FRESENIUS KABI

caring for life

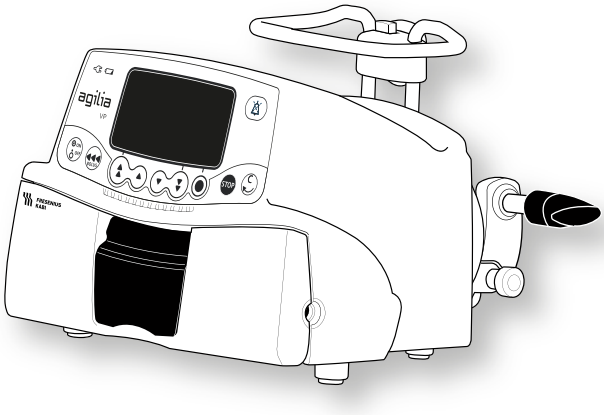
Agilia VP

Volumetric Infusion Pump

Applicable to software version 4.1

Instructions For Use

For Use in Healthcare Facilities and Homecare Environments



Symbols used in this document

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

Recommendations to be followed.

Labelling symbols

Warning
(Refer to the Instructions For Use)

Refer to the Instructions For Use

Product reference / part number

Product serial number

Input terminal - connector

Output terminal - connector

Electrical fuses

Alternating Current (AC)

Direct Current (DC)

IP22

Index of protection against solid foreign objects (> 12.5 mm) and dripping liquids

Part included in a recycling process

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

CE mark

Unique Device Identifier

Name and address of the manufacturer / Date of manufacture

Name and address of the manufacturing facility

Protection against electric shock: class II

Non-ionizing electromagnetic radiation

Fragile, handle with care

This way up

Keep away from rain

Temperature limitation

Humidity limitation

Atmospheric pressure limitation

General symbol for recyclable material

Eco packaging symbol

Medical Device

Table of Contents

1 Introduction

1.1 Scope

These Instructions for Use (IFU) are applicable to the Agilia VP large volume pump. This device is referred to throughout this manual as the "Agilia VP".

The user must adhere to the instructions specified in this IFU. Failure to adhere to these instructions may result in damage to the equipment, injury to patients or injury to users.

Warning

Check that this IFU is applicable to the current software version of the device.

- *The software version of the device is displayed on the start-up screen.*
- *The software version described in this IFU is displayed in the Release Notes, page 145.*

1.2 Principles of Operation

Agilia VP is a 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.

Agilia VP is a transportable and reusable device that can be used everyday.

Agilia VP can be used for intermittent or continuous infusions.

Agilia VP 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

Infusion pump and accessories for IV administration of fluids.

1.4 Intended Use

1.4.1 Indications

Warning

In homecare environment, the pump must only be used to infuse noncritical drugs. Otherwise, there is a risk of interruptions in the therapy which could have critical consequences for the patient. The following fluids can only be infused under the permanent supervision of a trained healthcare professional:

- *Catecholamines*
- *Morphine*
- *Chemotherapy*
- *Other critical drugs*

The pump is indicated to administer products through clinically accepted routes. These products include:

	Intended Products
Parenteral Fluids	▪ Standard solutions ▪ Colloids ▪ Parenteral nutrition
Medication	▪ Diluted drugs ▪ Antibiotics ▪ Chemotherapy ▪ Catecholamines ▪ Short acting drugs ▪ Anesthesia drugs
Blood and blood derivatives	▪ Blood ▪ Red blood cells ▪ Platelets ▪ Plasma ▪ Albumin

Warning

Infusion of bolus or small volume of chemotherapy vesicants through peripheral route should be administered according to the good clinical practice of the healthcare facility. If infusion pump is used, the patient should still be continually assessed for any signs of potential extravasation.

Warning

When using Agilia VP to infuse critical medications, ensure that adequate monitoring is provided.

When using Agilia VP to infuse critical medications in healthcare facilities, ensure that backup pumps and administration sets are available for immediate use.

Only use Agilia VP for the infusion of fluids that are intended for infusion pumps.

Do not use the pump for epidural use.
Do not use the pump for enteral nutrition.

Administration Routes

The system allows infusion via the following access routes:

- IV access with any device that administers a medical fluid to a vein and is equipped with a female Luer lock,
- Subcutaneous access.

1.4.2 Contraindications

There are no known contraindications to the use of the device when used according to this document.

1.4.3 Intended users

In **healthcare facilities**, the pump must only be used by qualified and trained healthcare professionals.

In **homecare environments**, the pump must only be used by appropriately trained users including homecare professionals, patients or their relatives (in case of patient's inability to correctly react to pump alarms) under the responsibility of healthcare professionals. In homecare environments, the IFU must be provided to the homecare nurse.

Two Quick Reference Guides are available (one for homecare professionals, one for the patient) in order to describe the typical operations performed at home. We recommend using them and keeping the Quick Reference Guide for the patient near the pump.

Typical initial training duration: 1 hour.
It is recommended that users attend a refresher training session of about 20 minutes every year.

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

1.4.4 Intended patients

Agilia VP is intended to be used according to healthcare facilities protocols on patients with the following characteristics:

	Patient Characteristics
Sex	Male Female
Age	Neonates (except in homecare environment) Pediatrics Adults Elderly
Weight	0.25 kg to 350 kg
Body Surface Area	0.05 m² to 4.5 m²

When using the pump with a very sensitive population such as the neonates, make sure to:

- Switch to night mode
- Set the alarm volume to the minimum level

1.4.5 Use Environment

Agilia VP is intended for use in the following environments:

- Healthcare facilities and in pre-hospital medical ground transportation, under the supervision of trained healthcare professionals.
- Homecare environment under the responsibility of trained healthcare professionals, by following specific precautions: See Section 1.4.6, page 13.

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

- Operating temperature range:
  5 °C to 40 °C
- Operating pressure range:
  700 hPa (525 mmHg / 10.15 PSI) to 1060 hPa (795 mmHg / 15.37 PSI)
- Operating humidity range:
  20 % to 90 % with no condensation
- Altitude:
  Up to 3000 m above sea-level

Warning

Do not use the pump in the following environments:

- *Explosive or flammable environments*
- *High humidity environments (shower, bath, etc.)*
- *Ultrasonic environments not to damage the pump or its components*
- *Magnetic Resonance Imaging (MRI) not to deteriorate the MRI images*
- *Hyperbaric chamber*

Warning

The functionality of the pump can be affected by pressure variations, mechanical shocks, heat ignition sources, and so on.

Warning

Device which may create pressure decrease downstream the pump (i.e. ECMO, dialyser) should be used carefully with the pump and appropriate measures should be taken to avoid influence on the pump performances.

Information

- *The pump can be used in ambulances exclusively with the Agilia Holder Ambulance accessory. Due to use in road ambulances, performances of the device can be modified. For more information, refer to Agilia Holder Ambulance IFU.*
- *For more information on using the device in specific conditions, contact your **Fresenius Kabi** representative.*

1.4.6 Specificities for Homecare Environments

Warning

Product version

Only pumps with software version 2.2 or above can be used in homecare environments. In early versions, all homecare functionalities are unavailable.

*If your software version is not compatible with homecare environments, contact your **Fresenius Kabi** representative.*

Environment Considerations

- Consider the following operational conditions to ensure proper device performance:
  - Do not expose to sun light, keep in dry place, at room temperature, normal pressure.
  - Keep in clean environment.
  - Keep away from objects which can potentially damage the device.
  - Keep away from any noise disturbance which could prevent patient or relatives from hearing the pump alarms.
  - Keep away from heat source, dust, fluff, direct and prolonged light exposure.
  - Keep away from animals, pests or children.
- Do not share an outlet with another electrical device.

General Considerations

- Healthcare professionals should not divulge to the patient or relatives the pump's lock system or any information that may allow an access to all programming and operating functions.
- The responsibility of using the pump is shared between the healthcare professional and the patient.
- Homecare providers or healthcare facilities are responsible for disposal of administration sets and bags used at home according to current standards in order to limit the risk of harm and infection.
- The use of the Drop Sensor is not recommended for homecare environments.

Warning

- *It is the healthcare professional's responsibility to ensure that the patient or his/her relatives have the required capacity (physical, cognitive or perceptive) to use the pump in homecare environments. Otherwise, there is a risk of usage errors and incorrect therapy which could have critical consequences for the patient.*
- *Homecare providers must ensure that they can provide backup sets and a backup pump within a short time period to avoid interruptions of administration which could have critical consequences in case of pump failure in the patient's home.*
- *Give particular attention to the risk of strangulation with cables and sets, and with the small parts that could be swallowed or inhaled.*

Maintenance Requirements

Homecare providers are responsible for periodic maintenance and calibration of pumps used in homecare environments.

Homecare providers must be informed if the device is dropped or if any malfunctions occur. In this case, do not use the device and contact your homecare providers.

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 Agilia VP infusion system are the following:

- Provide a controlled and accurate system for the infusion of large volume of drugs, fluids and blood products (volume delivery accuracy of the system is ±5%, flow rate adjustable from 0.1 to 1200 mL/h, compatible with a wide range of dedicated administration sets).
- Provide features and infusion functions adapted to the needs of patients and healthcare professionals (continuous infusion and bolus infusion, different flow rate modes, pause function, keep vein open function, view infusion history, night mode, infusion monitoring screen, wide range of drugs and fluids compatible).
- Provide safety features and relevant alarms that improve infusion safety and prevent unexpected infusion discontinuation (Dynamic Pressure System, pressure monitoring, adjustable air parameters, keypad lock options, alarm system compliant with EN/IEC 60601-1-8).

1.6 Side-effects

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

1.7 Risks for patients

Failure to follow all instructions described in this document or loss or degradation of essential performance (Section 15.1, page 99.) may result in: overdose, underdose, delay of therapy, incorrect therapy, exsanguination, toxicity, infection, air embolism, trauma or electric shock.

2 Agilia Connect Infusion System

Agilia Range		Description
Pump	Agilia VP range	**Volumetric Infusion Pump** Pumps designed to deliver the contents of parenteral infusion container (bag or bottle) through a line connected to a patient.
	Agilia SP range	**Syringe Infusion Pump** Pumps designed to deliver the contents of a syringe through a line connected to a patient.
	Agilia SP PCA	**Patient-Controlled Analgesia (PCA) syringe infusion pump** Pumps intended for PCA therapy and for the administration of analgesic drugs under the patient's or the clinician's control.
	Agilia ProNeo	**Enteral Nutrition Syringe Pump for Neonates** Pumps designed to deliver enteral nutrition to neonates, preterm babies and children via clinically accepted routes of administration.
Vigilant Software Suite	Vigilant Centerium	**Server Software** Software intended to report status of compatible Fresenius Kabi infusion devices according to the identified installed base for fleet management, to store and distribute datasets to connected infusion devices and to report distribution status, besides supporting system maintenance operations.
	Vigilant Bridge	**EMR Auto-documentation** Software intended to establish connection between compatible Fresenius Kabi infusion pumps and the Electronic Medical Records (EMR) system. Infusion data is then automatically transmitted to the EMR.
	Vigilant Insight	**Infusion Data Reporting Software** Software intended to collect and report infusion information received from compatible Fresenius Kabi connected infusion devices to analyze and improve clinical settings included into a dataset.
	Vigilant Master Med	**Drug Library Software** Software intended to create, customize, and manage drug library data and device configurations to be uploaded to compatible Fresenius Kabi infusion devices.Vigilant Master Med is part of a Dose Error Reduction System (DERS).
	Vigilant Sentinel	**Infusion visualization system** Software designed to provide qualified healthcare personnel with a centrally aggregated view of infusion pumps' status within a hospital or hospital-type setting.

Agilia Range		Description
Software	**Agilia Partner**	**Maintenance Software** Software designed to maintain, configure, test and calibrate compatible Agilia infusion devices and accessories.
Accessories	**Link Agilia** **Agilia Link** **Link+ Agilia**	**Stacking Rack Systems** Rack systems designed to stack 4, 6 or 8 Agilia infusion pumps. Link Agilia / Agilia Link are designed to centralize the power supply. Link+ Agilia is designed to centralize the power supply and to centrally replicate infusion pump signalling.
	Agilia MRI Guard	**MRI-Shielding System** Agilia MRI Guard is intended to accommodate and power up to four Agilia infusion pumps so that these pumps can be operated in a Magnetic Resonance Imaging unit.
	Agilia Duo	**Two-channel accessory** The Agilia Duo is intended to centralize mains power for two attached Agilia pumps.
	Agilia Holder Ambulance	Accessory intended to be used in road ambulances equipped with AC power source and a horizontal rail in order to fix an infusion pump.
	Drop Sensor	Accessory intended to detect drops in the administration set drip chamber when connected to a compatible volumetric pump.
Disposables	**Volumat Lines**	**Administration Sets** Administration sets can be in contact with the patient (applied part).

Information

For a list of compatible accessories, disposables and software, and for ordering information, refer to the System Components booklet.

3 Description

3.1 Front View

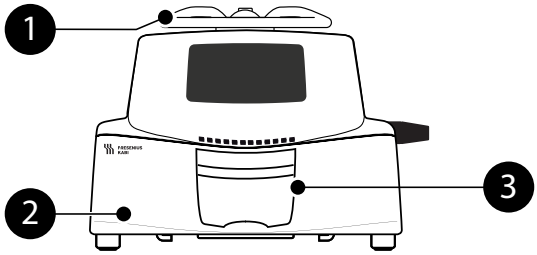
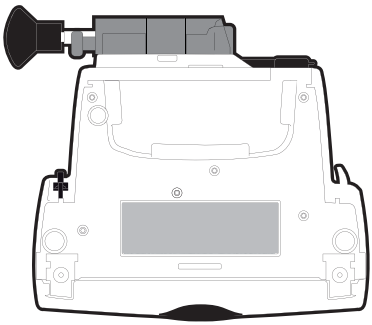


Figure 3.1: Front View

Legend			
1	Handle	3	Door Lever
2	Pump Door		

3.2 Bottom View (Device Identification Label)



On the device identification label, the UDI (Unique Device Identifier) is presented in machine-readable form (AIDC - Automatic Identification and Data Capture - technology) and as text:

UDI

- (01) Product Identifier GTIN
- (21) Product Serial Number
- (11) Date of Manufacture
- (240) Product Reference

For more information on device identification label symbols, see Symbols used in this document, page 2.

3.3 Back View

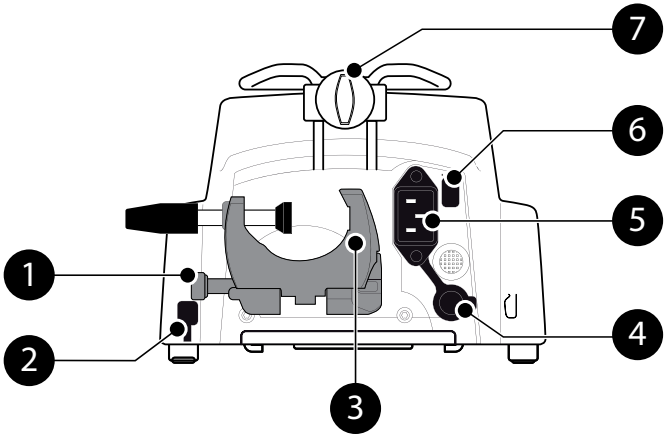


Figure 3.2: Back View

Legend

1	Release Button	5	Power Cord Inlet
2	Drop Sensor Connection Socket	6	Infrared Cell
3	Rotating Pole Clamp	7	Attachment Lock Knob
4	RS232 Communication Port		

Symbol	Location	Description
⚠ ⚠	Near Power Cord Inlet	***Warning*** See section 18, page 111.
⚠	Near RS232 Communication Port	***Warning*** See section 10, page 78.

3.4 Keypad

3.4.1 Keypad Description

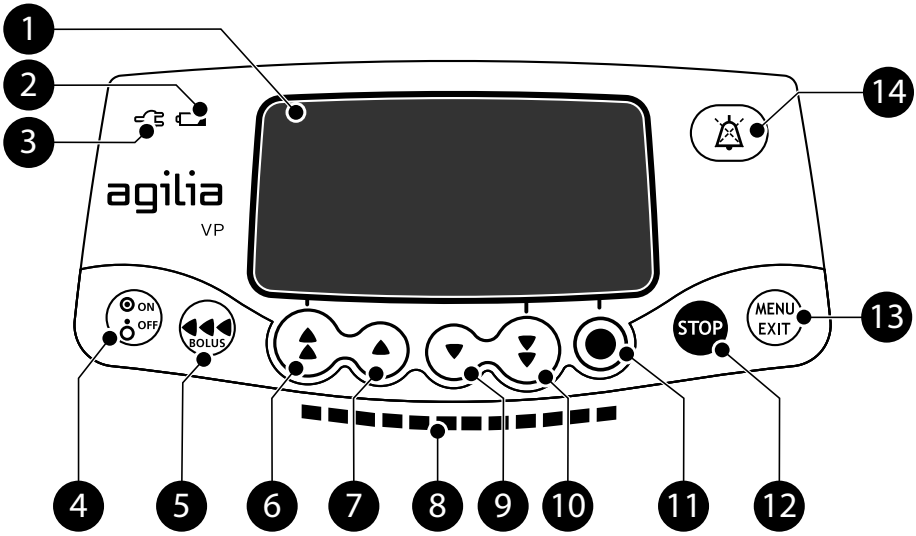
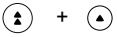
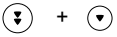


Figure 3.3: Keypad

Legend			
1	Screen	9	Decrement
2	Battery Charge Status Indicator	10	Fast Decrement
3	Power Supply Indicator	11	Confirm Value / Move to Next Field
4	On / Off	12	Stop
5	Bolus / Prime / Advance Air	13	Menu / Cancel Value / Move Back to Previous Field
6	Fast Increment		
7	Increment	14	Alarm Silence
8	Infusion Indicator Lights		

3.4.2 Keypad Details

3.4.2.1 Selection Keys

Key	Description
	**Arrow Keys** Keys for selecting volume, time, flow rate and other values.
	Fast Access to Maximum Value or Top of a List
	Fast Access to Minimum Value or Bottom of a List

Note:

- *Fast increment and decrement keys have been programmed with different levels corresponding to standardized volumes of bags and bottles.*
- *Pressing and holding any of the arrow keys results in faster increment or decrement.*

3.4.2.2 Infusion Indicator Lights

Indicator	Description
	Infusion in Progress (flashing green)
	Low-Priority Alarm (constant yellow)
	Medium-Priority Alarm (flashing yellow)
	High-Priority Alarm (flashing red)

Note:

- *Infusion indicator lights provide information about the infusion: in progress, or with a low, medium or high-priority alarm.*
- *Green indicator lights will continuously flash from right to left while the infusion is running.*
- *The frequency of flashing varies according to flow rate.*

3.4.2.3 Status Indicators

Indicator	Description
	**Power Supply Indicator** When the device is attached to an active power supply, the indicator light is a constant green. If the pump is not connected to the AC power, it does not light up.
	**Battery Charge Status Indicator** When the device is attached to an active power supply, the indicator light provides information about battery charge status: ▪ If the indicator is blinking, the battery is being charged. ▪ If the indicator is lit permanently, the battery is fully charged. If the pump is not connected to the AC power, it does not light up.

3.5 Display and Symbols

3.5.1 Infusion Status

Symbol	Description
	**Infusion in Progress** This symbol shows a drop falling into the drip chamber. The drop appears in the drip chamber when an infusion is in progress.
	**Infusion in Progress (Drop sensor connected)**
STOP	**Infusion Stopped** STOP remains in the center of the screen until the user starts the infusion again.

3.5.2 Screen Options

Symbol	Description
	**Battery Logo** ▪ This symbol shows three different charge levels. < 30 % battery charge 30 % - 70 % battery charge > 70 % battery charge ▪ If the 'Battery logo' option is enabled, this symbol is displayed constantly. ▪ If the 'Battery logo' option is disabled, this symbol is only displayed when the pump is operating on battery.
	**Pressure Logo** This symbol gives information about pump pressure settings and measured pressure levels.
	**Keypad locked symbol** This symbol informs the user that the keypad is locked.

3.5.3 Navigation Buttons

Symbol	Description
start	Start
OK	Confirm
enter	Access Function
New ?	Access Function and Clear Settings
exit	Exit Function
C	Change Selection
prog	Program Function
☑/☐	Select / Unselect
i	See More Information
⊕ / ⊖	Zoom in / Zoom out
«--- / ---»	Move the Event Marker to the Left / Right

3.5.4 Alarms and Safety Features

Symbol	Description
	Power Disconnection
	Alarm Silenced
	Pressure Increase
	Drop in Pressure

Note: For more information on alarms, see section 12, page 80.

3.6 Packaging

Depending on your country, the Agilia VP packaging contents is different.

	Agilia VP pump	Instructions For Use	System Components booklet	User information document (multilingual)	Power cord
Z019XXX	v	v	v	-	v
Z019X00*	v	-	-	v	-

* Product codes ending by 00 are for the multi-country versions.

If the power cord is not included in the packaging, it is to be ordered separately, see references in the System Components booklet.

Packaging weight: Approximately 530 g.
Packaging consists of: Recycled cardboard.

