running.
- Technical alarm occurs.
- Empty battery alarm occurs.

To activate the keypad lock:

1. Press  for 3 seconds to activate the keypad lock.



NOTE: A beep sound can be heard when keypad lock is activated.

2. Check the  symbol is displayed in the status bar to confirm the keypad has been locked.

Once keypad is locked,  is the only active key. If other keys are pressed, the forbidden key beep (1 beep) is triggered, keypad lock symbol  is displayed on the main screen (see figure below).

Keypad can be unlocked by pressing again the keypad lock key for 3 seconds.

5.9 Mute alarm

To temporarily release alarm sound, press .

When a high priority alarm is muted:

- the mute icon is displayed and blinks in the status bar;
- the alarm symbol is displayed and the red 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 and blinks in the status bar;
- the alarm symbol is displayed and the yellow LED is fixed;
- the alarm sound is off for 2 minutes.

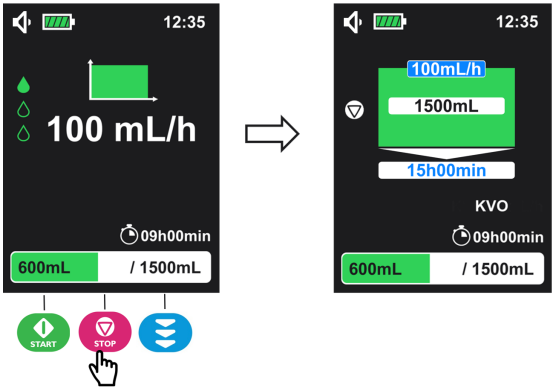
For further information about alarms, see *Alarms and safety features* on page 79.

INFORMATION
Technical alarms cannot be muted.

5.10 Terminate infusion

5.10.1 Stop infusion

- Press STOP key to stop infusion.

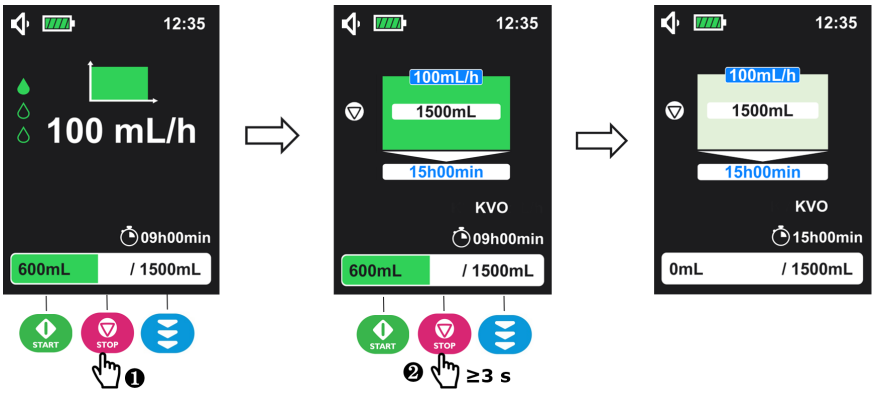


When infusion is stopped, infusion parameters can be adjusted. Then, infusion can be resumed by press START key.

5.10.2 Reset infusion progress

To reset infusion progress during pumping:

1. Press STOP key to stop infusion.
2. Press STOP key for 3 seconds to reset the infusion progress.



This action will reset the progress bar, remaining time and delayed start time (if delayed start is activated). A new infusion with programmed values can be launched again.

INFORMATION

- Stop an infusion to modify (or to validate) the delayed start settings (from menu configuring screen) or the maximum flow rate settings will reset the infusion progress.

- At the end of infusion (with or without KVO activate), press STOP key or switch off the pump can reset infusion progress.

5.11 Switch off pump

Infusion shall be stopped before switching off the pump.

Keep pressing for more than **3 seconds** to switch the pump off. The display will count down, 3-2-1, and the pump will then shut down.

INFORMATION

- When infusion is ongoing, the key is inactive: if pressed, the forbidden key beep is triggered but infusion continues.
- When pump is switched off before end of the infusion (with stop action prior to switch off), the next time pump switches on will resume infusion status at switch off point.
- The confirmed pump settings and history information are saved even if the battery is disconnected with no time limit.
- In the case of a powering down, the time of powering down is not retained in the history.

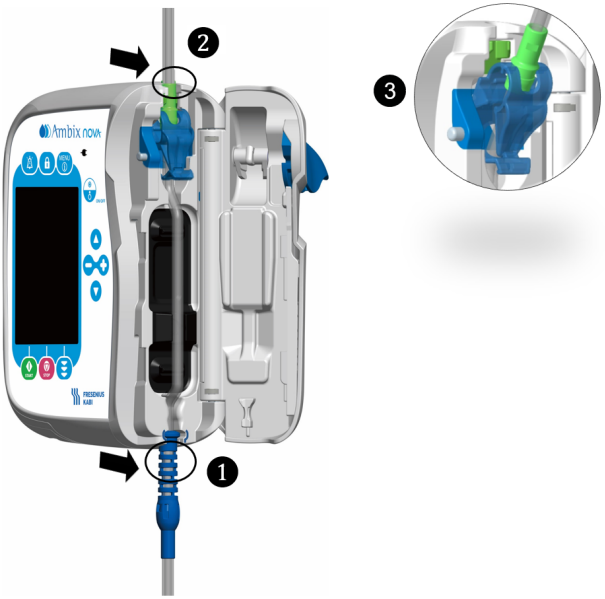
5.12 Removing/Changing the set from the pump

Replace the administration set according to your healthcare facilities or healthcare providers protocols.

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.

1. Push up the lever to unlock the door.
2. Open the door.
3. Remove the set by pull out the blue antikink ❶ from the slot first, then push the green connector ❷ out towards position ❸.



Install a new set in the pump (see *Loading the set* on page 27).

6 Pump menu

INFORMATION

- Menu is only accessible when infusion is stopped.
- A beep sound is triggered when a forbidden key (not active in specific screens) is pressed.
- In menu screen, if no action is taken after 1 minute, the display automatically returns to the main screen (infusion programming screen).

6.1 Access menu

The pump menu interface (see figure below) can be accessed at any time by press MENU key, except when infusion is in progress.

INFORMATION

- Press ▲ or ▼ to scroll up or down the menu list, the selected menu is displayed with light blue background.
- Press START (OK) to enter submenu or press STOP (↵) to go back to the previous screen.

6.2 Menus description

1st level menu	2nd level menu	Programming screen / Configuring screen
 Infusion mode menu	 Flow rate only mode	Program the flow rate Program delayed start duration (setting range is 1 min to 24 h when activated)
	 Continuous mode	Program the flow rate, the volume and the infusion duration Program delayed start duration (setting range is 1 min to 24 h when activated)
	 Ramp mode	Program the volume, the ramp-up duration, ramp-down duration and the infusion duration. Program delayed start duration (setting range is 1 min to 24 h when activated)
	 Intermittent mode	Program the flow rate, the volume per cycle, the number of infusion cycle and the duration of one cycle Program delayed start duration (setting range is 1 min to 24 h when activated)
 Basic settings menu	 Night mode	Activate / Deactivate night mode Select activation mode between 24 h or programmable time. Program start time / end time setting (if select programmable mode)
	 Date and time	Program day, month and year of date Select time format (12 h or 24 h) Set time
	 Delayed start	Activate / Deactivate delayed start Program delayed start duration
	 Sound	Adjust sound level (low, medium, high) Set time between two alarm sounds (range: 3 s to 15 s) Activate / Deactivate key beep
	 Light	Adjust brightness level (range: 1 to 10 level) Activate / Deactivate pumping LED Program LED blinking frequency (range: 1 s to 60 s)

1st level menu	2nd level menu	Programming screen / Configuring screen
 Advanced settings menu (access code required)	 Occlusion pressure / Air detection	Select occlusion pressure level between high and low Set single bubble volume detection (range: 0.125 mL to 0.75 mL) Set cumulated bubbles volume detection (volume range: 0.25 mL to 0.75 mL) / (duration range: 1 min to 30 min)
	 End of infusion pre-alarm	Activate / Deactivate end of infusion pre-alarm Select end of infusion pre-alarm mode setting between remaining time and remaining volume (when the end of infusion pre-alarm is actived) Program the value according to the selected mode
	 Nurse settings lock	Activate / Deactivate nurse settings lock
	 KVO (keep vein open)	Activate / Deactivate KVO Adjust KVO rate value (range: 1 mL/h to 10 mL/h)
	 Maximum flow rate	Set maximum flow rate (range: 1 mL/h to 600 mL/h)
	 Reset manufacturing settings	Reset pump to factory settings
 History menu	 Infusion history (consult the last 250 infusion events)	-
	 Cumulative counter (cumulated counter from 1 day to 99 days)	-
	 Alarm history (consult the last 250 infusion events)	-

1st level menu	2nd level menu	Programming screen / Configuring screen
Information	SN Serial number SV Software version Production date Last maintenance date Next maintenance date Total infused volume Total running time	-

6.3 Menu navigation

In a function configuring screen, when all the settings are customized, press START (OK) to validate the choice, the screen automatically goes back to the infusion programming screen.

To go back to the previous menu screen without validation, press STOP (↵) .

Keys and actions in menu and configuring screens

Keys	Actions
+	■ Activate the function ■ Select an option on the right ■ Increase value
−	■ Deactivate the function ■ Select an option on the left ■ Decrease value
▲	■ Scroll up in the menu list ■ Select previous value in the settings
▼	■ Scroll down in the menu list ■ Select next value in the settings
START	■ Enter selected menu in menu list ■ Validate the settings after programming
STOP	■ Back to previous menu list ■ Back to infusion programming screen

NOTE: In a configuring screen, when the function is activated, the related settings can be selected. The selected value is displayed in blue background.

6.4 Infusion mode

Ambix nova pump propose 4 infusion modes:

- Flow rate only mode (symbol: 

)
- Continuous mode (symbol: )
- Ramp mode (symbol: )
- Intermittent mode (symbol: )

6.4.1 Select the infusion mode

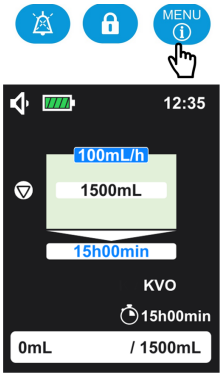
When the pump is switched on, the infusion programming screen is displayed with the last settings or presets (as example below in continues mode).

