FRESENIUS KABI

Agilia VP MC (WiFi)

Volumetric Infusion Pump

Applicable to software version 4.3

Instructions For Use

For Use in Healthcare Facilities and Homecare Environments

Symbols Description

Symbols used in this document

Danger: Warning of an imminent hazard that could result in serious personal injury and/or product damage if the written instructions are not followed.

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

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

Information: recommendations to be followed.

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)

Index of protection against solid foreign objects (> 2.5 mm) and dripping liquids

Part included in a recycling process

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

CE mark

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

UDI Unique Device Identifier

CH REP Indicates the authorised representative in Switzerland

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1 Introduction

1.1 Scope

These Instructions for Use (IFU) are applicable to the Agilia VP MC and Agilia VP MC WiFi large volume pumps. These devices are referred to throughout this manual as the "Agilia VP MC".

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.

INFORMATION
Check that this IFU is applicable to the software version currently in your devices.

- The software version of the device is displayed on start-up screen.
- The software version described in this IFU is displayed on the cover page and in the *Release notes* on page 171.

1.2 Principles of Operation

The Agilia VP MC infusion pump 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.

The Agilia VP MC infusion pump is a transportable and reusable device that can be used everyday.

The Agilia VP MC infusion pump can be used for intermittent or continuous infusions.

The Agilia VP MC infusion pump 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 Pumps and Accessories for Administration of Fluids.

NOTE: The device intended purpose is extracted from the “Device Group” intended purpose mentioned in the EU certificate.

1.4 Intended Use

1.4.1 Indications

WARNING
In homecare environment, the substances listed hereafter can be infused only under the constant supervision of a trained healthcare professional:

- Catecholamines
- Morphine

- Chemotherapeutics
- Any life-sustaining 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

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

Only use the Agilia VP MC infusion pump 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:

- Intravascular access with any device that administers a medical fluid 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

The Agilia VP MC infusion pump 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

The Agilia VP MC infusion pump 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 *Specificities for Homecare Environments* on page 12.

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 Agilia pumps in the following environments:

- Explosive or flammable environments
- High humidity environments
- Hyperbaric chambers

WARNING
Simultaneous use of the Agilia pumps with medical devices that affect the backpressure may affect some of their performance:

- flowrate,
- pressure evaluation,
- occlusion detection time.

Carefully monitor the behavior of the infusion to avoid any risk to the patient.

WARNING
The pump can be used in road 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 the IFU of the Agilia Holder Ambulance accessory.

INFORMATION

- The pump can be used in MRI unit exclusively with the Agilia MRI Guard accessory. For more information, refer to the IFU of the Agilia MRI Guard accessory.
- For more information on using the device in specific conditions, contact your Fresenius Kabi sales 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 sales 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 MC and Agilia VP MC WiFi 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 1500 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, dose rate and flow rate modes including ramp mode, sequential mode and secondary infusion mode, 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).
- Prevent infusion-related medication errors (with the use of up-to-date Dose Error Reduction Software [DERS] configured in line with policy/clinical practice of each healthcare facility).

1.6 Side-effects

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

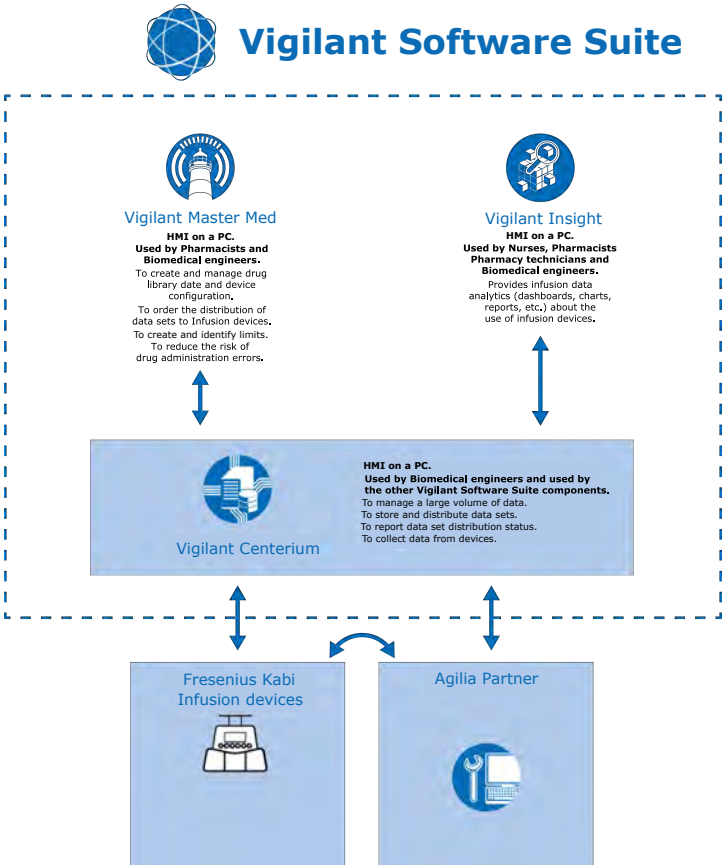
1.7 Risks for patients

Failure to follow all instructions described in this document or loss or degradation of essential performance (*Essential Features* on page 120) may result in: over-delivery, under-delivery, delay of therapy, incorrect therapy, exsanguination, biological/chemical contamination, undetected air infused to patient, traumatic injuries or electrisation.

1.8 Cybersecurity Safety considerations

1.8.1 Agilia VP Infusion System

The figure below shows how the pump operates within the Agilia VP Infusion System.



1.8.2 Cybersecurity Recommendations

The Agilia VP MC WiFi has been designed to allow the mitigation of commonly known cybersecurity threats targeting network and serial communications interfaces.

WARNING

To further protect the Agilia VP MC WiFi pump against unauthorized access and its removal from the premises, ensure the followings:

- Your premises are secured.
- The device is installed within a secure network perimeter to prevent TCP/IP network access from unauthorized external system(s).
- When not in use, the Agilia VP MC WiFi pump is securely stored.
- When not in use, the Agilia VP MC WiFi Serial or USB Cables are disconnected and securely stored.
- Secure storage access is restricted to authorized personal only.
- The latest version of the device firmware is installed.

- The device passwords and access codes are changed from their default values. Refer to Technical Manual.
- The Agilia VP MC WiFi pump shall enforce the usage of secure communications protocol for TCP/IP data flows exchanged with Vigilant Software Suite. Ensure WPA2 and HTTPS are configured on the Wifi module using Agilia Partner Maintenance Software.

The Agilia VP MC WiFi only stores and processes infusion and device status data. No patient or personal data are stored and processed by the device.

Refer to the Agilia VP MC WiFi Technical Manual for more information on how to protect against cybersecurity threats, including:

- General cybersecurity recommendations
- Device cybersecurity features
- Detailed descriptions of potential risks and countermeasures
- Practical cybersecurity guidelines for:
  - Installation (commissioning)
  - Operation (including maintenance servicing)
  - Security Updates
  - Incident detection and response
  - Disposal of device (decommissioning)

In case of issue (example: network connectivity, loss of maintenance access code), contact your biomedical department or your Fresenius Kabi representative.

In case any suspected cybersecurity event or vulnerabilities related to the Agilia VP MC WiFi shall be reported, please contact your local Fresenius Kabi representative or submit a request to the Fresenius CERT (*cert@fresenius.com*). For vulnerability reporting, please refer to Fresenius CVD portal: *https://www.fresenius.com/vulnerability-statement*.

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 epidural infusion 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. The Vigilant Master Med application software 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. The Link Agilia / Agilia Link devices are designed to centralize the power supply. The Link+ Agilia device is designed to centralize the power supply and to centrally replicate infusion pump signalling.
	Agilia MRI Guard	**MRI-Shielding System** The Agilia MRI Guard accessory 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 accessory 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.

INFORMATION
The Agilia Connect Infusion System is made up of medical devices that are subject to medical device regulations and market authorizations. Some devices, including software products, may not be available in your country at the time of publishing this document.

3 Description

3.1 Front View

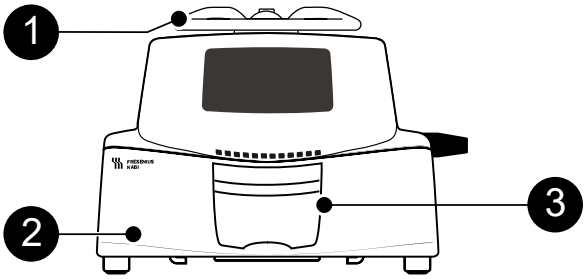


Figure 1: Front View

Legend	
1 Handle	3 Door Lever
2 Pump Door	

3.2 Bottom View (Device Identification Label)

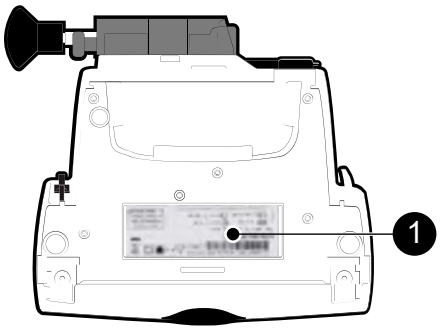


Figure 2: Bottom View

Legend
1 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 Description* on page 2.

3.3 Back View

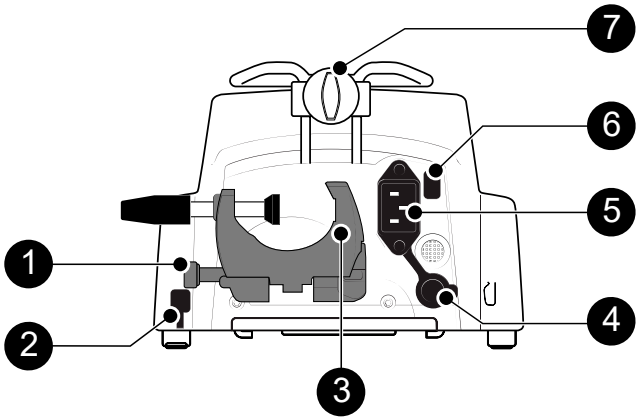


Figure 3: Back View

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 *Technical Characteristics* on page 135.
	Near RS232 Communication Port	Warning See *Data Communication* on page 98.

3.4 Keypad

3.4.1 Keypad Description

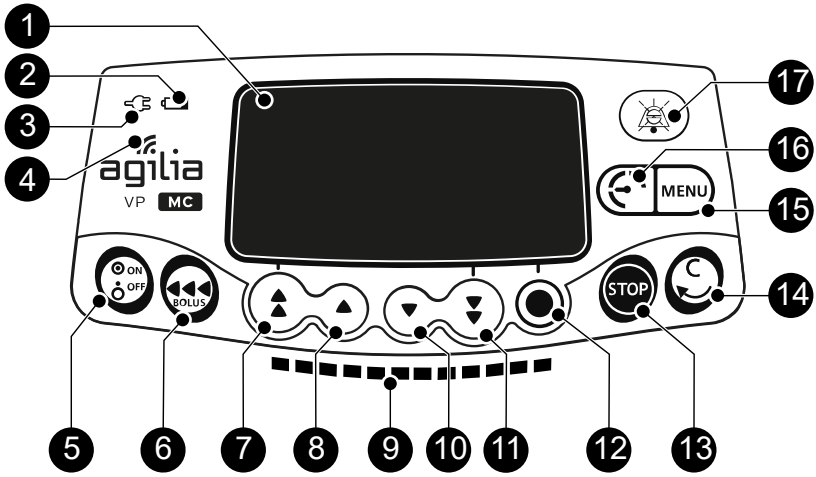
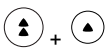
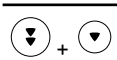


Figure 4: Keypad

Legend			
1	Screen	10	Decrement
2	Battery Charge Status Indicator	11	Fast Decrement
3	Power Supply Indicator	12	Confirm Value / Move to Next Field
4	Wi-Fi Symbol	13	Stop
5	On / Off	14	Cancel Value / Move Back to Previous Field
6	Bolus / Prime / Advance Air	15	Menu
7	Fast Increment	16	Pressure Menu
8	Increment	17	Alarm Silence
9	Infusion Indicator Lights		

3.4.2 Keypad Details

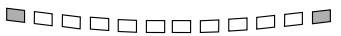
3.4.2.1 Selection Keys

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.

Indicator	Description
	**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 (All Profiles)** The drop appears in the drip chamber when an infusion is in progress.
	**Infusion in Progress (Drop sensor connected)**
	**Infusion in Progress (Custom Profiles with a drug library)** This symbol is displayed when the pump is infusing a drug customized with Drug Library Software.
STOPPED	**Infusion Stopped** STOPPED 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.

Symbol	Description
	**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.
	**Wi-Fi module status** ■  The Wi-Fi signal strength is high. ■  The Wi-Fi signal strength is medium. ■  The Wi-Fi signal strength is low. ■  No Wi-Fi signal (the Wi-Fi module is activated). ■  The Wi-Fi module is not activated.

3.5.3 Navigation Buttons

Symbol	Description
	Start
	Confirm
	Access function
	Access function and clear settings
	Exit function
	Change selection
	Program function
	Select / Deselect
	Edit settings
	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 *Alarms and Safety Features* on page 102.

3.5.5 Data Communication

Symbol	Description
	**Data Set Loaded** A new data set has been loaded to the pump.

3.6 Packaging

Depending on your country, the packaging contents of the Agilia VP MC infusion pump is different:

	Agilia VP MC pump	Instructions For Use	System Components booklet	User information document (multilingual)	Power cord
Z019XXX	✓	✓	✓	-	✓
Z019X01 *	✓	-	-	✓	-

* Product codes ending by 01 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 healthcare environment.

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

Custom profiles can be created and loaded to the pump with Drug Library Software. Custom profiles feature a specific pump configuration and a drug library.

A pump can manage up to 20 profiles:

- 1 Basic Profile.
- Up to 19 custom profiles.

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 whose settings have not been pre-defined with Drug Library Software. To program an infusion with Basic Profile, choose "Basic Profile" when selecting a profile.

Basic Profile has the following characteristics:

- All infusion settings are to be defined.
- The Drug Library Software's safeguards are unavailable:
  - The infusion is programmed without drug names.
  - Limits on drug infusion rates are not included.

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

4.1.2 Custom Profiles

Custom profiles can be configured and loaded to the pump with Drug Library Software. A custom profile contains the following:

- a specific device configuration (pump settings that control the mechanical functions of the pump such as alarm volume, air-in-line detection, and so on)
- a comprehensive list of medications and fluids to be infused (optional):
  - a drug library: a list with limits on drug infusion rates, see *Drug Libraries* on page 27,
  - a drug list: a list without limits on drug infusion rates.

Depending on the way it is pre-configured with Drug Library Software, a custom profile may or may not include all of the functionalities described in this IFU.

INFORMATION

- We recommend using a custom profile when infusing critical drugs.
- We recommend that you create and upload profiles in order to limit usage errors, and to better adapt the use of the pump to the local practices of the different care units. For example, make sure to limit flow rates for sensitive populations.
- We recommend creating a specific profile per patient population and/or care unit, therapy, protocol, and so on.

4.2 Drug Libraries

A drug library is a comprehensive list of drugs that includes limits on drug infusion rates.

INFORMATION

- Each drug library can support up to 200 drug entries that are defined and validated by healthcare professionals according to the drug protocols used at the healthcare facility and/or ward level.
- Drug settings may be adjusted on the pump according to pre-defined programming limits, such as dose limits.
- Infusion modes are not adjustable on the pump for drugs pre-configured with Drug Library Software.

4.3 Drug List

A drug list is a list of drugs that does not include limits on drug infusion rates.

4.4 Drugs

4.4.1 Infusion Rates

A drug can be pre-configured with Drug Library Software according to one of the following rates:

- Flow rate: Infusion of a volume over a period of time.
- Dose: Infusion of a specific amount of a drug corresponding to a dose rate.

4.4.2 Drug X (mL/h)

`Drug X (mL/h)` is an open entry that can be selected if the intended drug is not found in the drug library. It has the following characteristics:

- Fewer limits than the other drugs in the library.
- A full compliment of the Drug Library Software's safeguards are unavailable.

It is strongly recommended to use `Drug X (mL/h)` in a limited number of clinical cases and under close patient monitoring by the clinical staff.

For each custom profile, the healthcare facility can enable or disable `Drug X (mL/h)` using the Drug Library Software.

4.4.3 Hard Limits and Soft Limits

Programming limits can be set for each drug with Drug Library Software. Two types of limits can be set:

- Hard limits: limits that cannot be overridden when programming an infusion.
- Soft limits: limits that can be overridden within an authorized range when programming an infusion. An additional confirmation will be required.