Information

- *It is the healthcare facility's responsibility to check the pump integrity upon reception.*
- *If the packaging contents are incomplete or damaged, contact your* ***Fresenius Kabi*** *sales representative.*

4 Fundamentals

4.1 Profiles

A **profile** defines the device configuration and drug library used for a group of patients in a given health care environment.

By default, factory settings include only 1 profile (Basic Profile).

Information

For pumps used on only one group of patients, we recommend disabling the ability to select the profile, thus locking the pumps to the selected profile.

4.1.1 Basic Profile

Basic Profile allows programming of an infusion with the following characteristics:

- The infusion is programmed without drug names.
- Limits on drug infusion rates are not included.

To program an infusion with Basic Profile, choose "Basic Profile" when selecting a profile.

Configurations and settings accessible in Basic Profile may not be suitable for all patient groups and protocols.

4.1.2 Custom Profiles

Custom profiles feature a specific pump configuration and a drug library.

Custom profiles are not available with the pump described in this IFU (Agilia VP).

Information

*For more information on **Fresenius Kabi** devices that are compatible with custom profiles, contact your **Fresenius Kabi** sales representative.*

4.2 Infusion Modes

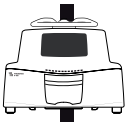
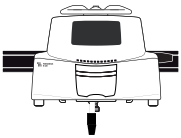
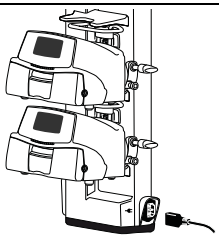
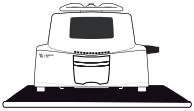
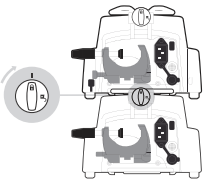
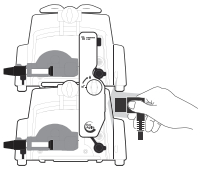
An infusion can be started according to the following modes:

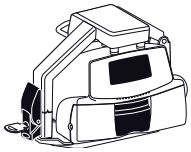
Infusion Mode	Description
Volume / Time / Rate (V/T/R)	This infusion mode gives access to the 3 infusion parameters (V, T, R)
Volume / Rate (V/R)	Infusion of a programmed volume of fluid at a programmed rate
Volume / Time (V/T)	Infusion of a programmed volume of fluid over a programmed period of time
Simple Rate	Infusion defined by a flow rate. Only available with the optional drop sensor fixed to the drip chamber and connected to the pump.

5 Installation

5.1 Types of Installations

A pump can be installed on any of the following:

Location		Comments
On a Pole		☞ See section 5.3.1, page 29. **Pole specifications:** ▪ Diameter: from 15 to 40 mm
On a Rail		☞ See section 5.3.2, page 31. **Rail specifications:** ▪ Height: from 25 to 35 mm ▪ Depth: from 8 to 10 mm
On the Agilia Link or Link Agilia or Link+ Agilia Rack		☞ Refer to the relevant accompanying documents.
On a Table		☞ See section 5.3.3, page 31. Only install a pump on a table if it is not possible to attach it to a pole, a rail or recommended Agilia accessory.
On Another Pump		☞ See section 5.3.4, page 32.
On an Agilia Duo		☞ Refer to the Agilia Duo accompanying documents.

Location		Comments
In an Agilia Holder Ambulance		☞ Refer to the Agilia Holder Ambulance accompanying documents.

Do not use accessories that appear to be damaged. For more information on accessories, refer to their respective accompanying documents.

Warning

- *The pump must be used in a horizontal and stable position to function properly.*
- *Use recommended Agilia accessories to ensure stability and prevent the pump from falling. Do not stack the pump with equipment other than those recommended.*

5.2 Using the Rotating Pole Clamp

The rotating pole clamp is located at the back of the pump.

When installing the pump on a pole or a rail, fasten the rotating pole clamp firmly to avoid any movement of the pump.

5.2.1 Rotating Pole Clamp Description

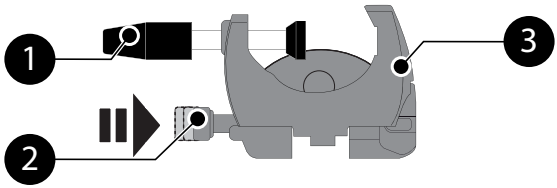


Figure 5.1: Rotating Pole Clamp System

Legend	
1	Screw Clamp
2	Release Button
3	Rotating Pole Clamp

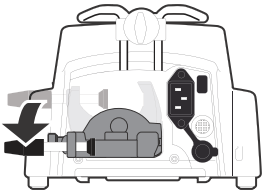
5.2.2 Using the Rotating Pole Clamp

You can secure the rotating pole clamp vertically or horizontally by folding it outward until the release button clicks into the locked position.

5.2.2.1 Folding the Clamp Down (outward)

You can fold the clamp down as follows:

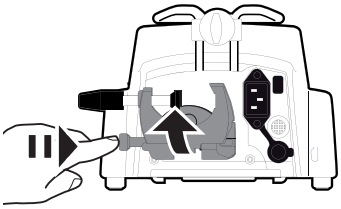
1. Push the release button.
2. Fold the clamp outward.



5.2.2.2 Folding the Clamp Up (inward toward the pump)

You can fold the clamp up as follows:

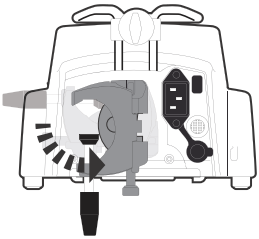
1. Push the release button.
2. Fold the pole clamp inward toward the pump.



5.2.2.3 Rotating the Clamp

You can rotate the clamp as follows:

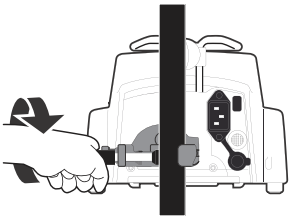
1. Fold the clamp up (see above).
2. Rotate the clamp to a vertical position.
3. If necessary, fold the clamp outward (see above).



5.3 Attaching the pump(s)

5.3.1 Attaching to a Pole

1. Fold the pole clamp down to the horizontal position: see section 5.2.2.1, page 29.
2. Unscrew the clamp, attach to the pole, and screw the clamp until the pump is fully secured to the pole.
3. Make sure that the pump is securely attached.
   For more information on installing the pump on a pole, consult the pole's Instructions For Use.



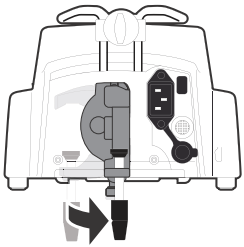
Information

When installed on a rolling stand, do not tip over the system more than 5°: it may fall.

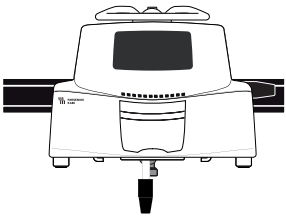
5.3.2 Attaching to a Rail

Only single pumps can be attached to a bed rail or gurney rail.

1. Rotate the pole clamp to the vertical position: see section 5.2.2.3, page 29.
2. Unscrew the clamp, attach to the rail, and screw the clamp until pump is fully secured to the rail.

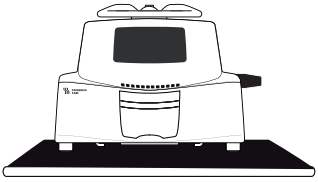


3. Make sure that the pump is securely attached.



5.3.3 Using on a Flat Table

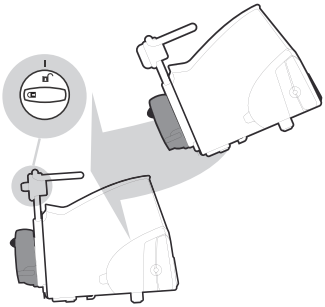
1. Fold the pole clamp up: see section 5.2.2.2, page 29.
2. Place the pump far enough from the table's edges to prevent it from accidentally being pushed off.



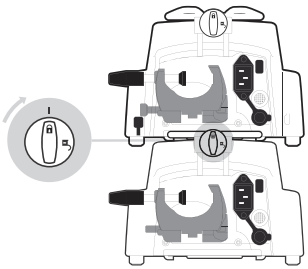
5.3.4 Attaching Two Pumps Together

You can attach two pumps together either for transport, or before fixing them to a pole.

1. Fold both pumps' pole clamps up: see section 5.2.2.2, page 29.
2. Slide the slot on the bottom of the upper pump onto the handle of the lower pump.



3. Turn the attachment lock knob on the lower pump handle clockwise until the locked symbol lines up with the marker.
4. Make sure the two pumps are securely attached together.
5. If needed, fold the two pole clamps down and secure them tightly to the pole.

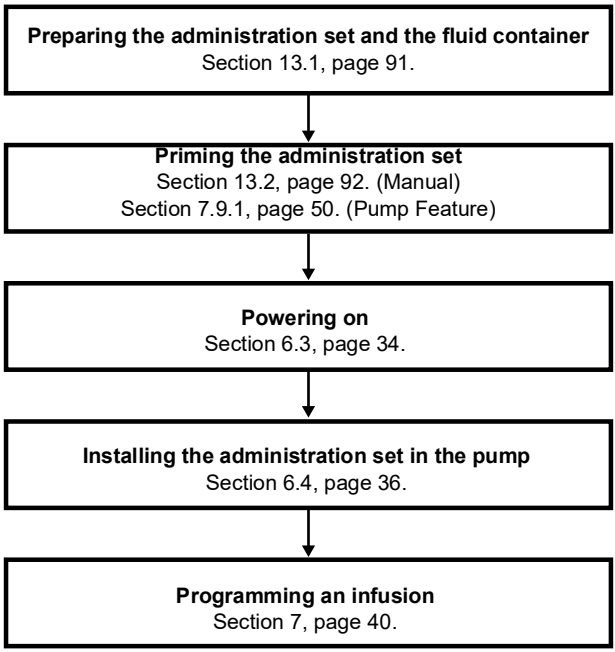


Symbol	Location	Description
	Attachment Lock Knob	Locked Position
	Attachment Lock Knob	Unlocked Position

6 Getting Started

6.1 Flowchart

Once the pump is installed at the bedside, you must follow the steps below in order to install an administration set and power on the pump.



Information

In order to ensure that all the safety features of the device are activated, make sure that the following instructions are applied:

- *The pump is powered on prior to being connected to the patient.*
- *The pump is not connected to the patient during the set-up.*

6.2 Using the Pump for the First Time

1. Make sure the pump is correctly installed at the bedside.
   See section 5, page 27.
2. Plug the pump into the AC power supply.
   See section 17.1, page 109.

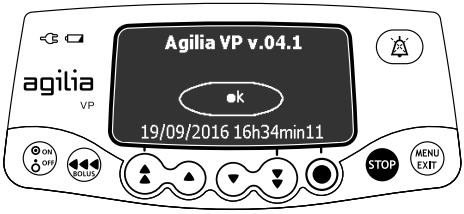
3. Before starting the pump for the first time, you must charge the battery for approximately **6 hours**.
   Wait until the pump is fully charged.
   Do not use the pump during the first charge.
4. Prepare the administration set. See section 13.1, page 91.
5. Power on the pump. See section 6.3, page 34.

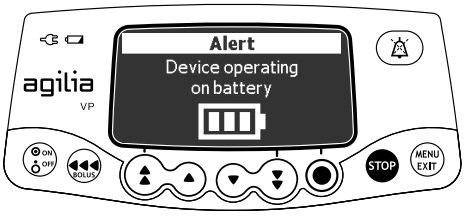
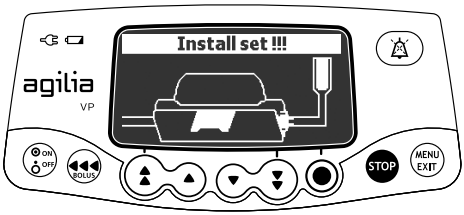
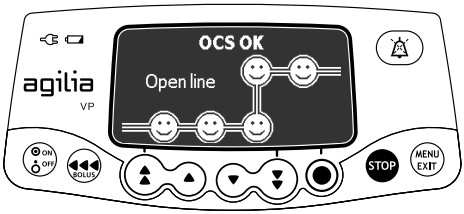
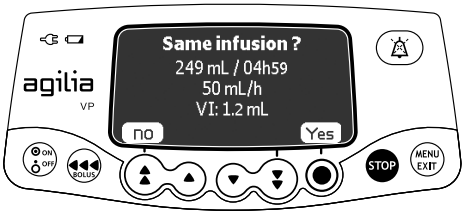
6.3 Powering on

Information

- *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 in order 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 cord and the wall plug are accessible.*
- *When plugged into a power supply, the pump automatically powers on when the pump door is opened. You can deactivate this option in the pump options. For more information, refer to the technical manual.*

1. Press ON/OFF or open the pump door by lifting the door lever.
   An auto-test checks the functionality of the pump.
2. Immediately after powering on the pump, make sure that all LED lights blink.
3. If the language screen is displayed, select the language. Then, enter the date.
   If the selection is incorrect, contact your biomedical department to reset the pump to its initial configuration.
4. Acknowledge the different screens listed in the table below.

Screen After Powering on	Description
	Startup screen: the following information is displayed: ▪ Product name / Ward name ▪ Date & time

Screen After Powering on	Description
	▪ The pump is operating on battery. ▪ The symbol shows three different charge levels: < 30 % battery charge 30 % - 70 % battery charge > 70 % battery charge
	▪ No administration set is installed on the pump. ▪ `Install set !!!` is displayed on top of the screen. ☞ Install an administration set. See section 6.4, page 36.
	▪ The administration set is loaded into pump. ▪ OCS test is successfully completed. ▪ The OCS test verifies the circuit and pump occlusivity at start-up, thus reducing the occurrence of unintentional gravity flow.
	▪ Maintenance reminder message (optional).
	▪ Same infusion screen (optional). Press **Yes** to keep previous infusion settings.

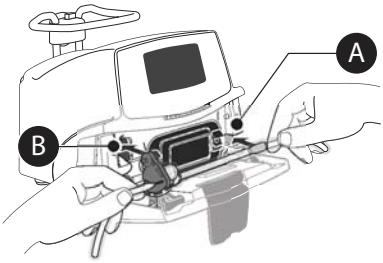
5. For multi-country devices, check that the device is parametrized as expected.

6.4 Installing the Administration Set in the Pump

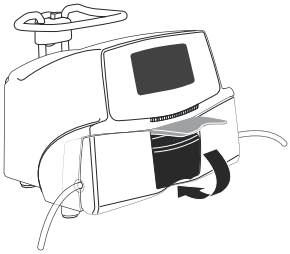
Warning

- *Do not open the roller clamp until the OCS test has successfully completed.*
- *During all manipulations of the pump with administration set (administration set installation, door opening, administration set removal), close the roller clamp and make sure the line is closed.*

1. Power on the pump, see section 6.3, page 34.
2. Open the pump door.
3. Align the fully primed administration set horizontally along the tube guides so that the green connector is on the right (green), and the SafeClip (blue anti-free-flow clamp) is in front of the clamp guide (blue).
4. Insert the green connector into the green slot [A].
5. Guide the SafeClip (blue clamp) into the blue slot, with the spherical hinge on top [B].
6. Push the SafeClip to move the spherical hinge into place.
7. Check that the tube is inserted in the left tube guide.



8. Push the door lever down to close the pump door.
   - *SafeClip engages automatically when it is inserted into the clamp guide and the pump door is closed.*
   - *The Occlusivity Check System (OCS) automatically clamps the line, activates pumping and checks for a rise in pressure.*



9. When the OCS test is successful, the infusion mode defined in the options is displayed.

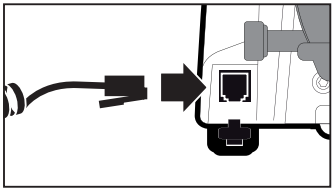
6.5 Connecting a Drop Sensor

Using a drop sensor is recommended if the actual volume of the fluid container is not known accurately.

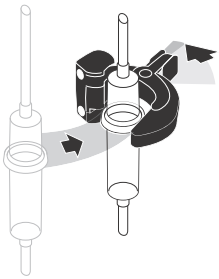
The pump automatically detects the presence of a drop sensor. The presence of the drop sensor can be set as mandatory in the pump options. For more information on drop sensor options, refer to the technical manual.

Always connect a drop sensor when the pump is off.

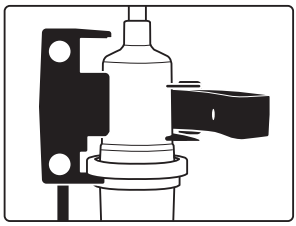
1. Before powering on the pump, connect the drop sensor plug to the connection socket on the back of the pump.



2. Press the drop sensor clip and align the vertical part of the drop sensor with the drip chamber's air vent.
3. Release the clip.
4. Check the following:

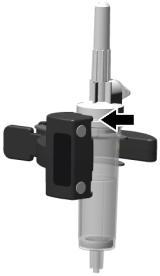


   - The drop sensor and the drip chamber are in a vertical position.
   - The drop sensor is correctly aligned with the drip chamber's air vent.
   - There are no drops on the drip chamber walls.
   - The drip chamber is filled approximately 1/2 full and the level of liquid is below the drop sensor.



   - The pump and the drop sensor are correctly installed. Do not use the drop sensor if it appears to be damaged.

Standard Drip Chamber (example: VL ST00)



Drip Chamber with Central Ring (example: VL ON42)

Note*: The drop sensor is equipped with two circular magnets. You can use these magnets to fix the drop sensor and the drip chamber on the right side of the pump.*

Information

When a drop sensor is detected on a pump, the following happens

- *Simple Rate infusion mode is available and recommended,*
- *Programmable infusion ranges are different.*

Warning

For transport during infusion, the pump with a drop sensor connected on it must be installed on a rolling stand.

6.6 Pump Height

Warning

Ideally, the volumetric pump should be level with the distal tip of the catheter (e.g., the site of fluid delivery; if accessing a central line the volumetric pump should be at the level of the patient's heart). If the pump height is raised relative to the distal tip of the catheter (e.g., during patient transport), the increase in height of the volumetric pump can result in a temporary increase in fluid delivery or bolus until the flow rate stabilizes. Alternatively, if the pump is lowered relative to the distal tip of the catheter, the decrease in height of the volumetric pump may result in a decrease in delivery or under-infusion until the flow rate stabilizes.

Hang the container between 20 to 80 cm above the pump.

We recommend that the container is positioned on the right side of the pump, to protect the pump from dripping fluids.

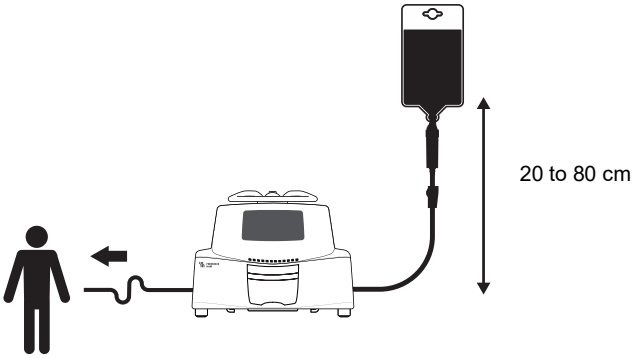


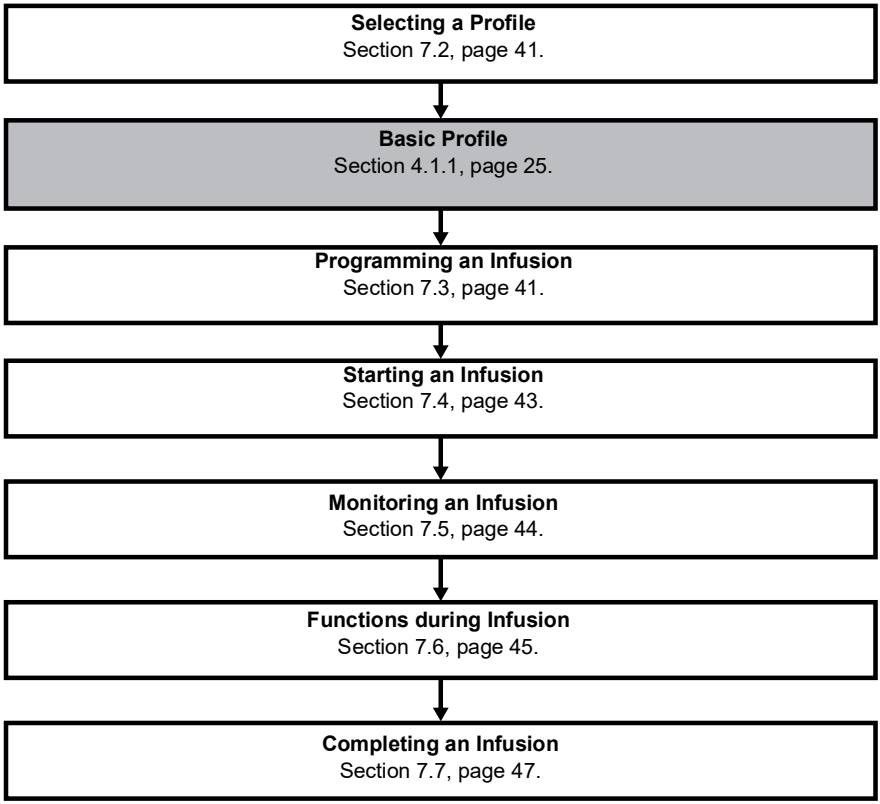
Figure 6.1: Global Installation

Precautions for pump position

- If using multiple volumetric pumps and it is not clinically feasible to have all pumps level with the distal tip of the catheter (or the site of fluid delivery), place the high risk or life-sustaining medications as close to level with the distal tip of the catheter as possible. When infusing multiple high risk or life-sustaining medications, consider placing the ones infusing at the lowest rates as close to the level with the distal tip of the catheter as possible.
- Minimize the height difference between the pump and the patient and avoid changes in the height of the pump (e.g., during transport of critically ill patients) to prevent unintended fluctuations in the flow rate.