For programming with the infusion mode displayed (for example, continuous mode), see *Programming the infusion settings* on page 32.

For programming with a different infusion mode (for example, ramp mode), following below steps:

1. Press 

key to enter main menu screen.

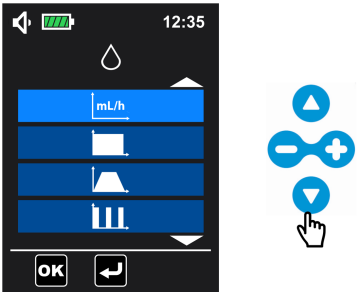


2. Press 

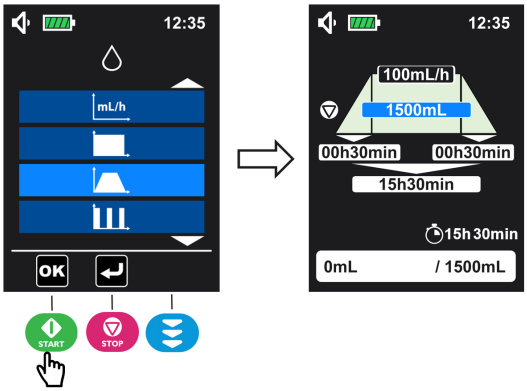
(

) key to enter the infusion mode selection menu.

3. Press or to select the applicable infusion mode (the selected infusion mode is in light blue background).



4. Press (OK) to confirm the selection and enter infusion programming screen.



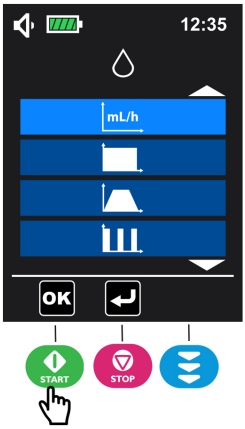
6.4.2 Flow rate only mode

INFORMATION

- Under flow rate only mode, the end of infusion pre-alarm cannot be triggered.
- Under flow rate only mode, KVO is only functional when delayed start is activated.

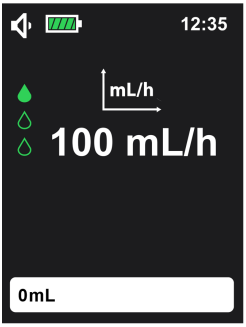
Flow rate only mode enables continuous infusion at an adjustable flow rate.

1. Select the flow rate only mode and press START (OK) to enter. For mode selection, see *Select the infusion mode* on page 44.



2. Press to adjust the flow rate value.

3. Press START to start the infusion.



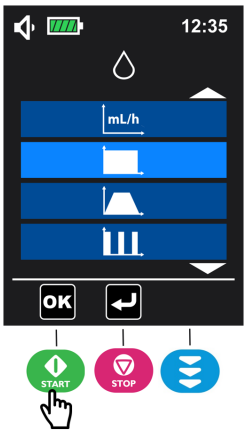
Accessing to information screen is described in *Start infusion* on page 33.

6.4.3 Continuous mode

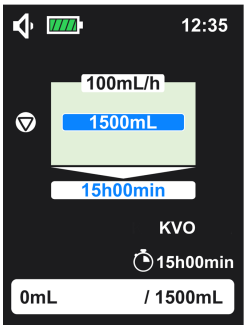
INFORMATION
The target duration can be set from 1 min. to 96 h with a default value of 15 h.

Continuous mode enables continuous infusion at an adjustable flow rate, volume and time.

1. Select the continuous mode and press (OK) to enter. For mode selection, see *Select the infusion mode* on page 44.

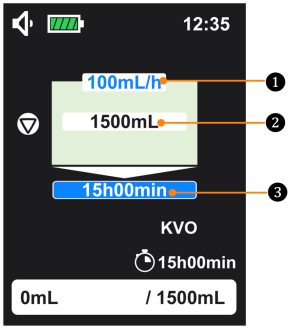


2. Press or to select the parameter to be programmed, then adjust the value by press .



3.Repeat step 2 until all parameters are set.

NOTE: In continuous mode, flow rate 1, volume 2 and duration 3 are programmable.



4. Press START to start the infusion.

Accessing to information screen is described in *Start infusion* on page 33.

6.4.4 Ramp mode

INFORMATION

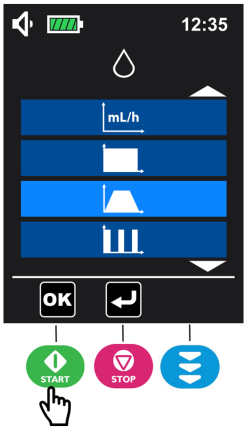
- The flow rate can not be set and will be calculated automatically and displayed.
- The flow rate displayed on the infusion screen is a rounded value (rounded to the nearest integer).
- The value of ramp up and ramp down duration can be set from 1 min. to 24 h with a default value of 30 min..
- The value of total duration can be set from 3 min. to 96 h with a default value of 15 h 30 min..
- Once ramp up phase infusion has started, stop the infusion, volume, total duration and ramp up duration cannot be adjusted anymore. Ramp down duration still can be adjusted.

Ramp mode enables three phases infusion at a preset volume and time:

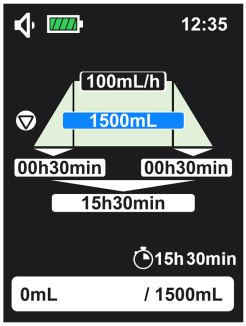
- Ramp up phase with a gradual flow rate increase
- Plateau phase with a constant flow rate

■ Ramp down phase with a gradual flow rate decrease

1. Select the ramp mode and press START (OK) to enter. For mode selection, see *Select the infusion mode* on page 44.

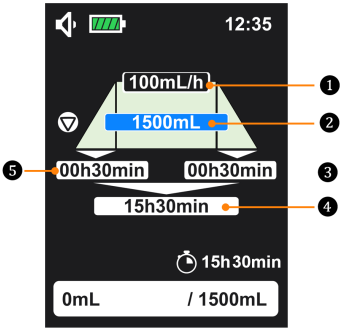


2. Press ▲ or ▼ to select the parameter, then adjust the value by pressing −/+.



3. Repeat step 2 until all parameters are set.

NOTE: Volume ❷, ramp up duration ❺, ramp down duration ❸ and total duration ❹ are programmable. Flow rate ❶ is calculated automatically and cannot be programmed.



4. Press START to start the infusion.

Accessing to information screen is described in *Start infusion* on page 33.

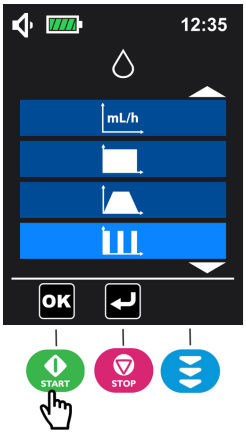
6.4.5 Intermittent mode

INFORMATION

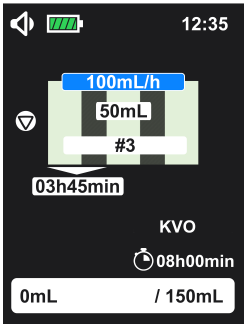
- The target volume of one cycle can be set from 1 mL to 9999 mL with a default value of 50 mL.
- The number of infusion cycle can be set from 2 to 99 with a default value of 3.
- The target duration of one cycle can be set from 15 min. to 24 h with a default value of 8 h.

Intermittent mode enables cyclic infusion at an adjustable flow rate, volume and time.

1. Select the intermittent mode and press START (OK) to enter. For mode selection, see *Select the infusion mode* on page 44.

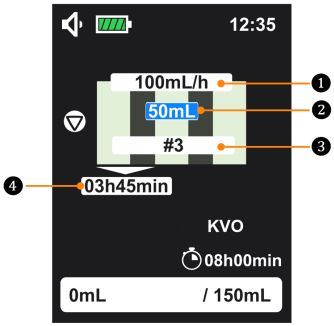


2. Press ▲ or ▼ to select the parameter, then adjust the value by pressing −/+.



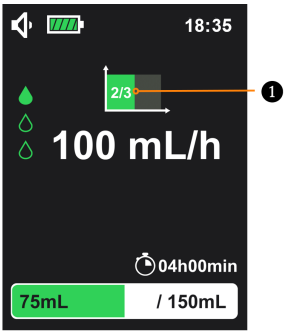
3. Repeat step 2 until all parameters are set.

NOTE: Flow rate ❶, volume per cycle ❷, number of infusion cycle ❸ and duration of one cycle ❹ are programmable.



4. Press START to start the infusion.

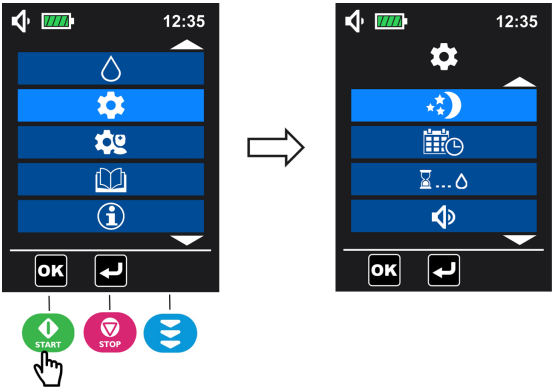
NOTE: ❶ "2/3" indicate the current cycle number / total number of infusion cycle programmed.



Accessing to information screen is described in *Start infusion* on page 33.

6.5 Basic settings menu

Under main menu screen (see *Access menu* on page 40), select basic settings menu ⚙ and press START (OK) to enter.



6.5.1 Night mode

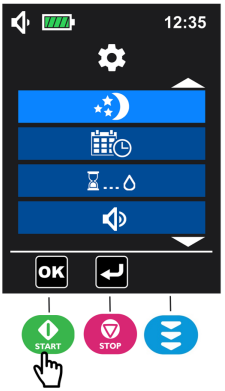
This function enables to manage pump luminosity at night.