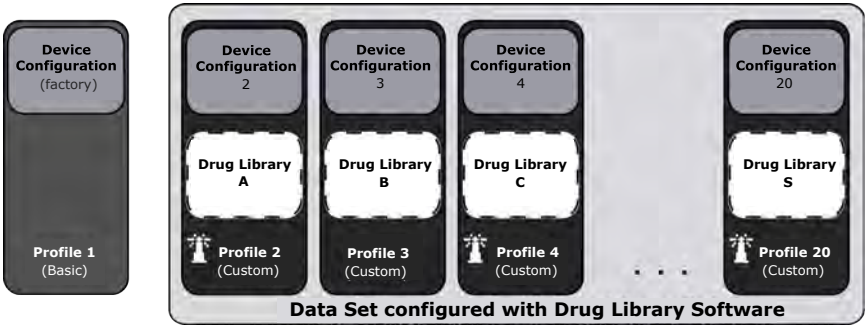
4.4.4 Infusion Modes

An infusion can be started according to the following modes:

Infusion Mode	Description	Infusion Rate	
		Flow Rate	Dose
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	✓	✓
Time / Rate (T/R)	Infusion over a programmed period of time, at a programmed rate	✓	✓
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.	✓	✓
Ramp-up / Ramp- down	Infusion defined by a total volume, a total infusion time, a ramp-up and ramp-down time and a plateau flow rate. This mode allows the flow rate to be increased gradually by intermediate stages in order to reach the plateau flow rate.	✓	x
Sequential	Infusion by sequences (up to a maximum of 20) defined by volume to be infused and the infusion flow rate for each sequence.	✓	x
Drops/min	Infusion defined by a flow rate expressed in drops per minute	✓	x

4.5 Data Set

A data set is a combination of custom profiles (up to a maximum of 19) that can be uploaded to Agilia pumps with Drug Library Software.

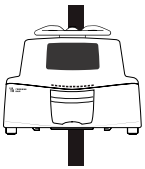
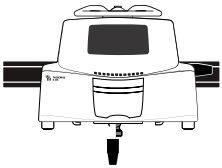
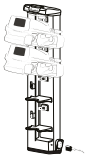
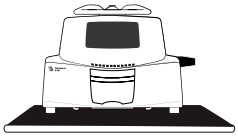
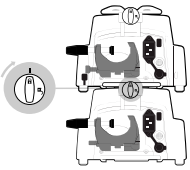
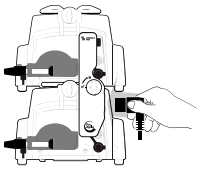


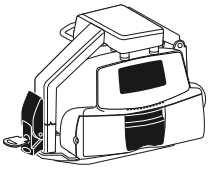
If there is no data set uploaded to the pump, the pump can be used with the Basic Profile, without the protections of the Drug Library Software.

5 Installation

5.1 Types of Installations

A pump can be installed on any of the following:

Location		Comments
On a Pole		■ See *Attaching to a Pole* on page 32. **Pole specifications:** ■ Diameter: from 15 to 40 mm
On a Rail		■ See *Attaching to a Rail* on page 33. **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 *Using on a Flat Table* on page 33. 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 *Attaching Two Pumps Together* on page 34.
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.

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.
- If Agilia devices or accessories appear damaged, stop using them and send them for maintenance instead.

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

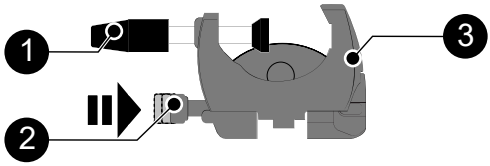


Figure 5: Rotating Pole Clamp System

Legend			
1	Screw Clamp	3	Rotating Pole Clamp
2	Release Button		

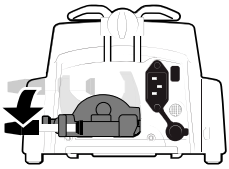
5.2.2 Using the Rotating Pole Clamp

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:

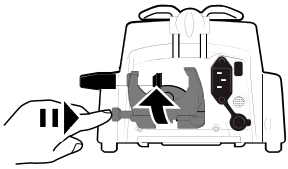
1. Push the release button.
2. Fold the clamp outward.



5.2.2.2 Folding the Clamp Up (inward toward the pump)

You can fold the clamp up as follows:

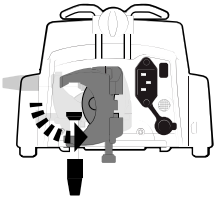
1. Push the release button.
2. Fold the pole clamp inward toward the pump.



5.2.2.3 Rotating the Clamp

You can rotate the clamp as follows:

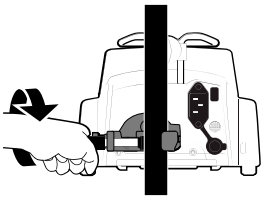
1. Fold the clamp up (see above).
2. Rotate the clamp to a vertical position.
3. If necessary, fold the clamp outward (see above).



5.3 Attaching the pump(s)

5.3.1 Attaching to a Pole

1. Fold the pole clamp down to the horizontal position: see *Folding the Clamp Down (outward)* on page 32.
2. Unscrew the clamp, attach to the pole, and screw the clamp until the pump is firmly secured to the pole.
3. Make sure that the pump is securely attached.



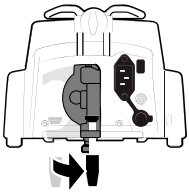
For more information on installing the pump on a pole, consult the pole's Instructions For Use.

CAUTION
When installed on a rolling stand, make sure it can accommodate the weight of the pump and accessories. Check with your biomedical department.

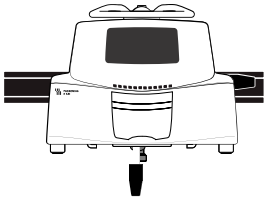
5.3.2 Attaching to a Rail

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

1. Rotate the pole clamp to the vertical position: see *Rotating the Clamp* on page 32.
2. Unscrew the clamp, attach to the rail, and screw the clamp until pump is fully secured to the rail.

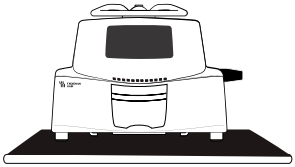


3. Make sure that the pump is securely attached.



5.3.3 Using on a Flat Table

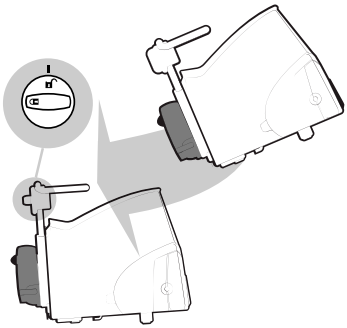
1. Fold the pole clamp up: see *Folding the Clamp Up (inward toward the pump)* on page 32.
2. Place the pump far enough from the table's edges to prevent it from accidentally being pushed off.



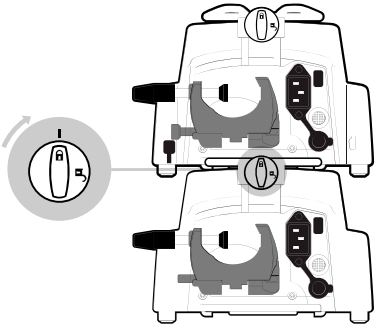
5.3.4 Attaching Two Pumps Together

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

1. Fold both pumps' pole clamps up: see *Folding the Clamp Up (inward toward the pump)* on page 32.
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.

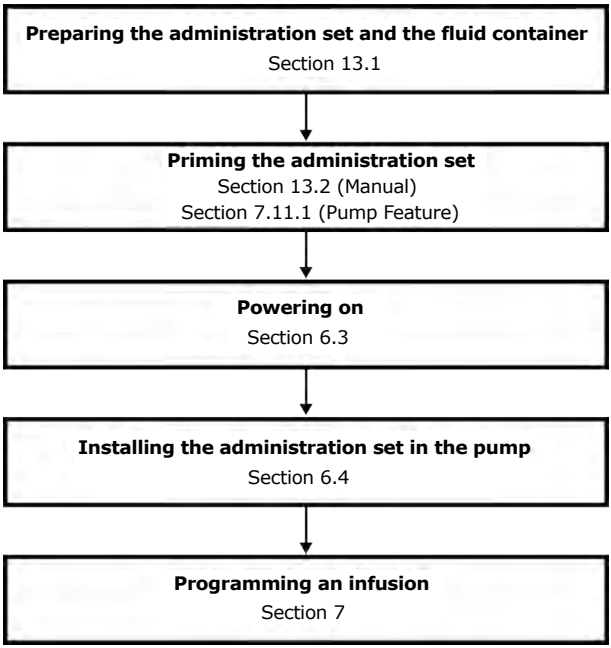


Symbol	Location	Description
🔒	Attachment Lock Knob	Locked Position
🔓	Attachment Lock Knob	Unlocked Position

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 *Installation* on page 30.
2. Plug the pump into the AC power supply. See *AC Power Supply Precautions* on page 133.
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 *Preparing the Administration Set and the Fluid Container* on page 113.
5. Power on the pump. See *Powering on* on page 36.

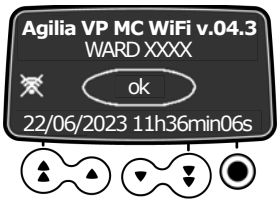
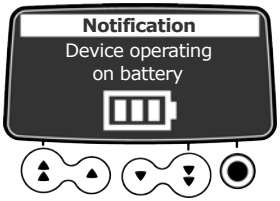
6.3 Powering on

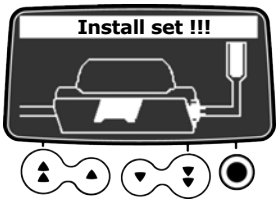
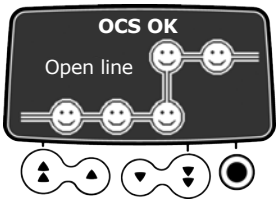
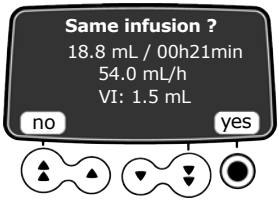
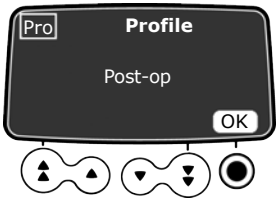
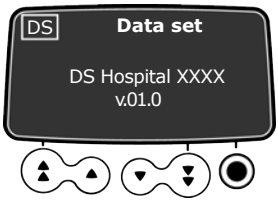
CAUTION
The pump can operate using the battery; however, we recommend that the pump be connected to a power supply as often as possible during use in order to ensure that the battery remains charged.

INFORMATION

- 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 needed, select the language and enter the date. If the selection is incorrect, contact your biomedical department to reset the pump to its initial configuration.
4. Successively acknowledge the screens listed in the table below.

Screen After Powering on	Description
	Startup screen: the following information is displayed: ■ Product name / Ward name ■ Wi-Fi module status (if applicable) ■ Date & time
	■ Displayed if the pump is operating on battery. ■ The symbol shows three different charge levels: – < 30% battery charge – 30% - 70% battery charge – > 70% battery charge

Screen After Powering on	Description
	■ No administration set is installed on the pump. ■ `Install set !!!` is displayed on top of the screen. ☞ Install an administration set. See *Installing the Administration Set in the Pump* on page 38.
	■ Maintenance reminder message (optional).
	■ 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.
	■ Same infusion screen (optional). Press ◉ to select **yes** in order to keep the previous infusion settings.
	■ Profile confirmation screen (optional). Press ◉ to select **OK** in order to confirm the profile. **NOTE:** This screen is associated with the "same infusion" function above.
	■ Data Set information (optional)

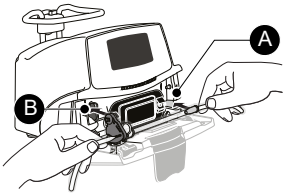
5. Check that the device is parametrized as expected.

6.4 Installing the Administration Set in the Pump

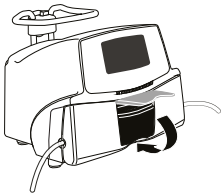
WARNING

- 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 *Powering on* on page 36.
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.

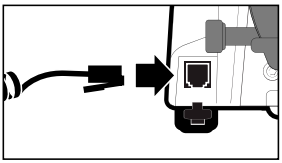
6.5 Connecting an Agilia Drop Sensor

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

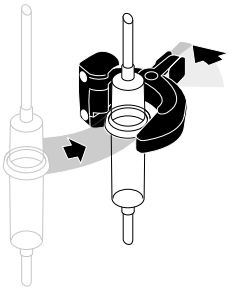
The pump automatically detects the presence of the drop sensor. The presence of the drop sensor can be set as mandatory in the pump options. For more information on drop sensor options, refer to the technical manual.

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.

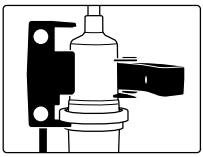


Figure 6: Standard Drip Chamber (example: VL ST00)

Figure 7: 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
Use only a drop sensor provided by Fresenius Kabi.
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.

INFORMATION
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
Avoid quick changes in the height of the Agilia pumps (example: during transport) to prevent unintended flowrate fluctuations or unintended boluses.

CAUTION
The Agilia pumps must be located at ±1 m relative to the distal tip of the catheter to ensure the highest pump performance.
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.

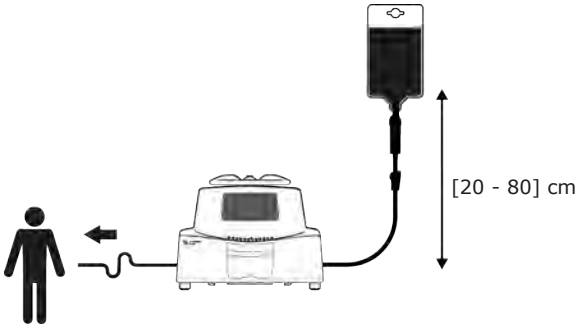


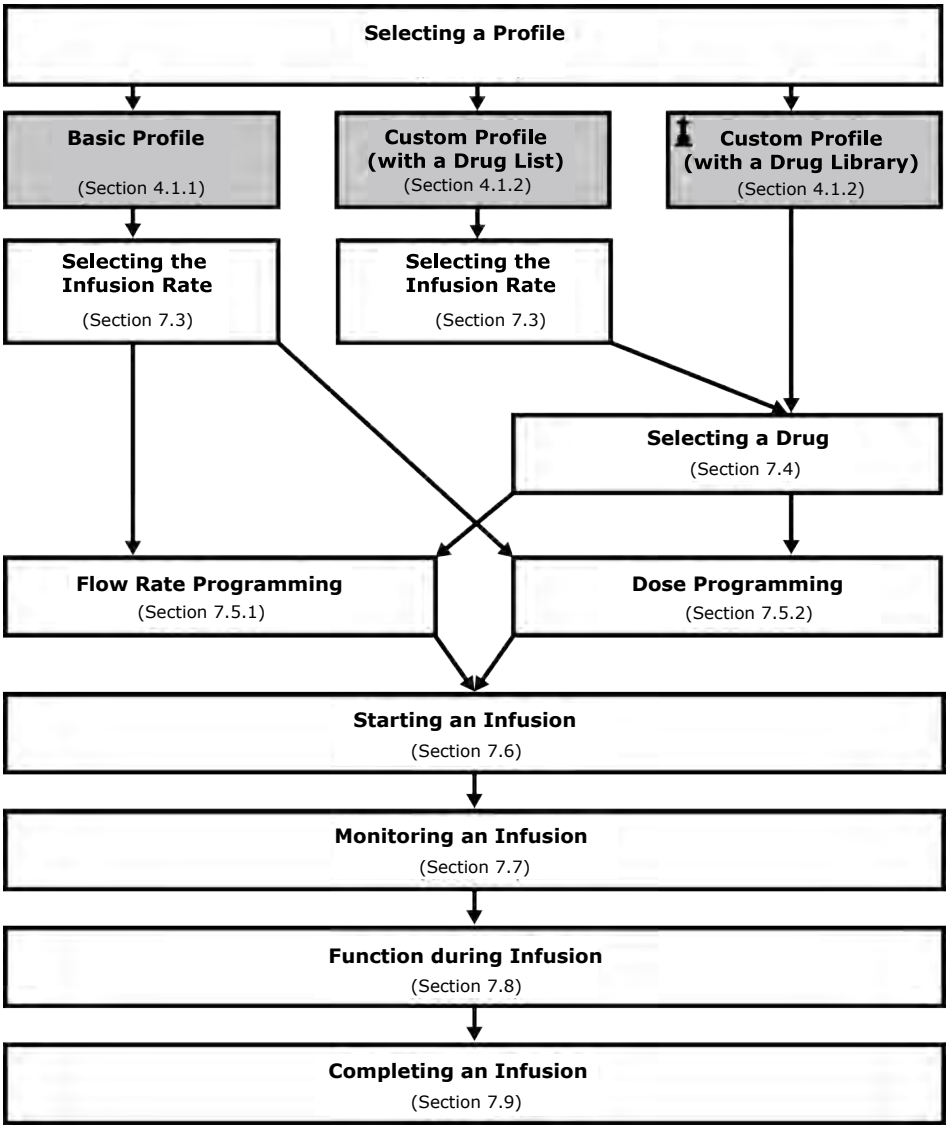
Figure 8: Global Installation

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 (example: during transport of critically ill patients) to prevent unintended fluctuations in the flow rate.
- During the infusion, if the infusion pump is moved 1 m above the patient, a bolus (up to 0.35 mL) may occur. If the infusion pump is moved 1 m below the patient, an under-infusion (up to 0.05 mL) may occur.