7 Operation

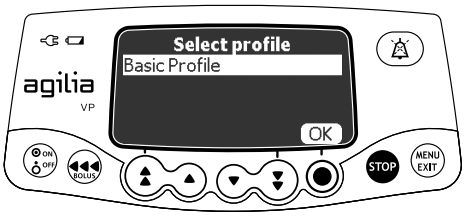
7.1 Flowchart



7.2 Selecting a Profile

You can only select a profile if more than one profile is loaded in the pump.

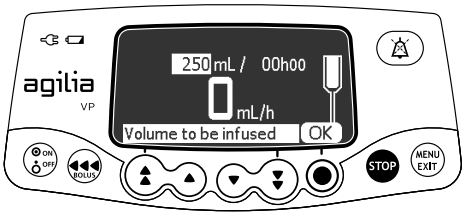
1. Press (ON/OFF) to power on the pump.



2. Press **OK** to select Basic Profile.
The OCS test is performed.

7.3 Programming an Infusion

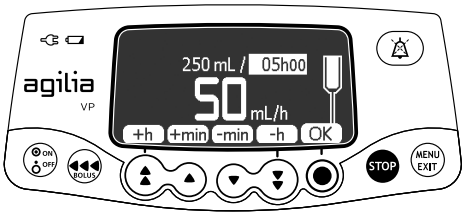
- This section describes the programming of an infusion with the **V/T/R** infusion mode.
- To change the infusion mode, see section 8.10, page 67.



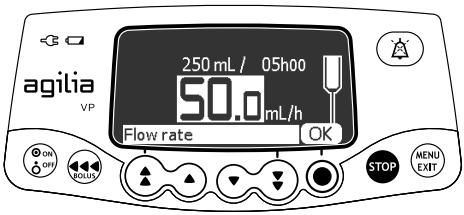
1. Press the arrow keys to program the Volume to be Infused (VTBI) and press **OK**.
(Press (▲▼) to select the VTBI from pre-defined values: 0.1 mL, 10 mL, 20 mL, 50 mL, 100 mL, 250 mL, 500 mL, etc.)

Information

- *Ensure VTBI is not greater than actual volume in the container to avoid air-in-line at the end of infusion.*
- *All volumes added or removed must be taken into consideration, including the volume of fluid contained in the administration set and lost during priming (priming volume varies by administration set; see the administration set IFU for priming volumes).*

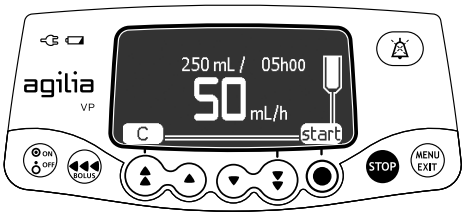


2. Press the arrow keys to program the infusion duration (__ h __), and press **OK**.



3. Press the arrow keys to program the flow rate, and press **OK**.

7.4 Starting an Infusion

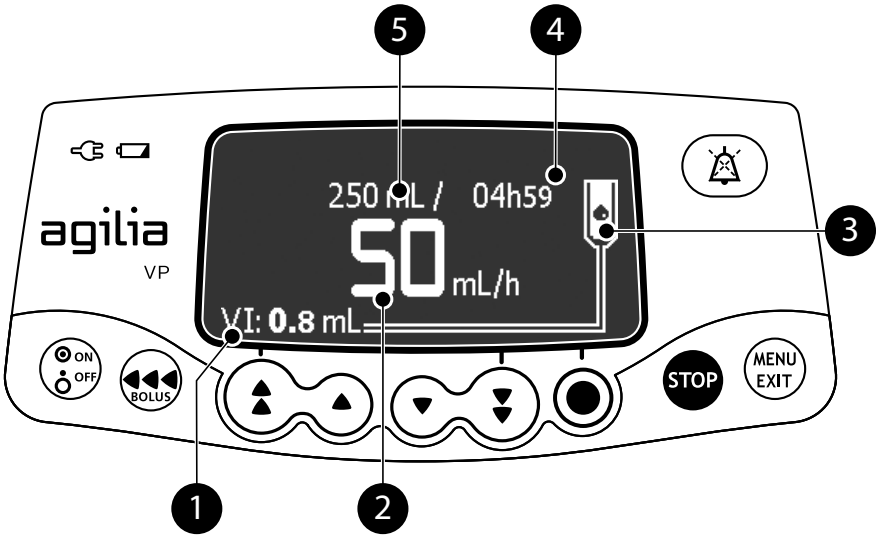


1. Check the administration set integrity.
2. Check that no air remains in the administration set.
3. Confirm that the administration set is correctly installed in the pump.
4. Open the roller clamp.
5. Connect the administration set to the patient's access device.
6. Check the infusion settings prior to starting the infusion.
7. Press **start** to start the infusion, or **C** to modify the infusion settings.

Warning

When connecting the administration set to the patient's access device, always use aseptic technique according to your healthcare facility policy.

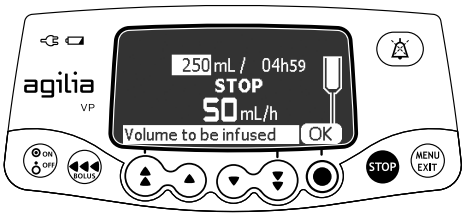
7.5 Monitoring an Infusion



Legend	
1	**VI** (Volume Infused). Will increase during the infusion. To clear VI, see section 8.7, page 63.
2	**Infusion Flow Rate (mL/h)** To change the flow rate during an infusion, see section 7.6.2, page 45. The flow rate is displayed with the largest font size.
3	**Infusion in Progress** The infusion in progress indicator displays falling drops.
4	**Infusion Duration** At the current rate, the remaining infusion time in hours and minutes.
5	**VTBI** (Volume To Be Infused) remaining. Will decrease during the infusion. To change VTBI during an infusion, see section 8.4, page 59.

7.6 Functions During Infusion

7.6.1 Stop



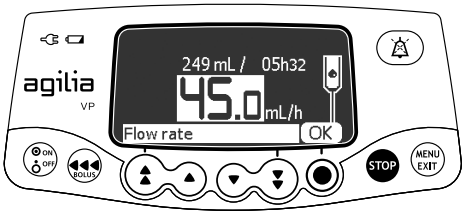
To stop the infusion, press STOP.
After 2 minutes, an alarm is generated as a reminder that the infusion is stopped.

To restart the infusion, first confirm or modify the programming settings, then start the infusion. See section 7.3, page 41.

7.6.2 Rate Titration

You can adjust the flow rate during the infusion. Depending on your pump configuration, stopping the infusion may be required before modifying the infusion rate.

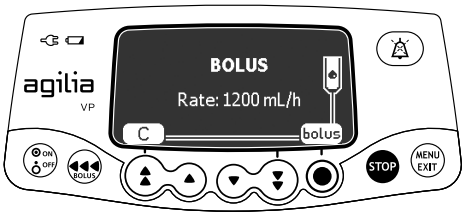
1. If required, stop the infusion, see section 7.6.1, page 45.
2. Press the arrow keys to modify the flow rate.
3. Press **OK** to confirm.



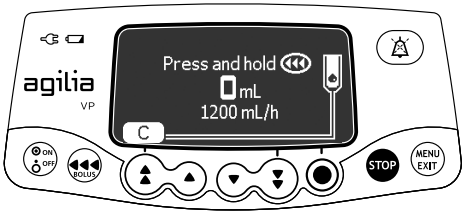
7.6.3 Administering a Direct Bolus

Note: This feature can be activated or deactivated in the pump options.

A **bolus** is an extra dose that a pump can deliver during an infusion.



1. During the infusion, press BOLUS.
2. Press **bolus** to confirm access to bolus function.



3. To administer a direct bolus, press and hold BOLUS.
4. Monitor the volume infused on the main display until the desired bolus is reached.
5. To stop the bolus, release the BOLUS key.
   The infusion resumes its previous rate after the bolus is delivered.

Information

- *The bolus volume is added to the Volume Infused (VI).*
- *The BOLUS key is not active when the menu screen is displayed.*
- *The occlusion pressure level is set to its maximum value: 750 mmHg / 100 kPa / 14.5 PSI.*

7.7 Completing an Infusion

7.7.1 Near End of Infusion Alert

Prior to the end of an infusion, a **near end of infusion** alert is automatically triggered. The following happens:

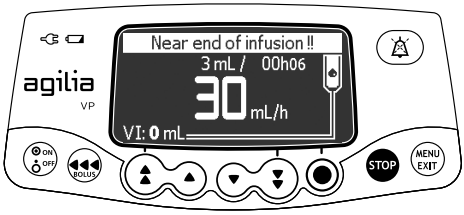
- An audible alarm is triggered.
- An alarm message appears on the pump screen.
- The infusion indicator lights flash yellow.

Near end of infusion alert is triggered when the first of the three criteria below is reached.

Setting	Range of Values	Default Pump Setting
Time Before the End of the Infusion	From 0 to 30 minutes	5 minutes
% of VTBI Remaining	From 0 to 15 %	5 %
Remaining VTBI	From 0 to 50 mL	5 mL

Near end of infusion alert settings are configurable in the pump options. For more information, refer to the technical manual.

Silencing Near End of Infusion Alert



1. Press (🔔) to silence the alarm.
   The infusion will continue until the VTBI reaches zero.

7.7.2 End of Infusion

When the VTBI reaches zero, the infusion is complete. The following happens:

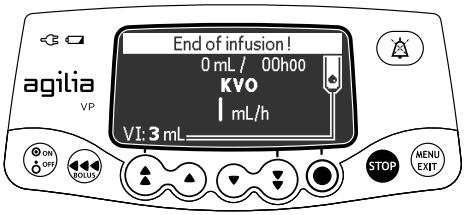
- An audible alarm is triggered.
- An alarm message appears on the pump screen.
- The infusion indicator lights flash yellow.
- **KVO** (Keep Vein Open) rate is maintained.

End of infusion settings (KVO rate, Silence duration) are configurable in the pump options. For more information, refer to the technical manual.

Information

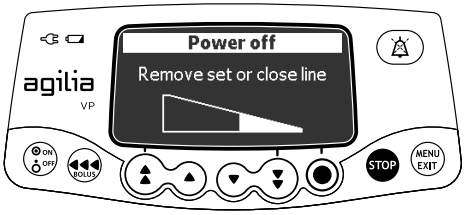
- *If KVO is disabled, the infusion indicator lights flash red, and pump stops infusing.*
- *If the programmed infusion rate is lower than the configured KVO rate, the pump continues infusing at the programmed rate.*

Silencing the Alarm



1. Press (🔔) to silence the alarm.
2. Prepare the new container, and adjust the settings for a new infusion.

7.7.3 Powering off



You can power off the pump as follows:

1. Press STOP to stop the infusion.
2. Close the roller clamp.
3. Press and hold ON OFF until the pump powers off.

7.8 Infusion Modes

You can program an infusion with the different infusion modes available, depending on the pump configuration.

To select an infusion mode, see section 8.10, page 67.
For more information on calculation rules, see section 15.8, page 104.

7.8.1 Volume / Time / Rate (V/T/R)

1. Press the arrow keys to select the VTBI and press **OK**.
2. Press the arrow keys to adjust the infusion duration and press **OK**.
   The flow rate is automatically readjusted.
3. Press the arrow keys to select the flow rate and press **OK**.
   The infusion duration is automatically readjusted.

For more information, see section 7.3, page 41.

7.8.2 Volume / Rate (V/R)

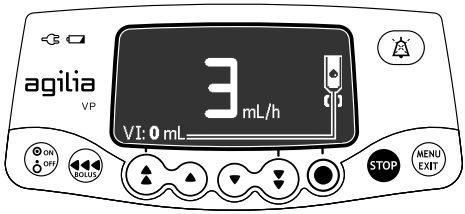
1. Press the arrow keys to select the VTBI and press **OK**.
2. Press the arrow keys to adjust the flow rate and press **OK**.
   The infusion duration is automatically readjusted.

7.8.3 Volume / Time (V/T)

1. Press the arrow keys to select the VTBI and press **OK**.
2. Press the arrow keys to adjust the infusion duration and press **OK**.
   The flow rate is automatically readjusted.

7.8.4 Simple Rate (only with Drop Sensor)

When a Drop Sensor is connected to the pump, Simple Rate infusion mode is available.



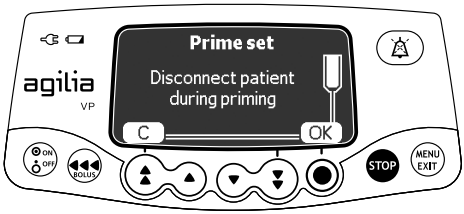
1. Press the arrow keys to select the flow rate.
2. Press **OK**.

When no more drops are detected, the infusion is stopped and an alarm is generated.

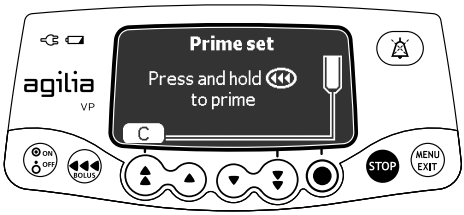
7.9 Other Functions

7.9.1 Priming the Administration Set

Note: This feature can be activated or deactivated in the pump options.



1. Press ⏻ to power on the pump.
2. Press ⏮.
3. Make sure the administration set is not connected to the patient, as indicated on screen.
4. Press **OK** to proceed.



5. Press and hold the BOLUS key to prime, or press **C** to cancel.
6. To end priming, release the BOLUS key.
7. Make sure there is no air in the infusion line.

Information

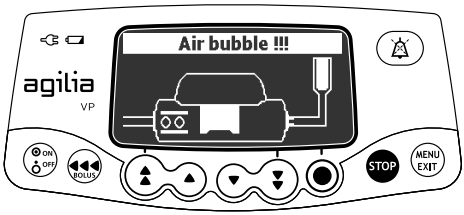
- *Priming is only accessible prior to starting the infusion.*
- *If an infusion is programmed but not started, the priming volume will not be subtracted from the programmed VTBI.*
- *The BOLUS key is not active when the menu screen is displayed.*
- *During priming, the occlusion pressure level is set to its maximum value 750 mmHg / 100 kPa / 14.5 PSI, and the air-in-line alarm is disabled.*
- *Priming is limited to 30 mL maximum. Above 30 mL, you must release and press the BOLUS key again to restart priming.*
- *The pump does not detect air bubbles or occlusions when priming.*

7.9.2 Advancing an Air Bubble

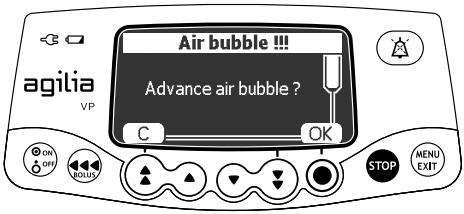
Note: This feature can be activated or deactivated in the pump options.

When an air bubble is detected by the air detector (behind the pump door), an alarm is triggered.

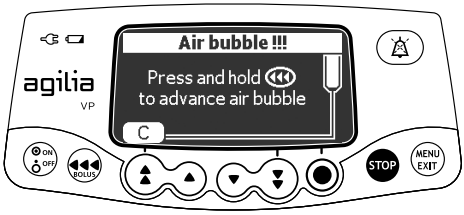
You can use the advance air bubble function to advance the air bubble beyond the air detector, avoiding the need to remove the administration set.



1. Press to silence the audible signal for 2 minutes.



2. Press .
3. Press **OK** to advance the air bubble.



4. Press and hold to advance the air past the air detector.
5. Restart the infusion, or press **C** to cancel the advance air bubble function.

Information

- *Air that has advanced past the air detector is still in the administration set.*
- *Ask for medical advice on whether or not the infusion can be restarted due to air in the set. If you decide to remove the air bubble, follow facility procedures for priming or changing the administration set.*
- *The air bubble advances at the programmed rate. The maximum volume advanced equals the configured air bubble detection setting.*

7.9.3 Auto-restart

Auto-restart is an optional feature that alters the pump's response when a downstream occlusion is detected.

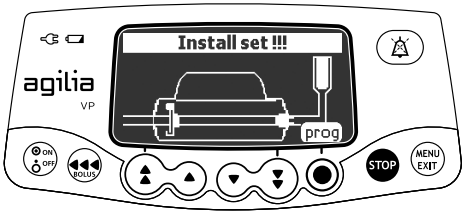
When this feature is activated, and when a downstream occlusion is detected, the following occurs:

- An alert is generated to inform the user that the pressure limit is reached.
- The infusion is stopped.
- The pressure sensor measures the pressure evolution during a configurable period of time:
  - If the pressure decrease is significant, the infusion automatically restarts.
  - If the pressure does not decrease, the downstream occlusion alarm is generated.

Information

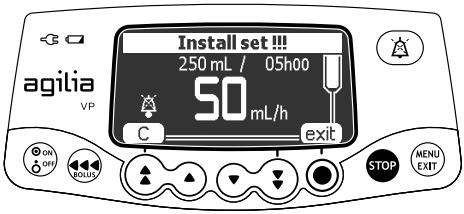
- *When the alert is generated, we recommend checking that the infusion line is not kinked.*
- *When this feature is deactivated, an alarm is immediately generated when a downstream occlusion is detected.*
- *For more information on how to activate or deactivate this feature, see section 8.3, page 57.*

7.9.4 Pre-programming the Pump



You can program the pump before installing the administration set.

1. Press ⏻ to power on the pump.
   `Install set !!!` is displayed on top of the pump screen.
2. Make sure the pump door is closed.
   *The **prog** symbol is displayed.*
3. Press **prog**.
4. Program the infusion.
   See section 7.3, page 41.



5. Press **exit** to confirm or **C** to reprogram.
6. When ready, install the administration set.
7. Press **start** to start the infusion, or **C** to change the settings.

8 Menus

8.1 Overview

8.1.1 Commands

Operation	Key
Access menu or exit menu	MENU EXIT
Select	▲▲ ▲ ▼ ▼▼
Confirm	● (corresponds to **enter** on the screen)
Select ☑ / Deselect ☐	▲▲

8.1.2 Menu Description

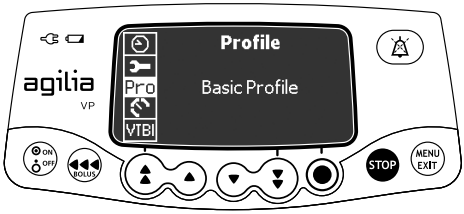
Menu	Symbol	Stop Infusion Required	Associated Procedure
Profile	Pro	NO	▪ Displaying active profile information, page 56.
Pressure		NO	▪ Modifying the pressure limit, page 57.
Volume to be infused	VTBI	NO	▪ Changing VTBI, page 59.
Keypad lock status		NO	▪ Locking / Unlocking the keypad, page 60.
Battery life		NO	▪ Viewing the battery life, page 62.
Volume Infused	mL?	NO	▪ Viewing and clearing the volume infused, page 63.
Pause		YES	▪ Programming a pause, page 64.
Day/Night mode		NO	▪ Switching between day mode and night mode, page 65.
Flow Rate (mL/h)	mL/h	YES	▪ Changing the infusion mode, page 67.
Alarm volume		NO	▪ Adjusting the alarm volume, page 68.
Call-back		NO	▪ Activating / Deactivating the call-back alert, page 69.
View flow rate history		NO	▪ Viewing flow rate history, page 71.
View pressure history		NO	▪ Viewing pressure history, page 72.
View event log		NO	▪ Viewing the event log, page 73.
Date / Time		NO	▪ Setting up the date and time, page 74.

Menu	Symbol	Stop Infusion Required	Associated Procedure
Maintenance		NO	▪ Displaying maintenance information, page 75.

Note: The displayed menu may change depending on the pump configuration.
For more information on factory configuration, refer to Appendix: Factory Configuration, page 142.

8.2 Profile

Symbol	Pro
Procedure	Displaying active profile information



You can display the active profile name as follows:

1. Press MENU EXIT.
2. Press the arrow keys to select Pro .
   The active profile information is displayed.

8.3 Pressure

Symbol	
Procedure	Modifying the pressure limit

The pump pressure limit is pre-defined in the pump options in one of the following modes:

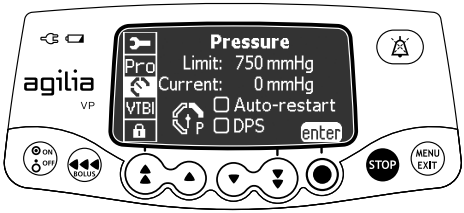
- **3 levels** (low , medium , high).
  The pressure limit is adjustable according to 3 pre-set values.
- **Variable**
  The pressure limit is adjustable within a pre-defined range.