When the night mode is active:

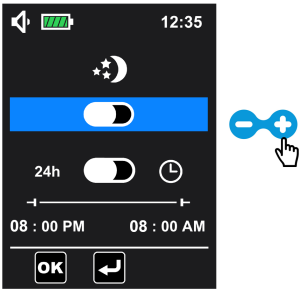
The display backlight and power LED are set to minimum level when the pump is working.

In case of alarm, the backlight turns back to normal.

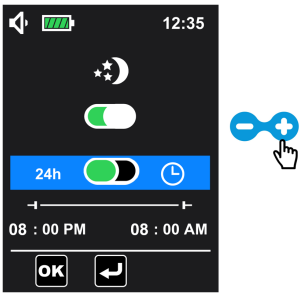
1. Under basic settings menu screen (see *Basic settings menu* on page 51 to access), select the night mode menu and press START (OK) to enter.



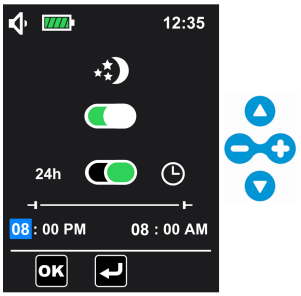
2. Press to activate (press to deactivate) the night mode (deactivate by default).



3. Once the night mode is activated, it is automatically for 24 hours mode (the programmable start time and end time are not activated). To choose programmable time mode , press to go down, then press to select programmable time mode .



4. Once programmable mode activated, press to move down to set the start time and end time of night mode: press or to switch from one parameter to another, and press to adjust the value of the selected parameter.

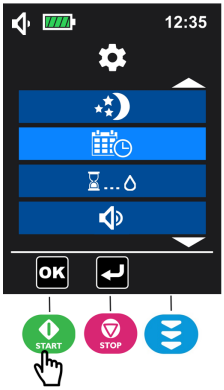


5. Validate the settings by pressing (OK). Pump returns to the infusion programming screen.

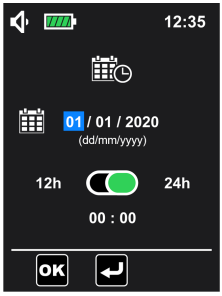
6.5.2 Date and time

This function enables to customize pump clock and calendar.

1. Under basic settings menu screen (see *Basic settings menu* on page 51 to access), select the date and time menu and press (OK) to enter.

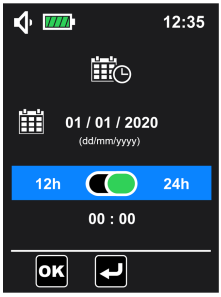


2. Press or to select the day, month or year that need to be set, press to adjust the value of the selected one.

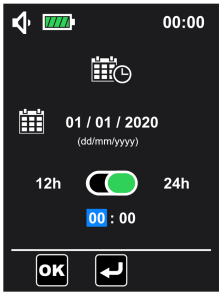


NOTE: The year can be set from 2020 to 2099 with a default value of 2020.

3. Press to go down to select the time format, press to select 12 h, or press to select 24 h (the time format is 24 h by default).



4. Press to go down to set the time: press or to switch from one parameter to another and press to adjust the value of the selected parameter.



5. Press (OK) to validate the settings. Pump returns to the infusion programming screen.

NOTE: If 12 h format is selected, AM or PM choice must be done.
On this screen, the date is 01/01/2020, the time format is 24 h and the time is 00:00, which are factory configuration.

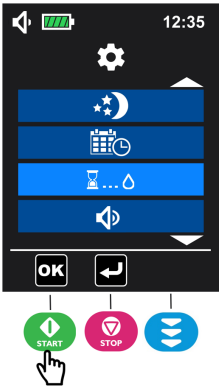
6.5.3 Delayed start

This function enables to postpone start of a new infusion.

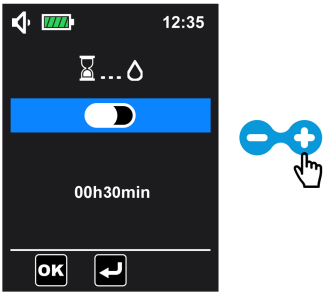
INFORMATION

- The delayed start duration can be adjusted from 1 minute to 24 hours with a step of 1 minute or 1 hour.
- Delayed start duration is included in the infusion remaining time.
- During an infusion, modify the delayed start settings from menu confirguring screen will reset the infusion progress.

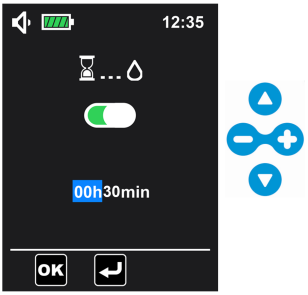
1. Under basic settings menu screen (see *Basic settings menu* on page 51 to access), select the delayed start menu and press (OK) to enter.



2. Press to activate the delayed start (deactivated by default).



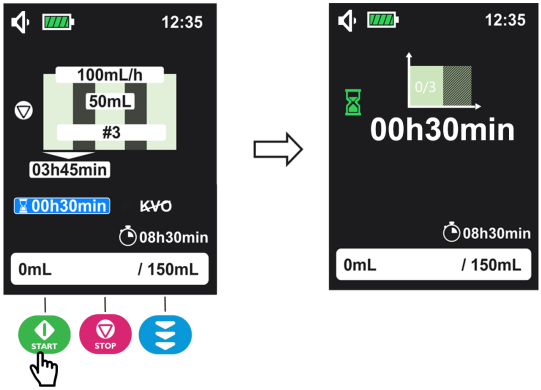
3. Press to go down to program the duration: press or to switch from one parameter to another and press to adjust the value of the selected parameter.



4. Press (OK) to validate the settings. Pump returns to the infusion programming screen.

If the delayed start function is activated on the menu configuring screen, the duration of delayed start can also be adjusted from the infusion programming screen (the selected area

in the figure below). When delayed start is launched, the symbol and the time before start of infusion are displayed on the monitoring screen. On this screen, the infusion will start 30 minutes later.

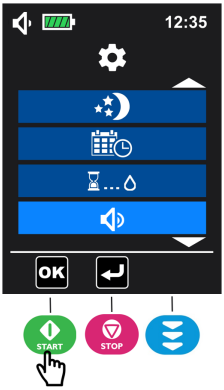


6.5.4 Sound

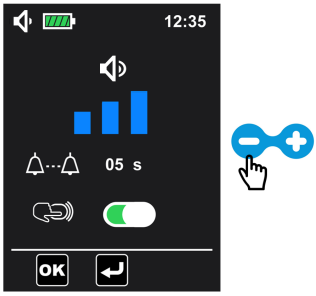
This function enables to customize sound of alarms and beep.

1. Under basic settings menu screen (see *Basic settings menu* on page 51 to access), select the sound menu and press (OK) to enter. On this screen, you can:

- adjust the sound level;
- set the time between 2 alarm sounds;
- activate / deactivate the key beep.

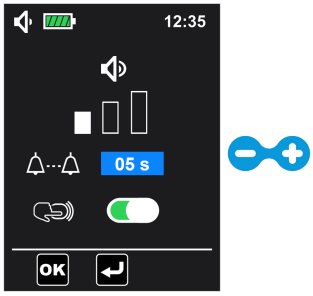


2. Press to decrease the sound level (or press to increase).



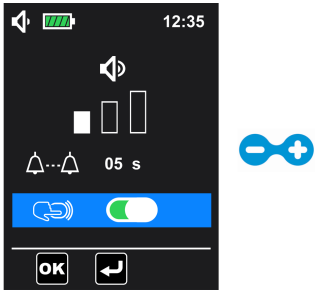
NOTE: The volume adjustment has 3 levels - low, medium, high level. The sound level is high by default.

3. Press to select the time between 2 alarm sounds setting, then press to adjust the value.



NOTE: Time between 2 alarm sounds can be adjusted from 3 seconds to 15 seconds with step of 1 second . This adjustment can modify the perception of an alarm. On this screen, the time between 2 alarm sounds is 5 seconds (by default).

4. Press to select the key beep activation / deactivation setting. Press to turn off the key beep sound. Conversely, press for activation.



NOTE: The key beep sound is activated by default.

5. Press START (OK) to validate all the settings. Pump returns to the infusion programming screen.

WARNING
Alarm sound level is adjustable. Proper set depends on the use environment, make sure that you can hear and recognize the alarms, especially when the pump is used on battery.

INFORMATION

- When the sound level is adjusted, press START (OK) to validate the settings, the sound symbol is modified in accordance in the status bar.
- The time between two alarm sounds can only be set for high priority alarms. For low priority alarm, the interval between two alarm sounds is 30 seconds and cannot be adjusted.

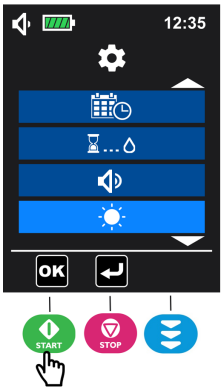
6.5.5 Light

This function enables to customize screen brightness and pumping LED blinking frequency.

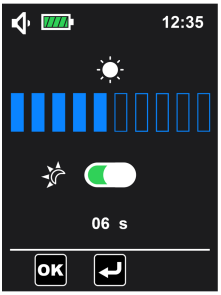
There are 10 levels of brightness setting and the default value is 5.

1. Under basic settings menu screen (see *Basic settings menu* on page 51 to access), select the light menu and press START (OK) to access. On this screen, you can:

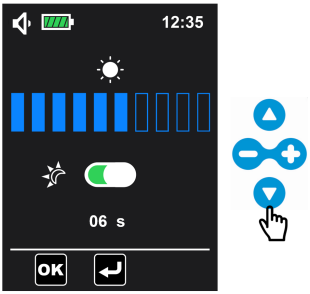
- Adjust the brightness of the screen backlight;
- Activate / deactivate pumping LED and set its blinking frequency if activate;



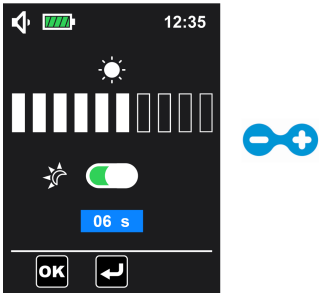
2. Press + to increase (or press − to decrease) the brightness of the screen backlight.



3. Press to select pumping LED activation (activated by default).



4. When pumping LED is activated (to deactivate, press), press to select the pumping LED blinking frequency (6 sec. by default, range 01~60 sec.), and press to adjust the value.