7 Operation

7.1 Flowchart

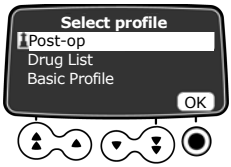


7.2 Selecting a Profile

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

You can switch to another a profile without turning off the pump. See *Profile* on page 74.

1. Press ⏻ to power on the pump, and acknowledge all screens displayed until you reach the **Select profile** screen.

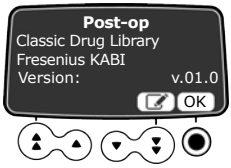


2. Press the arrow keys to select a profile that corresponds to your needs.

   The (lighthouse) symbol refers to custom profiles that contain drug libraries and have been configured with Drug Library Software.

3. Press ◉ to select **OK** in order to confirm.

   The selected profile information is displayed.



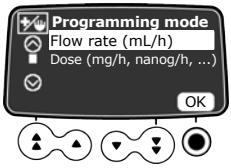
4. Press ◉ to select **OK** in order to confirm the drug library version, or press the arrow key to select ✎ to change the profile.
   - The drug library is loaded for the profile selected.
   - The OCS test is performed.

7.3 Selecting the Infusion Rate (Flow rate or Dose)

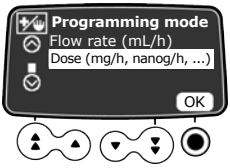
The programming mode step allows you to select the infusion rate. This step occurs just after selecting Basic Profile, or a custom profile with a drug list.

NOTE: The infusion rates for each drug of a drug library are pre-defined with Drug Library Software.

➪ Press ◉ to select **OK** in order to confirm the infusion rate or press the arrow key in order to change it.



Flow rate



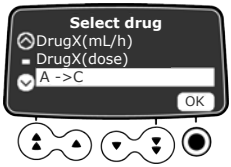
Dose

7.4 Selecting a Drug

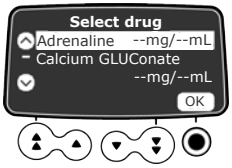
NOTE: The drug selection step is not applicable with Basic Profile.

Drugs are sorted alphabetically by the first letter of their names:

- A → C
- D → F
- G → I
- J → L
- M → O
- P → R
- S → U
- V → Z
- Drug X (mL/h)
- Drug X (Dose)



1. Press the arrow keys to scroll to the drug's first letter, and press ◉ to select **OK**.



2. Press the arrow keys to scroll to the drug's name, and press ◉ to select **OK**.
   A clinical advisory message may appear, if one is configured for the selected drug.
3. Press ◉ to select **OK** to acknowledge the clinical advisory message and continue programming or Ⓒ to change the drug.

7.5 Programming an Infusion

- This section describes the programming of an infusion with the V/T/R infusion mode.
- To change the infusion mode, see *Infusion mode / Dose* on page 85.

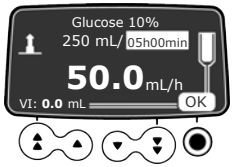
7.5.1 Programming an Infusion by Flow Rate

1. Press the arrow keys to program the Volume to be Infused (VTBI) and press **OK**.

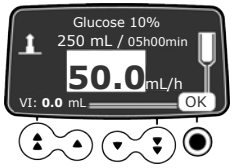
   (Press ⏫ to select the VTBI from pre-defined values: 0.1 mL, 10 mL, 20 mL, 50 mL, 100 mL, 250 mL, 500 mL, etc.)

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 __min, and press **OK**.



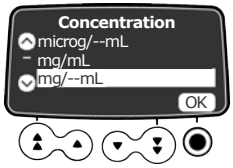
3. Press the arrow keys to program the flow rate, and press **OK**.

7.5.2 Programming an Infusion by Dose

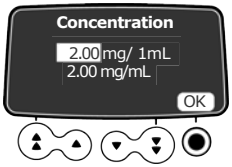
7.5.2.1 Selecting the Drug Concentration

Profile	Drug Concentration Selection Procedure
Basic Profile	*A- Basic Profile and Custom Profile (with a Drug List)* on page 45.
Custom Profile (with a drug list)	
Custom Profile (with a drug library)	*B- Custom Profiles* on page 46.

A- Basic Profile and Custom Profile (with a Drug List)



1. Press the arrow keys to select the drug concentration unit, and press ◉ to select **OK**.



2. Press the arrow keys to select a mass value, and press ◉ to select **OK**.
3. Press the arrow keys to select a volume value, and press ◉ to select **OK**.
   The concentration is automatically calculated and displayed in the unit selected above.
4. Press ◉ to select **OK** in order to confirm.

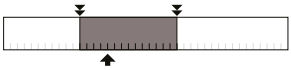
B- Custom Profiles

The selected drug is configured in Drug Library Software to allow adjustments to its concentration in one of the following ways:

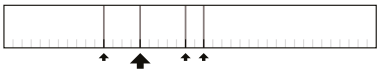
- Within an authorized range
- At authorized finite values (up to 5)

If no adjustment of the concentration is allowed, see *Selecting the Patient's Characteristics* on page 47.

Authorized Concentration Range



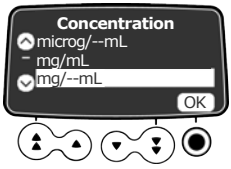
Authorized Finite Concentrations



Legend

Unauthorized Range	Hard Limits
Authorized Range	Default Value
	Finite Values

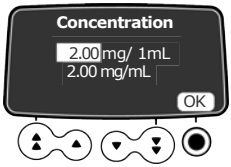
Selecting the Drug Concentration



Concentration Setting

If a Concentration unit is selected:

1. Press the arrow keys to select the Concentration.
2. Press ◉ to select **OK** in order to confirm.

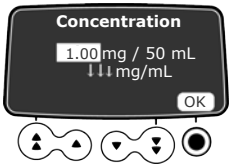


Dilution Setting

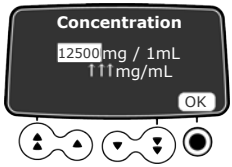
If a Dilution unit is selected:

1. Press the arrow keys to select the Dose then press ◉ to select **OK** to confirm.
2. Press the arrow keys to select the Volume then press ◉ to select **OK** to confirm.

   NOTE: The resulting concentration will be automatically calculated. If arrows are displayed instead of this concentration, it means the value is outside the authorized range defined in Drug Library Software.



Concentration below the Drug Library Software hard limit

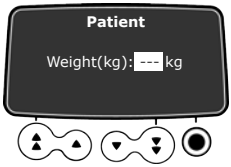


Concentration above the Drug Library Software hard limit

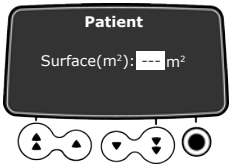
   NOTE: User will not be able to proceed to the next screen until he changes the Dose or Volume settings in order to have an authorized concentration value.

7.5.2.2 Selecting the Patient's Characteristics

NOTE: This step is only applicable with custom profiles that contain a drug library.



Weight



Body Surface Area

1. Press the arrow keys to enter the patient's weight or body surface area.
2. Press ◉ to confirm.

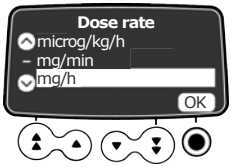
INFORMATION

- The weight entry screen only appears if the selected drug uses weight for dose rate calculations.
- The body surface area entry screen only appears if the selected drug uses body surface area for dose rate calculations.

- A pre-populated default weight or body surface area will be configured with the Drug Library Software.

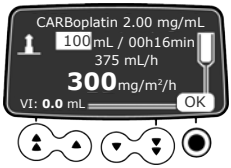
7.5.2.3 Selecting the Infusion Unit

NOTE: This step is only applicable with Basic Profile and custom profiles that contain a drug list. The infusion units for each drug of a drug library are pre- defined with Drug Library Software.



1. Press the arrow keys to select the infusion unit.
2. Press ◉ to select **OK** in order to confirm.

7.5.2.4 Programming the Infusion

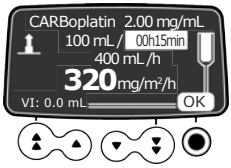


1. Press the arrow keys to program the Volume to be Infused (VTBI), and press **OK**.

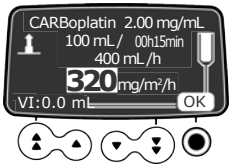
   (Press ⏫ to select the VTBI from pre-defined values: 1 mL, 10 mL, 20 mL, 50 mL, 100 mL, 250 mL, 500 mL, etc.)

INFORMATION

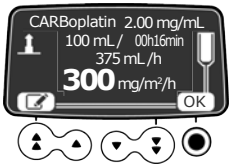
- Ensure VTBI is not greater than actual volume in the container to avoid air-in-line at the end of infusion.
- All volumes added or removed must be taken into consideration, including the volume of fluid contained in the administration set and lost during priming (priming volume varies by administration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



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



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



4. Press **OK** to confirm the infusion settings, or  to cancel.

7.5.2.5 Programming a Loading Dose

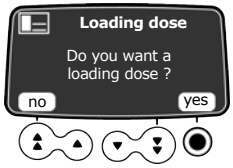
NOTE: This feature can be activated or deactivated in Drug Library Software (custom profiles).

INFORMATION
The loading dose is only available with the first start of an infusion. If no is pressed inadvertently, power the pump off and then on to access the loading dose again.

If enabled for the selected drug, you can program a loading dose after programming an infusion defined by dose.

The screens below will appear prior to starting the infusion.

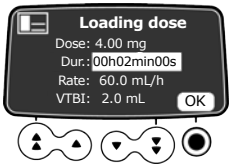
Selecting a Loading Dose



On the loading dose screen:

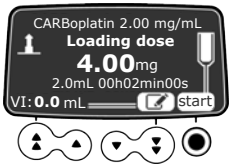
- Press the arrow key to select **no** to return to the programming screen.
- Press ◉ to select **yes** in order to program a loading dose prior to starting the primary infusion.

Programming a Loading Dose



1. Press the arrow keys to enter a value for the dose, and press ◉ to select **OK** in order to confirm.
2. Press the arrow keys to program the loading dose duration (__ h __min__s), and press ◉ to select **OK** to confirm.
   The VTBI and the flow rate are automatically calculated based on dose and duration settings.
3. Press the arrow keys to program the flow rate.
   The duration and the rate are interdependant.
4. Press ◉ to select **OK** in order to confirm the loading dose settings.

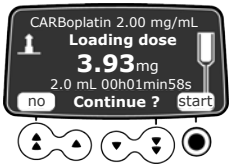
   If needed, press the arrow key to select ✎ or ↺ in order to change the loading dose settings before starting.



5. Press ◉ to select **start** to initiate the loading dose.
   Once the loading dose is finished, the pump automatically starts the programmed primary infusion.

INFORMATION
In Volume/Time (or Dose/Time mode), the volume of the loading dose is substracted from the VTBI (or DTBI)

Interrupting a Loading Dose



1. To pause the loading dose, press STOP.
   The screen displays `Continue?`

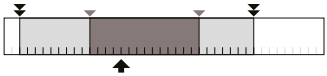
2. Choose one of the following options:

   - Press the arrow key to select **no** or STOP in order to stop the loading dose and proceed to the programmed primary infusion.
   - Press ◉ to select **start** in order to continue with the loading dose.

7.5.3 Programming Beyond Soft Limits

NOTE: This step is only available with custom profiles that contain a drug library.

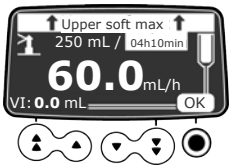
You can override soft limits, and adjust flow rate and dose within the authorized ranges. You cannot override a hard limit.



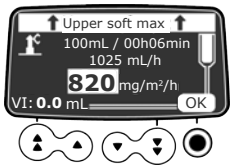
Legend			
	Unauthorized Range	⏬	Hard Limits
	Programmable Range (warning and confirmation)	▼	Soft Limits
	Authorized Range	▲	Default Value

7.5.3.1 Overriding a Soft Limit

1. If you reach a soft limit when programming an infusion, the pump displays a message at the top of the screen:
   - `Upper soft max` = the upper soft limit is exceeded
   - `Lower soft min` = the lower soft limit is exceeded

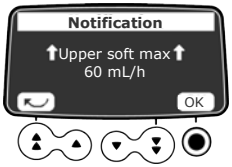


Flow rate

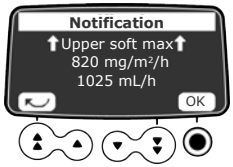


Dose

2. If the displayed settings correspond to the intended flow rate or dose, press ◉ to select **OK**.



Flow rate



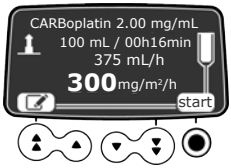
Dose

3. Carefully review the program settings.
   The original infusion settings continue until you confirm the new settings.

4. Press ◉ to select **OK** or **start** in order to confirm the soft limit override.
   During infusion, the upper or lower soft limit message will alternate with the drug name and concentration at the top of the screen.

7.6 Starting an Infusion

Flow rate



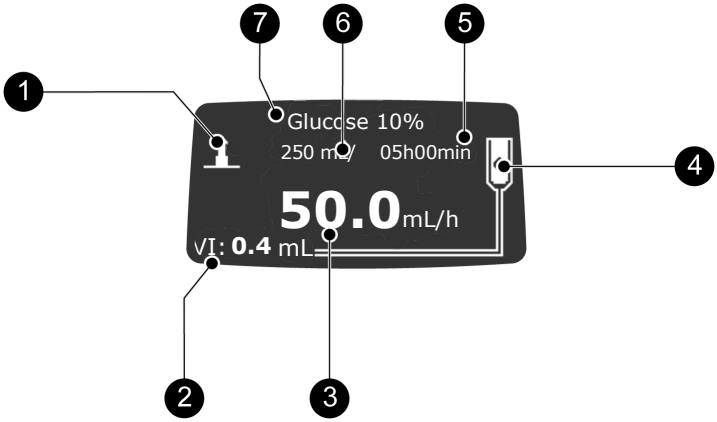
Dose

△ **CAUTION**
Prior starting an infusion, check the infusion line integrity to ensure the Agilia infusion pump correct functioning.

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

7.7 Monitoring an Infusion

7.7.1 Monitoring an Infusion when Programmed by Flow Rate



Legend

1. Custom Profile Sign

   When infusing a drug selected from the Drug Library Software library, this lighthouse sign is displayed on the screen continuously.

2. VI (Volume Infused).
   Will increase during the infusion. To clear VI, see *Volume Infused / Dose Infused* on page 81.

3. Infusion Flow Rate (mL/h)
   To change the flow rate during an infusion, see *Rate Titration* on page 55.
   The flow rate is displayed with the largest font size.

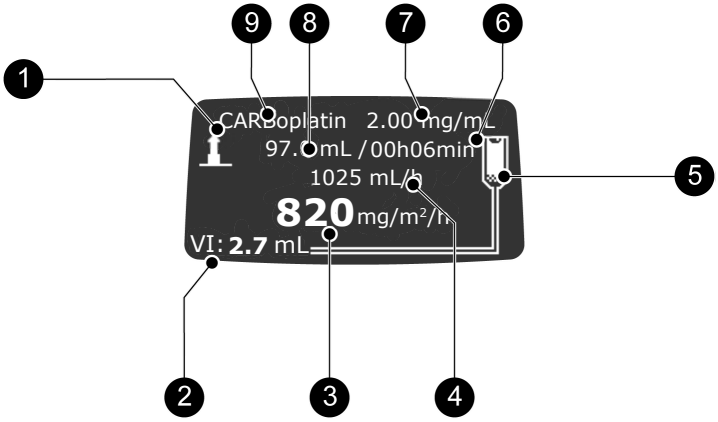
4. Infusion in Progress
   The infusion in progress indicator displays falling drops.

5. Infusion Duration
   At the current rate, the remaining infusion time in hours and minutes.
   Infusion duration may or may not be displayed depending on the configuration preset with Drug Library Software for this drug.

6. VTBI (Volume To Be Infused) remaining.
   Will decrease during the infusion.
   To change VTBI during an infusion, see *Volume To Be Infused (VTBI)* on page 77.

7. Drug Name (Custom Profiles only)

7.7.2 Monitoring an Infusion when Programmed by Dose



Legend

1. **Custom Profile Sign**

   When infusing a drug selected from the Drug Library Software library, this lighthouse sign is displayed on the screen continuously.

2. VI (Volume Infused).
   Will increase during the infusion. To clear VI, see *Volume Infused / Dose Infused* on page 81.

3. **Dose**
   To change the dose during an infusion, see *Rate Titration* on page 55.
   The flow rate is displayed with the largest font size.

4. **Infusion Flow Rate**

5. Infusion in Progress
   The infusion in progress indicator displays falling drops.

6. Infusion Duration
   At the current rate, the remaining infusion time in hours and minutes.
   Infusion duration may or may not be displayed depending on the configuration preset with Drug Library Software for this drug.

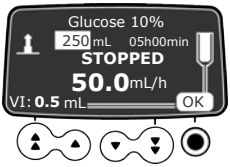
7. **Drug Concentration**

8. VTBI (Volume To Be Infused) remaining.
   Will decrease during the infusion.
   To change VTBI during an infusion, see *Volume To Be Infused (VTBI)* on page 77.