When the pressure limit is reached, an occlusion alarm is triggered. You must silence the alarm, resolve the occlusion and start the infusion again.

To consult the pressure settings, see section 15.6, page 101.

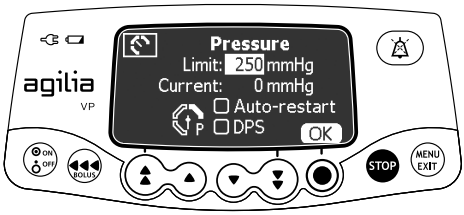
Warning

When addressing or clearing an occlusion, ensure the fluid flow to the patient is OFF to prevent administering an unintended bolus. An occlusion may pressurize the administration set, which can result in an unintended bolus of drug when the occlusion is cleared. In order to prevent this additional bolus, disconnect the administration set or relieve the excess pressure through a stopcock, if present. The health care professional should weigh the relative risks of disconnection with the risks of an unintended bolus of drug.

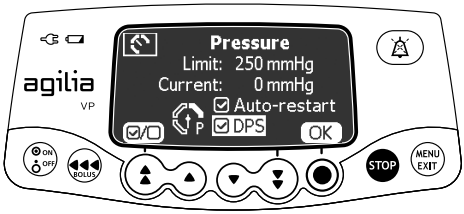


You can modify the pressure limit as follows:

1. Press MENU EXIT.
2. Press the arrow keys to select .
3. Press **enter** to access the pressure limit screen.



4. Press the arrow keys to increase or decrease the pressure limit.
5. Press **OK** to validate.



6. Press (☑/☐) to enable or disable the Auto-restart function (optional).
7. Press **OK** to confirm.
8. Press (☑/☐) to enable or disable the DPS function (optional).
9. Press **OK** to confirm.

Warning

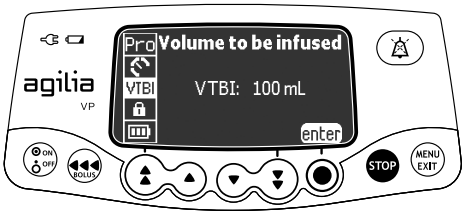
To avoid the presence of air and to minimize the amount of time it takes the pump to recognize an occlusion and generate an alarm while infusing at low rates (e.g., less than 5 mL per hour, and especially flow rates less than 0.5 mL per hour): consider occlusion pressure threshold setting and adjust it, as necessary. The lower the occlusion pressure threshold setting, the shorter the occlusion detection time. However, when infusing viscous or thick fluids (e.g., lipids), the occlusion pressure threshold setting may need to be adjusted to reduce false alarms.

Information

- *For more information on the Auto-restart function, see section 7.9.3, page 53.*
- *The Dynamic Pressure System (DPS) informs the user of any sudden rise or drop in pressure before the pressure limit is reached.*
- *If variable pressure mode is enabled, a pre alarm is triggered when the pressure reaches 50 mmHg below maximum pressure (25 mmHg when maximum pressure is 50 mmHg).*
- *If other pumps are used in parallel, it is recommended that their pressure limits be adjusted to the same level.*

8.4 Volume To Be Infused (VTBI)

Symbol	VTBI
Procedure	Changing VTBI



You can change the VTBI as follows:

1. Press MENU EXIT.
2. Press the arrow keys to select VTBI .
   The active VTBI is displayed.
3. Press **enter**.
4. Press the arrow keys to modify the VTBI.
5. Press **OK** to confirm.

8.5 Keypad Lock Status

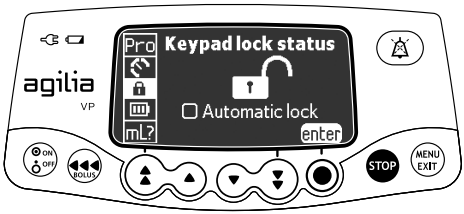
Symbol	
Procedure	Locking / Unlocking the keypad

You can use this feature to avoid inadvertent key presses.

Note: The following features can be activated or deactivated in the pump options:

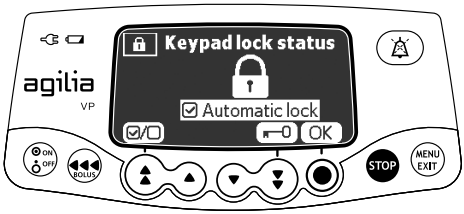
- *Automatic lock: The keypad will lock automatically at infusion start, or after a time-out.*
- *Unlock code: The user must enter a code to unlock the keypad.*

Locking the Keypad



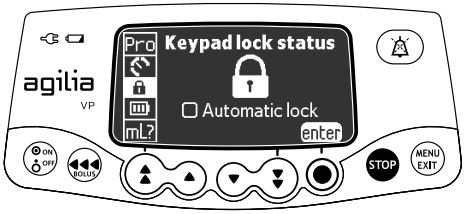
You can lock the keypad as follows:

1. Press MENU EXIT.
2. Press the arrow keys to select .
3. Press **enter**.



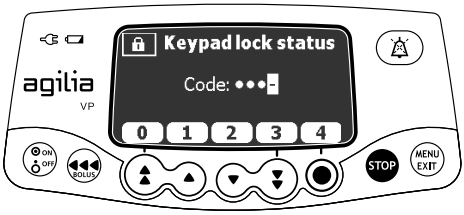
4. Lock the keypad as follows:
   - Press to lock the keypad.
     The keypad is locked and the screen displays .
   - Press ☑/☐ to activate the automatic lock.
     The keypad will lock automatically at infusion start. If the keypad is unlocked during the infusion, it will lock again automatically after a time-out.
5. Press **OK** to confirm.

Unlocking the Keypad

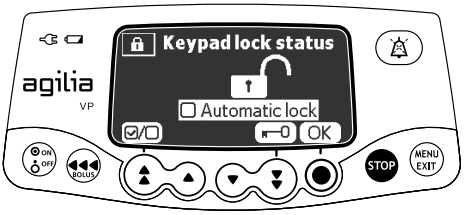


You can unlock the keypad as follows:

1. Press MENU EXIT.
2. Press **enter**.



Unlock code enabled



Unlock code disabled

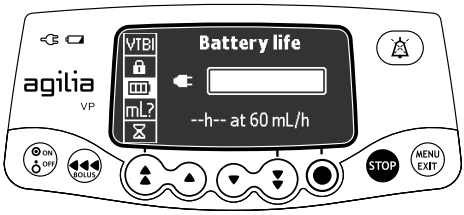
3. Unlock the keypad as follows:
   - If a code is required, press the keys to enter the unlock code. *The keypad is unlocked.*
   - If no code is required, press , and press **OK** to confirm. *The keypad is unlocked and the screen displays .*

Information

- *The STOP and keys remain functional when the keypad is locked.*
- *During keypad lock, the key is functional when the infusion is stopped.*
- *During keypad lock, the ON OFF key is functional when an alarm occurs, or at the end of infusion.*
- *The keypad locked status is memorized when the pump is powered off.*
- *In case of forgotten unlock code, contact your biomedical department.*

8.6 Battery Life

Symbol	
Procedure	Viewing the battery life



You can view the battery life as follows:

1. Press MENU EXIT.
2. Press the arrow keys to select .
   The time remaining under current flow rate conditions is displayed.

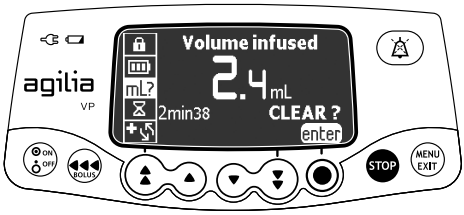
The bar graph shows a visual representation of battery life.

The symbol displayed shows the following:

- : The pump is plugged into the AC power supply.
- : The pump is operating on battery.

8.7 Volume Infused

Symbol	mL?
Procedure	Viewing and clearing the volume infused



You can view and clear the volume infused as follows:

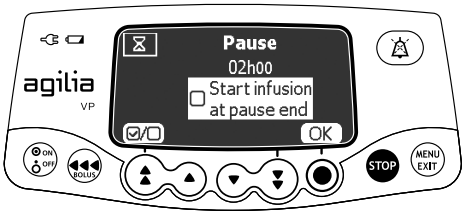
1. Press MENU EXIT.
2. Press the arrow keys to select mL? .
   The total volume infused includes boluses. The length of time over which they were infused is also displayed.
3. To clear the volume infused, press **enter**.
4. Press **OK** to confirm.

Information

When the pump is powered off, the volume infused is cleared.

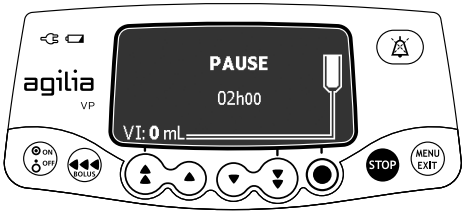
8.8 Pause

Symbol	⧖
Procedure	Programming a pause



You can program a pause as follows:

1. Press STOP to stop the infusion.
2. Press MENU EXIT.
3. Press the arrow keys to select ⧖ .
4. Press **enter**.
5. Press the arrow keys to program the pause duration in hours and minutes, and press **OK**.
6. Press the ☑/☐ button to activate the "Start infusion at pause end" feature (optional).
7. Press **OK** to begin the programmed pause.
8. To restart the infusion before the end of the pause period, press ◉, and **start**.



Information

If you do not activate the "Start infusion at pause end" option, an audible alarm is generated at the end of the pause. The infusion must be started manually to continue the infusion.

8.9 Day/Night Mode

Symbol	☾
Procedure	Switching between day mode and night mode

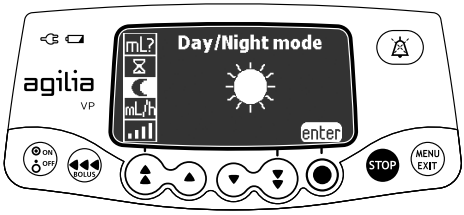
This function switches between day mode ☀ and night mode ☾.

The default night mode settings are as follows:

- The key-press beep is silenced.
- Infusion indicators and screen brightness are dimmed.

Depending on your pump configuration, the switch between day and night mode may be managed either through this menu (manual mode), or according to pre-defined settings (auto mode). For more information, refer to the technical manual.

Switching from Day Mode to Night Mode

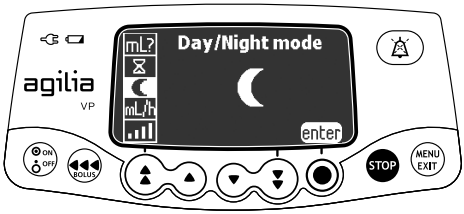


You can switch to night mode as follows:

1. Press MENU EXIT.
2. Press the arrow keys to select ☾.
3. Press **enter**.

4. Press ☀/☾ to activate night mode.
   The screen displays ☾.
5. Press **OK** to confirm.

Switching from Night Mode to Day Mode



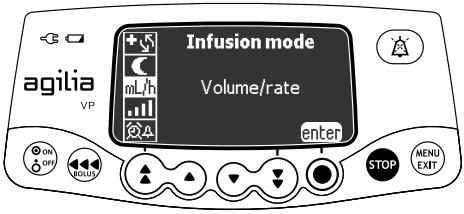
You can switch to day mode as follows:

1. Press MENU EXIT.
2. Press the arrow keys to select ☾.
3. Press **enter**.

4. Press ☀/☾ to activate day mode.
   The screen displays ☀.
5. Press **OK** to confirm.

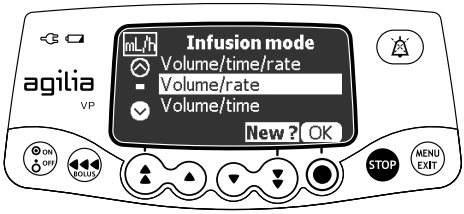
8.10 Flow Rate (mL/h)

Symbols	mL/h
Procedure	Changing the infusion mode



You can change the infusion mode as follows:

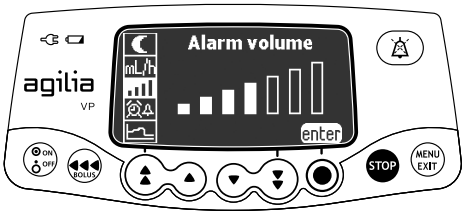
1. Press MENU EXIT.
2. Press the arrow keys to select mL/h .
3. Press **enter**.
   The available infusion modes are displayed.



4. Press the arrow keys to select a new infusion mode.
5. Press **OK** to apply the selected infusion mode to the current infusion settings, or **New ?** to apply the selected infusion mode and clear the infusion settings.

8.11 Alarm Volume

Symbol	
Procedure	Adjusting the alarm volume



You can adjust the alarm volume as follows:

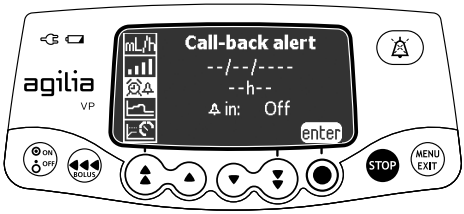
1. Press MENU EXIT.
2. Press the arrow keys to select .
3. Press **enter**.
4. Press the arrow keys to select the alarm volume.
   The pump emits an alarm at the selected volume level.
5. Press **OK**.

8.12 Call-back Alert

Symbol	
Procedure	Activating / Deactivating the call-back alert

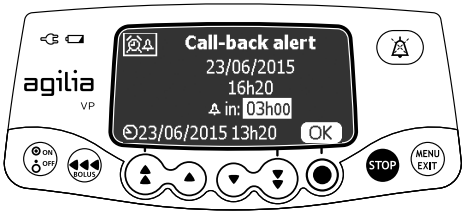
The call-back alert notifies the user when the set time interval has elapsed.

Activating the Call-back Alert



You can activate the call-back alert as follows:

1. Press MENU EXIT.
2. Press the arrow keys to select .
3. Press **enter**.

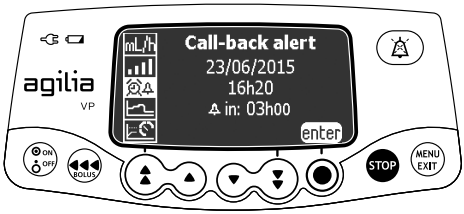


4. Press the arrow keys to set the interval in hours and minutes (__h__) before the alert.
5. Press **OK**.

Information

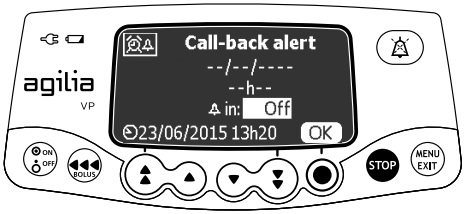
- *The activation time is calculated according to the device time, which is indicated at the bottom of the screen.*
- *If the device is powered off during the call-back period, a warning message is displayed when the device is powered on.*

Deactivating the Call-back Alert



You can deactivate the call-back alert as follows:

1. Press MENU EXIT.
2. Press the arrow keys to select .
3. Press **enter**.

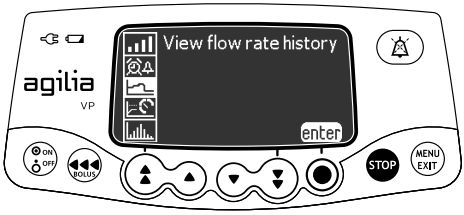


4. To deactivate the programmed call-back alert, press the down arrow keys to set the duration period to "Off".
5. Press **OK**.

8.13 View Flow Rate History

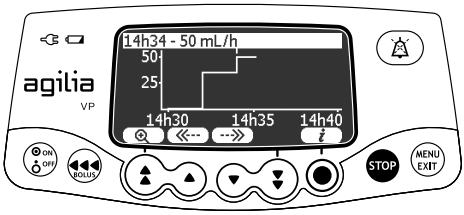
Symbol	
Procedure	Viewing flow rate history

This function allows the user to check the current infusion's history information in order to verify the dose administered.



You can view flow rate history as follows:

1. Press MENU EXIT.
2. Press the arrow keys to select .
3. Press **enter**.
   The following information is displayed:
   - An event marker (cursor)
   - The event details (time and flow rate)
   - The measured flow rate (solid line)



4. Press the «-- and --» buttons to browse the events.
5. Press i to view information about the selected event.

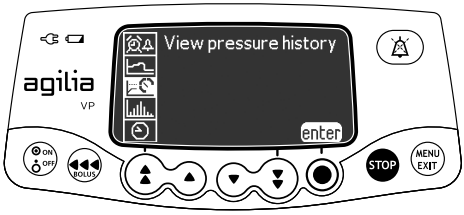
Information

- *The history is not refreshed while the history screen is displayed. To refresh the history data, exit and select the history again.*
- *Flow rate history is not stored after powering off.*

8.14 View Pressure History

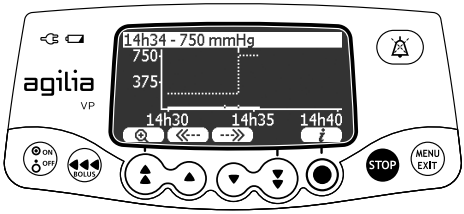
Symbol	
Procedure	Viewing pressure history

This function allows the user to check the current infusion's history information in order to verify changes in pressure.



You can view pressure history as follows:

1. Press MENU EXIT.
2. Press the arrow keys to select .
3. Press **enter**.
   The following information is displayed:
   - An event marker (cursor)
   - The event details (time and pressure limit)
   - The pressure limit (dotted line)
   - The measured pressure (solid line)



4. Press the «-- and --» buttons to browse the events.
5. Press i to view information about the selected event.

Information

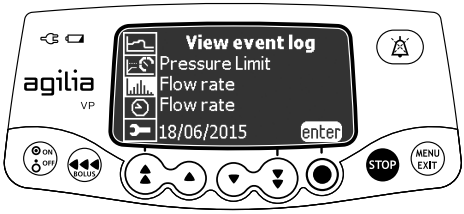
- *The history is not refreshed while the history screen is displayed. To refresh the history data, exit and select the history again.*
- *Pressure history is not stored after powering off.*

8.15 View Event Log

Symbol	
Procedure	Viewing the event log

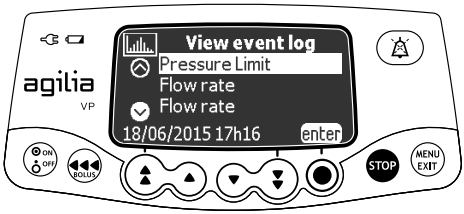
The event log displays details of the last events that occurred on the pump. Events are stored in the log even after the pump is powered off and on again. The log can store up to 1500 events. Older events are overwritten.

Note: When the AC Power is disconnected for a period of time, or when the batteries are not operating, the log file is kept in a non-volatile memory for approximately 10 years.

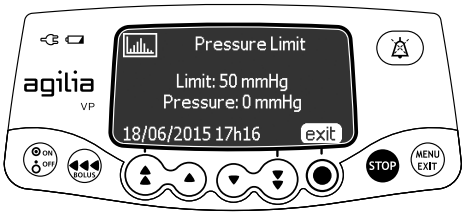


You can view the event log as follows:

1. Press MENU EXIT.
2. Press the arrow keys to select .
3. Press **enter**.



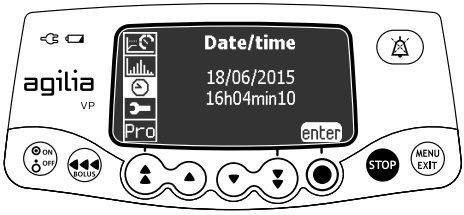
4. Press the arrow keys to select the desired event.
5. Press **enter**.
   The details of the event are displayed.



6. Press **exit** to return to the previous screen.

8.16 Date / Time

Symbol	
Procedure	Setting up the date and time



You can set the date and time as follows:

1. Press MENU EXIT.
2. Press the arrow keys to select .
3. Press **enter**.
4. Press the arrow keys to set the following:
   - Day
   - Month
   - Year
   - Hours
   - Minutes
5. Press **OK** to confirm.

8.17 Maintenance

Symbol	
Procedure	Displaying maintenance information

You can display maintenance information as follows:

1. Press MENU EXIT.
2. Press the arrow keys to select .
3. Press **enter**.
4. Press the arrow keys to scroll through the maintenance information.

The following information is displayed:

- *Pump serial number*
- *Next maintenance date (dd/mm/yyyy)*
- *Pump model*
- *Software version*
- *Total operating time since last maintenance*

9 Options

9.1 Commands

Operation	Key
Options access	ON/OFF + MENU/EXIT
Option selection	▲▲ ▲ ▼ ▼▼
Confirm	● (corresponds to **enter** on the screen)
Select ☑ / Deselect ☐	▲▲

Selected current values are stored when the device is powered off after programming.
To return to the normal menus, power off then power on again.