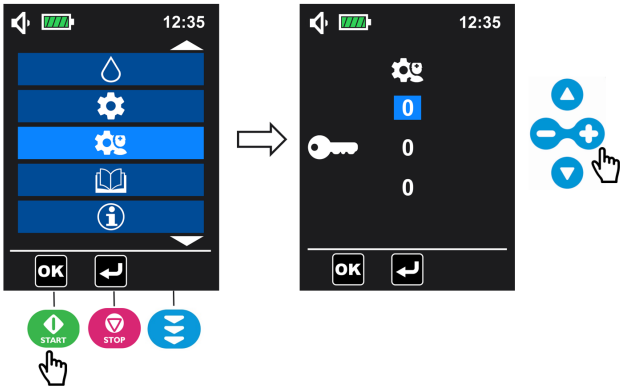


5. Validate the settings by pressing ( ), and pump returns to the infusion programming screen.

NOTE: Activation of night mode function does not automatically deactivate pumping LED.

6.6 Advanced settings menu

An access code is required to enter into the advanced settings menu.



1. Under main menu screen (see *Access menu* on page 40), select the advanced settings menu and press START (OK) to enter into the access code screen.
2. Enter the access code by adjusting each digit (0 to 9) using keys , then press START (OK) to validate and access to advanced settings menu.

INFORMATION

- To get the access code, contact your Fresenius Kabi sales representative.
- If the code is wrong, is displayed on the screen for 3 seconds, then the pump goes back to the access code screen in order to enter a new code.

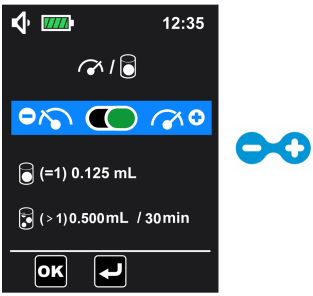
6.6.1 Occlusion pressure / Air detection

This function enables to customize occlusion pressure and air detection alarms settings.

1. Under advanced settings menu (see *Advanced settings menu* on page 60 to access), select Occlusion pressure / Air detection menu / and press START (OK) to enter. On this screen, you can:

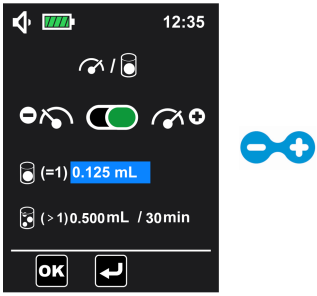
- Select occlusion detection pressure level (High or Low);
- Set the single bubble detection volume ();
- Set the cumulated bubbles detection volume and duration ();

2. For level of occlusion pressure setting, press to select the low level or press to select the high level of occlusion pressure (high by default).



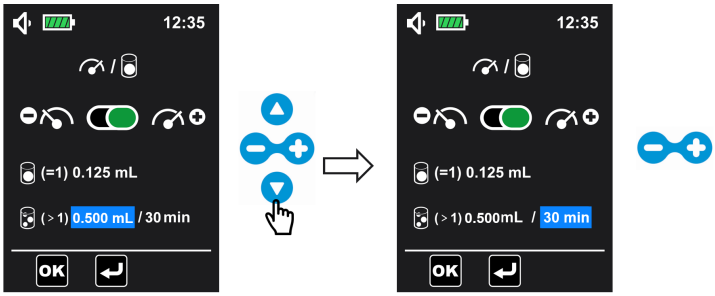
NOTE: Low level = an occlusion alarm will be triggered for a pressure value of 487.5 mmHg ± 187.5 mmHg in the administration set; High level = an occlusion alarm will be triggered for a pressure value of 787.5 mmHg ± 262.5 mmHg in the administration set.

3. Press to select the single bubble setting. Press or to adjust the value.



NOTE: Air in line alarm will be triggered when the detected single bubble volume is ≥ to the customized volume value. The single bubble setting can be adjusted from 0.125 mL to 0.75 mL, with step of 0.125 mL (default setting: 0.125 mL).

4. Press to go down to select the cumulated bubbles volume setting. Press or to switch between volume and duration settings and press to adjust the value of the selected setting.



NOTE: Air in line alarm will be triggered when the detected cumulated bubbles volume is ≥ to the customized volume value throughout the customized duration. The adjustment range of cumulated volume is from 0.25 mL to 0.75 mL by step of 0.125 mL, the adjustment range of time is 1 min, 5 min , 10 min, 15 min, 20 min, 25 min, 30 min (cumulated bubbles volume setting is 0.5 mL / 30 min by default).

5. Validate the settings by press (START) (OK) and pump returns to the infusion programming screen.

INFORMATION

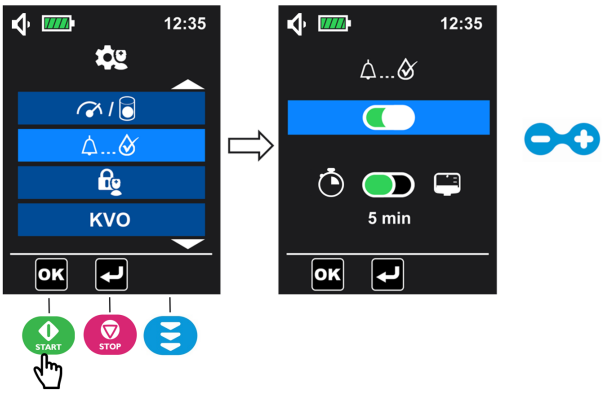
- The value of single bubble means the minimum size of the single bubble that can be detected by the pump, the detection will last until the end of infusion.
- The cumulated bubbles volume detection is used to detect the total volume of air bubbles during the set duration, the detection will last until the end of infusion.

6.6.2 End of infusion pre-alarm

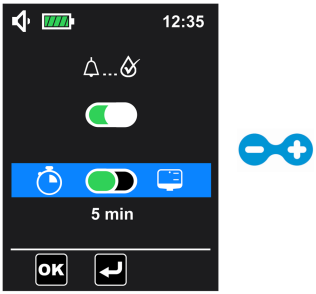
This function enables to customize alarm to notify approaching end of infusion.

Ambix nova enables pre-alarm before the end of infusion for Continuous mode, Intermittent mode and Ramp mode.

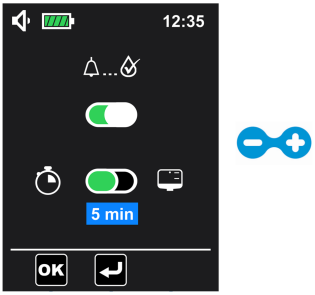
1. Under advanced settings menu (see *Advanced settings menu* on page 60 to access), select the infusion pre-alarm menu and press (START) (OK) to enter. Press to deactivate or press to activate (active by default).



2. Once the pre-alarm is activated, press to go down to choose the mode to trigger the pre-alarm. Press to select remaining volume before end of infusion or press to select remaining time before end of infusion (activated by default).



3. Press to go down and press to adjust the parameters.



4. Press to validate the settings. Pump returns to the infusion programming screen.

INFORMATION

- By default, end of infusion pre-alarm is activated and will be triggered when remaining time is 5 min. before end of infusion.
- Time before end of infusion setting range is 1 ~ 59 min. (preset is 5 min.).
- The remaining volume before end of infusion can be set from 1 mL to 999 mL (preset is 10 mL).

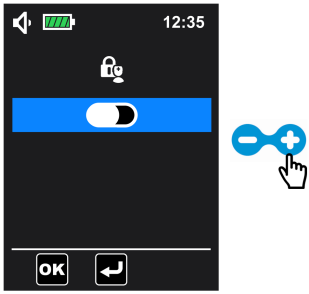
6.6.3 Nurse settings lock

This function enables to lock the pump to avoid misuse. The nurse settings lock is deactivated by default.

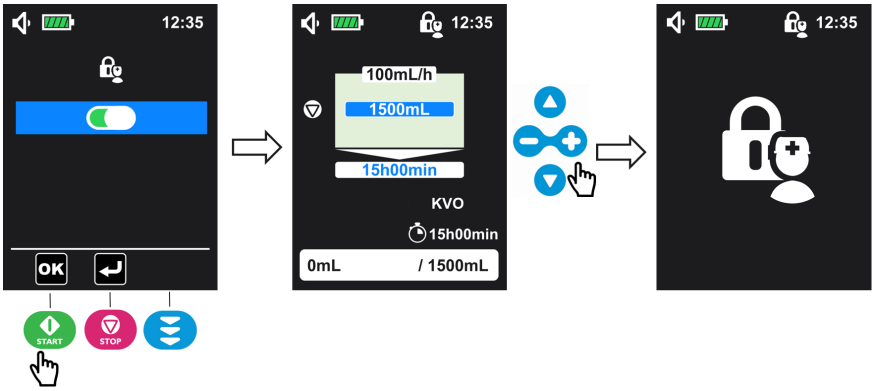
When nurse settings lock is activated, the infusion parameters (flow rate, volume, duration, etc.) cannot be changed.

1. Under advanced settings menu (see *Advanced settings menu* on page 60 to access), select nurse settings lock menu and press START (OK) key to enter.

2. Press key to activate (or press to deactivate) the nurse settings lock.



3. Press START (OK) to validate. Pump returns to the infusion programming screen. is displayed in the status bar. All keys are accessible except keys in infusion programming screen.



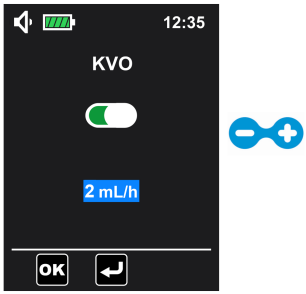
6.6.4 KVO (Keep Vein Open)

This function enables to customize the KVO. KVO is a low flow rate to keep vein open during all infusion interruptions (delayed start, end of infusion and pause period of an intermittent cycle).

1. Under advanced settings menu (see *Advanced settings menu* on page 60 to access), select KVO menu and press START (OK) to access KVO setting.

2. Press for activation. Conversely, press to deactivate KVO (activated by default).

3. Press to select the KVO flow rate value and adjust it by pressing (the parameter can only be selected when KVO is activated).



NOTE: KVO rate setting range is from 1 mL/h to 10 mL/h, the default value is 2 mL/h.