9. Drug Name (Custom Profiles only)

7.8 Functions During Infusion

7.8.1 Stop



Flow rate

Dose

To stop the infusion, press STOP.

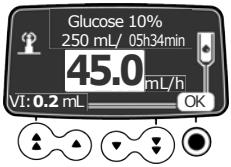
After 2 minutes, an alarm is generated as a reminder that the infusion is stopped.

To restart the infusion, first confirm or modify the programming settings, then start the infusion. See *Programming an Infusion* on page 44.

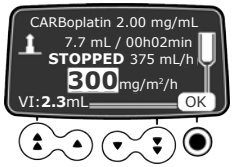
7.8.2 Rate Titration

You can adjust the infusion rate (flow rate or dose) 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 *Stop* on page 55.
2. Press the arrow keys to modify the flow rate or dose.
3. Press the ◉ key to select **OK** in order to confirm.



Flow rate



Dose

7.8.3 Secondary (Piggyback) Infusions

NOTE: This feature can be activated or deactivated in Drug Library Software (custom profiles) or in the pump options (Basic profile).

A secondary infusion delivers the contents of a secondary bag or bottle, by connecting a secondary line to the upstream access port of the primary line. When the secondary infusion is complete, the return to primary infusion can be done manually or automatically, depending on the drug's settings.

INFORMATION

- You can only add a secondary infusion when the primary infusion is programmed by flow rate.
- The secondary infusion drug must be programmed by flow rate.
- You can configure the end of secondary infusion settings in the pump options.
- An end of secondary alert may be activated or deactivated in the pump options.

7.8.3.1 Connecting the Secondary Line

1. Prime the secondary administration set.
2. Lower the primary container and hang the secondary approximately 20 cm higher than the primary container.
3. Press STOP to pause the primary infusion.
4. Using aseptic technique, connect the secondary line to the upper access port on the primary line.

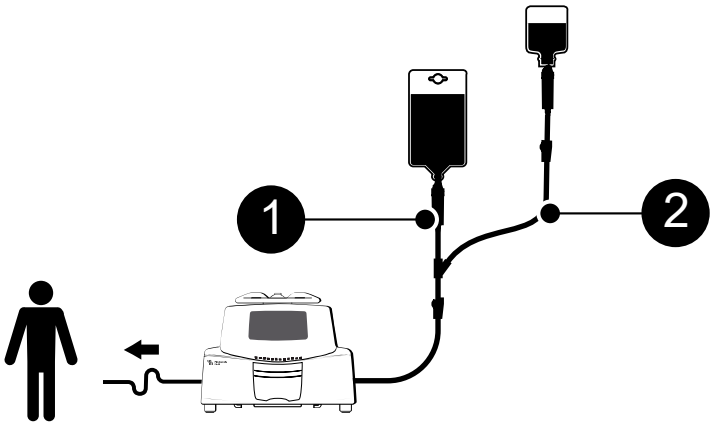


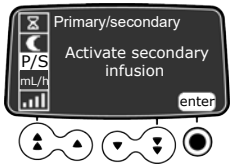
Figure 9: Primary and Secondary Infusion

Legend	
1 Primary Line	2 Secondary Line

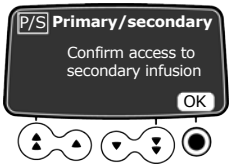
INFORMATION

- Specific administration sets are available for secondary infusions. For more information, refer to the instructions on the administration set packaging.
- It is recommended to use a primary administration set with a back check valve above the upper access port.

7.8.3.2 Accessing Secondary Infusion

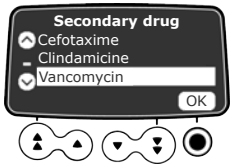


1. Open the Primary / Secondary menu:
   - Press MENU.
   - Press the arrow keys to select `P/S`.
2. Press **enter**.



3. Press **OK** to confirm access to the secondary infusion (optional).

7.8.3.3 Programming Secondary Infusion



1. Select a secondary drug (only when using a custom profile) and press **OK**.

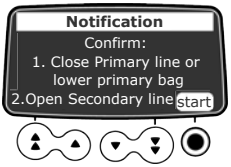
2. Press the arrow keys to program the secondary VTBI, and press **OK**.
3. Press the arrow keys to program the infusion duration, and press **OK**.
4. Press the arrow keys to program the secondary flow rate and press **OK**.
5. Press **OK** to proceed.

INFORMATION

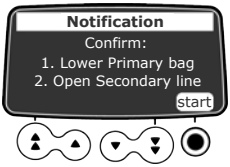
- The current volume infused displayed becomes the secondary volume infused while infusing the secondary.
- `Pri VI` indicates the total primary volume infused since it was last cleared.

- `Sec VI` indicates the volume infused since the start of the current secondary infusion.

7.8.3.4 Secondary Infusion Start



Manual Return



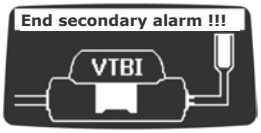
Automatic Return

1. Confirm the following:
   - The secondary line is connected to the primary upper port.
   - The roller clamp is open.
   - The secondary container is hung approximately 20 cm above the primary container.
2. Press **start** to start the secondary infusion.

7.8.3.5 End of Secondary Infusion

INFORMATION
The near end of infusion alert is not activated in secondary infusion.

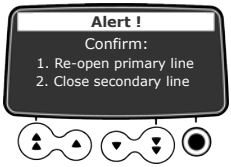
Manual Return to Primary Infusion



1. Press  to silence the alarm.

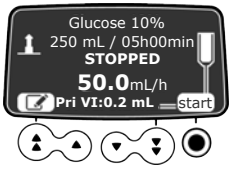
2. Answer the question `Continue sec ?`
   - Press **yes** to program another secondary infusion.
   - Press **no** to return to primary infusion.

   An alert message is displayed (optional).



3. Ensure that the primary line is open.

4. Press  to acknowledge the message.

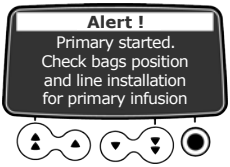


5. Press **start** to resume primary infusion.

Automatic Return to Primary Infusion

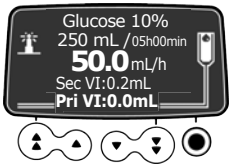
At the end of secondary infusion, a short beep is emitted.

An alert message is displayed (optional).



1. Ensure that the primary line is open.

2. Press  to acknowledge the message.



The infusion automatically returns to the programmed primary infusion.

7.8.4 Administering a Bolus

A bolus is an extra dose that a pump can deliver during an infusion. There are two ways to deliver a bolus dose during an infusion:

- Direct bolus
- Programmed bolus

	Direct Bolus	Programmed Bolus
Access Key		 or MENU

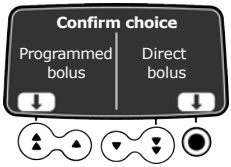
	Direct Bolus	Programmed Bolus
Occlusion Pressure Level	Set to its maximum value: 750 mmHg / 100 kPa / 14.5 PSI	

INFORMATION

- The bolus volume is added to the Volume Infused (VI).
- In Basic Profile, programmed bolus is only available for primary infusion, not secondary infusion.
- The BOLUS key is not active when the menu screen is displayed.
- The BOLUS key is not active when the following infusion modes are selected:
  - Ramp-up / ramp-down
  - Sequential

During the infusion, you can start a Programmed bolus or a Direct bolus:

1. Press the Bolus key BOLUS on the keypad.

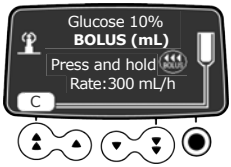


2. Select **Programmed bolus** using the arrow key or **Direct bolus** using the ◉ key.
3. Then, see *Direct Bolus* on page 60 or see *Programmed Bolus* on page 61.

7.8.4.1 Direct Bolus

NOTE: This feature can be activated or deactivated in Drug Library Software (custom profiles) or in the pump options (Basic profile).

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



3. To administer a direct bolus, press and hold the BOLUS key.
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 volume (or dose) infused is displayed for a few seconds on the screen. The infusion resumes its previous rate after the bolus is delivered.

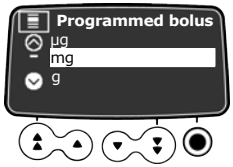
7.8.4.2 Programmed Bolus

NOTE: This feature can be activated or deactivated in Drug Library Software (custom profiles) or in the pump options (Basic profile).

During the infusion, you can program a bolus in one of the following two ways:

- Press BOLUS, then the arrow key to select **Programmed bolus**.
- Press MENU, and select ☰ in the menu. Press **enter** to confirm.

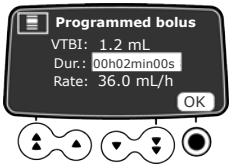
Programming a Bolus



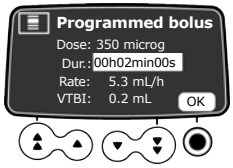
1. Press the arrow keys to select the programmed bolus unit, and press ◉ to select **OK**.

   NOTE: This step is only applicable with Basic & TCI profile and custom profiles that contain a drug list. The infusion units for each drug of a drug library are pre-defined with Drug Library Software.

2. Press the arrow keys to program the bolus volume or dose, and press ◉ to select **OK** in order to confirm.
3. Press the arrow keys to program the bolus duration (__ h __ min __ s), and press ◉ to select **OK** in order to confirm.
   The flow rate is calculated automatically.
4. Press the arrow keys to program the flow rate.
   The duration and the rate are interdependant.

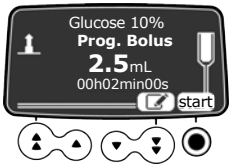


Flow rate



Dose

5. Press ◉ to select **OK** in order to confirm the programmed bolus settings.



Flow rate

Dose

6. At this stage, you can:

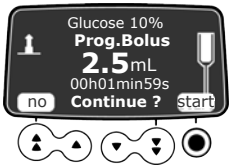
- Press the ◉ key to select **start** in order to administer the bolus immediately.
- Press the C key in order to save the settings without administering the bolus.
- Press the arrow key to select ✎ in order to change the bolus settings.

7. Monitor the progression of the bolus infusion on the screen.
The infusion resumes its previous rate after the bolus has been delivered.

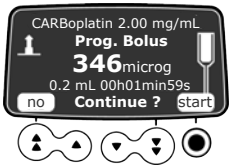
If you press ◀◀◀ BOLUS again then select **Programmed bolus**, a screen is displayed with the settings of the last bolus.

Interrupting a Programmed Bolus

1. Press STOP to interrupt the bolus.



Flow rate



Dose

2. Answer the question: `Continue?`

- Press the arrow key to select **no** or press STOP in order to stop the bolus and resume the infusion.
- Press ◉ to select **start** to continue the bolus.

7.9 Completing an Infusion

7.9.1 Near End of Infusion Alert

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

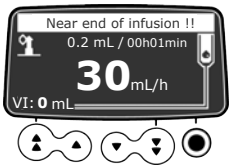
- An audible alarm is triggered.
- An alarm message appears on the pump screen.
- The infusion indicator lights flash yellow.

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

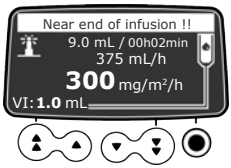
Setting	Range of Values	Default Pump Setting
Time Before the End of the Infusion	From 0 to 30 minutes	5 minutes
% of VTBI Remaining	From 0 to 15%	5%
Remaining VTBI	From 0 to 50 mL	5 mL

Near end of infusion alert settings are configurable with Drug Library Software (custom profiles), or in the pump options (Basic Profile). For more information, refer to the technical manual.

Silencing Near End of Infusion Alert



Flow rate



Dose

⇨ Press  to silence the alarm.
The infusion will continue until the VTBI reaches zero.

7.9.2 End of Infusion

WARNING
The KVO (Keep Vein Open) function shall not be used with critical or life-sustaining drugs, as it may lead to critical harm for the patient.

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

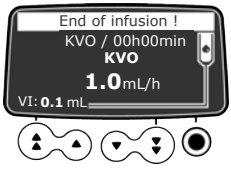
- An audible alarm is triggered.
- An alarm message appears on the pump screen.
- The infusion indicator lights flash yellow.
- KVO (Keep Vein Open) rate is maintained.

End of infusion settings (KVO rate, Silence duration) are configurable with Drug Library Software (custom profiles), or in the pump options (Basic Profile). 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.

7.10 Infusion Modes

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

To select an infusion mode, see *Infusion mode / Dose* on page 85.

For more information on calculation rules, see *Calculation Rules* on page 126.

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

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

For more information, see *Programming an Infusion* on page 44.

7.10.2 Volume / Rate (V/R)

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

7.10.3 Volume / Time (V/T)

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

7.10.4 Time / Rate (T/R)

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

7.10.5 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 the arrow key to select **OK**.

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

7.10.6 Ramp-up / Ramp-down

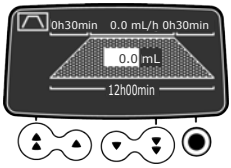
In ramp mode, you can divide an infusion into three different phases:

- Ramp-up: the flow rate increases by 10 intermediate steps up to a programmed value
- Plateau: the flow rate remains constant
- Ramp-down: the flow rate gradually falls to zero by 10 intermediate steps

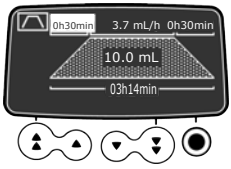
7.10.6.1 Programming the Ramp-up / Ramp-down Infusion

You can program an infusion with the ramp-up / ramp-down infusion mode as follows:

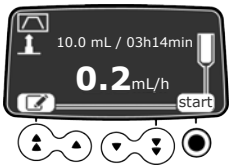
1. In the Infusion mode menu, select the ramp-up / ramp-down infusion mode, see *Infusion mode / Dose* on page 85.
2. Press **OK** to confirm the new infusion mode.
3. Press **OK** to confirm the drug.



4. Press the arrow keys to program the VTBI, and press **OK**.
5. Press the arrow keys to program the total infusion duration (__ h __min), and press **OK**.
6. Press the arrow keys to program the ramp-up duration (__ h __min), and press **OK**.
7. Press the arrow keys to program the ramp-down duration (__ h __min), and press **OK**.
8. Press the arrow keys to program the plateau flow rate, and press **OK**.



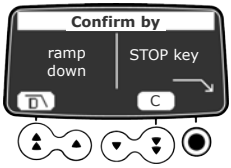
9. Press **OK** to confirm, or C to cancel the settings.



10. Press **start** to start the infusion.

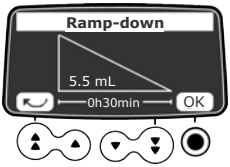
INFORMATION
During the infusion, a part of the ramp symbol blinks. This part corresponds to the current infusion phase (: Ramp-up, / \: Plateau, : Ramp-down).

7.10.6.2 Stopping the Ramp-up / Ramp-down infusion



1. During the infusion plateau, press STOP and choose one of the following actions:

- Press D\ to start the ramp-down.
- Press **C** to cancel the previous action (pressing STOP), and return to the infusion screen.
- Press STOP to stop the infusion.



2. If ramp-down is selected, check the ramp-down values and press **OK**.

7.10.7 Sequential Infusion

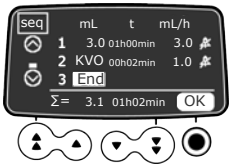
You can program up to 20 infusion sequences with the sequential infusion mode, each with their own VTBI and flow rate.

You can also program the following sequences:

- **Stop**: programming of a pause between two sequences
- **KVO**: programming of a KVO sequence
- **Repeat**: Up to 20 repetitions of the already programmed sequences (limited by the total VTBI)
- **End**: end of the programming sequences

To program a sequential infusion, proceed as follows:

1. In the Infusion mode menu, select the sequential infusion mode, *Infusion mode / Dose* on page 85.
2. Press **OK** to confirm the new infusion mode.
3. Press **OK** to confirm the drug.



4. Press **OK** to program sequence 1, or the down arrow key to move to sequence 2.
5. Follow the instructions in the table below to program the desired sequence.

   NOTE: When the sequence number is selected, press the down arrow key to move to the next sequence.

Sequence	Programming
VTBI	■ Press the arrow keys to program the VTBI, and press **OK**. The infusion duration is automatically calculated. ■ Press the arrow keys to program the flow rate, and press **OK**. The infusion duration is automatically readjusted. ■ Press the arrow keys to activate or mute the end of sequence beep, and press **OK**.
Stop	■ Press the arrow keys to select **Stop**, and press **OK**. ■ Press the arrow keys to select the pause duration, and press **OK**. ■ Press the arrow keys to activate or mute the end of sequence beep, and press **OK**. ☞ Other sequences can be programmed after a "Stop" sequence.
KVO	■ Press the arrow keys to select **KVO**, and press **OK**. ■ Press the arrow keys to select the KVO duration, and press **OK**. ■ Press the arrow keys to activate or mute the end of sequence beep, and press **OK**. ☞ Other sequences can be programmed after a "KVO" sequence.
Repeat	■ Press the arrow keys to select **Repeat**, and press **OK**. ■ Press the arrow keys to select the number of repetitions, and press **OK**. ☞ No other sequence can be programmed after a "Repeat" sequence.
End	■ Press the arrow keys to select **End**. ■ Press **OK**. ☞ No other sequence can be programmed after a "End" sequence.