9.2 Option Descriptions

Four different option groups are available on the pump. This IFU only describes the "Pump Settings" options.

Option	Access Code?	Description
Pump Settings	No	Section 9.3, page 77.
Basic Profile Configuration	Yes	Technical Manual
Profile	Yes	Technical Manual
Maintenance	Yes	Technical Manual

Information

If the wrong access code is entered, `error` *is displayed.*

9.3 Pump Settings

The following options have different functions that you can select or deselect to customize your Agilia VP.

Function	Choice	Default Pump Setting
[User 1]: Screen option	▪ Selection assistance: display or hide selection assistance banner at the bottom of the screen to help the user program an infusion	Enabled
[User 2]: Menu items	▪ Maintenance: display or hide maintenance menu	Disabled
	▪ Date / Time: display or hide date/time menu	Disabled
[User 3]: Contrast	▪ Adjustment of screen contrast using the fast increment and decrement keys	Medium level
[User 7]: Date/Time	▪ Date selection: dd/mm/yyyy	Production plant date and time
	▪ Time selection: __ h __	
[User 8]: Language	▪ A scrolling list with all available languages	Official language of the target country
[Par 13]: AC power disconnection	▪ Enable/Disable "AC power disconnection" message and "Device operating on battery" message at power on	Enabled
[Par 28]: Auto power on at door opening	▪ Enable/Disable automatic device powering on at door opening	Enabled
[Par 35]: Dose display format	▪ Enable/Disable display of the decimal "0" after a dose value	Remove trailing 0 / Remove trailing 0 during programming
[Par 37]: Alarm system	▪ Enable/Disable preventive silence for alarm system	Enabled
[Par 38]: Keypad unlock code	▪ Set or disable keypad unlock code (4-digit). Disable value: 0000	1234

10 Data Communication

You can connect the pump to a PC for maintenance (via Agilia Partner software).

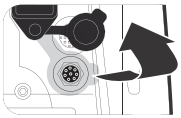
10.1 Data Communication Cables

Information

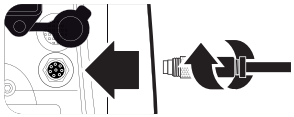
- *Only use recommended Agilia cables.*
- *All connections and disconnections must be performed by qualified and appropriately trained staff.*
- *All IT devices (including computers, hubs and switches) inside the patient area (< 1.5 m) must comply with IEC/EN 60601-1 (leakage current).*
- *IT devices connected outside the patient area (> 1.5 m) must be at least IEC/EN 60950 compliant.*

10.1.1 Using the Communication Port

1. Remove the protective cap from the pump's RS232 communication port.



2. Connect the cable to the RS232 communication port by turning the cable wheel.



Information

Do not disconnect communication cables while data is being transferred.

11 User Test

The following protocol provides the user with a quick integrity check guide to ensure that the pump system is functional. Perform this user test before each use of the pump.

1. Check the external appearance of the pump for the absence of cracks or other visible damage.
2. Check for the absence of visible damage on the power cord inlet and the power cord.
3. When used on a pole or a rail, check that the pump is securely attached.
4. Connect the pump to the AC power supply, and check that the power indicator lights up and a beep is emitted.
5. Power on the pump, and wait for the auto-test to complete. Check the display and light indicators.
6. Press any key and listen for a key beep (if key beep is activated).

12 Alarms and Safety Features

12.1 Introduction

Agilia VP has a continuous monitoring system that begins when the pump is started.

When an alarm is triggered, a message is displayed on the pump screen. We recommend that the user stand in front of the pump to read the message before acknowledgment.

Warning

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

12.2 Alarm Descriptions

There are several different levels of alarm priorities:

- High-priority alarms
- Medium-priority alarms
- Low-priority alarms
- Information signals

Alarm Priority	Required Operator Response	Description
High (!!!)	Immediate response	▪ The infusion stops. ▪ The infusion indicator lights flash **red**. ▪ The pump emits audible alarm signals. ▪ An alarm description is displayed on the pump screen. ▪ Depending on the alarm, the (🔔) key silences the alarm for no time limit or for a defined duration. For detailed description of each alarm, please refer to List of Alarms, page 81.
Medium (!!)	Prompt response	▪ The infusion continues. ▪ The infusion indicator lights flash **yellow**. ▪ The pump emits audible alarm signals. ▪ Depending on the alarm, the (🔔) key silences the alarm for no time limit or for a defined duration. For detailed description of each alarm, please refer to List of Alarms, page 81.

Alarm Priority	Required Operator Response	Description
Low (!)	Awareness	▪ The infusion continues. ▪ The infusion indicator lights (LEDs) **yellow** are ON. ▪ The pump emits audible alarm signals. ▪ Depending on the alarm, the (🔔) key silences the alarm for no time limit or for a defined duration. For detailed description of each alarm, please refer to List of Alarms, page 81.
Information Signals	Awareness	▪ The infusion continues. ▪ An information message is displayed on the pump screen.

12.3 General Remarks

- Alarms are not configurable.
- 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.
- When the cause of a high-priority alarm has been fixed, the red indicators switch off. However, the message remains displayed at the top of the screen as a reminder of the cause of the alarm.
- The device guarantees the triggering of high-level priority alarms in every use condition.
- A maximum of 1 mL may be infused due to a single fault condition.
- For all alarms (except occlusion alarms), the amount of time between the alarm condition and the alarm generation is less than 5 seconds.
- If the AC power is disconnected and if the battery is discharged, the alarms settings are not modified and are stored indefinitely.

12.4 List of Alarms

12.4.1 Installed Set Alarms

Message	Priority	Stops Infusion?	Problem / Resolution
`Install set !!!`	High (!!!)	Yes	At start-up, the administration set is not loaded or the door is open. ☞ Install the administration set and close the door. Note: the (🔔) key silences the alarm for 2 minutes.
`Check set installation !!!`	High (!!!)	Yes	There is no administration set in front of the upstream or downstream sensor. ☞ Check the administration set installation. Note: the (🔔) key silences the alarm for 2 minutes.
`Door opened !!!`	High (!!!)	Yes	The door is open (during the infusion, or while the infusion is stopped). ☞ Check the administration set installation and close the door. Note: the (🔔) key silences the alarm for 2 minutes.
`Set / air installation !!!`	High (!!!)	Yes	The administration set is incorrectly positioned in front of the air sensor. ☞ Check the administration set installation in front of the air sensor and close the door. Note: the (🔔) key silences the alarm for 2 minutes.
`Air bubble !!!`	High (!!!)	Yes	An air bubble has been detected (at start-up, during the infusion, or while the infusion is stopped). ☞ Remove the air from the administration set. Note: the (🔔) key silences the alarm for 2 minutes.
`Air alarm !!!`	High (!!!)	Yes	An air bubble has been detected during the infusion. ☞ Remove the air from the administration set. Note: the (🔔) key silences the alarm for no time limit.

12.4.2 OCS Alarms

Message	Priority	Stops Infusion?	Problem / Resolution
`OCS failure !!!`	High (!!!)	Yes	The OCS control system has detected a failure. ☞ Close the roller clamp, check the administration set installation, check the door integrity, check the administration set integrity. ☞ If the problem cannot be resolved, contact your **Fresenius Kabi** sales representative. Note: the (🔔) key silences the alarm for 2 minutes.
`Open and close door for OCS test`	Information Signal	No	Under specific conditions, the pump asks you to open and close the door to perform the OCS test. ☞ Open and close the door.

12.4.3 Infusion Alarms

Message	Priority	Stops Infusion?	Problem / Resolution
`End of infusion !!!`	High (!!!)	Yes	The VTBI is completed. ☞ Press STOP to select new infusion settings (if required). Note: the (🔔) key acknowledges the alarm.
`Near end of infusion !!`	Medium (!!)	No	One of the near end of infusion alert criteria is reached (time before the end of infusion, % of VTBI remaining, remaining VTBI) ☞ Check whether the remaining volume in the container corresponds to the remaining VTBI. ☞ If needed, prepare a container for a new infusion sequence. Note: the (🔔) key silences the alarm for no time limit.
`Check settings !!`	Medium (!!)	No	The flow rate has been modified using the keys but has not been confirmed. ☞ Check the flow rate and press **OK** to confirm. Note: the (🔔) key silences the alarm for 2 minutes.

Message	Priority	Stops Infusion?	Problem / Resolution
`Waiting settings !!`	Medium (!!)	No	A value must be entered. ☞ Enter a value and press **OK** to confirm. Note: the (🔔) key silences the alarm for 2 minutes.
`Waiting start !!`	Medium (!!)	No	The infusion settings have been entered but have not been confirmed with **start**. ☞ Check the infusion settings, and press **start** to start the infusion. Note: the (🔔) key silences the alarm for 2 minutes.
`End of infusion !` `Stop for new infusion !`	Low (!)	No	**End of infusion - with KVO** The VTBI is completed and the KVO is activated according to its configuration in the pump options. ☞ Press STOP to select new infusion settings (if required). Note: the (🔔) key silences the alarm for a time duration from 1 minute to 12 hours.
`Reached hard limit`	Information signal	No	The upper or lower hard limit is reached.

12.4.4 Pressure Alarms

Message	Priority	Stops Infusion?	Problem / Resolution
`Downstream occlusion !!!`	High (!!!)	Yes	The pressure in the infusion line has reached the threshold level. ☞ Check whether the infusion line is occluded. ☞ If necessary, readjust the pressure threshold in relation to the flow rate. Note: the (🔔) key silences the alarm for 2 minutes if the pressure condition is still present. Otherwise, alarm is acknowledged.

Message	Priority	Stops Infusion?	Problem / Resolution
`Upstream occlusion !!!`	High (!!!)	Yes	The pressure in the upstream line is too low. ☞ Check the roller clamp. ☞ Check the container and line. ☞ Check the container height. ☞ Check air vent (if a bottle is used). ☞ Check for kinked line. Note: the (🔔) key silences the alarm for 2 minutes.
`Wait during pressure measurement checking !!!`	High (!!!)	Yes	A downstream occlusion has been detected by the device. ☞ Check the line. ▪ If the occlusion is released before the end of temporization, the infusion will restart automatically. ▪ Otherwise, a downstream occlusion alarm is triggered.
`Occlusion pre alarm !!`	Medium (!!)	No	In-line pressure has reached 50 mmHg / 5 kPa / 1 PSI below the programmed threshold. ☞ Check the infusion line. ☞ Set the correct pressure threshold. Note: the (🔔) key silences the alarm for no time limit.
`Pressure increase !`	Low (!)	No	The pressure is increasing in the infusion line. This warning can be selected as an option. ☞ Check for occlusions in the infusion line. Note: the (🔔) key acknowledges the alarm.
`Drop in pressure !`	Low (!)	No	The pressure is decreasing in the infusion line. This warning can be selected as an option. ☞ Check the downstream Luer lock connection and the integrity of the entire line. Note: the (🔔) key acknowledges the alarm.

12.4.5 Battery Alarms

Message	Priority	Stops Infusion?	Problem / Resolution

`Alert !!!`
`Very low battery`
`Connect to power`
`and wait`
	High (!!!)	Yes	The battery is discharged.
			☞ The pump will power OFF automatically within 5 minutes.
			☞ Connect the pump to a power supply immediately.
			☞ The pump displays "`Battery alarm solved`" message.
			
			Note: the (🔔) key silences the alarm for 2 minutes.

`Alert !!!`
`Very low battery`
`Too low to use`
`Wait for charge`
	High (!!!)	Yes	Very low battery.
			☞ Allow time to charge.
			
			Note: the (🔔) key silences the alarm for 2 minutes.

`Alert !!`
`Low battery`
`Connect to power`
	Medium (!!)	No	Low battery.
			☞ Connect the pump to a power supply.
			
			Note: the (🔔) key silences the alarm for no time limit.

	Low (!)	No	If the pump is not used during an extended period, connect to a power supply and wait until the battery is charged.

12.4.6 Power Alarms

Message	Priority	Stops Infusion?	Problem / Resolution
`AC power failure !`	Low (!)	No	The power supply is inconsistent. ☞ Contact your technical support. Note: the (🔔) key acknowledges the alarm.
`Power disconnection`	Information signal	No	The pump is disconnected from the AC power. A single beep is emitted. ☞ Press (🔔) to acknowledge. ☞ Check that the battery life is sufficient for the expected infusion duration. ☞ If the disconnection was unintentional, check the power connection.

12.4.7 Keypad Alarms

Message	Priority	Stops Infusion?	Problem / Resolution
`Keypad lock status`	Information signal	No	The keypad is locked. ☞ Unlock the keypad.
`Keypad locked` `Unlock keypad to continue`	Information signal	No	The keypad is locked and the door was opened and closed. ☞ Unlock the keypad.

12.4.8 Drop sensor

Message	Priority	Stops Infusion?	Problem / Resolution
`Connect drop sensor !!!`	High (!!!)	Yes	This message is displayed only if the drop sensor is mandatory. At start-up, the drop sensor is not connected to the pump. ☞ Connect the drop sensor to the pump and the drip chamber. Note: the (🔔) key silences the alarm for 2 minutes.
`No drop sensor !!!`	High (!!!)	Yes	During the infusion or when the infusion is stopped, the drop sensor is connected to the pump. ☞ Disconnect the drop sensor from the pump. Note: the (🔔) key silences the alarm for 2 minutes.
`Underflow !!!`	High (!!!)	Yes	The flow rate detected by the drop sensor is inferior to the programmed flow rate. ☞ Check the container. ☞ Check the roller clamp. ☞ Check that the fluid drip forms ~20 drops/mL. ☞ Check that the drip chamber is in a vertical position. ☞ Check that the drop sensor is installed as recommended. Note: the (🔔) key acknowledges the alarm.

Message	Priority	Stops Infusion?	Problem / Resolution
`Overflow !!!`	High (!!!)	Yes	The flow rate detected by the drop sensor is superior to the programmed flow rate. ☞ Open the pump door and check the administration set positioning. ☞ Check the fluid temperature. ☞ Check that the fluid drip forms ~20 drops/ mL. ☞ Check that the drop sensor is installed as recommended. Note: the (🔔) key acknowledges the alarm.
`Uncontrolled flow !!!`	High (!!!)	Yes	At start-up or when the infusion is stopped, a free flow is detected by the drop sensor. ☞ Close roller clamp. ☞ Check the drop sensor and the administration set installation. Note: the (🔔) key acknowledges the alarm. If free flow continues, alarm will be raised again.
`No drop sensor !`	Low (!)	No	During the infusion or when the infusion is stopped, the drop sensor is connected to the pump. ☞ Disconnect the drop sensor from the pump. Note: the (🔔) key silences the alarm for no time limit.

12.4.9 Technical Error Alarms

Message	Priority	Stops Infusion?	Problem / Resolution
`Erxx(yyyy) !!!`	High (!!!)	Yes	Technical alarm. ☞ Contact your qualified technician or your **Fresenius Kabi** sales representative. Note: the (🔔) key silences the alarm for 30 seconds.
`High internal temperature !`	Low (!)	No	Temperature increase. ☞ Check device environment. Note: the (🔔) key silences the alarm for 2 minutes.

Message	Priority	Stops Infusion?	Problem / Resolution
`Alarm reporting not available on the Link !`	Low (!)	No	The pump is mounted on a Link+ Agilia rack that has not been upgraded. ☞ Contact your qualified technician or your **Fresenius Kabi** sales representative. Note: the (🔔) key acknowledges the alarm.

In the case of a system malfunction, the alarm sounds and an error message `Erxx(yyyy) !!!` is displayed.

1. Record the error message `Erxx(yyyy) !!!`.
2. Close the roller clamp.
3. Disconnect the pump from the power supply.
4. Switch the pump off by pressing the (ON/OFF) key.

Warning

*If the alarms persist when the pump is powered on again, do not use the device on a patient, and contact qualified biomedical engineering staff in your healthcare facility or your **Fresenius Kabi** sales representative.*

12.5 Audio Only Information Signals

Type	Comment	Stops Infusion?	Activation
Pressure measurement checking	4 beeps	Yes	When auto-restart is activated and a downstream occlusion is detected
Switch mode	Beep until key is released	No	Beep starts when action is not allowed
Start infusion at the end of pause	3 beeps	N/A	At the end of a pause, when the infusion automatically starts
AC power connection	1 beep	No	When power is connected
Forbidden key	1 beep	No	Repeated until key is released
Key beep	1 beep	No	For each key pressed
Other non validation beep	1 beep	No	For each key pressed
Call-back	1 beep	No	At the end of call-back
Direct bolus	1 beep	No	Repeated for each mL infused
Air advance	1 beep	N/A	Repeated every 5 seconds
Administration set prime	1 beep	N/A	Repeated every 5 seconds
End of pause	4 beeps	N/A	At the end of pause - repeated

13 Volumat Lines

13.1 Preparing the Administration Set and the Fluid Container

Agilia Volumat Lines are supplied sterile and are indicated for single use.

1. Prepare the fluid container according to your healthcare facility's protocol.
2. Select a Volumat Line.
3. Check the container, the line and access device integrity.

Refer to the Instructions for Use of the Volumat Lines for more information on the following elements: name, description, expiration date, intended use, contraindications, compatibility between the administration set and the administered fluid (for example, photosensitive fluids, degassing fluids, etc.)

To use the SafeClip with gravity infusions, see section 13.3.2, page 95.

Warning

- *Only use recommended Agilia Volumat Lines. Use of any other administration sets may affect the accuracy of the infusion, and result in injury to the patient and damage to the pump.*
- *Do not use an administration set if its packaging appears to be damaged or opened.*

Information

- *The fluid in the administration set, the administration set and the bag or bottle must be within normal operating temperature conditions: 18 °C to 30 °C.*
- *Do not use in conjunction with positive pressure infusion devices that could generate back pressure higher than 2000 hPa (1500 mmHg): doing so will damage the administration set and the pump.*
- *Some administration sets may have components such as a burette or filter that require special instructions.*
- *For administration sets with two spikes, only open one line at a time.*
- *When administering a manual bolus using Luer lock syringe via the needle-free downstream port, it is recommended to stop the infusion and close the Roberts clamp (pinch clamp).*
- *Certain drugs may require specific administration sets for infusion or transfusion.*
- *Some administration sets may have components such as a filter that require special instructions (e.g., air filter).*
- *When using an administration set with a filter, verify that the fluid to be infused is compatible with the size of the filter.*
- *Follow your healthcare facility's protocol for installing and replacing the fluid container.*

Precautions for the use of administration sets

- Use administration sets which have the smallest internal volume or “deadspace” to minimize residual volumes when administering medications or fluids at low infusion rates (e.g., less than 5mL per hour, and especially flow rates less than 0.5 mL per hour). This reduces the amount of time it takes for fluid to reach the patient, maintains delivery accuracy, and reduces occlusion detection times. For example:
  - *Administration set internal diameter: Small bore or microbore tubing is recommended when infusing at low rates*
  - *Administration set length: Administration set length should be minimized, when possible*
  - *Filters: Internal volume (deadspace) of in-line filters should be minimized*
  - *Connection sites: The number of connection sites such as stopcocks and Y-sites should be limited, and high risk or life sustaining solutions should be connected as close to the intravenous access site as possible.*
- Avoid use of manifolds with ports containing high pressure valves. High pressure valves require additional pressure (e.g., 50-200 mmHg) to open and allow fluid flow. These high pressure valves may cause a significant delay in therapy followed by a sudden bolus once the valve is opened, particularly at low infusion rates (e.g., less than 5 mL per hour, and especially flow rates less than 0.5 mL per hour).

13.2 Priming the Administration Set Before Use

The administration set is primed with fluid to displace air from the set.

It is recommended to prime the administration set immediately before starting the infusion.

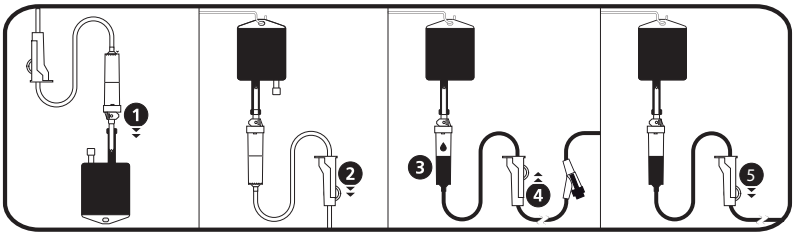
Certain administration sets may require specific priming procedures. Refer to the specific IFU provided with the administration sets.

Warning

During priming, make sure that the administration set is not connected to the patient.

13.2.1 With a Bag

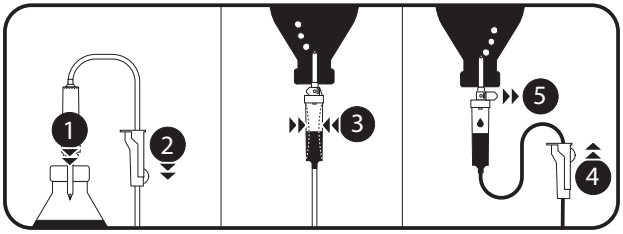
The following diagram shows how to prime the administration set with a bag:



1. Remove the cap from the spike and insert the spike into the bag.
2. After hanging the bag, close the roller clamp.
3. Fill the drip chamber approximately 1/2 full.
4. Slowly open the roller clamp for priming.
   Invert the needle-free port while priming, and gently tap the valve to remove all air.
5. When the administration set is fully primed, close the roller clamp and check carefully for the absence of air bubbles.
   For gravity infusions, the flow rate is regulated by the roller clamp.