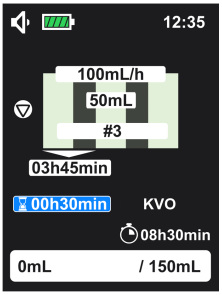
4. Press (OK) to validate the setting. Pump returns to the infusion programming screen.

INFORMATION

- Check KVO settings before start infusion, make sure KVO rate is appropriate for the patient.
- KVO status is displayed on the infusion programming screen and infusion information screen (except in flow rate only mode) but cannot be adjusted. Under flow rate only mode, KVO is only functional when delayed start function is activated.
- After activation, KVO is functional during all infusion interruptions:
  - Delayed start
  - Pause periods of an intermittent infusion cycle
  - End of infusion

KVO display

KVO is activated



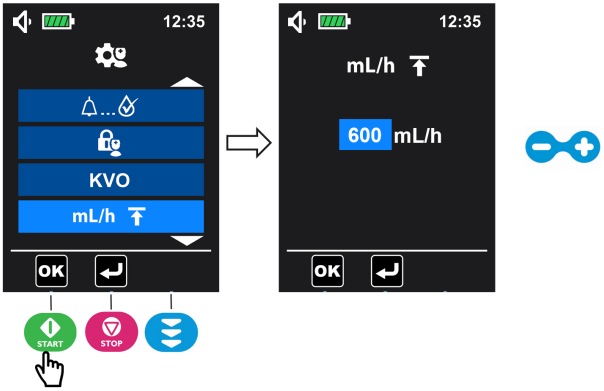
KVO is deactivated

KVO is ongoing

6.6.5 Maximum flow rate

This function enables to customize a pump flow rate value to not exceed.

The maximum flow rate of the Ambix nova is 600 mL/h, this maximum flow rate can be limited to a value between 1 and 600 mL/h with increment of 1 mL/h, the preset is 600 mL/h.

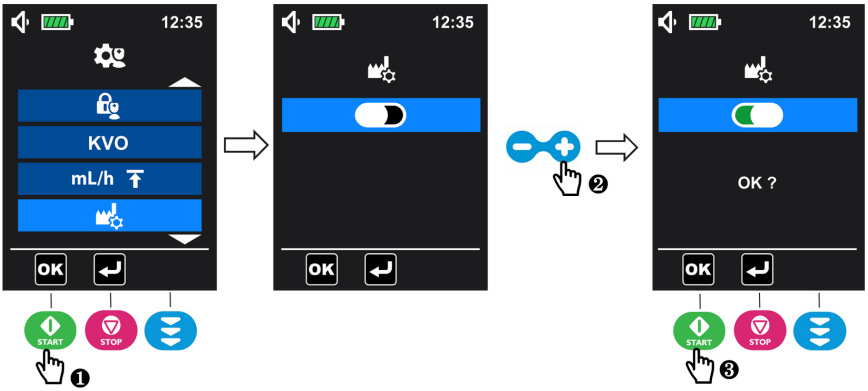


1. Enter advanced settings menu (see *Advanced settings menu* on page 60) to select maximum flow rate menu mL/h and press START (OK) to enter.
2. Press to adjust the maximum flow rate value and press START (OK) to validate

NOTE: Long press function is activated.

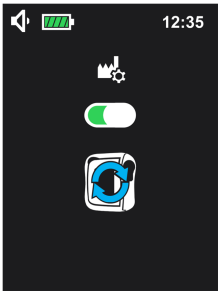
6.6.6 Reset manufacturing

This function enables to reset pump settings and history information.



1. Under advanced settings menu (see *Advanced settings menu* on page 60 to access), select reset manufacturing menu and press (OK) to enter.
2. Press to activate reset manufacturing settings.
3. Press (OK) to confirm.

   Once reset is confirmed, the reset symbol displays and rotates for 3 seconds, the pump returns to the menu screen.



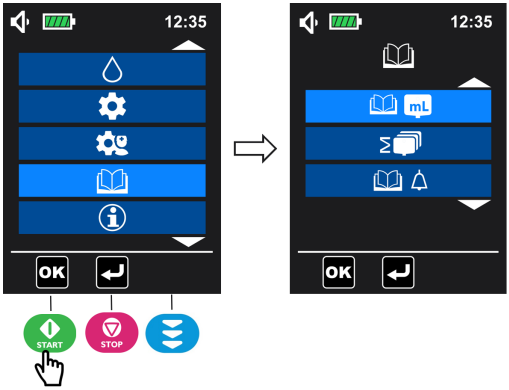
INFORMATION

When reset manufacturing settings is done:

- Pump settings revert back to factory settings (except date and time settings).
- The records in the history menu are erased and back to factory settings: including infusion history, alarm history and cumulated counter.

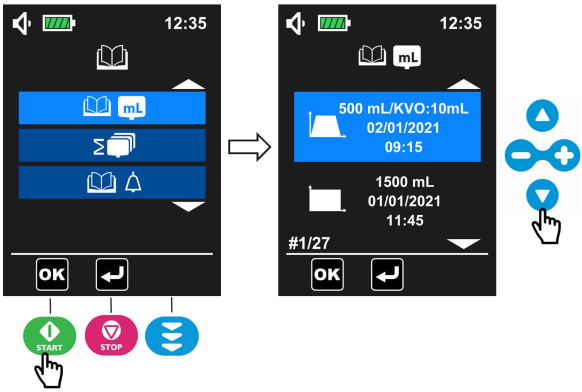
6.7 History

Under main menu screen (see *Access menu* on page 40), select the history menu and press (OK) to access the history menu.



6.7.1 Infusion history

This menu enables to consult information of previous infusion events.



1. Under history menu screen (see *History* on page 69 to access), select the infusion history menu mL and press START (OK) to enter.
2. Press ▲ or ▼ to switch from one infusion event to another.

For each infusion event, the infusion history indicates:

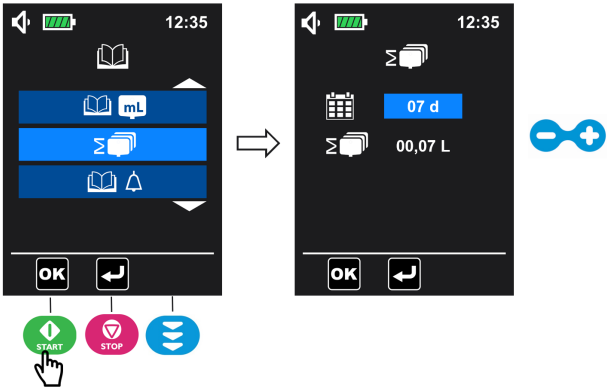
- Infusion mode
- Volume infused (KVO volume is not included)
- KVO volume infused (not displayed if no KVO volume has been infused)
- Date and time of end of infusion

The pump can keep 250 events of infusion in memory.

6.7.2 Cumulative counter menu

This menu enables to consult the cumulative volume infused during a selected period of days.

1. Under history menu screen (see *History* on page 69 to access), select the cumulated counter menu and press (OK) to enter.
2. Press or to define the period of days from the current day, the cumulative volume value is displayed automatically.

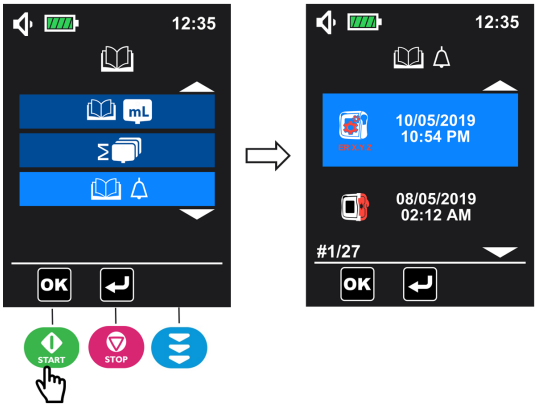


INFORMATION
You can consult the cumulative volume infused during the number of days (from 1 to 99 days) defined by the user. The counting start from the present day.

6.7.3 Alarm history

This menu enables to consult information of previous alarm events.

Alarm events are automatically saved in the pump memory.



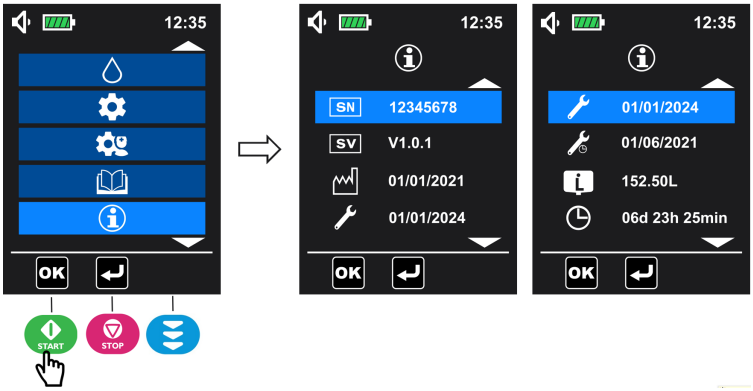
1. Under history menu screen (see *History* on page 69 to access), select the alarm history menu and press START (OK) to enter.
2. To review the alarm events, press ▲ or ▼ to switch from one alarm event to another.

INFORMATION

- Each event is characterized by an alarm symbol and its time and date of occurrence.
- The pump can keep 250 alarm events in memory.
- When the history is full, the system overwrites the oldest event with any new event.

6.8 Information

This menu enables to consult pump technical information.



1. Under main menu screen (see *Access menu* on page 40), select the information menu  and press  () to access.
2. Press  or  to check the information.

NOTE: the information menu displays:

 Serial number

 Software version

 Production date (dd/mm/yyyy)

 Last maintenance date (dd/mm/yyyy)

 Next maintenance date (dd/mm/yyyy)

 Total infused volume

 Total running time

7 Cleaning and disinfection

Clean pump and holder as soon as they become contaminated with fluids, 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.

WARNING

- Do not submerge the pump in water or any liquid.
- Do not put in dishwasher.
- Do not sterilize the pump, it may damage the pump.
- Do not exchange pumps' doors, miss match between the door and the pump can lead to false alarm or system failure.
- The Ambix nova backpack must be cleaned before inserting the pump. Please refer to its specific accompanying documents.
- Do not use the pump if contamination is not cleaned.