6. Press **start** to start the infusion.

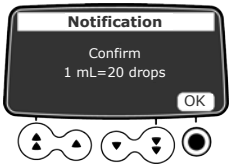
INFORMATION

- When editing a stopped infusion with repetition (on infusion screen by pressing Cancel/C), you can change a step with a repetition. There is no change on all other repetitions and steps.
- To modify a sequential infusion, in the sequential menu, see *Sequential Infusion* on page 86. In this case, you can only modify a sequence that has not started yet.

7.10.8 Drops/min

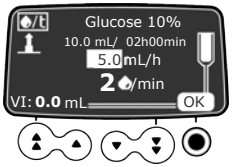
You can program an infusion with the drops/min infusion mode as follows:

1. Select the drops/min infusion mode, see *Infusion mode / Dose* on page 85.
2. Press **OK** to confirm the new infusion mode.
3. Press **OK** to confirm the drug.



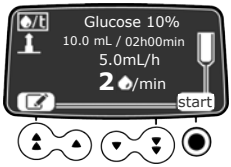
4. Check the equivalent quantity of drops per mL and press **OK**.

   NOTE: The conversion in drops/min can differ according to the choice of the drug.



5. Press the arrow keys to program the VTBI and press **OK**.
6. Press the arrow keys to program the flow rate or the number of drops per minute and press **OK**.

   The setting to program depends on the pump configuration.



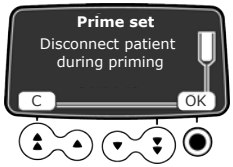
7. Press **start** to start the infusion.

7.11 Other Functions

7.11.1 Priming the Administration Set

DANGER
When priming, the patient must not be connected to the pump. Otherwise, air may be infused to the patient causing severe harm.

NOTE: This feature can be activated or deactivated in Drug Library Software (custom profiles) or in the pump options (Basic profile).

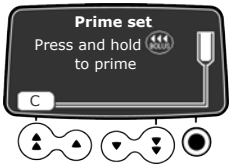


1. Press ON/OFF to power on the pump.

2. Press BOLUS.

3. Make sure the administration set is not connected to the patient, as indicated on screen.

4. Press the key to select **OK** in order to proceed.



5. Press and hold the BOLUS key to prime, or press the arrow key to select **C** in order 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.

7.11.2 Advancing an Air Bubble

NOTE: This feature can be activated or deactivated in Drug Library Software (custom profiles) or in the pump options (Basic profile).

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

4. Press and hold BOLUS 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.

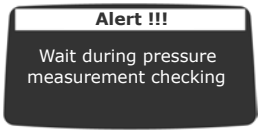
- Ask for medical advice on whether or not the infusion can be restarted due to air in the set. If you decide to remove the air bubble, follow facility procedures for priming or changing the administration set.
- The air bubble advances at the programmed rate.
- The maximum volume advanced equals the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

7.11.3 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.

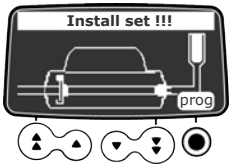


CAUTION
When infusing with critical drugs or on vulnerable patients (such as young pediatric patients), pay special attention to configuring Auto-restart to meet clinical requirements.

CAUTION
When the alert `Wait during pressure measurement checking` is displayed, wait while the downstream line pressure normalizes: the pump automatically restarts pumping or triggers an occlusion alarm.

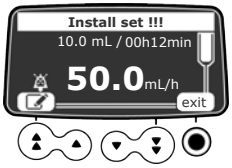
INFORMATION
- When this feature is deactivated, an alarm is immediately generated when a downstream occlusion is detected.
- For more information on how to activate or deactivate this feature, see *Pressure* on page 75.

7.11.4 Pre-programming the Pump



You can program the pump before installing the administration set.

1. Press ON/OFF 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 the ◉ key to select **prog**.
4. Program the infusion.
   See *Programming an Infusion* on page 44.



5. Press the ◉ key to select **exit** in order to confirm or press the arrow key to select ✎ in order to reprogram.
6. When ready, install the administration set.
7. Press the ◉ key to select **start** in order to start the infusion, or press the arrow key to select ✎ in order to change the settings.

7.11.5 Powering off

1. If an infusion is running, press STOP to stop the infusion.
2. Close the roller clamp.
3. Press and hold ON/OFF until the pump powers off.

8 Menus

8.1 Overview

8.1.1 Commands

Operation	Key
Access menu or exit menu	MENU
Select	(correspond to arrow keys)
Confirm	(corresponds to **enter** on the screen)
Select ☑ / Deselect ☐	

8.1.2 Menu Description

Menu	Symbol	Stop Infusion Required	Associated Procedure
Profile	Pro	No	■ *Profile* on page 74.
Pressure		No	■ *Pressure* on page 75.
Volume to be infused	VTBI	No	■ *Volume To Be Infused (VTBI)* on page 77.
Keypad lock status		No	■ *Keypad Lock Status* on page 77.
Keypad automatic lock	AUTO	No	■ *Keypad Automatic Lock* on page 79.
Battery life		No	■ *Battery Life* on page 80.
Volume Infused	mL?	No	■ *Volume Infused / Dose Infused* on page 81.
Dose Infused			
Pause		Yes	■ *Pause* on page 81.
Drug		Yes	■ *Drug* on page 82
Patient		No	■ *Patient* on page 83.
Day/Night mode		No	■ *Day/Night Mode* on page 84.
Primary / Secondary	P/S	Yes	■ *Primary / Secondary* on page 85.
Programmed bolus		No	■ *Programmed Bolus* on page 85.

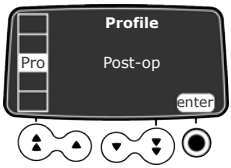
Menu	Symbol	Stop Infusion Required	Associated Procedure
Infusion mode	mL/h	Yes	■ *Infusion mode / Dose* on page 85.
Dose	Dose	Yes	
Ramp-up / Ramp-down		Yes	■ *Ramp-up / Ramp-down* on page 86.
Sequential	seq	Yes	■ *Sequential Infusion* on page 86.
Alarm volume		No	■ *Alarm Volume* on page 87.
Call-back		No	■ *Call-back Alert* on page 87.
View flow rate history		No	■ *View Flow Rate History* on page 88.
View pressure history		No	■ *View Pressure History* on page 89.
View event log		No	■ *View Event Log* on page 90.
Date / Time		No	■ *Date / Time* on page 91.
Maintenance		No	■ *Maintenance* on page 91.
Library information		No	■ *Library Information* on page 92.
Clinical information		No	■ *Clinical Information* on page 93.
Data Set	DS	No	■ *Data Set* on page 93.

NOTE: The displayed menu may change depending on the pump configuration.

For more information on factory configuration, refer to *Appendix: Factory Configuration* on page 166.

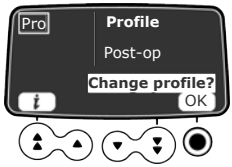
8.2 Profile

Symbol	Pro
Procedure	Displaying active profile information. Switching to another profile.

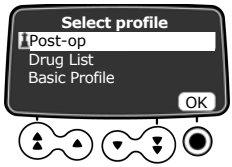


You can display the active profile name as follows:

1. Press MENU.
2. Press the arrow keys to select `Pro`.
3. Press ◉ to select **enter**.
4. Perform one of the following operations:
   - press the arrow keys to select ⓘ in order to view information about the selected profile.
   - or press ◉ to select **OK** in order to change the profile.



5. If you want to change the profile:
   a. Press the arrow keys to select a profile that corresponds to your needs.



   b. Press ◉ to select **OK** in order to confirm.

8.3 Pressure

Symbol	
Procedure	Modifying the pressure limit

Agilia pumps control the pressure inside the infusion line. If the infusion line is partially or totally blocked (called an "occlusion") for any reason, the pressure level inside the line increases. This triggers the occlusion alarms. The pressure limit that triggers these alarms can be configured as shown below.

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

- `3 levels` (low P, medium P, high P).

  The pressure limit is adjustable according to 3 pre-set values.

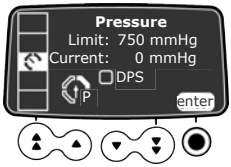
- `Variable` P

  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.

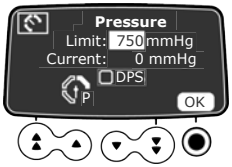
To consult the pressure settings, see *Pressure Management* on page 123.

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 healthcare 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.
2. Press the arrow keys to select .
3. Press ◉ to select **enter** to access the pressure limit screen.



4. Press the arrow keys to increase or decrease the pressure limit.
5. Press ◉ to select **OK** to validate.
6. Press ☑/☐ to enable or disable the Auto-restart function (optional).
7. Press ◉ to select **OK** in order to confirm.
8. Press the arrow keys to select ☑/☐ to enable or disable the DPS function (optional).
9. Press ◉ to select **OK** in order 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): To minimize the occlusion detection time and the time to trigger the

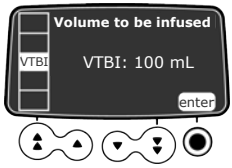
related alarms, especially at flow rates below 1 mL/h, consider adjusting the pressure thresholds according to the route of administration and to the infused medication. The lower the occlusion pressure threshold is, the shorter the occlusion detection time will be.

INFORMATION

- For more information on the Auto-restart function, see *Auto-restart* on page 71.
- 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.
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** in order to confirm.

8.5 Keypad Lock Status

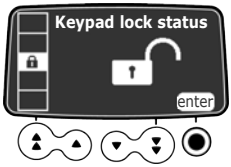
Symbol	🔒
Procedure	Locking / Unlocking the keypad

You can use this feature to avoid inadvertent key presses.

NOTE: The following feature can be activated or deactivated in the pump options:

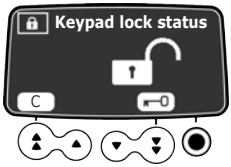
■ Unlock code: The user must enter a code to unlock the keypad.

Locking the Keypad



You can lock the keypad as follows:

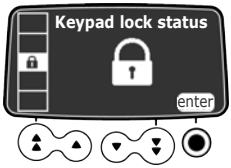
1. Press MENU.
2. Press the arrow keys to select .
3. Press ◉ to select **enter**.



4. Press to lock the keypad.

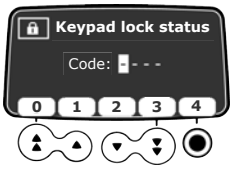
   The keypad is locked and the screen displays .
5. Press ◉ to select **OK** in order to confirm.

Unlocking the Keypad

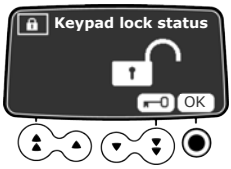


You can unlock the keypad as follows:

1. Press MENU.
2. Press ◉ to select **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 to select **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 Keypad Automatic Lock

Symbol	AUTO
Procedure	Activating / Deactivating the keypad automatic lock

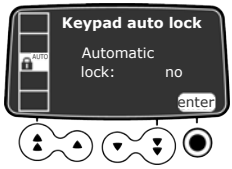
You can use this feature to avoid inadvertent key presses. Depending on the device configuration, the keypad automatic lock feature may or may not be available.

If keypad automatic lock is selected, the keypad will lock automatically at infusion start or after a time-out.

Activating the Keypad Automatic Lock

You can activate the keypad automatic lock as follows:

1. Before starting the infusion, press MENU.
2. Press the arrow keys to select AUTO



3. Press to select **enter**.

4. Press the arrow keys to set the Automatic lock to `yes`
   The keypad will lock automatically at infusion start. If the keypad is unlocked during the infusion, it will lock again automatically after a configured time-out.

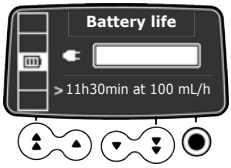
Deactivating the Keypad Automatic Lock

To deactivate the keypad automatic lock:

1. Unlock the keypad: see *Unlocking the Keypad* on page 78.
2. Press MENU.
3. Press the arrow keys to select AUTO
4. Press ◉ to select **enter**.
5. Press the arrow keys to set the Automatic lock to `no`.

8.7 Battery Life

Symbol	
Procedure	Viewing the battery life



You can view the battery life as follows:

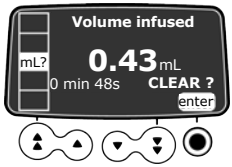
1. Press MENU.
2. Press the arrow keys to select .
   The time remaining under current flow rate conditions is displayed.

The bar graph shows a visual representation of battery life. The symbol displayed shows the following:

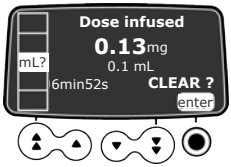
- : The pump is plugged into the AC power supply.
- : The pump is operating on battery.

8.8 Volume Infused / Dose Infused

Symbol	mL?
Procedure	Viewing and clearing the volume or dose infused



Volume infused



Dose infused

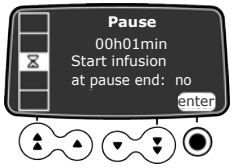
You can view and clear the volume or dose infused as follows:

1. Press MENU.
2. Press the arrow keys to select mL?.
   The total volume, or total dose, infused includes primary and secondary infusions, loading doses and boluses. The length of time over which they were infused is also displayed.
3. To clear the volume or dose infused, press ◉ to select **enter**.
4. Press ◉ to select **OK** in order to confirm.

INFORMATION
When the pump is powered off or a new drug is selected, the volume or dose infused is cleared.

8.9 Pause

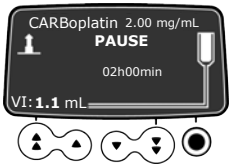
Symbol	⧖
Procedure	Programming a pause



You can program a pause as follows:

1. Press STOP to stop the infusion.
2. Press MENU.
3. Press the arrow keys to select ⧖ .

4. Press ◉ to select **enter**.
5. Press the arrow keys to program the pause duration in hours and minutes, and press ◉ to select **OK**.
6. Press the arrow keys to select `yes` or `no` to activate the **Start infusion at pause end** feature.
7. Press ◉ to select **OK** to begin the programmed pause.
   The display shows the pause in progress.

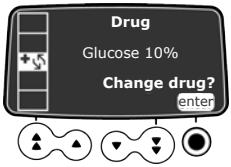


8. To restart the infusion before the end of the pause period, press twice ◉.

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.

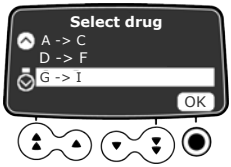
8.10 Drug

Symbol	✚↺
Procedure	Changing the drug selection



You can change the drug selection as follows:

1. Press STOP to stop the infusion.
2. Press MENU.
3. Press the arrow keys to select ✚↺.
4. Press **enter**.
5. Press **OK** in order to confirm.



6. Press the arrow keys to select the new drug.
7. Press **OK** to confirm selection.
8. Press **OK** to validate new drug's settings.
9. Press **OK** to acknowledge the drug modification and continue programming infusion, or **C** to select another drug.
10. Program the infusion for the new drug.

INFORMATION

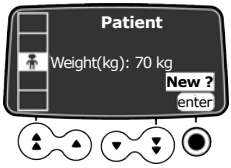
- Changing a drug resets the infusion settings.
- If the previous infusion was programmed by flow rate, the new drug's confirmation screen will display VI (Volume Infused).
- If the previous infusion was programmed by dose, the new drug's confirmation screen will display DI (Dose Infused).

8.11 Patient

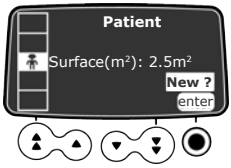
Symbol	
Procedure	Changing a patient's weight or body surface area

INFORMATION

- If the selected dose rate unit is weight-based (kg), the screen displays the patient's weight.
- If the selected dose rate unit is body surface area-based (m²), the screen displays the patient's body surface area.



Weight



Body Surface Area

You can change the patient's weight or body surface area as follows:

1. Press MENU.

2. Press the arrow keys to select .
3. Press ◉ to select **enter** or **New?**.
4. Press ◉ to select **OK** to change the patient's weight or body surface area.
5. Press ◉ to select **OK** to confirm the infusion settings.

8.12 Day/Night Mode

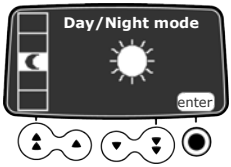
Symbol	
Procedure	Switching between day mode and night mode

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.

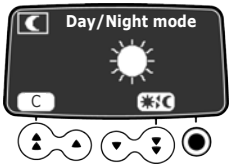
Depending on your pump configuration, the switch between day and night mode may be managed either through this menu (manual mode), or according to pre- defined settings (auto mode). For more information, refer to the technical manual.

Switching from Day Mode to Night Mode or from Night Mode to Day Mode



You can switch to night mode or day mode as follows:

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

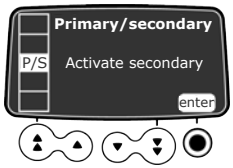


4. Press to activate night mode (the screen displays) or day mode (the screen displays).

5. Press ◉ to select **OK** in order to confirm.

8.13 Primary / Secondary

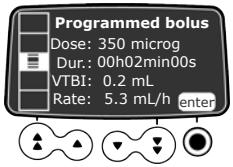
Symbol	P/S
Procedure	Programming a secondary infusion



To program a secsondary infusion, see *Secondary (Piggyback) Infusions* on page 55.