13.2.2 With a Bottle

The following diagram shows how to prime the administration set with a bottle:



1. Open the roller clamp, close the air vent, and push the spike down into the bottle.
2. Close the roller clamp.
3. Hang the bottle upside down, then squeeze and release the drip chamber in order to fill it approximately 1/2 full.
4. Slowly open the roller clamp for priming.
5. Open the air vent, and allow the liquid to flow into the administration set.
   Invert the needle-free port while priming, and gently tap the valve to remove all air.
6. When the administration set is fully primed, close the roller clamp and check carefully for the absence of air bubbles.
   For gravity infusions, the flow rate is regulated by the roller clamp.

13.3 Other Uses of Administration Sets

13.3.1 Access Ports

The administration set may be equipped with access ports, that can be used to connect a gravity line, a secondary line, or administer a manual bolus (needle-free port).

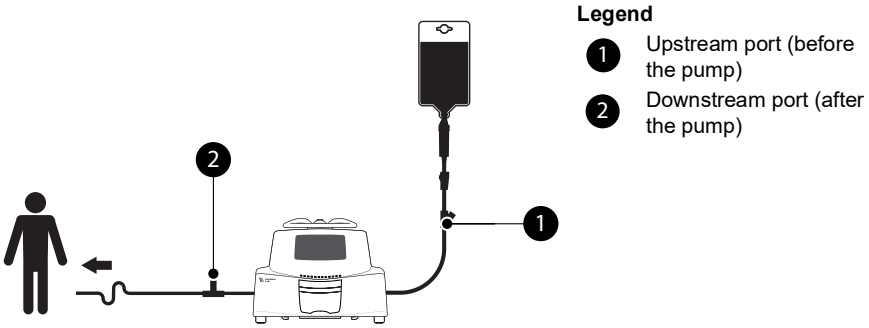


Figure 13.1: Needle-Free Ports

Information

- *Use aseptic technique when accessing the ports.*
- *Stop the infusion before accessing the ports.*
- *Do not use the upstream access ports to deliver a manual bolus into the line. They should only be used to connect a secondary infusion line.*
- *Do not use the downstream ports to connect a secondary line.*
- *For multi-line infusions, connect administration sets as close as possible to the patient.*

13.3.2 Use of Administration Sets for Gravity Infusion

13.3.2.1 Gravity Infusion (without pump)

In order to use the administration set to infuse the contents of the fluid container via gravity, without the pump, release the SafeClip as follows:

1. Close the roller clamp.
2. Slide the blue part of the SafeClip to the open position.
3. Adjust the roller clamp on the administration set to regulate gravity flow.

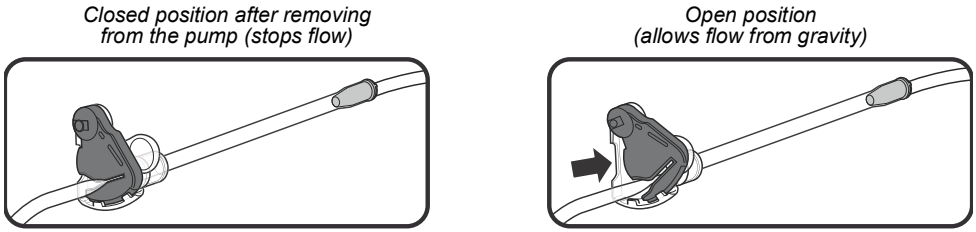


Figure 13.2: Operation of the SafeClip (blue anti-free flow clamp)

13.3.2.2 Gravity Infusion in Parallel with a Pump

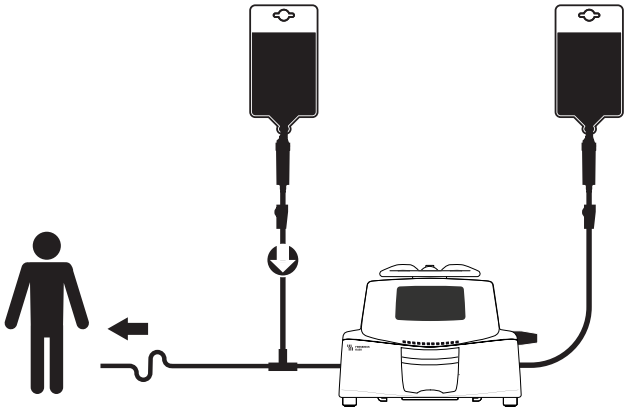


Figure 13.3: Gravity Infusion (in parallel with a pump)

Information

- ***Fresenius Kabi*** *recommends the use of a back check valve or positive pressure infusion devices when an infusion on the pump is connected to a gravity line. This will prevent the back-up of IV fluid or medication into the gravity line.*
- *If there is no back check valve on a gravity infusion line during a multi-line infusion, it may be impossible to detect patient-side occlusions. Such an occlusion could cause the pumped drug to back up into the gravity line, and later be infused in an uncontrolled manner when the occlusion is released.*
- *When connecting a pump-based infusion to a gravity line, connect the pump administration set as close as possible to the patient, to minimize dead space and the impact of the gravity line flow rate changes.*

13.4 Removal and Replacement of Administration Sets

13.4.1 Removing an Administration Set

1. Press STOP to stop the infusion.
2. Close the roller clamp.
3. Open the pump door.
4. Press (🔔) to silence the audible signal for 2 minutes.
5. Remove the administration set from the pump.
6. Disconnect the administration set from the access device in accordance with healthcare facility protocol.

13.4.2 Changing an Administration Set

1. Remove the administration set.
   See section 13.4.1, page 96.
2. Install another administration set, and follow the steps described in the flowchart.
   See section 6.1, page 33.

Information

Properly dispose of used administration sets as per the healthcare facility's guidelines.

13.4.3 Administration Set Replacement Interval

The mechanical properties of the administration set in association with the pump are designed to maintain pumping performance for a maximum of 10 liters or a 96-hour period.

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

14 Device Storage

14.1 Precautions for Storage

- Handle the device with care during storage.
- Store the device in a cool, dry place. The storage area must be clean and organized.
- Clean and disinfect the device prior to storage.

Warning

If the device is not used for an extended period (longer than 2 months), it is recommended that the battery be removed from the device and put in storage by authorized personnel. If the battery cannot be removed, or the device will be used in less than 2 months, charge the battery at least once a month by connecting the device to the AC power supply for at least 6 hours.

14.2 Storage and Transport Conditions

Observe the following conditions for storage and transport:

- Temperature: -10 °C to +60 °C
- Pressure: 500 hPa (375 mmHg / 7.25 PSI) to 1060 hPa (795 mmHg / 15.37 PSI)
- Relative humidity: 10 % to 90 % without condensation
- Altitude: Up to 3000 m

14.3 Preparing the Device for Storage

Prepare the device for storage as follows:

1. Power the pump OFF and remove the disposable.
2. If necessary (long-term storage), disconnect the pump's power cord and all data communication cables.
3. Remove the pump from its mounting point.
4. Clean the pump.
5. Handle the pump with care, and store it in a compliant area.

For detailed instructions, refer to the related chapters in this document.

14.4 Using the Device After Storage

The device can be used immediately after storage without any cooling or warm up period.

If the battery has been removed for long-term storage, contact your biomedical department in order to reinstall the battery prior to use.

We recommend charging the battery for at least 6 hours.

We recommend that the "User test" is performed when the device is installed after storage, and before being used on a patient, see section 11, page 79.

15 Specifications

Information

The range of settings and default values described in this section correspond to the factory configuration. Range of settings and default values may be adjusted in the pump options.

15.1 Essential Features

The pump's essential features are defined in standard operating conditions:

Feature	Refer to
Flow Rate Accuracy	Section 15.7.1, page 102. Section 18.10, page 114.
Time to Detect Occlusion	Section 15.7.3, page 102.
Bolus Volume After Occlusion Release	Section 15.7.4, page 103.
Management of High-priority Alarms	Section 12, page 80.

15.2 Flow Rate

	Format	Range of Settings	Default Value	Minimum Increment
Primary Infusion	mL/h	0.1 ➔ 1200*	N/A	0.01 (0.10 ➔ 9.99) 0.1 (10.0 ➔ 99.9) 1 (100 ➔ 1200)
Direct Bolus	mL/h	50 ➔ 1200	1200	50
KVO	mL/h	0 ➔ 20	1	1
Priming	mL/h	1200	N/A	N/A

* The maximum value can be adjusted between 50 and 1200 in the pump options (Basic Profile).

15.3 Volume To Be Infused (VTBI)

	Format	Range of Settings	Default Value	Minimum Increment
VTBI	mL	0.1 ➔ 9999	N/A	0.1 (0.1 ➔ 99.9) 1 (100 ➔ 9999)
Direct Bolus	mL	0.1 ➔ 60	N/A	0.1

15.4 Infusion Time

	Format	Range of Settings	Default Value	Minimum Increment
Primary	__ h __	00h01 ➔ 168h00*	N/A	00h01
KVO Silence Alarm Duration	__ h __	00h01 ➔ 12h00	01h00**	00h01
Pause	__ h __	00h01 ➔ 24h00	N/A	00h01

* If the calculated infusion time exceeds this value, ↑ 168h00 will be displayed on the pump.
** The default value may change depending on the pump configuration.

15.5 Air Detection

	Format	Range of Settings	Default Value	Minimum Increment
Total Air Volume Over 15 minutes	microL	10 ➔ 2000	250	10
Air Bubble Filter	microL	0 ➔ 250	50	10

15.6 Pressure Management

Information

You can change the Basic Profile's infusion pressure settings in the pump options. See section 9, page 76.

	Setting Description	Setting Format	Default Value
Mode	Infusion pressure mode.	3 levels / Variable	Variable
DPS	Allows DPS option activation on the pump pressure menu.	Yes / No	Yes
Unit	Pressure unit selection.	mmHg / kPa / PSI	mmHg
Limit Stored	The last pressure limit adjustment is automatically stored in memory for the next startup.	Enabled / Disabled	Disabled
DPS Stored	The last DPS adjustment is automatically stored in memory for the next startup.	Enabled / Disabled	Disabled

		Format	Range of Settings	Default Value	Minimum Increment
3 Levels	**Low**	mmHg	50 ➔ 300	100	50
	Medium	mmHg	150 ➔ 600	250	50
	High	mmHg	250 ➔ 750	500	50
Variable	**Full Range**	mmHg	50 ➔ 750	500	25 (50 ➔ 250) 50 (250 ➔ 750)
	Maximum Limit	mmHg	300 ➔ 750	750	50
DPS	**Raise Threshold**	mmHg	50 ➔ 400	300	50
	Drop Threshold	mmHg	100 ➔ 400	200	50

Note: 1 bar = 750 mmHg = 100 kPa = 14.5 PSI.

15.7 Accuracy

Warning

Accuracy (flow rate, time, volume infused, pressure) can be influenced by administration set model, administration set configuration, fluid viscosity, and fluid temperature.

Note: All tests below are in accordance with the IEC 60601-2-24 standard.

15.7.1 Flow Rate Accuracy

	Accuracy
Cumulative Flow Rate	± 5 % for 96 hours with an infusion of 10 liters maximum

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

15.7.2 Effects of Pressure Variations on Accuracy

	Accuracy	
Effects of Pressure Variations on Flow Rate Accuracy*	**Back pressure**	**Accuracy (from mean values)**
	+ 39.9 kPa	~ - 3 %
	+ 13.33 kPa	~ - 1.5 %
	- 13.33 kPa	~ + 1.5 %
Effects of Negative Solution Container Heights on Flow Rate Accuracy**	**Container Height**	**Accuracy (from mean values)**
	-0.5 m	- 10 %
	+ 0.2 ➔ 0.8 m	± 3 %

* Test condition: *Container height:* 50 cm

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

15.7.3 Occlusion Alarm Accuracy

	Accuracy		
Occlusion Alarm Response Time*		**Occlusion Alarm Threshold**	
	Rate	**50 mmHg**	**750 mmHg**
	0.1 mL/h	< 3 hours	< 24 hours
	1 mL/h	< 15 minutes	< 2 hours
	25 mL/h	< 30 seconds	< 4 minutes

* Test condition: *Temperature:* 20 °C, *Administration set:* VLST00, *Administration set length:* 270 cm

Note: The maximum values of the occlusion alarm response time specified above don't take into account the auto-restart feature when it is activated. When auto-restart is triggered, a period of 30 seconds maximum is added depending on the configurable period of pressure measurement. ***See section 7.10.3, page 77****. It is the healthcare professional's responsibility to define whether the auto-restart feature must be activated or not depending on the clinical practices.*

15.7.4 Volume Accuracy

	Accuracy		
Direct Bolus*	< 10 mL: ± 0.5 mL > 10 mL: ± 5 %		
Limit to Detect Upstream Occlusion*	≤ 1.0 mL		
Bolus Volume at Occlusion Release*		**Bolus Volume at Occlusion Release**	
	Rate	**50 mmHg**	**750 mmHg**
	25 mL/h	-0.05 ≤ X ≤ 0.35 mL	-0.05 ≤ X ≤ 0.35 mL
Limit to Detect Flow Rate Deviation with Drop Sensor	-70% ≤ X ≤ +250%		

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

Note:

- *A back flow pumping is provided to reduce the bolus volume at occlusion release.*
- *During pump movement from 0 to 1 m above the patient, a bolus (-0.05 ≤ X ≤ 0.35 mL) may occur.*

15.7.5 Pressure Accuracy

	Accuracy
Pressure*	< 500 mmHg: ± 75 mmHg > 500 mmHg: ± 15 %

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

15.8 Calculation Rules

	Infusion Stopped	During Infusion
V/T	Modify **V**, ☞ **T** is calculated according to **T = V/R**	Modify **R**, ☞ **T** is calculated according to **T = V/R**
	Modify **T**, ☞ **R** is calculated according to **R = V/T**	
V/R	Modify **V**, ☞ **T** is calculated according to **T = V/R**	Modify **R**, ☞ **T** is calculated according to **T = V/R**
	Modify **R**, ☞ **T** is calculated according to **T = V/R**	
T/R	Modify **T**, ☞ **V** is calculated according to **V = R x T**	Modify **R**, ☞ **T** is calculated according to **T = V/R**
	Modify **R**, ☞ **V** is calculated according to **V = R x T**	
V/T/R	Modify **V**, ☞ **T** is calculated according to **T = V/R**	Modify **R**, ☞ **T** is calculated according to **T = V/R**
	Modify **T**, ☞ **R** is calculated according to **R = V/T**	
	Modify **R**, ☞ **T** is calculated according to **T = V/R**	

V = Volume To Be Infused, T = Infusion Time, R = Rate

Calculated value		Examples
V	Rounded up to the nearest mL	▪ Calculated V = 1.8 mL ▪ Displayed V = 2 mL
T	Rounded up to the nearest minute	▪ Calculated T = 1 hour 12 min 32 sec ▪ Displayed T = 01h13
R	Rounded at ± 0.05 mL/h	▪ Calculated R = 42.57 mL/h ▪ Displayed R = 42.6 mL/h
		▪ Calculated R = 42.32 mL/h ▪ Displayed R = 42.3 mL/h
		Actual infusion rate = calculated rate

16 Cleaning and Disinfecting

To avoid the risks of infection and microbial transmission, make sure to adequately clean and disinfect the equipment.

Warning

- *The disinfecting procedure must be done immediately after cleaning. Disinfecting the pump without prior cleaning is not effective.*
- *The pump is not intended to be sterilized; sterilization may result in damage to the pump.*
- *In case of contamination by blood or bodily fluids when the pump is in use, and if allowed by your local practices and healthcare facility policies, immediately perform the quick cleaning described below. Always follow your local protection rules.*

Quick Cleaning Only

Note:

- *This quick cleaning does not replace the need for a complete cleaning.*
- *In homecare environments, this quick cleaning protocol is suitable to be applied by the nurse.*

1. Check that the keypad is locked in order to avoid unintended modification of the infusion parameters. Do not move the pump.
2. Use ready-to-use wipes to wipe down all exposed surfaces of the pump.
3. At the end of the infusion, perform the complete cleaning protocol, see section 16.3.1, page 107.

16.1 When to Clean and Disinfect the Pump

Thoroughly clean and disinfect the pump in the following cases:

- After each patient use
- Before any maintenance
- On a routine basis when the pump is not in use
- Before storage

16.2 Recommended and Prohibited Agents

We recommend the following cleaning and disinfecting agents:

16.2.1 Recommended Agents

	Recommended Agent
Cleaning	Didecyldimethylammonium chloride (example: Wip'Anios Excel by *Anios*)
Disinfecting	Didecyldimethylammonium chloride (example: Wip'Anios Excel by *Anios*)

16.2.2 Prohibited Agents

The following cleaning and disinfecting agents are prohibited:

- Trichloroethylene
- Abrasive detergents
- Undiluted alcohol

These aggressive agents may damage the plastic parts of the pump and cause it to malfunction.

16.3 Instructions for Cleaning and Disinfecting

Follow the instructions provided to ensure effective cleaning and disinfecting of the equipment.

- Use the agents according to the manufacturer's instructions. This may include wearing personal protective equipment (gloves, lab coat, glasses, and so on), or diluting the agent according to the manufacturer's guidelines.
- For disinfectants, respect the contact time required for the antimicrobial agents to act (the time the agent must be left on the pump for disinfection to be effective).

The following warning is provided to protect staff against electric shock, and to protect the pump from damage that can cause it to malfunction.

Warning

- *Only trained staff can clean and disinfect the pump.*
- *Do not place the pump in an autoclave or immerse it in liquid.*
- *Do not spray liquids directly on connectors. Instead, use a cleaning cloth or disposable wipes.*

16.3.1 Cleaning Instructions

Prerequisites

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

Protocol

1. Place the pump on a clean surface or disposable underlay.
2. Use a ready-to-use wipe to remove any major grime.
3. Thoroughly wipe down all exposed surfaces (housing, keyboard, pump door, door lever, etc.) of the pump, from top to bottom. You can use the silver handle to lift and move the pump.
   - *When wiping down the sides, avoid wetting the connector sockets.*
   - *Do not allow liquids to run, leak, or drip into the pump housing.*
4. Make sure the pump remains damp for at least 1 minute.
5. Set down the pump, and wipe down the silver handle, the attachment lock knob, the screw clamp and the release button.
6. Open the pump door, and gently wipe down the exposed surfaces (tube guides, blue clamp).
7. Using a fresh ready-to-use wipe, thoroughly wipe down all exposed surfaces, including the tube guides and the back of the door lever.
8. Make sure the pump remains damp for at least 1 minute to dissolve all organic matter.
9. Use a swab to gently scrub the exposed surfaces of the pump. Be sure to scrub along the seams and edges of the control panel, and the narrow or hard-to-reach areas.
10. Wipe down the power cord and any pump accessories.
11. Allow the pump to dry completely at room temperature.

Warning
To avoid short circuits, make sure that the air sensor is completely dry after cleaning.

16.3.2 Disinfecting Instructions

Prerequisites

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

Protocol

1. Place the previously cleaned pump on a clean surface or disposable underlay.
2. Use a ready-to-use wipe to wipe down all exposed surfaces of the pump, making sure to cover all cracks, crevices, and hard-to-reach areas. You can use the silver handle to lift and move the pump.
   - *When wiping down the sides, avoid wetting the connector sockets.*
   - *Do not allow liquids to run, leak, or drip into the pump housing.*
3. Set down the pump, and wipe down the silver handle, the attachment lock knob, the screw clamp and the release button.
4. Open the pump door, and gently wipe down the exposed surfaces (tube guides, blue clamp).
5. Using a fresh ready-to-use wipe, repeat steps 2 to 4.
6. Leave the disinfecting agent on the pump for at least 3 minutes.
7. Wipe down the power cord and any pump accessories.
8. Allow the pump to dry completely at room temperature.

17 Power Management

17.1 AC Power Supply Precautions

Check that the AC power supply voltage corresponds to the value indicated on the label on the bottom of the device. Do not exceed the permitted voltage.

The power outlet must remain accessible at all times to allow emergency power supply disconnection.

Warning

- *The pump and its accessories can only be connected to the AC power supply with the power cord supplied by* ***Fresenius Kabi****, or with a power supply accessory from the Agilia product range.*
- *Do not use an extension cord when connecting the pump to the AC power supply.*
- *Pumps must be plugged into a medical grade power strip if one is used.*

17.2 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 AC or battery power. Disconnect the power cord 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 instructions.*
- *Do not try to charge or discharge the battery outside of the device.*
- *For more information on replacing the battery, refer to the technical manual.*

17.3 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 AC power supply. The battery charges when the pump is connected to AC power supply.

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

Information

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

18 Technical Characteristics

18.1 Power Supply

It is mandatory to use an Agilia power cord compliant with the IEC 60227 standard.

The power cord conductor must have a cross section of at least 0.75 mm^2.

For a list of compatible power cords, refer to the System Components booklet.