7.1 Recommended cleaning and disinfection agents

Didecyldimethylammonium chloride.

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

7.2 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

7.3 Cleaning instructions

Prerequisites

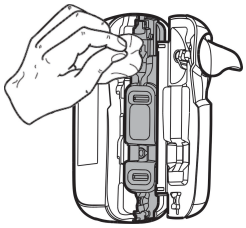
- The pump is disconnected from the patient.
- The pump is switched off.
- The power cable and all other cables are unplugged.
- The pump is disconnected from the holder.
- The air is at room temperature (20 to 25 °C).
- The operator is wearing suitable protective equipment.

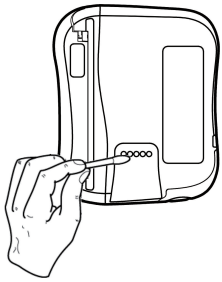
Protocol

1. Place the pump and the holder on a cleaned surface or disposable underlay.

2. During cleaning, do not turn the pump upside-down to avoid liquid leak into the pump.
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, blue insert).

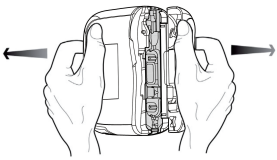
   A minimum cleaning of 1 minute is recommended (allow to remain visibly wet for 1 minute), until all organic matter is dissolved and removed. Do not allow liquids to run, leak, or drip into the pump housing. Use cotton wool to clean the contact pins.

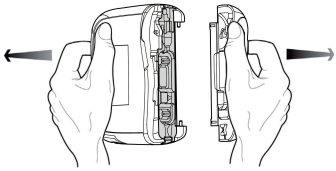




5. Repeat step 4 with the pump door and holder.

   The door can be removed from the pump to facilitate the cleaning.





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

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.

   NOTE: After step 8, perform disinfection procedure described in *Disinfection instructions* on page 75.

7.4 Disinfection instructions

Prerequisites

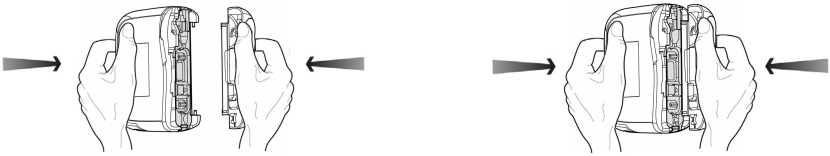
- The cleaning protocol has been performed.
- The pump is disconnected from the patient.
- The pump is switched off.
- The power cable and all other cables are unplugged.
- The pump is disconnected from the holder.

- 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. Place the original door back to pump as indicated in the figure below.

   NOTE: Check the **serial number (SN:** xxxxxxxx**)** on the door is the same as on the pump to make sure it is the original door when placing the door back to the pump.



8 Quick check protocol

The following checks allow user to confirm device behaviour according to these instructions for use. Fresenius Kabi recommends to perform these tests before connecting Ambix nova to patient.

WARNING
Do not use the device in case of check test failure and contact the appropriate department or Fresenius Kabi sales representative for additional verification.

Action	Yes
Before use	
1 - Check if the Ambix nova pump, holder and power cable are not damaged in any way	☐
2 - Check the general status of the display	☐
3 - Install the Ambix nova pump on the holder	☐
4 - Connect holder to the mains	☐
5 - Switch on the pump	☐
6 - Check the autotest sequence (LCD display intact, speaker, LED and the backlight). Do not use with a damaged screen.	☐
7 - Check the mains LED lights up	☐
8 - Remove the Ambix nova pump from its holder and check the battery symbol on the display	☐
9 - Install the Ambix nova pump on the holder	☐
10 - Check that the pump and its holder are securely attached or positioned	☐
11 - Check that all menu settings are adapted to the next patient	☐
12 - Connect a set to a filled container, install the set in the pump and close the door	☐
13 - Prime the set	☐
14 - Set pump at prescribed parameters	☐
15 - Start infusion	☐
16 - Check the infusion information (droplet animation)	☐
17 - Check that pumping is effective	☐
After use	
1 - Check if pump, holder and power cable are not damaged in any way	☐
2 - Clean the pump, holder and power cable	☐

Action	Yes
3 - Check the membrane of Ambix nova pump is intact (no cracks, no wear)	□
Once a year	
Check the following alarms and messages (symbol on the display, beep sound, blinking status light indicator)	
1 - Missing set alarm	□
2 - Door open alarm	□
3 - Upstream occlusion alarm	□
4 - Downstream occlusion alarm	□
5 - Empty bag / Air in Line alarm	□
6 - Empty battery alarm	□
7 - End of infusion alarm	□
8 - End of infusion pre-alarm	□
9 - Action reminder	□
10 - Empty battery pre-alarm	□
11 - Check the flow rate by measuring the delivered volume	□

9 Alarms and safety features

9.1 Introduction

The Ambix nova pump has a continuous inspection system that operates as soon as it is in use, but it cannot replace the users present at the bedside.

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

Please make sure the appropriate reaction to alarm is undertaken. A wrong or delayed reaction can lead to a delay of 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 to the user, taking into account the environment.

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

Three different alarm sound levels are available to choose: low, medium and high. To set the alarm sound level, please go to *Sound* on page 57.

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

9.2 The different types of information signal or alarm

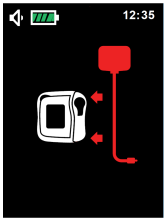
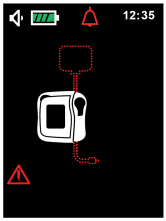
Description	Type	Required Operator Response
 OR  Information signal sound (1 beep)	Information signal	Awareness
 Fixed yellow LED and alarm sound (sequences of 3 beeps).	Functional alarm (Low priority alarm)	Prompt response
 Flashing red LED and alarm sound (sequences of 10 beeps)	Technical alarm / Functional alarm (High priority alarm)	Immediate response
 Flashing red LED and buzzer sound	Fail safe technical alarm / Speaker fail technical alarm (High priority alarm)	Immediate response

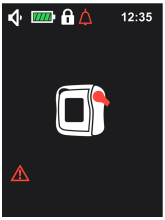
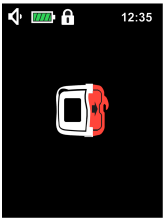
9.3 Alarm description

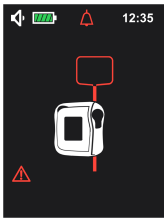
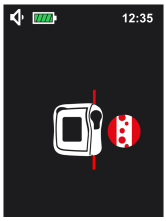
INFORMATION

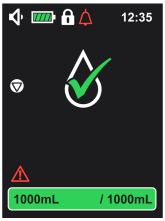
- Displays, symbols and status of an alarm situation described in table below must be identified to understand the meaning and conduct the appropriate action.
- All alarms display animated screens.

Functional alarms

Symbol	Pumping status	Alarm condition	Actions
High priority - Red LEDs are flashing and alarm sound (sequences of 10 beeps)			
Missing set  and  appears alternatively	Pumping stops	Missing set.	■ Install the set into the pump. □ See *Loading the set* on page 27.
		Set not properly installed.	■ Check position of the set above and below the pump mechanism and insert correctly if necessary.
		Wrong set installed.	■ Replace the wrong set with compatible Ambix nova set.
		Area where set clamp is inserted is contaminated.	■ Remove dirt with cloth and soapy water or as directed by healthcare facility or healthcare provider policy. ■ Allow the pump to dry. □ See *Cleaning and disinfection* on page 74.

Symbol	Pumping status	Alarm condition	Actions
Door open  and  appears alternatively	Pumping stops	Pump door not properly closed at start.	■ Close pump door. □ See *Loading the set* on page 27.
		Pump door opened after start.	■ Close pump door. □ See *Loading the set* on page 27.
		Pump door removed from its anchoring.	■ Re-hang door.
		Door mechanism is faulty.	■ Contact your biomedical department.
Upstream occlusion  	Pumping stops	Upstream flowpath is blocked between the container and the pump.	■ Open the door, check that the set is installed properly, close the door. □ See *Loading the set* on page 27. ■ Check that the set is not kinked. ■ Check that upstream clamp (pinch clamp, roller clamp) is open. ■ Check the absence of upstream / downstream occlusion in the line.

Symbol	Pumping status	Alarm condition	Actions
Downstream occlusion  	Pumping stops	Downstream flowpath is blocked after the pump, at the patient side.	■ Open the door, check that the set is installed properly, close the door. □ See *Loading the set* on page 27. ■ Check that the set is not kinked. ■ Check that the infusion tube is clear. ■ Flush tube if necessary. ■ Re-position and verify that fluid flows freely after adjustment. ■ Check the absence of upstream / downstream occlusion in the line.
Empty bag / Air in line  and  appears alternatively	Pumping stops	Infusion container is empty.	■ End infusion or connect to a filled container.
		Air is in the set.	■ Fill set to the end. □ See *Priming the set with the pump (recommended)* on page 29.
		Dirt in sensor area (lower tube guide).	■ Open the door and remove dirt with cloth and soapy water or as directed by healthcare facility policy or healthcare provider policy (see *Cleaning and disinfection* on page 74). ■ Allow the pump to dry.
		The set not properly connected to the container.	■ Check position of the set and insert correctly if necessary. □ See *Loading the set* on page 27.

Symbol	Pumping status	Alarm condition	Actions
End of infusion 	Pumping stops if KVO deactivated or pumping continues with KVO flow rate	The target volume is reached. (Complete progress bar)	■ Stop infusion or restart a new one.
Empty battery 	Pumping stops	Minimum battery voltage is not available. Appears approx. 10 min. before battery is fully discharged.	■ Connect the pump to the mains via the pump holder. Charge battery to resume pump operation.
Low priority - Yellow LEDs are fixed and alarm sound (sequences of 3 beeps)			
End of infusion pre-alarm 	Pumping continues	Target volume will be reached. The time of message before target volume is reached can be set in the menu. □ See *End of infusion pre-alarm* on page 63.	■ Get prepared for end of infusion

Symbol	Pumping status	Alarm condition	Actions
Empty battery pre-alarm  **NOTE:** The battery icon becomes **Yellow**. The number of bars may vary, depending on the battery performance.	Pumping continues	Minimum battery voltage is not available. Appears at least 30 min. before the empty battery alarm.	■ Connect the pump to the mains via the pump holder.
Action reminder  	Pumping stops	Pump is switched on but not operating for 2 minutes (3 beeps).	■ Proceed to next step or switch pump off.