8.14 Programmed Bolus

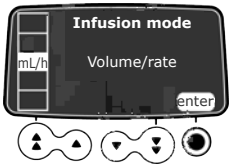
Symbol	☰
Procedure	Programming a bolus



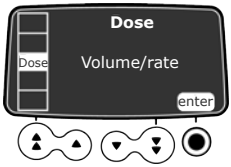
To program a bolus, see *Programmed Bolus* on page 61.

8.15 Infusion mode / Dose

Symbol	mL/h Dose
Procedure	Changing the infusion mode



Flow rate

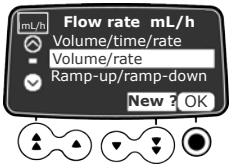


Dose

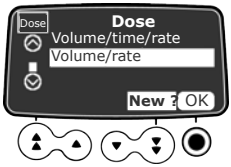
You can change the infusion mode as follows:

1. Press MENU.

2. Press the arrow keys to select `mL/h` or `Dose`.
3. Press **enter**. The available infusion modes are displayed.



Flow rate

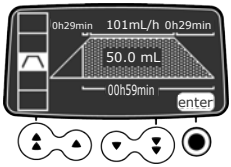


Dose

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.

8.16 Ramp-up / Ramp-down

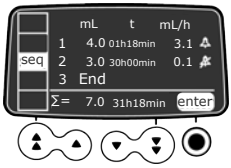
Symbol	
Procedure	Modifying a ramp-up /ramp-down infusion
Prerequisite	Ramp-up/ramp-down infusion mode must be selected, see *Infusion mode / Dose* on page 85.



To program an infusion in the ramp-up /ramp-down infusion mode, see *Ramp-up / Ramp-down* on page 65.

8.17 Sequential Infusion

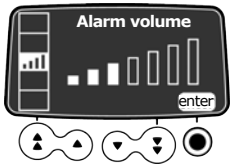
Symbol	`seq`
Procedure	Modifying a sequential infusion
Prerequisite	Sequential infusion mode must be selected, see *Infusion mode / Dose* on page 85.



To program an infusion in the sequential infusion mode, see *Sequential Infusion* on page 66.

8.18 Alarm Volume

Symbol	
Procedure	Adjusting the alarm volume



You can adjust the alarm volume as follows:

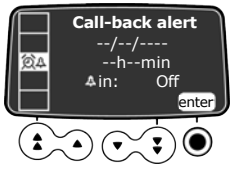
1. Press MENU.
2. Press the arrow keys to select .
3. Press ◉ to select **enter**.
4. Press the arrow keys to select the alarm volume.
   The pump emits an alarm at the selected volume level.
5. Press ◉ to select **OK** in order to confirm.

8.19 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.

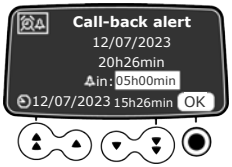
Activating the Call-back Alert



You can activate the call-back alert as follows:

1. Press MENU.
2. Press the arrow keys to select .

3. Press **enter**.

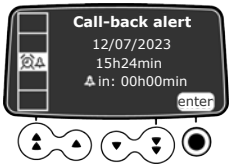


4. Press the arrow keys to set the interval in hours and minutes (__ h __min) before the alert.
5. Press **OK**.

INFORMATION

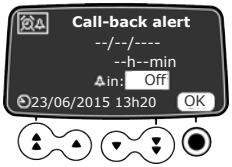
- The activation time is calculated according to the device time, which is indicated at the bottom of the screen.
- If the device is powered off during the call-back period, a warning message is displayed when the device is powered on.

Deactivating the Call-back Alert



You can deactivate the call-back alert as follows:

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

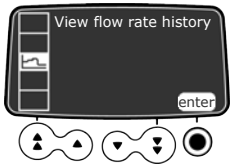


4. To deactivate the programmed call-back alert, press the down arrow keys to set the duration period to "Off".
5. Press **OK**.

8.20 View Flow Rate History

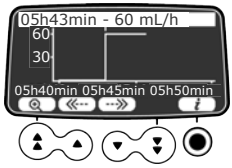
Symbol	
Procedure	Viewing flow rate history

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.
2. Press the arrow keys to select .
3. Press ◉ to select **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 arrow keys to select «-- and --» in order to browse the events.
5. Press ◉ to select i in order to view information about the selected event.

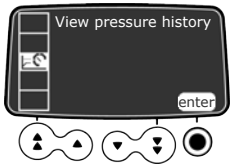
INFORMATION

- 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.

8.21 View Pressure History

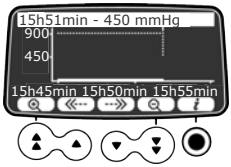
Symbol	
Procedure	Viewing pressure history

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.
2. Press the arrow keys to select .
3. Press ◉ to select **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 arrow keys to select «-- and --» in order to browse the events.
5. Press ◉ to select i in order to view information about the selected event.

INFORMATION

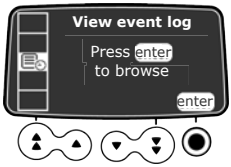
- The history is not refreshed while the history screen is displayed. To refresh the history data, exit and select the history again.
- Pressure history is not stored after powering off.

8.22 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.

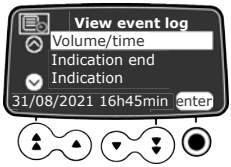
NOTE: When the AC Power is disconnected for a period of time, or when the batteries are not operating, the log file is kept in a non-volatile memory for approximately 10 years.



You can view the event log as follows:

1. Press MENU.
2. Press the arrow keys to select .

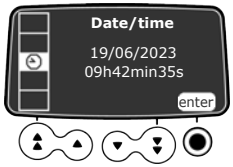
3. Press ◉ to select **enter** in order to browse the events.



4. Press the arrow keys to select the desired event.
5. Press ◉ to select **enter** in order to display the details of the event.
6. Press ◉ to select **exit** to return to the previous screen.

8.23 Date / Time

Symbol	
Procedure	Setting the date and time



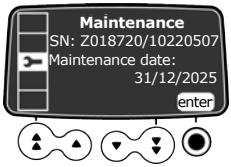
When the Agilia pump connects wirelessly to the Vigilant Software Suite server, the pump's date and time are set automatically to the date and time of the server.

You can set the pump date and time as follows:

1. Press MENU.
2. Scroll to by using the arrow keys. Then, press ◉ to select **enter** to display the Date/time settings.
3. Use the arrow keys to set the Day, Month, Year, Hours and Minutes.
4. Press ◉ to select **OK** to save your changes.

8.24 Maintenance

Symbol	
Procedure	Displaying maintenance information

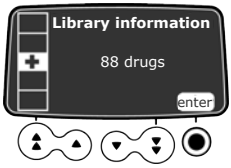


You can display maintenance information as follows:

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

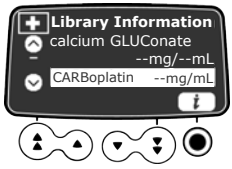
8.25 Library Information

Symbol	✚
Procedure	Displaying drug library information



You can display drug library information as follows:

1. Press MENU.
2. Press the arrow keys to select ✚.
   The number of drugs contained in the drug library is displayed.
3. Press ◉ to select **enter**.
   All the drugs contained in the drug library are displayed.

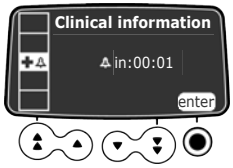


4. Press the arrow keys to select a drug.
5. Press ◉ to select (i) to view information on the selected drug.

8.26 Clinical Information

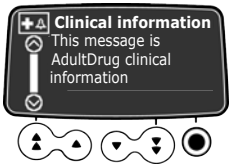
Symbol	✚🔔
Procedure	Viewing remaining time before clinical information display

If configured for the selected drug with Drug Library Software, a protocol message will be displayed on the pump screen after a pre-defined period of time.



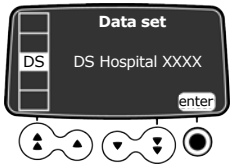
You can view the remaining time before clinical information display as follows:

1. Press MENU.
2. Press the arrow keys to select ✚🔔.
   The remaining time before clinical information is displayed.
3. Press ◉ to select **enter**.
   The clinical information message is displayed.



8.27 Data Set

Symbol	DS
Procedure	Displaying active data set information



You can display active data set information as follows:

1. Press MENU.
2. Press the arrow keys to select DS.

3. Press ◉ to select **enter**.
   The active data set information is displayed.

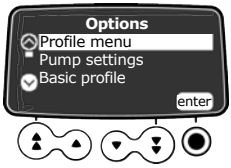
9 Options

This section describes the options available to configure the pump's behavior and the menus displayed.

9.1 Accessing the Pump Configuration Options

Display the pump configuration options as follows:

➪ Pump off, simultaneously press ON/OFF + MENU.
The **Options** screen is displayed. See *Pump Settings* on page 96 for details on the **Pump settings** options. For information on other options, refer to the Technical manual.



9.2 Commands

Operation	Key
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.

9.3 Option Groups

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

Option	Access Code?	Description Location
Profile menu	Yes	Technical Manual
Pump settings	Yes Default code: 0100	*Pump Settings* on page 96.
Basic Profile Configuration	Yes	Technical Manual
Maintenance	Yes	Technical Manual

INFORMATION
If the wrong access code is entered, `error` is displayed.
The Default access code may be modified using Agilia Partner Maintenance Software.

9.4 Pump Settings

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

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 ■ Frame on editable values:display or hide the dotted lines around the values that can be modified	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 __min	
`[User 8]: Language`	■ A scrolling list with all available languages	Official language of the target country
`[User 14]: Wi-Fi module`	■ Enable/Disable the Wi-Fi module	Enabled
`[Par 13]: AC power disconnection alert`	■ 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 33]: Drops/min`	■ Enable/Disable `volumic flow rate (mL/h)` and `Drops/min flow rate`	Enabled
`[Par 35]: Dose display format`	■ Enable/Disable display of the decimal "0" after a dose value	Remove trailing 0 (Disabled) / Remove trailing 0 during programming (Disabled)
`[Par 37]: Alarm system`	■ Enable/Disable preventive silence for alarm system	Enabled

Function	Choice	Default Pump Setting
[Par 38]: Keypad unlock code	■ Set or disable keypad unlock code (4-digit). Disable value: 0000	0000 (Disabled)

10 Data Communication

10.1 Overview

Important cybersecurity recommendations

The Agilia VP Infusion System protects against wireless network and physical cable interface cybersecurity threats. It enforces WPA-2 wireless security protocols.

To further protect the Agilia VP Infusion System against unauthorized access and its removal from the premises, you must ensure your premises are secured and that you securely store the Agilia VP Infusion System when not in use.

Cable Communication	Wi-Fi Communication
Connection of 1 pump to a PC for the following purposes: ■ Data set upload (via Drug Library Software) ■ Maintenance (via Agilia Partner) Cable connection of Link+ Agilia to a hospital information system server to manage identified pumps data for the following purposes: ■ Monitoring at bed side (via Vigilant Sentinel) ■ HL7 autodocumentation (via Vigilant Bridge)	Communication between a hospital information system server and a number of identified pumps for the following purposes: ■ Data set upload ■ Pump history retrieval ■ HL7 Auto-documentation (via Vigilant Bridge)

INFORMATION

- Ensure that Fresenius Kabi systems are compatible with the facilty information system. For more information, contact your technical services representative.
- Before connecting the pump to a hospital information system, ask your IT or biomedical department to configure the device.

To prevent unauthorized connections to the Agilia VP MC Volumetric Infusion Pumps (cybersecurity threats), do as follows:

- Always disable the serial communications port when it is not in use
- Only connect to known secured networks, computers and software.

10.2 Communication via Agilia Cables

10.2.1 Data Communication Cables

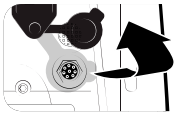
INFORMATION

- Only use recommended Agilia cables.
- All connections and disconnections must be performed by qualified and appropriately trained staff.

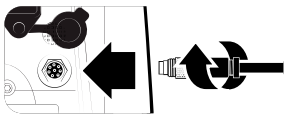
- All IT devices (including computers, hubs and switches) inside the patient area (< 1.5 m) must comply with IEC/EN 60601-1 (leakage current).
- IT devices connected outside the patient area (> 1.5 m) must be at least IEC/EN 60950 compliant.

10.2.2 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.

10.3 Communication via Wi-Fi

The Wi-Fi option allows the pump to connect to a hospital information system without cables. To know if your pump is equipped with a Wi-Fi module, check for the presence of the Wi-Fi logo on the pump's keypad.

See *Keypad Description* on page 21.

Wi-Fi pump

Non Wi-Fi pump

To activate or deactivate the Wi-Fi module, see *Pump Settings* on page 96. For more information on the Wi-Fi module, refer to the technical manual.

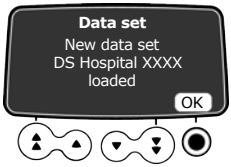
Wi-Fi pumps can be configured with Wi-Fi module enabled or disabled.

10.4 Data Set Upload

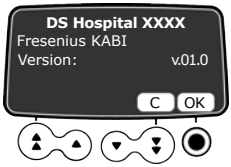
A new data set may be uploaded to the pump while it is infusing. The new data set will be installed at the next pump start-up.

When a new data set has been uploaded since the last start-up of the pump, the ⬇ symbol is displayed on the screen.

1. Power on the pump.



2. Press ◉ to select **OK** to acknowledge.
   The data set information is displayed.



3. Press ◉ to select **OK** to acknowledge this information, or press the arrow key to select **C** to return to the previous screen.
   The data set is installed in the pump.

INFORMATION
It is the hospital's responsibility to define a data set and upload it to the Server Software for distribution to the device.

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 MC 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.

CAUTION

- 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.
- For pumps used in a dedicated ward (ICU, surgery rooms, etc.), it is recommended that you disable the ability to select the profile, thereby locking the pumps to the selected profile. This ensures that all alarms that may be triggered by the pumps behave the same way in a given ward.

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, see *List of Alarms* on page 103.
Medium (!!)	Prompt response	■ The infusion continues. ■ The infusion indicator lights flash **yellow**. ■ The pump emits audible alarm signals. ■ The key silences the alarm for no time limit or for a defined duration. For detailed description of each alarm, see *List of Alarms* on page 103.

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. ■ The  key silences the alarm for no time limit or for a defined duration. For detailed description of each alarm, see *List of Alarms* on page 103.
Information Signals	Awareness	■ The infusion continues. ■ An information message is displayed on the pump screen. ■ For detailed description of each alarm, see *List of Alarms* on page 103.

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.

Message	Priority	Stops Infusion?	Problem / Resolution
`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 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.
`End secondary alarm !!!`	High (!!!)	Yes	The secondary infusion is completed (only with manual return to primary). ☞ Restart the primary infusion. **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.

Message	Priority	Stops Infusion?	Problem / Resolution
Check settings !!	Medium (!!)	No	The flow rate (or dose) has been modified using the keys but has not been confirmed. ☞ Check the flow rate (or dose) and press **OK** to confirm. **NOTE:** the key silences the alarm for 2 minutes.
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 the infusion has not been started with **start** key. ☞ Check the infusion settings, ☞ 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 Drug Library Software or 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.
Re-open primary line ! Close secondary line !	Low (!)	No	End of secondary infusion. ☞ Press to acknowledge.
Upper soft max	Information signal	No	The upper soft limit is exceeded, according to the drug settings defined in the drug library.
Lower soft min	Information signal	No	The lower soft limit is exceeded, according to the drug settings defined in the drug library.
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. See *Pressure* on page 75. **NOTE:** the  key silences the alarm for 2 minutes if the pressure condition is still present. Otherwise, alarm is acknowledged.
`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 potential downstream occlusion has been detected by the device. ■ See *Auto-restart* on page 71. ■ 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 or reconnect to the AC power supply. ☞ 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
`No 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.
`Drop sensor present !!!`	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 drip 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  acknowledges the alarm. If free flow continues, alarm will be raised again.
Drop sensor present !	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  key.

CAUTION
If an alarm persists after restarting the pump, do not use it and contact your biomedical department or a Fresenius Kabi representative.

12.5 Audio Only Information Signals

Type	Comment	Stops Infusion?	Activation
Switch off	Beep until key is released	No	Beep starts when action is not allowed
Return to primary mode	Depends on configuration	No	At the end of secondary mode
Pressure measurement checking	4 beeps	Yes	When auto-restart is activated and a downstream occlusion is detected
End of secondary	3 beeps	No	At the end of secondary when automatic mode is activated
End of loading dose	3 beeps	No	At the end of the loading dose
End of programmed bolus	3 beeps	No	At the end of a programmed bolus
End of sequence	3 beeps	No	At the end of each sequence (sequential mode)
Start infusion at the end of pause	3 beeps	N/A	At the end of a pause, when the infusion automatically starts
End of pause	4 beeps	N/A	At the end of pause - repeated

Type	Comment	Stops Infusion?	Activation
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	3 beeps	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

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.