AC Power	 Power supply	100 V - 240 V ~ / 50 / 60 Hz with functional earth
	Maximum consumption	10-15 VA
	Protective fuse	1 X T1.6AH 250V accessible in the battery compartment

18.2 Battery

Disconnect the battery before opening the device. Avoid short circuits and extreme temperatures.

If the device is not used for more than 3 months, the date is erased (all other settings are stored permanently). When you power on the pump, you must set the date again.

Characteristics	7.2 V 2.2 Ah - Li-ion Smart battery	
Weight	Approximately 100 g	
Battery Life	**Flow Rate**	**Battery Life**
	25 mL/h	> 8 h
	1200 mL/h	> 5 h
Battery Recharge	Pump OFF: < 6 h / Pump ON: < 20 h	

18.3 Power Consumption

The pump typically consumes about 4.3 W in standard operating conditions.

18.4 Communication Port

The connector located at the back of the device allows data communication with a PC.

Serial Cable	TTL output
Power Input	 10 V / 15 W to power supply the product
Power Output	 5 VDC / 150 mA to power Agilia USB cable

18.5 Infrared Communication

The pump is equipped with an infrared cell located at the back of the device.

Mode	Wireless optical communication using infrared light
Compatibility	Asynchronous Serial Infrared (SIR) physical layer irPHY 1.0, baseband no carrier
Transport Protocol	Proprietary
Speed	115.2 kb/s max
Wavelength	880 nm to 900 nm infrared band with 45 nm spectral bandwidth
Eye Safety	Class 0 of IEC 62471

18.6 Drop Sensor Connector

Power Output	 3.3 V / 45 mA to power drop sensor

18.7 Sound Levels

18.7.1 Operating Pump Sound Levels (without alarms)

Flow Rate (mL/h)	Sound Level (dBA)
0	21
1	30
100	37
400	33
1200	46

Note: These values are provided for information purposes only.

18.7.2 Alarms Sound Levels

Alarm Priority	Sound Level (dBA)	
	min	Max
High-priority	55	63
Medium-priority	50	57
Low-priority	49	53

18.8 Compliance

ElectroMedical Equipment Safety	Compliant with the following standards: ▪ IEC 60601-1 ▪ IEC 60601-1-8	**IP22**	Index of protection against ingress of water or particulate matter
EMC (ElectroMagnetic Compatibility)	Compliant with the following standard: ▪ IEC 60601-1-2		Protection against leakage current: Defibrillation-proof type CF applied part*
Particular Standards	▪ IEC 60601-2-24		Protection against electric shocks: class II
			Functional earth**

** After a defibrillation, the pump recovery time is around 2 seconds.*
*** The functional earth is directly connected to the power supply cord. It reduces residual current that may disturb ECG or EEG devices.*

18.9 Dimensions and Weight

H / W / D	135 x 190 x 170 mm
Weight	Approximately 2 kg
Screen Size	70 x 35 mm

18.10 Trumpet and Start-up Curves

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

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

The test protocol used to obtain these results is described in IEC60601-2-24:2012.

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

Administration set used: VLST00
Fluid used: distilled water

Recommendations to improve performances and safety when the pump is commonly used at low flow rates (≤ 20 mL/h):

- Limit the range of available flow rates in accordance with the maximum flow rate to be used.
- Lower the pressure limit in order to gain in time to detect occlusion.
- For the infusion of very short half-life at flow rate below 5 mL/h, we recommend using syringe pumps that usually offer better performances of instant flow rates.

18.10.1Flow Rate: 1 mL/h

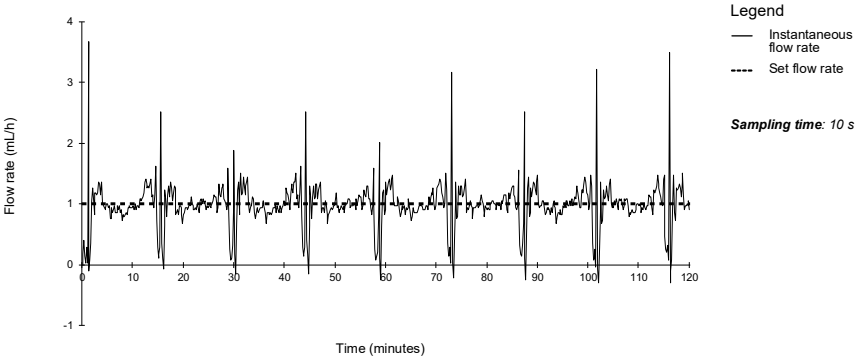


Figure 18.1: Start-up and instantaneous flow rate (1 mL/h over first 2 hours on 96 hours)

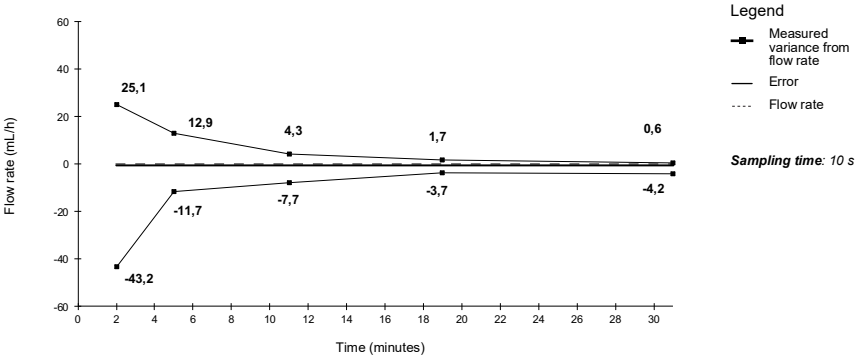


Figure 18.2: Trumpet curves for 2, 5, 11, 19, 31 minutes observation windows (1 mL/h over first 2 hours on 96 hours)

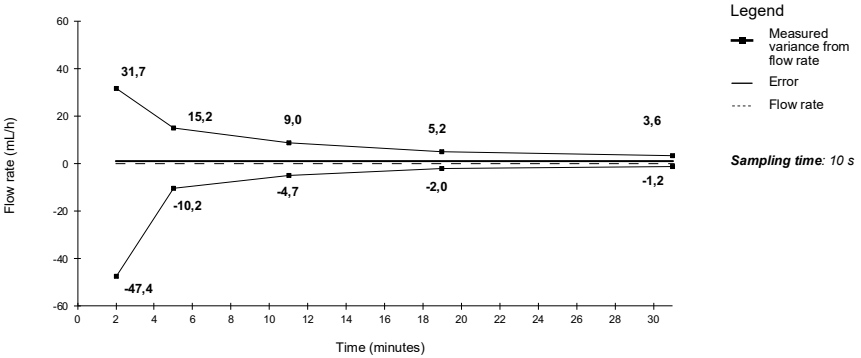


Figure 18.3: Trumpet curves for 2, 5, 11, 19, 31 minutes observation windows (1 mL/h over last 2 hours on 96 hours)

18.10.2Flow Rate: 25 mL/h

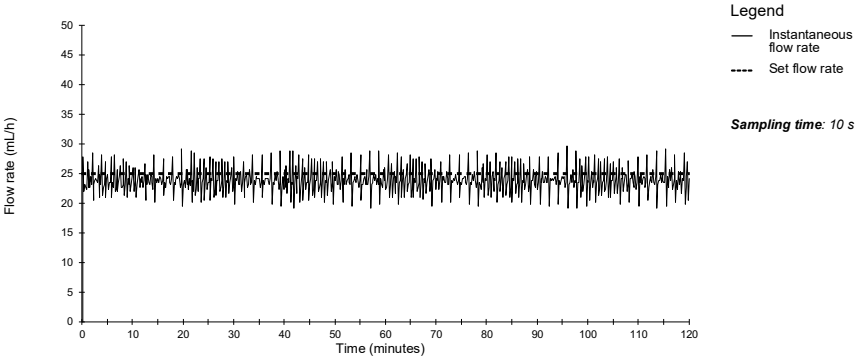


Figure 18.4: Start-up and instantaneous flow rate (25 mL/h over first 2 hours on 96 hours)

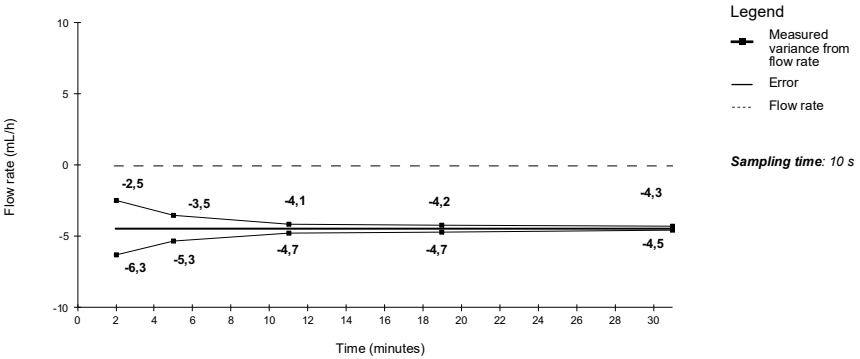


Figure 18.5: Trumpet curves for 2, 5, 11, 19, 31 minutes observation windows (25 mL/h over first 2 hours on 96 hours)

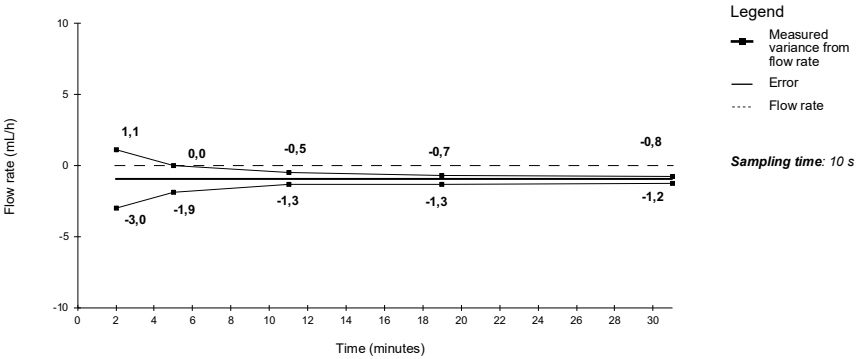


Figure 18.6: Trumpet curves for 2, 5, 11, 19, 31 minutes observation windows (25 mL/h over last 2 hours on 96 hours)

19 Troubleshooting

Issue	Recommended Actions
The pump is unstable when mounted.	▪ Check that the rotating pole clamp is fastened.
The pump is damaged, or you notice something abnormal (unusual noise, abnormal heat or smoke).	▪ Remove the power cord. ▪ Contact your biomedical department or your **Fresenius Kabi** sales representative immediately.
The pump has been dropped or was subjected to a force that may have produced internal damage.	▪ Do not use the pump. ▪ Contact your biomedical department or your **Fresenius Kabi** sales representative.
The pump cannot be installed or removed from the Link Agilia or Agilia Link or Link+ Agilia.	▪ Check the rotating pole clamp position. ▪ Contact your biomedical department or your **Fresenius Kabi** sales representative.
The pump does not start after pressing  .	▪ Connect the pump to the AC power supply to see if the battery is fully discharged. ▪ Contact your biomedical department or your **Fresenius Kabi** sales representative.
Data communication cables cannot be connected or removed from the pump.	▪ Check the cable connector. ▪ Check the pump connector. ▪ Contact your biomedical department or your **Fresenius Kabi** sales representative.
Flow rate variance is higher than flow rate accuracy.	▪ Check the infusion line configuration. ▪ Check the fluid viscosity. ▪ Check that the fluid temperature is within the recommended range. ▪ Contact your biomedical department or your **Fresenius Kabi** sales representative.
Keypad problem (keys, LEDs).	▪ Check the general condition of the keypad. ▪ Check the contrast. ▪ Contact your biomedical department or your **Fresenius Kabi** sales representative.
The power supply indicator does not light up.	▪ Connect the pump to the AC power supply. ▪ Contact your biomedical department or your **Fresenius Kabi** sales representative.
The pump powers off on its own.	▪ Connect the pump to the AC power supply. ▪ Contact your biomedical department or your **Fresenius Kabi** sales representative.
The battery alarm is ON even though the pump has been correctly charged.	▪ Check the AC power voltage. ▪ Contact your biomedical department or your **Fresenius Kabi** sales representative.
The pump powers off when it is disconnected from the AC power supply.	▪ The battery is completely discharged: charge the battery. ▪ Contact your biomedical department or your **Fresenius Kabi** sales representative.

Issue	Recommended Actions
At start-up, the pump displays: "Software is upgrading...".	▪ Connect the pump to the AC power supply. Then, wait few minutes without touching the keypad until the message disappears and the pump starts as usual. ▪ Contact your biomedical department, or your **Fresenius Kabi** sales representative.

20 Recycling

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.

Information

- *For more information on waste processing regulations and dismantling, contact your **Fresenius Kabi** sales representative or the local distributor.*
- *Follow healthcare facility policy regarding proper disposal after use.*

21 Warranty

21.1 General Warranty Conditions

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.

21.2 Limited Warranty

To benefit from the materials and workmanship guarantee from our **Fresenius Kabi** sales representative or authorized agent, make sure to observe the following conditions:

- The device must have been used according to the instructions described in this document and in other accompanying documents.
- The device must not have been damaged while being stored or repaired, and must not show signs of improper handling.
- The device must not have been altered or repaired by unqualified 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

- *If one or more of these conditions have been violated, **Fresenius Kabi** will prepare a repair estimate covering all required parts and labor.*
- *To repair or return a device, contact your **Fresenius Kabi** sales representative.*

21.3 Warranty Conditions for Accessories

Batteries and accessories may have specific warranty conditions.

Contact your **Fresenius Kabi** sales representative for more information.

22 Guidance and Manufacturer's Declaration on EMC

22.1 Electromagnetic Compatibility

Warning

- *The Agilia pump and its accessories are intended to be used in the electromagnetic environments specified below.*
- *The customer or the user of the Agilia pump should ensure that it is used in such environments.*
- *The Agilia pump must not be used in the presence of intense electromagnetic fields, such as those generated by certain electrically powered medical devices. Do not use the pump in MRI.*
- *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.*

When mounted on the Link+ Agilia, the pump is intended to be used in the electromagnetic environment specified in the Link+ Agilia IFU.

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

Points (e.g. screws) and surfaces that are only accessible for maintenance also require precautions. Points (e.g. battery contacts for battery replacement) and surfaces that are accessible only by maintenance staff also require precautions.

22.2 Electrostatic Discharge (ESD)

Information

- *Electronic components and semiconductors can be destroyed by electrostatic discharge (ESD). In particular, components made with metal oxide semiconductor (MOS) can be damaged from direct or indirect discharges. Damage caused by ESD may not be immediately identifiable, and malfunctions can even occur after a longer period of operation.*
- *Exceeding and / or repeating the test level attained in guidance & manufacturer's declaration on EMC may permanently damage the device and / or cause serious malfunctions (for example, loss of communication and system failures).*

The following environmental conditions related to electrostatic sensitive components (ESD standards) must be observed:

- Floors coated with wood, tiles or concrete
- Relative humidity of at least 30%

If it is not possible to guarantee this environment, the following additional precautions must be taken:

- Use of anti-static equipment
- Preliminary user discharge (explained below)
- Anti-static clothing

The best precaution is preliminary user discharge on a grounded metal object such as a rail, a pole or a metal part located at the rear of the Agilia pump.

For maintenance operations performed on the Agilia pump, place the device on a conductive working surface, and wear a special ESD conductive wristband.

22.3 Electromagnetic Compatibility and Interference Guidance

The Agilia pump 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 Agilia pump 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 reorienting the equipment.

Warning

- *Use of the Agilia pump adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.*
- *Use of accessories, transducers and cables other than those specified or provided by the manufacturer of the Agilia pump could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.*

- *Portable RF communications equipment (including peripherals such as antenna cables, internal and external antennas) should be used no closer than 10 cm for cell phones and 30 cm for other equipments, to any part of the Agilia pump, including cables specified by the manufacturer. Otherwise, degradation of the essential performances of Agilia pump could result.*
- *Electrosurgical equipment (including base unit, cables, electrodes) should be used no closer than 30 cm, to any part of the Agilia pump, including cables specified by the manufacturer. Otherwise, degradation of the essential performances of Agilia pump could result.*

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

If the Agilia pump is placed near RF communication equipment such as cell phones, DECT phones or wireless access points, RFID reader & tags,... It is essential to observe a minimum distance between the Agilia pump and this equipment specified above. If the Agilia pump causes harmful interference or if it is itself disrupted, the user is encouraged to try to correct the interference by one of the following actions:

- Reorient or relocate the Agilia pump, the patient or disruptive equipment.
- Change the routing of cables.
- Connect the Agilia pump power plug to a protected / backed-up / filtered supply or directly to the UPS circuit (uninterruptible power supply).
- Increase the separation between the Agilia pump and disruptive equipment.
- Plug the Agilia pump into an outlet on a different circuit from the one 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 correct setup and location.

22.4 EMC and essential performances

In the case of electromagnetic disturbances, if the essential performance, Section 15.1, page 99, is lost or degraded, the consequences for the patient are as follows: overdose, underdose, delay of therapy, air embolism, trauma, exsanguination.

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

Warning

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

Emission Test	Compliance Obtained by the Device	Electromagnetic Environment - Guidance
RF emissions CISPR 11	Group 1	The Agilia pump only uses RF energy for its internal operation. Its RF emissions are therefore very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The Agilia pump is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC61000-3-2	Class A	
Voltage fluctuations Flicker emissions IEC 61000-3-3	Compliant	
Conducted emissions 150 kHz - 108 Mhz CISPR25	Class 5	The Agilia pump is suitable for use in automotive environments.
Radiated emissions 150 kHz - 2.5 Ghz CISPR25	Class 3	

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

Warning

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

Immunity Test	IEC 60601-1-2 - - - - - - - - - - - - - - IEC 60601-2-24 Test Level	Compliance Level Obtained by the Device	Electromagnetic Environment - Guidance
Electrostatic Discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air - - - - - - - - - - - - - - ± 8 kV contact ± 15 kV air	± 8 kV contact ± 15 kV air	Floor coverings made from wood, tiles and concrete, with relative humidity level at least 30 %, make it possible to guarantee the necessary level of conformity. If it is not possible to guarantee this environment, additional precautions must be taken, such as: use of anti-static equipment, preliminary user discharge and the wearing of antistatic clothing.
Electrical fast Transient / burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input output lines	± 2 kV for power supply lines ± 1 kV for input output lines	AC power quality should be that of a typical commercial or healthcare facility environment.
Surge IEC 61000-4-5	± 1 kV differential mode ± 2 kV common mode	± 1 kV differential mode ± 2 kV common mode	AC power quality should be that of a typical commercial or healthcare facility environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	< 5% Ut (> 95% dip in Ut) for 0.5 cycles	< 5% Ut (> 95% dip in Ut) for 0.5 cycles	AC power quality should be that of a typical commercial or healthcare facility environment. For short and long interruptions (< than battery life) of AC power, the internal battery provides continuity of service.
	40% Ut (60% dip in Ut) for 5 cycles	40% Ut (60% dip in Ut) for 5 cycles	
	70% Ut (30% dip in Ut) for 25 cycles	70% Ut (30% dip in Ut) for 25 cycles	
	< 5% Ut (> 95% dip in Ut) for 5 s	< 5% Ut (> 95% dip in Ut) for 5 s	
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m - - - - - - - - - - - - - - 400 A/m	400 A/m	If necessary, the power of the magnetic field should be measured in the intended installation location to ensure that it is lower than compliance level. If the measured field in the location where the Agilia pump is used exceeds the applicable magnetic field compliance level above, observe the Agilia pump to verify that it is operating normally. If you notice abnormal performance, additional measures may be necessary, such as reorienting or relocating the Agilia pump, or installing magnetic shielding.