Technical alarms

Symbol	Pumping status	Alarm condition	Actions
High priority - Red LEDs are flashing and alarm sound (sequences of 10 beeps(1 beep repeats for power supply failure and sequences of 3 beeps for speaker failure))			

Symbol	Pumping status	Alarm condition	Actions
Technical alarm 	Pumping stops	A technical alarm code is displayed with the “Pump error alarm” drawing. In case of a technical failure related to LCD screen, the technical alarm code cannot be displayed as the screen will goes off.	■ Note the technical error code (ER X.Y.Z). ■ To release technical alarms, press STOP or  for 3 seconds. The pump will then switch off instantly (no count-down). ■ Contact your biomedical department.
Fail safe technical alarm	Pumping stops	Power supply failure.	■ Contact your biomedical department.

NOTE: The volume infused between failure and alarm generation is maximum 10 mL, except for occlusion above drip chamber where its own volume must be considered.

INFORMATION

- If the alarm persist when the pump is powered on again, do not use the device on a patient, and contact your biomedical department or your Fresenius Kabi sales representative.
- Battery technical alarm that occurred before switch off the pump will be reminded at the next switch on.
- Technical alarms are described in the Technical Manual, the event of technical alarms are logged in the device history.

9.4 Reacting to alarms

When a functional alarm occurs:

- To mute alarm sound, press  , see *Mute alarm* on page 36;
- To view the information about the alarm and how to solve it, do the following:
  - Looking at the drawing displayed on the pump to detect the specific problem causing the alarm or pre-alarm condition;
  - Make a corrective action (see *Alarm description* on page 80);
  - For high priority alarm (except empty battery alarm), press STOP to release alarm;
  - If necessary, press START key to restart infusion.

9.5 Maximum alarm raising delay

Time between alarm condition and alarm generation is less than 5 seconds, except for Missing set, Upstream and Downstream occlusions and Empty bag / Air in Line alarms (see *Performance* on page 88).

INFORMATION

- When two alarms occur at the same time, the higher priority alarm is displayed.
- When two alarms with the same priority level are triggered at the same time, the pump software assigns them a priority.

9.6 Alarm settings

The following alarm settings are available:

- Adjust audible alarm signals, see *Sound* on page 57;
- Select the occlusion pressure level, see *Occlusion pressure / Air detection* on page 61;
- Set the air detection values, see *Occlusion pressure / Air detection* on page 61;
- Set the time of end of infusion pre-alarm, see *End of infusion pre-alarm* on page 63;

If the device is disconnected from the mains and if the battery is discharged, the alarm settings are not modified, and they are stored indefinitely.

10 Troubleshooting

Issue description	Recommended action
Pump is not stable when mounted	■ Check that the clamp screw is fastened
Pump or Smart Holder Power is damaged, noisy, smoking or with an abnormally hot part. Pump screen is damaged.	■ Remove the holder 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
Flow rate variance is higher than flow rate accuracy	■ Check 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 backlight ■ Contact your biomedical department or Fresenius Kabi sales representative if problem remains
The mains connection LED does not light up when pump has been connected to the mains supply	■ Check pump connection to the mains supply ■ Check that the LED on the holder lights. If not, unplug and plug the power cable 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 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
Technical error ER X.Y.Z	■ Contact service provider (homecare provider) ■ Contact your biomedical department or Fresenius Kabi sales representative if problem remains

11 Technical information

11.1 Performance

11.1.1 Essential performance

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

- flow rate accuracy (see *Flow rate accuracy* on page 88);
- occlusion detection time (< 4 min. at 25 mL/h with medical water);
- management of high priority alarms, see *The different types of information signal or alarm* on page 79.

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

11.1.2 Flow rate accuracy

	Accuracy
Flow rate ≥ 10 mL/h	± 5%*
Flow rate < 10 mL/h	± 0.5 mL/h*

* In Ramp mode, the values stated are the average flow rate accuracy of the ramp up phase and the ramp down phase.

Test initial conditions following 60601-2-24. Cumulative volume measured on a two-hour period, with 25 mL minimum volume and medical water (apply to 12 mL/h above).

Temperature: 20 ± 2 °C.

Container height: 50 cm above the upside of the pump.

11.1.3 Flow rate range

	Range	Default value	Increments
Flow rate only mode	From 1 mL/h to 600 mL/h	100 mL/h	1 mL/h from 1 mL/h to 600 mL/h
Continues mode	From 1 mL/h to 600 mL/h	100 mL/h	1 mL/h from 1 mL/h to 600 mL/h
Ramp mode*	From 10 mL/h to 600 mL/h	100 mL/h	N/A
Intermittent mode	From 1 mL/h to 600 mL/h	100 mL/h	1 mL/h from 1 mL/h to 600 mL/h
KVO	From 1 mL/h to 10 mL/h	2 mL/h	1 mL/h from 1 mL/h to 10 mL/h
Priming	N/A	600 mL/h	N/A

* the values in this mode refer to the flow rate of plateau phase, which is automatically calculated and cannot be programmed.

11.1.4 Volume to be infused (VTBI) Range

	Range	Default value	Increments
Continues mode	From 1 mL to 9999 mL	1500 mL	1 mL from 1 mL to 9999 mL
Ramp mode	From 1 mL to 9999 mL	1500 mL	1 mL from 1 mL to 9999 mL
Intermittent mode*	From 2 mL to 9999 mL	150 mL	N/A

* In intermittent mode, the VTBI is automatically calculated and cannot be programmed.

11.1.5 Time to detect occlusion

Occlusion alarm response time at different flow rate:

Downstream occlusion detection time			Upstream occlusion detection time
Flow rate	**Low pressure level (487.5 mmHg ± 187.5 mmHg)**	**High pressure level (787.5 mmHg ± 262.5 mmHg)**	
1 mL/h	< 30 minutes	< 2 hours	< 1 hour 30 minutes
25 mL/h	< 75 seconds	< 4 minutes	< 4 mintues
100 mL/h	< 20 seconds	< 2 minutes	< 1 minute

NOTE: Maximum infusion pressure generated by the pump is 1050 mmHg.

11.1.6 Bolus volume at occlusion release

	Accuracy		
Bolus volume at Occlusion Release*	Flow rate 25 mL/h	Low pressure level < 1 mL	High pressure level < 1.5 mL

*Test condition: Back pressure: 0 mmHg; Container height: 50 cm above the upside of the pump.

11.1.7 Missing set alarm response time at different flow rates

Flow rate	Missing set alarm detection time
1 mL/h	15 minutes maximum
25 mL/h	40 seconds maximum
100 mL/h	12 seconds maximum
600 mL/h	4 seconds maximum

11.1.8 Empty bag / Air in Line detection time at different flow rates

The table below illustrates the single bubble air detection time at its maximum selectable volume of 0.75 mL.

Empty bag / Air in Line detection time	
Flow rate	**Air volume of single bubble = 0.75 mL**
1 mL/h	46 minutes maximum
25 mL/h	2 minutes maximum
100 mL/h	35 seconds maximum
600 mL/h	7 seconds maximum

INFORMATION
The detection time of cumulated air bubbles is customized by the user. To set the air detection volume and the detection time of cumulated air bubbles, see *Occlusion pressure / Air detection* on page 61.

11.2 Technical characteristics

11.2.1 Operation mode

The Ambix nova pump is a reusable device. The pump ensures fluid delivery in 4 kinds of infusion mode (for *Infusion mode* on page 44), using pumping and clamping fingers to push the liquid to the patient.

11.2.2 Power supply specifications

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

Smart Holder input	AC input voltage: 100-240 Vac AC input frequency: 50/60 Hz AC input current: 110 mA-205 mA
Smart Holder output	9 Vdc ± 5 % / 9 W (maximum load)
Power cable length	Approx. 2 m

11.2.3 Battery specifications

Characteristics	7.2 V Lithium Ion rechargeable battery / 16.2 W
Weight	Approximately 0.095 kg
Maximum charging time	6 h with pump off

11.2.4 Power consumption

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

11.2.5 Dimensions - Weight

	Weight	Dimensions (H x W x D)
Pump	~ 0.66 kg	Approx. 156.4 mm x 129.7 mm x 49 mm
Smart Holder Power	~ 0.45 kg	Approx. 132 mm x 118 mm x 46 mm (without pole clamp)
Packaging	~ 0.28 kg	Approx. 112 mm x 272 mm x 230 mm

11.2.6 Trumpet curves

The trumpet curves show the variations in the mean flow accuracy over specific observation periods.

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

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

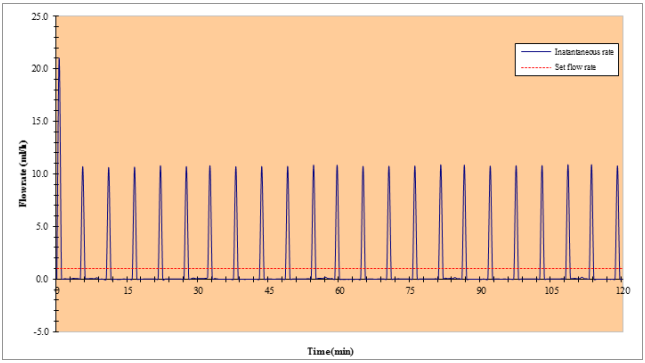
The curves presented below are drawn from the test data of the same pump.