CAUTION
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 *Use of Administration Sets for Gravity Infusion* on page 116.

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.

WARNING
When infusing solution that can generate air-in-line (example: outgas) or for particular patients (neonates, patients with foramen ovale), it is recommended to use extension sets with an air filter along with the Agilia pumps. These filters may have some specific instructions.

INFORMATION

- Preferentially, use Luer lock connectors to limit the risk of disconnection of the infusion line, of leakage, of air in line and of infection during infusion.

- 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.
- 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.
- Follow your healthcare facility's protocol for installing and replacing the fluid container.
- Especially, verify that the fluid to be infused is compatible with the size of the filter.

Precautions for the use of extension sets

WARNING
Starting an infusion at flow rate below 5 mL/h may cause a delay in medication delivery due to a longer start-up time.

CAUTION
Preferentially use administration sets with the lowest deadspace possible. This will reduce the time for fluid to reach the patient and the occlusion detection time. Avoid using manifolds with high pressure valves. This kind of valves may cause a delay in therapy followed by a sudden bolus once opened.

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.

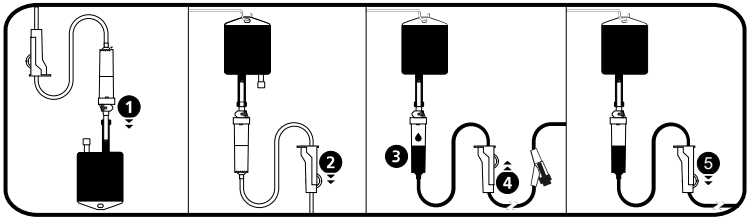
Certain administration sets may require specific priming procedures. Refer to the specific IFU provided with the administration sets.

DANGER
When priming, the patient must not be connected to the pump. Otherwise, air may be infused to the patient causing severe harm.

INFORMATION
Priming the set with the pump is recommended to ensure best performances and to ensure the shortest start-up time.

13.2.1 With a Bag

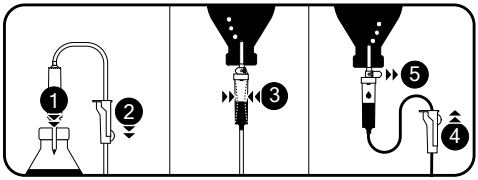
The following diagram shows how to prime the administration set with a bag:



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).

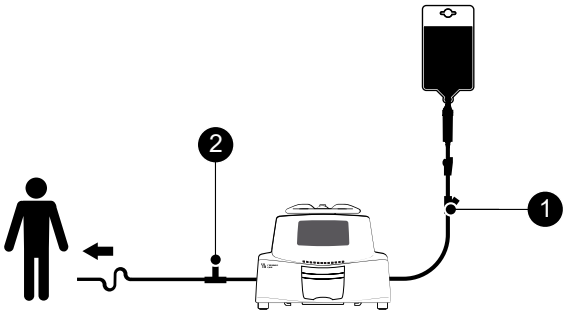


Figure 10: Needle-Free Ports

Legend	
❶ Upstream port (before the pump)	❷ Downstream port (after the pump)

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.

Closed position after removing from the pump (stops flow)

Open position (allows flow from gravity)

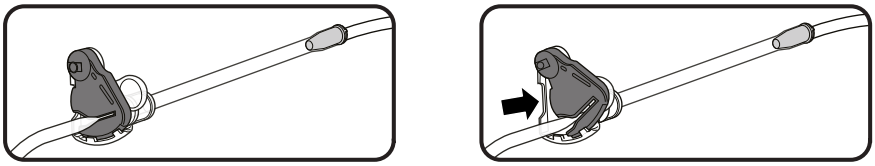


Figure 11: Operation of the SafeClip (blue anti-free flow clamp)

13.3.2.2 Gravity Infusion in Parallel with a Pump

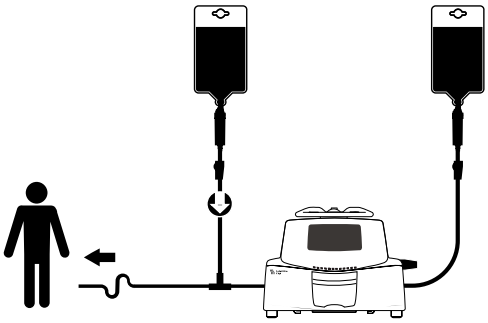


Figure 12: Gravity Infusion (in parallel with a pump)

WARNING
Mixing different drugs in the same infusion line can result in chemical instability or a loss of the intended therapeutic effects. Avoid mixing drugs in the same infusion line whenever possible.

CAUTION
The gravity infusion lines used in parallel must be equipped with a back check valve or positive pressure infusion devices. This will prevent the back-up of IV fluid or medication into the gravity line.

INFORMATION

- If there is no back check valve on a gravity infusion line during a multi-line infusion, it will 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. Remove the administration set from the pump.
5. 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 *Removing an Administration Set* on page 117.
2. Install another administration set, and follow the steps described in the flowchart. See *Flowchart* on page 35.

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

13.4.3 Administration Set Replacement Interval

CAUTION
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.

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 *User Test* on page 101.

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 (Basic Profile) or in Drug Library Software (custom profiles). Increment rules may be modified by Drug Library Software (custom profiles).

15.1 Essential Features

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

Feature	Refer to
Flow Rate Accuracy	*Flow Rate Accuracy* on page 124. *Trumpet and Start-up Curves* on page 138.
Time to Detect Occlusion	*Occlusion Alarm Accuracy and Bolus Volume at Occlusion Release* on page 125.
Bolus Volume After Occlusion Release	*Occlusion Alarm Accuracy and Bolus Volume at Occlusion Release* on page 125.
Management of High-priority Alarms	*Alarms and Safety Features* on page 102.

15.2 Flow Rate

	Format	Range of Settings	Default Value	Minimum Increment
Primary Infusion	mL/h	0.1 up to 1500* 0.1 up to 1100* with drop sensor	N/A	0.01 (0.10 ➔ 9.99) 0.1 (10.0 ➔ 99.9) 1 (100 ➔ 1500)
Direct Bolus	mL/h	50 up to 1500* 50 up to 1100* with drop sensor	1500	50
Programmed Bolus	mL/h	0.1 up to 1500 0.1 up to 1100 with drop sensor	N/A	0.01 (0.10 ➔ 9.99) 0.1 (10.0 ➔ 99.9) 1 (100 ➔ 1500)
Secondary Infusion	mL/h	0.1 up to 1500**	N/A	0.01 (0.10 ➔ 9.99) 0.1 (10.0 ➔ 99.9) 1 (100 ➔ 1500)
KVO	mL/h	1*** up to 20	1	1
Loading Dose	mL/h	0.1 up to 1500 0.1 up to 1100 (with drop sensor)	N/A	0.01 (0.10 ➔ 9.99) 0.1 (10.0 ➔ 99.9) 1 (100 ➔ 1500)

	Format	Range of Settings	Default Value	Minimum Increment
Ramp (plateau)	mL/h	2 up to 1500 2 up to 1100 (with drop sensor)	N/A	0.1 (2.0 ➔ 99.9) 1 (100 ➔ 1500)
Sequential	mL/h	0.1 up to 1500	N/A	0.1 (0.1 ➔ 99.9) 1 (100 ➔ 1500)
Priming	mL/h	1500	N/A	N/A

* The maximum value can be adjusted between 50 and 1500 in the pump options (Basic Profile).

** The maximum value can be adjusted between 50 and 1000 in the pump options (Basic Profile).

*** 1 is the minimum value for activation, "0" value deactivate the KVO functionality.

For more information, refer to the technical manual.

15.3 Volume To Be Infused (VTBI)

	Format	Range of Settings	Default Value	Minimum Increment
VTBI (Primary)	mL	0.1 ➔ 9999	N/A	0.1 (0.1 ➔ 99.9) 1 (100 ➔ 9999)
VTBI (Secondary)	mL	0.1 ➔ 9999*	N/A	0.1 (0.1 ➔ 99.9) 1 (100 ➔ 9999)
Direct Bolus	mL	0.1 ➔ 60**	N/A	N/A
Programmed Bolus	mL	0.1 ➔ 1000	N/A	0.1 (0.1 ➔ 99.9) 1 (100 ➔ 1000)
Ramp	mL	0.1 ➔ 9999	N/A	0.1 (0.1 ➔ 99.9) 1 (100 ➔ 9999)
Sequential	mL	0.1 ➔ 9999	N/A	0.1 (0.1 ➔ 99.9) 1 (100 ➔ 9999)

* Basic Profile: 2000 mL

** 60 mL with drug, 20 mL without drug

15.4 Dose To Be Infused (DTBI)

	Unit	Range of Settings	Default Value	Minimum Increment
Dose	All	0.01* ➔ 9999*	0*	0.01 (0.01 ➔ 9.99) 0.1 (10.0 ➔ 99.9) 1 (100 ➔ 9999)

	Unit	Range of Settings	Default Value	Minimum Increment
Programmed Bolus	All	0.01* ➔ 9999*	0.01*	0.01 (0.01 ➔ 9.99) 0.1 (10.0 ➔ 99.9) 1 (100 ➔ 9999)
Loading Dose	All	0.01* ➔ 9999*	0.01*	0.01 (0.01 ➔ 9.99) 0.1 (10.0 ➔ 99.9) 1 (100 ➔ 9999)

* Only applicable if value is not defined in current drug.

15.5 Infusion Time

	Format	Range of Settings	Default Value	Minimum Increment
Primary / Secondary	__ h __min	00h01min ➔ 168h00min*	N/A	00h01min
Programmed Bolus	__ h __min__s	00h00min01sec ➔ 24h00min00sec	N/A	00h00min01sec 00h00min00sec ➔ 00h59min59sec 00h01min00sec 1h00min00sec ➔ 24h00min00sec
Loading Dose	__ h __min__s	00h00min01sec ➔ 24h00min00sec	N/A	00h00min01sec 00h00min00sec ➔ 00h59min59sec 00h01min00sec 1h00min00sec ➔ 24h00min00sec
KVO Silence Alarm Duration	__ h __min	00h01min ➔ 12h00min	01h00min**	00h01min
Pause	__ h __min	00h01min ➔ 24h00min	N/A	00h01min
Ramp (Total Duration)	__ h __min	00h01min ➔ 48h00min***	12h00min	00h01min
Ramp (Ramp-up / Ramp-down)	__ h __min	00h00min ➔ 06h00min	N/A	00h01min

* If the calculated infusion time exceeds this value, ↑ 168h00min will be displayed on the pump.

** The default value may change depending on the pump configuration.

*** If the calculated infusion time exceeds this value, ↑ 48h00min will be displayed on the pump.

15.6 Concentration

	Unit	Range of Settings	Default Value	Minimum Increment
Concentration	Dose unit	0.01 ➔ 70000	N/A	0.01 (0.01 ➔ 9.99) 0.1 (10.0 ➔ 99.9) 1 (100 ➔ 70000)
Volume of Diluent	mL	1 ➔ 2000*	N/A	1

* Maximum volume of diluent is 9999 mL with a drug

15.7 Patient Data

	Format	Range of Settings	Default Value	Minimum Increment
Patient Weight	kg	0.25 ➔ 350	N/A	0.01 (0.25 ➔ 9.99) 0.1 (10.0 ➔ 19.9) 1 (20 ➔ 350)
Patient Body Surface Area	m^2	0.05 ➔ 4.5	N/A	0.01

15.8 Air Detection

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

15.9 Pressure Management

INFORMATION

- You can change the Basic Profile's infusion pressure settings in the pump options. See *Options* on page 95.
- You can pre-configure custom profiles' infusion pressure settings with Drug Library Software.

	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

	Setting Description	Setting Format	Default Value
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

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

* These values are in mmHg

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

15.10 Accuracy

WARNING
Accuracy (flow rate, time, volume infused, pressure) can be influenced by administration set model, administration set configuration, fluid viscosity, and fluid temperature. Accuracy may be reduced when the infusion flow rate is below 1 mL/h.

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

15.10.1 Flow Rate Accuracy

	Accuracy
Cumulative Flow Rate (Primary/Secondary)*	± 5% for 96 hours with an infusion of 10 liters maximum

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

15.10.2 Effects of Pressure Variations on Accuracy

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

* Test condition: Container height: 50 cm

** Test condition: Back pressure: 0 mmHg

15.10.3 Occlusion Alarm Accuracy and Bolus Volume at Occlusion Release

	Accuracy		
		Occlusion Alarm Threshold	
Occlusion Alarm Response Time*	**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 *Auto-restart* on page 71. It is the healthcare professional's responsibility to define whether the auto-restart feature must be activated or not depending on the clinical practices.

	Accuracy		
Bolus Volume at Occlusion Release*	**Rate**	**Bolus Volume at Occlusion Release**	
		50 mmHg	**750 mmHg**
	25 mL/h	-0.05 ≤ X ≤ 0.35 mL	-0.05 ≤ X ≤ 0.35 mL

* 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.

15.10.4 Volume Accuracy

	Accuracy
Direct Bolus*	≤ 10 mL: ± 0.5 mL > 10 mL: ± 5%
Programmed Bolus*	≤ 8 mL: ± 0.4 mL > 8 mL: ± 5%
Limit to Detect Upstream Occlusion*	≤ 1.0 mL (without drop sensor) ≤ 0.7 mL (with drop sensor)
Limit to Detect Flow Rate Deviation with Drop Sensor	-70% ≤ X ≤ +250%

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

15.10.5 Pressure Accuracy

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

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

15.11 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	

	Infusion Stopped	During Infusion
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

15.12 Units and Conversion Rules

15.12.1 Concentration Units

	Units	Suffix
Concentration Units	nanog, microg, mg, g	/mL, /--mL
	mmol	
	mUnit, Unit	
	cal, kcal	
	mEq	

15.12.2 Dose Units

	Units
Dose Units	nanog/h, nanog/kg/min, nanog/kg/h
	microg/min, microg/h, microg/kg/min, microg/kg/h
	mg/min, mg/h, mg/24h, mg/kg/min, mg/kg/h, mg/kg/24h, mg/m²/h, mg/m²/24h
	g/h, g/kg/min, g/kg/h, g/kg/24h
	mmol/h, mmol/kg/h, mmol/kg/24h
	mUnit/min, mUnit/kg/min, mUnit/kg/h
	Unit/min, Unit/h, Unit/kg/min, Unit/kg/h
	kcal/h, kcal/24h, kcal/kg/h
	mEq/min, mEq/h, mEq/kg/min, mEq/kg/h
	mL/kg/min, mL/kg/h, mL/kg/24h

15.12.3 Conversion Rules

Conversion Rules	1 micro unit = 1000 nano unit	
	1 m unit = 1000 micro unit	
	1 k unit = 1000 unit	
	1 unit/h = 24 unit/24 h	
	1 unit/min = 60 unit/h	
	$mL/h = \frac{\text{unit/kg/h (dose) x kg (weight)}}{\text{unit/mL (concentration)}}$	Conversion of a dose including the unit/kg into volume flow rate (mL/h)
	$mL/h = \frac{\text{unit/m}^2\text{/h (dose) x m}^2\text{(body surface area)}}{\text{unit/mL (concentration)}}$	Conversion of a dose including the unit/m² into volume flow rate (mL/h)
	$mL/h = \frac{\text{unit/h (dose)}}{\text{unit/mL (concentration)}}$	Expression of a volumetric flow rate
	$mL = \frac{\text{unit/kg (dose) x kg (weight)}}{\text{unit/mL (concentration)}}$	Conversion of a dose including the unit/kg into volume (mL)
	$mL = \frac{\text{unit/m}^2\text{(dose) x m}^2\text{(body surface area)}}{\text{unit/mL (concentration)}}$	Conversion of a dose including the unit/m² into volume (mL)

	$mL = \frac{\text{unit (dose)}}{\text{unit/mL (concentration)}}$	Expression of a volume (mL)

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.
- 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

Quick cleaning procedures can be done at any time, whenever you notice soiling.

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 *Cleaning Instructions* on page 131.

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

CAUTION

Recommended agents

- Cleaning: Didecyldimethylammonium chloride (example: Wip'Anios Excel by Anios)
- Disinfecting: Didecyldimethylammonium chloride (example: Wip'Anios Excel by Anios)

CAUTION
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.

Only trained staff can clean and disinfect the pump.

CAUTION
The following actions may damage the device and make it unusable:

- The pump is not intended to be sterilized. Do not put it in an autoclave or immerse it in any liquid.
- Do not spray liquids directly on connectors: preferentially use cleaning 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.

CAUTION
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.

WARNING
It is recommended to use the pump and its accessories with the power cord or accessory from the Agilia range supplied by Fresenius Kabi. If such power cord is not available, be sure to use a cable with the same specifications.

CAUTION

- Pumps must be plugged into a medical grade power strip if one is used.
- The power outlet must always remain accessible to allow emergency power supply disconnection.

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.