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

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

Warning

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

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

Notes:

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

22.4.4 Table 6 - Recommended Separation Distances Between Portable and Mobile RF Communication Equipment and the Agilia Pump

Information

- *The Agilia pump and its accessories are intended for use in electromagnetic environments in which radiated RF disturbances are controlled.*
- *Users of the Agilia pump may prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communication equipment (transmitters) and the Agilia pump as recommended below, and according to the maximum output power of the communication equipment (transmitters).*
- *The device should not be used next to other equipment. If adjacent use is necessary, observe the device to verify that it operates normally in the configuration in which it will be used (pump with a AC power cord, an RS232 cable).*

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

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

Information

- *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.*

22.4.5 EMC test deviations and supplementary tests

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

Immunity test	IEC 60601-1-2 IEC 60601-2-24 Test level	Compliance level obtained by the device	Electromagnetic environment – guidance
Discharge (ESD) IEC 61000-4-2	± 8 kV contact ± 15 kV air	± 8 kV contact ± 15 kV air	Wooden, tiled or concrete flooring, with a relative humidity level at least 30%, makes it possible to guarantee the level of necessary conformity. If it is not possible to guarantee this environment, the additional precautions must be taken, such as: use of anti-static material, preliminary user discharge and wearing anti-static clothing.
Radiated RF - IEC 61000-4-3	10 V/m, 80 MHz à 2,7 GHz	10 V/m, 80 MHz à 2,7 GHz	Portable and mobile RF communications equipment should be used no closer to any part of the Agilia pump, including cables, than the recommended separation distance calculated from the equation applicable to the frequency and power of transmitter For standard communication services and equipment, the specific frequencies were tested for a minimum approach distance of 30 cm and 10 cm (see below)
Near field radiated RF IEC 61000-4-3 test method	385 MHz, PM 18Hz, 27 V/m 450 Mhz, 1 KHz, 28 V/m 710 MHz, PM 217 Hz, 9 V/m 745 MHz, PM 217 Hz, 9 V/m 780 MHz, PM 217 Hz, 9 V/m 810 MHz, PM 18 Hz, 28 V/m 870 MHz, PM 18 Hz, 28 V/m 930 MHz, PM217 18 Hz, 28V/m 1720 MHz, PM 217 Hz, 28 V/m 1845 MHz, PM 217 Hz, 28 V/m 1970 MHz, PM 217 Hz, 28 V/m 2450 MHz, PM 217 Hz, 28 V/m 5240 MHz, PM 217 Hz, 9 V/m 5500 MHz, PM 217 Hz, 9 V/m 5785 MHz, PM 217 Hz, 9 V/m	Not tested Not tested Not tested Not tested Not tested Not tested Not tested Not tested Not tested Not tested Not tested 2450 MHz, PM 217 Hz, 28 V/m 5240 MHz, PM 217 Hz, 9 V/m 5500 MHz, PM 217 Hz, 9 V/m 5785 MHz, PM 217 Hz, 9 V/m	For minimal distance approach 30 cm (12 inches) "Not tested" frequencies are replaced by IEC 61000-4-39 test method and reduced minimal distance approach (see below) Portable and mobile RF communications equipment should be used no closer to any part of the Agilia pump, including cables, than the recommended minimal separation distance (30 cm) for these frequencies
Near field radiated RF - special test IEC 61000-4-39 test method	450 MHz, PM 217 Hz, 28 V/m 710 MHz, PM 217 Hz, 28 V/m 787 MHz, PM 217 Hz, 28 V/m 810 MHz, PM 217 Hz, 44 V/m 830 MHz, PM 217 Hz, 44 V/m 870 MHz, PM 217 Hz, 44 V/m 1750 MHz, PM 217 Hz, 28 V/m 1875 MHz, PM 217 Hz, 28 V/m 1970 MHz, PM 217 Hz, 28 V/m 2560 MHz, PM 217 Hz, 28 V/m 2655 MHz, PM 217 Hz, 28 V/m	450 MHz, PM 217 Hz, 28 V/m 710 MHz, PM 217 Hz, 28 V/m 787 MHz, PM 217 Hz, 28 V/m 810 MHz, PM 217 Hz, 44 V/m 830 MHz, PM 217 Hz, 44 V/m 870 MHz, PM 217 Hz, 44 V/m 1750 MHz, PM 217 Hz, 28 V/m 1875 MHz, PM 217 Hz, 28 V/m 1970 MHz, PM 217 Hz, 28 V/m 2560 MHz, PM 217 Hz, 28 V/m 2655 MHz, PM 217 Hz, 28 V/m	For minimal distance approach 10 cm 250 mW average power for 28 V/m test level 600 mW average power for 44 V/m test level Portable and mobile RF communications equipment should be used no closer to any part of the Agilia pump, including cables, than the recommended minimal separation distance (10 cm) for these frequencies

Immunity test	IEC 60601-1-2 IEC 60601-2-24 Test level	Compliance level obtained by the device	Electromagnetic environment – guidance
Electrical Fast transient / Burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input output lines 100 KHz repetition	± 2 kV for power supply lines ± 1 kV for input output lines 100 KHz repetition	Electricity power quality should be that of a typical domestic, commercial or hospital environment
Surge IEC 61000-4-5	± 1 kV differential mode ± 2 kV common mode	± 1 kV differential mode ± 2 kV common mode	Electricity power quality should be that of a typical domestic, commercial or hospital environment. For very exposed establishments or buildings with the lightning, a protection must be installed on electricity power. Class II product and no earth connexion.
Conducted RF IEC 61000-4-6	3 Vrms 150 KHz to 80 MHz And 6 Vrms in the ISM and amateur radio bands	3 Vrms 150 KHz to 80 MHz And 6 Vrms in the ISM and amateur radio bands	Portable and mobile RF communications equipment should be used no closer to any part of the Agilia pump including cables, than the recommended separation distance calculated from the equation applicable to the frequency and power of transmitter (see table 6)
Power frequency (50 / 60 Hz) magnetic field IEC 61000-4-8	**400 A / m**	**400 A / m**	If necessary, the power magnetic field should be measured in the intended installation location to make sure it is lower than the compliance level. If the measured field in the location where the Agilia pump is used exceeds the applicable magnetic field compliance level above, the Agilia pump should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Agilia pump, or installing magnetic shielding.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0 % Ut (100% dip in Ut) for 0,5 cycle at 0°, 45°, 90°, 135°,180°, 225°, 270°,and 315° 0% Ut (100% dip in Ut) for 1 cycle 70% Ut (30% dip in Ut) for 25 cycles at 50 Hz for 30 cycles at 60 Hz at 0°	0 % Ut (100% dip in Ut) for 0,5 cycle at 0°, 45°, 90°, 135°,180°, 225°, 270°,and 315° 0% Ut (100% dip in Ut) for 1 cycle 70% Ut (30% dip in Ut) for 25 cycles at 50 Hz for 30 cycles at 60 Hz at 0°	Electricity power quality should be that of a typical domestic, commercial or hospital environment. For short and long interruptions (< than battery autonomy) of electricity power supply, the internal battery provides the continuity of service. For very long (> than battery autonomy) interruptions of electricity power supply, the Agilia pump must be powered from an external Uninterruptible Power Supply (UPS). Note: Ut is the a/c mains voltage prior to application of the test level.

23 Servicing

23.1 Information on Device Servicing

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

23.2 Maintenance Requirements

Warning

Perform preventive maintenance at least once every 3 years. This includes replacing the battery and the pumping membrane.

Warning

Do not modify the device (except in the case of operations recommended by Fresenius Kabi).

Warning

Do not perform any maintenance or service operation while the device is used on a patient.

To ensure the device continues to operate normally, follow the instructions below:

- Preventive maintenance should be performed by trained and qualified technical personnel in compliance with the technical manual and procedures. Only authorized service personnel should attempt to repair the device.
- The qualified personnel must be informed if the device is dropped or if any malfunctions occur. In this case, do not use the device and contact your biomedical department or **Fresenius Kabi**.
- Failure to comply with these maintenance procedures could damage the device and lead to a functional failure. Internal inspection of the device requires compliance with special procedures to avoid damage to the device.
- When replacing components, only use spare parts from **Fresenius Kabi**.

The life cycle of the pump is 10 years provided that the maintenance is properly performed as described above.

Information

*If the device needs upgrading, **Fresenius Kabi** or its representative will provide relevant instructions. It is the healthcare facility's responsibility to follow **Fresenius Kabi**'s instructions.*

23.3 Quality Control

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

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

Information

- *These control 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.*

23.4 Notification of serious incident

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

Information and contact information:

Fresenius Kabi AG
Else-Kröner-Str. 1
61352 Bad Homburg, GERMANY
Tel: +49 (0) 6172 / 686-0

www.fresenius-kabi.com

24 Cybersecurity

24.1 Cybersecurity and IT-Network environment

Fresenius Kabi infusion systems including its software components are intended to be deployed primarily on a healthcare facility network with the following characteristics:

- Monitoring and control of access from outside of the network perimeter.
- Appropriate authentication and authorisation of users on the network.
- Monitoring, prevention and containment of malware and computer viruses.
- Systematic data backup procedures.
- Periodically conducting audit trail.
- Well-defined IT segmentation and security perimeters.

In addition to these IT-Network characteristics, it is presumed that the host facility should have established IT-Network policies and procedures that comply with IEC 80001 series standard, such as IEC 80001-1 "Application of risk management for IT-Networks incorporating medical device - Part 1: Roles, Responsibilities and Activities". It is also recommended but not required that the IT-Network environment includes provision of dedicated medical device network (such as VLAN) for deployment of medical devices along with dedicated medical device applications only.

Warning

Institutionalizing strong cybersecurity policies and following the industry best practices relative to IT security could minimize exposure to threats. These threats may include but are not limited to: data leak, data corruption, data loss, network or service outage, and so on.

***Fresenius Kabi** strongly advises to follow IEC/ISO 80001 to manage risks regarding IT-Network and Cybersecurity.*

Policy recommendations

- Have top management strongly involved in the risk and the cybersecurity policies and role definition.
- Have a risk management process led by a medical IT-Network risk manager.
- Use a medical IT-Network risk management file to provide traceability for hazards.
- Define who is in charge of gathering information around risk; analysing, assessing and storing them.
- Check for the correct functioning of medical devices at a regular interval.

IT-Network recommendations

- Perform a full analysis of existing IT-Network, using different views (either relative to physical, data or process parts).
- Define the scope of each separated network and its needs to be isolated or not.
- Define how IT-Network security can be implemented.

Software used to maintain or operate medical devices may be deployed on different host computers: desktop, laptop, servers, …
However, such software deployment shall comply with the same use conditions as those for healthcare facility network deployment. Ideally, the host computer will belong to the healthcare facility network, and therefore will be protected in the same manner as the network.

Information
Fresenius Kabi *strongly advises these recommendations to be applied to all software application, including operational, maintenance and direct configuration tools.*

24.2 Inherent design

Warning
Perform preventive maintenance at least once every 3 years. This includes replacing the battery.

Agilia system pumps design includes security mechanisms.
Communication with software application are secured, Wi-Fi communication can be protected using WPA2 encryption, integrity and availability of data is verified, user interface can be locked on demand, Agilia pumps only communicate at their initiative on a configurable manner.
Fresenius Kabi strongly recommends to read and implement good practices included in Section 24.3, page 133.

24.3 Information regarding cybersecurity

Compliance with industry-wide IT policies, such as password complexity and mandatory periodic updates is strongly recommended.

Warning
Organization IT policy should be compliant with IEC 80001-2, Application of risk management for IT networks incorporating medical devices.

- Establish usage policies to help to proactively reduce the risk of security breaches as a result of employee negligence.
- Secure Internal Network.

Warning
Medical devices must be deployed within a secure network perimeter to prevent access from unauthorized external system(s).

- Develop and maintain a Security Patch Management process to minimize system vulnerabilities.

Warning
Ensure physical security of the premise and the Agilia system components.

- Ensure that appropriate up-to-date virus/worm protection mechanisms are in place to protect the system.

Information
In order to avoid any loss of data, periodic backups are recommended. Follow institutional SOPs for the appropriate backup intervals.

Network configuration

It is recommended that network installation and use be consistent with commonly-accepted industry best practices related to cyber and information security, including but not limited to the following:

- Design network infrastructure to eliminate single point of failure.
- Optimize network for low latency.
- Use strong authentication and encryption (WPA2-Enterprise) for Wi-Fi network.
- Ensure a full Wi-Fi coverage of the facility.

Warning
Ensure boundary protection devices (for example, VPN, firewall, VLAN, separated or out-of-band networks, etc.) are used appropriately.

- Perform and qualify the hospital network where Agilia system components are to be deployed.
- Design IT network to enable separation of medical devices from administrative applications.
- Design network infrastructure to provide adequate data bandwidth for the number of deployed devices.
- Ensure appropriate authentication (for example, password policy) and authorisation (principle of least privilege) policy are in place to ensure only intended users have access to use the device.
- Have a policy in place to manage application of security updates to off-the-shelf components.
- Verify that the appropriate training requirements are met for a potential user before creating a user account.
- Monitor network traffic to identify and isolate devices suspected of generating malicious, excessive or unusual network traffic.

Login and passwords

Individual institutional Information Technology (IT) policies should identify security controls that maintain the pairing of a login and password following IEC 80001-2.

Hardening

The default configuration of most operating systems is not designed with security as the primary focus. Instead, default setups focus more on usability, communications and functionality. To protect the servers, it is recommended to establish solid and sophisticated server hardening policy and checklist.

Warning

- *Perform OS/Server hardening to the server before deploying the software application used for operational, maintenance and direct configuration purpose.*
- *Disable booting from removable media option for the software host computer.*
- *Disable all unused services.*
- *Close all unused inbound or outbound ports.*

24.4 Firewall configuration

Ensure that the ports specified during installation are allowed through the Windows firewall or your facility firewall. Also, ensure all unnecessary inbound or outbound traffic are blocked.

24.5 Potential vulnerabilities

The following table includes known or identified vulnerabilities that could be found in typical IT network

Vulnerability	Typical Threat Events
Communication and network configuration vulnerabilities	
Improperly configured or non-existent firewall or logical protective barrier	A lack of properly configured firewall could permit unnecessary data to pass between networks, such as device and facility networks, allowing adversary or malware to spread between networks, making critical or sensitive data susceptible to monitoring, eavesdropping and to be subjected to Man-in-the-Middle attack.
Standard, well-documented plain text communication protocol	Adversaries can use a protocol analyzer (commercially available) or other utilities to decode the data transferred by protocols, such as telnet, FTP, HTTP and NFS. It is relatively easier for adversaries to perform attacks on these communications.

Vulnerability	Typical Threat Events
Lack of integrity checking	Adversaries could manipulate communications undetected.
Inadequate authentication between wireless clients and access points	Strong mutual authentication between wireless clients and access points is needed to ensure that clients do not connect to a rogue access point deployed by an adversary.
Inadequate data protection between wireless clients and access points	Sensitive data between wireless clients and access point should be protected using strong encryption to ensure that adversaries cannot gain unauthorized access to the unencrypted data. Ensure protection from fraudulent Wi-Fi access points (Evil Twin) that appear to be legitimate but are set up to eavesdrop on wireless communications.
Poor remote access controls	Remote access capabilities must be adequately controlled to prevent unauthorised individuals from gaining access to the system.
Inadequate firewall and router logs	Without proper and accurate logs, it might be impossible to determine what cause a security incident to occur.
Unprotected ports or services	Unused ports (such as ForgotDoor) and services must be closed or turned off.
Physical Access	
Unauthorised personnel have physical access to devices	▪ Physical theft or damage of data ▪ Unauthorised personnel add, remove or change resources of devices ▪ Install unauthorised utilities (undetectable interception of data)
Unsecured physical ports	▪ Flash/thumb drivers ▪ Keystroke logger ▪ Other unauthorised utilities to exploit unsecure physical ports
Network Configuration and Communication	
A flat network with no zones (no segregation between corporate and device networks)	▪ Unauthorised access to medical devices through facility's IT-network ▪ Distribute malware across facility's IT-networks ▪ Intercept or manipulate unencrypted messages (plain text)
Improperly selected and configured firewall (weak firewall rules)	▪ Phishing attack (spear phishing, mobile phishing) ▪ Identity spoofing ▪ Firewall bypassed ▪ Man-in-the-middle attacks
Malware protection not installed or not up-to-date	▪ Disseminate virus, ransomware among networks ▪ Plant spyware (for monitoring and eavesdropping) ▪ Audit log manipulation or destruction

Vulnerability	Typical Threat Events
Software vulnerabilities	
Inadequately assess security of OTS	A wide variety of security implications and vulnerabilities have been identified with various OTS operating systems or control protocols such as OLE, DCOM, RPC, OPC, etc.
Database vulnerabilities	Databases with web interfaces may be vulnerable to typical web attacks like XSS, SQL injection. The information contained in database makes them high-value targets for any attacker.
Security Policies and Procedures	
Lack of or inadequate authentication, authorisation, access control policies and incident detection and response plan or procedure	▪ Vulnerabilities regarding authentication, authorisation, access control policies, incident detection and response plan or procedure could lead to multiple threat events (attacks) or more likely. ▪ For example incident detection (such as unusual CPU usage due to Cryptojacking) and response plans, procedures and methods are necessary for rapidly detecting incident, minimizing loss and destruction, preserving evidence for later forensic examination, mitigating the weakness that were exploited, and restoring system services. ▪ Having an inadequately shared network between Medical Device Network and Corporate Network (for example, it does not have dedicated VLAN for medical devices) could make it possible for virus and worm to spread to medical devices.

25 Glossary of Terms

Term	Description
A	Amperes
AC	Alternating Current
Ah	Ampere-hours
AIDC	Automatic Identification and Data Capture
AM	Amplitude Modulation
A/m	Amperes per meter
BPSK	Binary Phase Shift Keying
BSA	Body Surface Area
cal	Calorie
CCK	Complementary Code Keying
CDC	Centers for Disease Control
CISPR	Special International Committee on Radio Interference
CT Scan	Computed Tomography
dBA	Decibels
dBm	Decibels-Milliwatts
DC	Direct Current
DCOM	Distributed Component Object Model
DECT	Digital Enhanced Cordless Telecommunications
DEHP	Di(2-ethylhexyl) phthalate
DERS	Dose Error Reduction Software
DHCP	Dynamic Host Configuration Protocol
DTBI	Dose to Be Infused
DI	Dose Infused
DPS	Dynamic Pressure System
DSSS	Direct Sequence Spread Spectrum

Term	Description
DUR	Duration
ECG	Electrocardiogram
ECMO	ExtraCorporeal Membrane Oxygenation
EEG	Electroencephalogram
EMC	Electromagnetic compatibility
ErXX	Error message
ESD	Electrostatic Discharge
FCC	Federal Communications Commission
FM	Frequency Modulation
ft	Feet
FTP	File Transfer Protocol
GPL	General Public License
GTIN	Global Trade Item Number
H/W/D	Height / Width / Depth
HF	High Frequency
hPa	Hectopascals
HTTP	HyperText Transfer Protocol
Hz	Hertz
IC	Industry Canada
IEC	International Electrotechnical Commission
IEEE	Institute of Electrical and Electronics Engineers
IFU	Instructions For Use
in	Inches
IT	Information Technology
IV	Intravenous
kg	Kilograms
KVO	Keep Vein Open

Term	Description
lb(s)	Pound(s)
LED	Light Emitting Diode
mA	Milliamperes
mEq	Milliequivalents
mL/h	Milliliters per hour
mmHg	Millimeters of Mercury
mmol	Millimole
MOS	Metal Oxyde Semiconductor
MRI	Magnetic Resonance Imaging
mW/sr	Milliwatts per steradian
N/A	Not Applicable
NFS	Network File System
NMR	Nuclear Magnetic Resonance
OCS	Occlusivity Check System
OFDM	Orthogonal Frequency Division Multiplexing
OLE	Object Linking and Embedding
OPC	Open Platform Communications
OTS	Off-The-Shelf
OR	Operating Room
PC	Personal Computer
PSI	Pounds per Square Inch
PSK	Phase Shift Keying
QAM	Quadrature Amplitude Modulation
QPSK	Quadrature Phase Shift Keying
REF	Product reference / part number
RF	Radio Frequency
RFID	Radio Frequency IDentification

Term	Description
RPC	Remote Procedure Control
RS232	Serial interface connector
SN	Serial Number
SELV	Safety Extra Low Voltage
SIR	Asynchronous Serial Infrared
SQL	Structured Query Language
TCP	Transmission Control Protocol
UDI	Unique Device Identifier
USB	Universal Serial Bus
Ut	Test specification level
V	Volts
VA	Volt-Amperes
VDC	Volts Direct Current
VI	Volume Infused
VLAN	Virtual Local Area Network
VPN	Virtual Private Network
Vrms	Root Mean Square Voltage
VTBI	Volume to Be Infused
V/m	Volts per meter
W	Watts
WPA	Wi-Fi Protected Access
XSS	Cross-Site Scripting

Appendix: Factory Configuration

	Feature	Availability
Menus	Profile	×
	Pressure management	✓
	Volume to be infused	✓
	Keypad lock status	✓
	Battery life	✓
	Volume Infused	✓
	Pause	✓
	Day/Night mode	✓
	Infusion mode	✓
	Alarm volume	✓
	Call-back alert	×
	View flow rate history	×
	View pressure history	×
	View event log	×
	Date / Time	×
	Maintenance	×

	Feature	Availability
Infusion Modes	V/T/R	✓
	V/R	✓
	V/T	✓
	Simple Rate	✓
Infusion Features	Direct Bolus	✓
	KVO	✓
	Prime Set	×
	Advance Air Bubble	✓
	Dynamic Pressure System (DPS)	✓

✓ = Activated with factory configuration (Basic Profile).

× = Not activated with factory configuration. Can be activated in the pump options. Otherwise can be activated on request.

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Release Notes

Date	Software Version	Description
February 2021	4.1	Creation
July 2021	4.1	New packaging list. Selection of the language and entry of the date are added to the "Powering on" procedure.

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

The screenshots in this document are for illustrative purposes only. Screen contents may vary based on individual configurations and minor software modifications; therefore, some screenshots may appear slightly different from what you see on the product.

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Local Contacts for Servicing

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FRESENIUS KABI

caring for life

Fresenius Kabi AG
Else-Kröner-Str. 1
61352 Bad Homburg, GERMANY
Tel.: +49 (0) 6172 / 686-0
www.fresenius-kabi.com

Fresenius Vial S.A.S.
Le Grand Chemin
38590 Brézins - FRANCE