Administration set used: Ambix nova stationary set

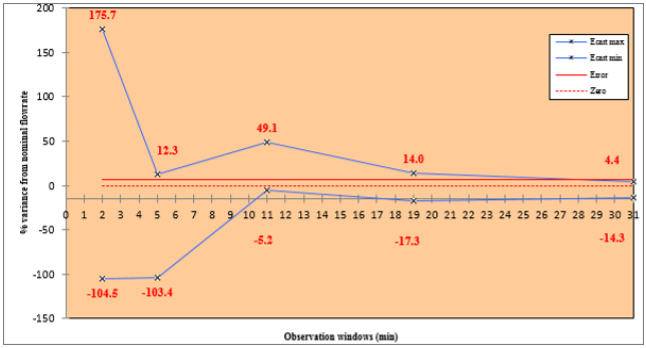
Fluid used: distilled water

11.2.6.1 Minimum flow rate: 1 mL/h

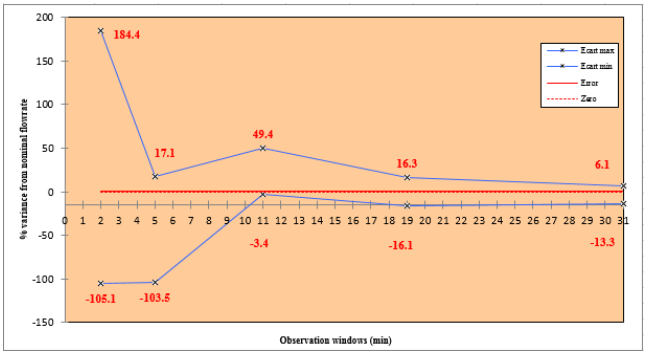
Sampling time: 30 seconds



Start up and instantaneous flow rate (1 mL/h, during first 2 hours of the set change interval, 24 hours)



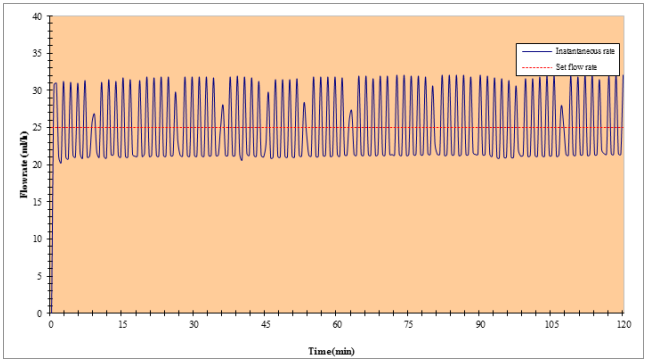
Trumpet curves for 2, 5, 11, 19, 31 minute observation windows (1 mL/h, during second hour of the set change interval, 24 hours)



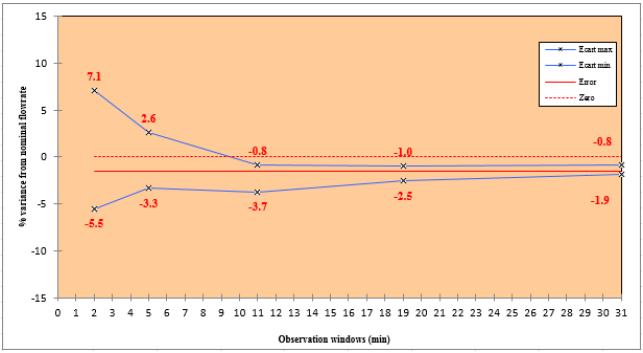
Trumpet curves for 2, 5, 11, 19, 31 minute observation windows (1 mL/h, during last hour of the set change interval, 24 hours)

11.2.6.2 Intermediate flow rate: 25 mL/h

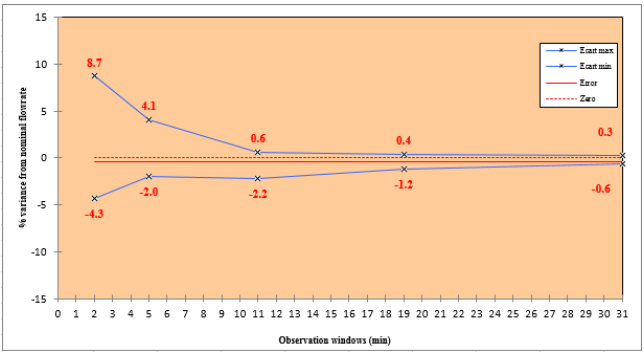
Sampling time: 30 seconds



Start up and instantaneous at intermediate flow rate (25 mL/h, during first 2hours of the set change interval, 24 hours)



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



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

11.2.7 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 93/42/EEC Medical Directive 0123 : Notified body number (TÜV SÜD Product Service GmbH, Ridlerstrasse. 65, 80339 München, Germany)

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

12 Transport, storage and recycling conditions

12.1 Storage and transport conditions

WARNING
The pump must be stored and transported under **specified conditions** listed below to ensure pump performance and to avoid malfunction.

Observe the following conditions for storage and transport:

- **Temperature range:** - 20°C to + 45°C
- **Humidity range:** 10% to 85%, no condensation
- **Pressure range:** 700 hPa to 1060 hPa
- **Altitude range:** less than 3000 m

12.1.1 Storage

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

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

12.1.1.1 Prepare the device for storage

WARNING
Remove the battery and store it as per storage conditions above in case of a **prolonged storage period**.

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 set (see *Removing/Changing the set from the pump* on page 38).
3. Disconnect pump power cable (see *Electrical disconnection* on page 22).
4. Remove the pump and its holder from pole or rails (see *Removing the pump from the pump holder* on page 22).
5. Clean the pump (see *Cleaning and disinfection* on page 74).
6. Handle the pump with care and store it in a compliant area.

12.1.1.2 Install the device after storage

INFORMATION
- If the battery has been removed for storage, please contact your biomedical department to replace the battery into the device prior to using the pump.

- We recommend charging the battery, by leaving the device connected to the mains power supply for at least 6 hours. After prolonged storage, a few minutes may be required before using the pump (an hourglass will be displayed).
- We recommend that the *Quick check protocol* on page 77 is performed when the device is installed after transport, in case of prolonged storage, or before being used on a new patient.

12.2 Recycling and disposal

Batteries, accessories and devices with this label must not be disposed of with general waste.
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 information on waste processing regulations and dismantling, please contact your Fresenius Kabi sales representative.

13 Guidance and manufacturer's declaration on EMC

The Ambix nova pump is intended to be used in the electromagnetic environment specified below.

The customer or the user of the Ambix nova 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 Ambix nova 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 88, are lost or degraded, the consequences for the patient can be: delay of therapy, underdose, overdose, electric shock or trauma.

13.1 Electromagnetic compatibility and interference guidance

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

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

If the Ambix nova 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 Ambix nova and this equipment (see *Recommended separation distances between portable and mobile RF communication equipment and pump* on page 98). If the Ambix nova 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 nova or patient or disruptive equipment;
- change the routing of cables;
- connect the Ambix nova mains plug on protected / backed-up / filtered supply or directly on UPS circuit (uninterruptible power supply);
- increase the separation between the Ambix nova and patient or disruptive equipment;
- connect the Ambix nova 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.

13.2 Guidance and manufacturer's declaration - Electromagnetic immunity

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

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

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

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

Users of the Ambix nova may prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Ambix nova 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 Ambix nova, 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.

WARNING

- At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.
- These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.
- The device should not be used next to other equipment. If adjacent use is necessary, the device should be observed to verify normal operation in the configuration in which it will be used (Ambix nova pump with a Smart holder, a USB cable and a nurse call cable).

14 Services

14.1 Warranty

14.1.1 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.

14.1.2 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 (SN) 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.

14.1.3 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.

14.2 Quality control

Upon request by the healthcare facility, a **quality control** check can be performed on the Ambix nova **every 12 months**.

A regular quality control (not included in the guarantee) consists of various inspection operations listed in the technical manual.

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, refer to the technical manual or contact your Fresenius Kabi sales representative.

14.3 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.
- 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 sales representative.
- 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 Ambix nova pump: 10 years provided that the maintenance is properly performed as described above.

14.4 Service policy and rules

If the device must be sent for servicing, proceed as follows:

1. Contact Fresenius Kabi to have packaging shipped to your facility.
2. Clean and disinfect the device.
3. Pack the device in the provided packaging.
4. Ship the device to Fresenius Kabi.

INFORMATION

Fresenius Kabi is not liable for loss or damage to the device during transport. For more information on servicing, please contact your Fresenius Kabi sales representative.

14.5 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

61346 Bad Homburg

Germany

Tel.:+49(0)61 72/6 86-0

15 Ordering information

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

15.1 Instructions for use

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

15.2 Administration sets

Ambix nova sets are single use. Use only recommended administration sets list below:

Administration sets	Reference
Ambix nova Ambulatory Set	M46421820
Ambix nova Stationary Set	M46421910

15.3 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
activ Rucksack	2892091
activ Rucksack mini	2892101
Smart Holder Power EU Accessory	CS1000428*
Smart Holder COM EU Accessory	CS1000429*
USB Partner Cable	D3040016

*AC power cable for plug type C is provided within the package. Additional power cable must be ordered seperately, each product reference includes its own appropriate wall plug, depending on the country.

Please contact your Fresenius Kabi sales representative for orders.

16 Glossary of terms

Term	Description
°C	Celsius Degree
A	Amper
AC	Alternating Current
Ah	Ampere hours
Ambix nova	Infusion pump manufactured by Fresenius Kabi
Approx.	Approximately
CE mark	European Conformity Mark
CISPR	Special International Committee on Radio Interference
cm	Centimeters
d	Days
dB	Decibel
DECT	Digital Enhanced Cordless Telecommunications
ECG	Electrocardiogram
EEG	Electroencephalogram
EMC	Electromagnetic compatibility
ER X.Y.Z	Error message
g	Gram
h	Hours
H x W x D	Height / Width / Depth
HF	High Frequency
hPa	Hecto Pascal
Hz	Hertz
SN	Serial number
IEC	International Electrotechnical Commission
IFU	Instructions for Use
IV	Intravenous
LED	Light Emitting Diode
m	Meters

Term	Description
max	Maximum
MHz	MegaHertz
min	Minumum
min.	Minutes
mL	Milliliter
mL/h	Milliliter per hour
mm	Millimeters
MRI	Magnetic Resonance Imaging
NMR	Nuclear Magnetic Resonance
RF	Radio Frequency
RFID	Radio Frequency Identification
s	Seconds
UPS	Uninterruptable Power Supply
V	Volt
Vac	Volt Alternating Current
Vdc	Volt Direct Current
W	Watt

Release notes

Date	Software version	Description
October 2020	V1.0	Creation

Made in China

Revision date: November 2020

Reference: DHF-0279-10_Master_IFU_Ambixnova_eng

http://www.fresenius-kabi.com

CE 0123

Local contacts for servicing

DHF-0279-10_Master_IFU_Ambixnova_eng

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