CAUTION
Do not replace with a battery other than the one provided by Fresenius Kabi. Always manipulate the battery with the pump turned off and the power cord unplugged.
An incorrect handling of the battery may make it unusable. Using a defective or a damaged battery could cause a premature stop of the infusion and/or a Lithium leakage that can be harmful for the users and the patients.
If the battery appears damaged or does not work as expected, please contact your biomedical department or your Fresenius Kabi sales representative.

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. The essential performance and behaviour of the device are not affected during charging.

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 mm².

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.

The device is equipped with one of these batteries:

- 7.2 V 2.2 Ah
- 7.34 V 2.75 Ah

To identify the type of battery installed, refer to the technical manual of the pump.

Characteristics	7.2 V 2.2 Ah - Li-ion Smart battery		
Weight	Approximately 100 g		
Battery Life	**Flow Rate**	**Wi-Fi**	**Battery Life**
	25 mL/h	✓	> 5 h
	25 mL/h	x	> 8 h
	1500 mL/h	✓	> 4 h
	1500 mL/h	x	> 5 h
Battery Recharge	Pump OFF: < 6 h / Pump ON: < 20 h		

Characteristics	7.34 V 2.75 Ah - Li-ion Smart battery		
Weight	Approximately 100 g		
Battery Life	**Flow Rate**	**Wi-Fi**	**Battery Life**
	25 mL/h	✓	> 8 h
	25 mL/h	x	> 13 h
	1500 mL/h	✓	> 5 h
	1500 mL/h	x	> 7 h
Battery Recharge	Pump OFF: < 7 h / Pump ON: < 21 h		

✓ = Wi-Fi enabled

x = Wi-Fi disabled or not used

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 (dB(A))
0	21
1	30
100	37
400	33

Flow Rate (mL/h)	Sound Level (dB(A))
1200	46

NOTE: These values are provided for information purposes only.

18.7.2 Alarms Sound Levels

Alarm Priority	Range for sound alarm volume adjusted at minimum (see *Alarm Volume* on page 87)			Range for sound alarm volume adjusted at maximum (see *Alarm Volume* on page 87)		
	Range values		Measured values	Range values		Measured values
High	55	70	64.1	70	80	75.8
Medium	54	64	59.2	64	75	70.6
Low	52	62	57.6	59	70	64.8

NOTE: dB(A) is the A-weighted sound pressure level measured in a hemisphere with a radius of 1 m following Table B.1 of ISO 3744:2010 and defined in IEC 60601-1-8: ed 2006; Am.2: 2020.

18.8 Compliance

Electro-medical equipment safety	Compliant with the following standards: ■ EN/IEC 60601-1 ■ EN/IEC 60601-1-8	IP32	Index of protection against ingress of water or particulate matter
EMC (Electromagnetic compatibility)	Compliant with the following standard: ■ EN/IEC 60601-1-2		Protection against leakage current: Defibrillation-proof type CF applied part*
Particular standards	■ EN/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

WARNING
Starting an infusion at flow rate below 5 mL/h may cause a delay in medication delivery due to a longer start-up time.

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.

INFORMATION
For the infusion of critical drugs or 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.

18.10.1 Flow Rate: 1 mL/h

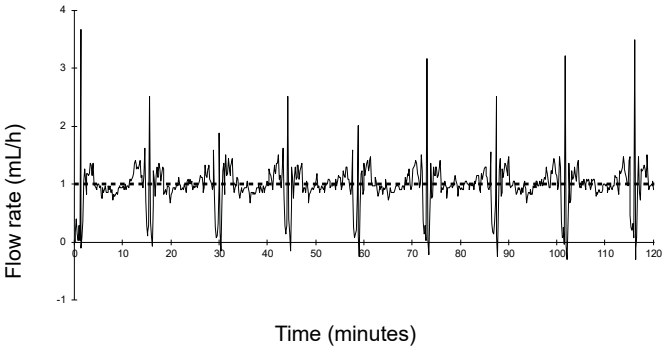


Figure 13: Start-up and instantaneous flow rate (1 mL/h over first 2 hours on 96 hours)

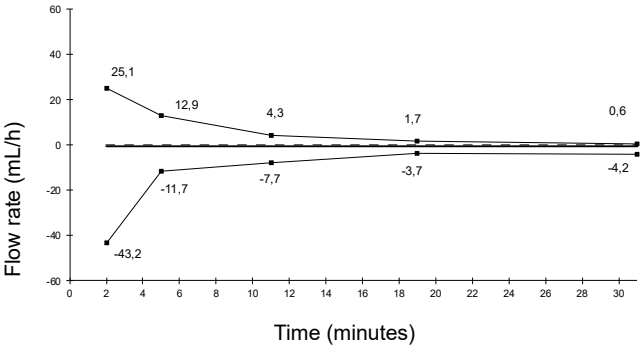


Figure 14: Trumpet curves for 2, 5, 11, 19, 31 minutes observation windows (1 mL/h over first 2 hours on 96 hours)

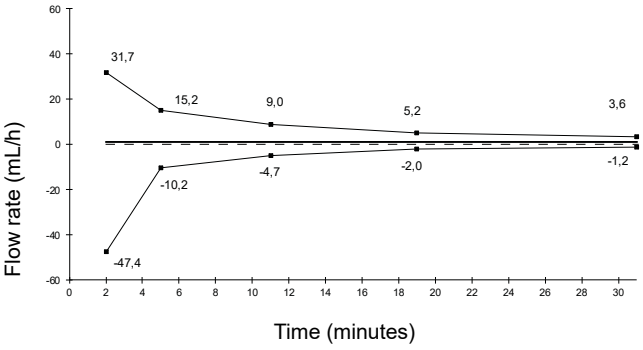
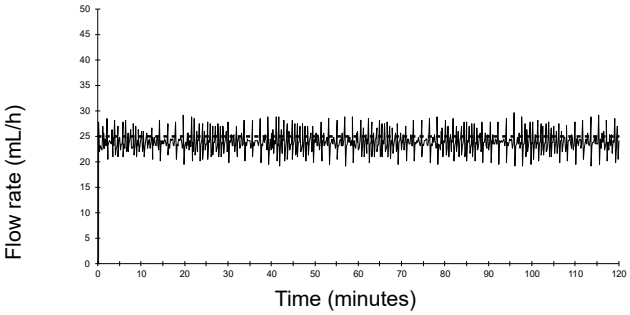


Figure 15: Trumpet curves for 2, 5, 11, 19, 31 minutes observation windows (1 mL/h over last 2 hours on 96 hours)

18.10.2 Flow Rate: 25 mL/h



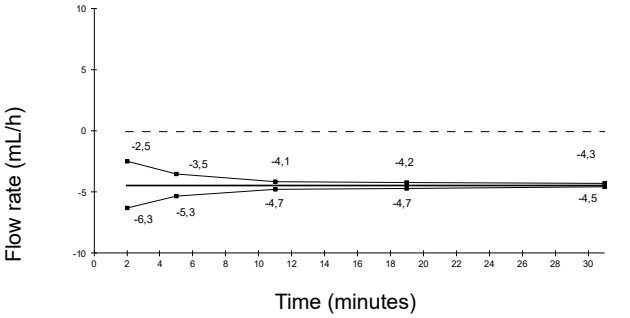
Legend

Instantaneous flow rate

Set flow rate

Sampling time: 10 s

Figure 16: Start-up and instantaneous flow rate (25 mL/h over first 2 hours on 96 hours)



Legend

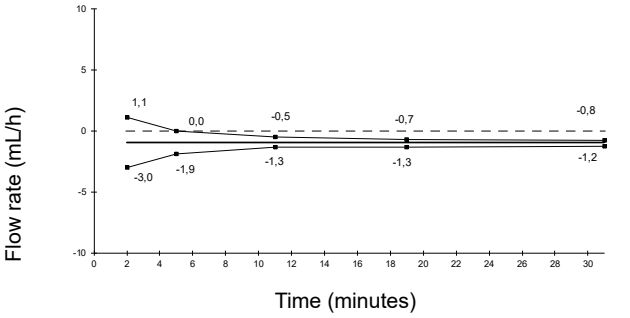
Measured variance from flow rate

Error

Flow rate

Sampling time: 10 s

Figure 17: Trumpet curves for 2, 5, 11, 19, 31 minutes observation windows (25 mL/h over first 2 hours on 96 hours)



Legend

Measured variance from flow rate

Error

Flow rate

Sampling time: 10 s

Figure 18: Trumpet curves for 2, 5, 11, 19, 31 minutes observation windows (25 mL/h over last 2 hours on 96 hours)

19 Wi-Fi

19.1 General Information

The Agilia Connect Infusion System includes an IEEE 802.11 radio-frequency transmitter incorporated in the Agilia WiFi pumps. It operates using the following standards and frequencies:

- IEEE 802.11a: 5 GHz Frequency Band
- IEEE 802.11b: 2.4 GHz Frequency Band
- IEEE 802.11g: 2.4 GHz Frequency Band
- IEEE 802.11n: 2.4 GHz Frequency Band

INFORMATION
For more information on differentiation between WiFi and non WiFi pumps, see *Communication via Wi-Fi* on page 99.

The Wi-Fi module incorporated in the Agilia WiFi pumps is intended to perform the following, via periodic communication cycles:

- Transfer data sets (from Server Software to pump)
- Transfer pump history (from pump to a server)
- Communicate general information on the operating status of the pump

Agilia infusion pumps contain transmitter with the following IDs:

- FCC ID: Z64-CC3235MOD
- IC ID: 451I-CC3235MOD

Agilia WiFi pumps must be installed to provide a separation distance of at least 8 in (20 cm) from all persons and must not be co-located or operating in conjunction with any other antenna or transmitter.

Agilia infusion pumps support a hidden network.

The Agilia WiFi pumps must be configured by qualified and appropriately trained staff.

INFORMATION
If communication with the wireless network is interrupted, the pump can be used as intended. For more information, contact your Fresenius Kabi sales representative.

19.2 Specifications

19.2.1 Technical Specifications

	Description
Technology	IEEE 802.11 a/b/g/n

	Description
Frequency Band	■ 2.412 ➔ 2.472 GHz (2.4 GHz is ISM band) ■ 5.180 ➔ 5.825 GHz (High Band)
Modulation	DSSS, CKK, OFDM, MCS7
Wireless Security	WPA/WPA2-Entreprise, WPA/WPA2-PSK
Network Protocols	IPv4 and IPv6 TCP/IP, DHCP, HTTP/HTTPS
Typical Transmit Power (± 2 dBm)	■ 16 dBm for 802.11b DSSS ■ 16.3 dBm for 802.11b CCK ■ 15.3 dBm for 802.11g/n OFDM ■ 15.1 dBm in 802.11a mode

19.2.2 Electromagnetic Compatibility

For information on electromagnetic compatibilty, see *Guidance and Manufacturer's Declaration on EMC* on page 147.

19.2.2.1 USA - FCC Notice

The users manual or instruction manual for an intentional or unintentional radiator shall caution the user that changes or modifications not expressely approved by the party responsible for compliance could void the user's authority to operate the equipment.

19.2.2.2 Europe - RED

This product is designated as a radio device that utilizes harmonized frequencies and power levels for Europe.

19.2.3 Protocols and Standards

This wireless functionality references and uses the following protocols and standards:

- IEEE 802.11a/b/g/n standard
- WPA/WPA2-Entreprise, WPA/WPA2-PSK (Wi-Fi protected access) is a long-term security solution for wireless networks. For more information, refer to the IEEE 802.11.
- TCP (Transmission Control Protocol / Internet Protocol), IPv4 (Internet Protocol Version 4), IPv6(Internet Protocol Version 6) , DHCP (Dynamic Host Configuration Protocol), HTTP (Hypertext Transfer Protocol) and HTTPS (Hypertext Transfer Protocol Secure) are standard data transport protocol used for the internet and other similar networks.

Agilia infusion pumps do not require an active wireless communication to function as intended (infuse). All wireless transactions are initiated by the device and are periodic in nature. The absence of connection (for example, out of range) does not affect the device ability to infuse. Data that is pending is stored and re-transmitted when the connection becomes available. Data integrity and quality of service are inherent in the design. The system should be ensured and maintained by a qualified and trained technical user, or a Fresenius Kabi representative.

20 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 device.	■ 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.

Issue	Recommended Actions
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.
Wi-Fi communication error.	■ Contact your IT or biomedical department, or your Fresenius Kabi sales representative.
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.

21 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.

22 Warranty

22.1 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.

22.2 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.

22.3 Warranty Conditions for Accessories

Batteries and accessories may have specific warranty conditions. Contact your Fresenius Kabi sales representative for more information.

23 Guidance and Manufacturer's Declaration on EMC

23.1 Electromagnetic Compatibility

DANGER
Do not use Agilia pumps in an MRI environment unless in an Agilia MRI Guard.

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.

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

23.2 Electrostatic Discharge (ESD)

CAUTION

- 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 and 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.

23.3 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.

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.
- Maintain a minimum distance of 30 cm between Agilia pumps and any portable radiofrequency (such as smartphones, antennas…). For RTLS tags use, see *Real Time Location System Tag* on page 160. Electromagnetic perturbations may damage the Agilia devices and alter their performance if this distance is not maintained.
- Maintain a minimum distance of 30 cm between Agilia pumps and electrosurgical equipment. Electromagnetic perturbations may damage the Agilia devices and alter their performance if this distance is not maintained.
- Do not expose the Agilia pumps directly to ultrasonic devices. Mechanical perturbations may damage the devices and alter their performance it the distance is not maintained.
- 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.
- 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.

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.

23.4 EMC and essential performances

In the case of electromagnetic disturbances, if the essential performance, *Section 15.1, page 127*, is lost or degraded, the consequences for the patient are as follows: over-delivery, under-delivery, delay of therapy, undetected air infused to patient, traumatic injuries, exsanguination.

23.4.1 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	

Emission Test	Compliance Obtained by the Device	Electromagnetic Environment - Guidance
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	

23.4.2 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 Ed3 - - - - - - - - - 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.

Immunity Test	IEC 60601-1-2 Ed3 - - - - - - - - - IEC 60601-2-24 Test Level	Compliance Level Obtained by the Device	Electromagnetic Environment - Guidance
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.

23.4.3 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 Ed3 - - - - - - - - - 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: 

NOTE:

- 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.

23.4.4 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) IEC 60601-1-2 Ed3		
	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.

23.4.5 EMC test deviations and supplementary tests

To ensure compatibility with the new EMC standard IEC / EN 60601-1-2 Ed4.1 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 to 2.7 GHz For radio conformity according to IEC 301489-1 and IEC 30189-17: 3 V/m, 2.7 GHz to 6 GHz	10 V/m, 80 MHz to 2.7 GHz 3 V/m, 2.7 GHz to 6 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.

Immunity test	IEC 60601-1-2 IEC 60601-2-24 Test level	Compliance level obtained by the device	Electromagnetic environment – guidance
Near field radiated RF 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	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	For minimal distance approach 30 cm (12 inches) 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
Electrical Fasttransient / 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
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)

Immunity test	IEC 60601-1-2 IEC 60601-2-24 Test level	Compliance level obtained by the device	Electromagnetic environment – guidance
Power frequency (50 / 60 Hz) magnetic field IEC 61000-4-8	30 A / m	400 A / m	If necessary, the power magnetic field should be measured in the intended installation location to make sure it is lower than the compliance level. If the measured field in the location where the 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.

Immunity test	IEC 60601-1-2 IEC 60601-2-24 Test level	Compliance level obtained by the device	Electromagnetic environment – guidance
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.
Proximity magnetic field IEC 61000-4-39 Test method	134.2 KHz Pulse modulation 2.1 KHz 13.56 MHz Pulse modulation 50 KHz 30 KHz Modulation CW	65 A/m 7.5 A/m 8 A/m	The RFID Immunity phenomena should be in the frequency range 9 KHz to 13.56 MHz.

24 Servicing

24.1 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.

24.2 Maintenance Requirements

WARNING
Perform preventive maintenance and pumping membrane replacement at least once every 3 years. Failure to comply with these maintenance procedures could damage the device and result in altered performances.

WARNING
Do not use a device that has been dropped or that doesn't operate as expected. Contact your biomedical department or your Fresenius Kabi representative.

CAUTION
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.
- 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.

24.3 Quality Control

A 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.

24.4 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

25 Real Time Location System Tag

25.1 Tag Installation

WARNING
The positioning of the RTLS tag must be strictly respected to avoid any perturbations that may impact the pump performances.

CAUTION
Remove the RTLS tag if the pump does not behave as expected when it is attached to the pump.

1. Locate a 44 x 34 mm area on the side panel of the pump.
The tag must be positioned in the greyed area as shown below.

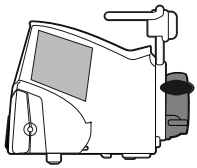


Figure 19: Agilia VP range of pumps (right panel)

CAUTION
The installation of the RTLS tag on the pump must respect the integrity of the pump housing. Any modification may damage the pump and/or its internal components and make it unusable. Only use biocompatible material to position a RTLS tag on Agilia pumps.

2. Stick the double-sided tape supplied with the tag in the location defined above.

3. Stick the tag ❶.

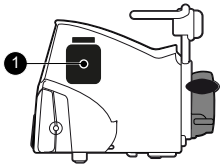


Figure 20: Location for Agilia VP range of pumps

25.2 Use environment

The RTLS tags must be used in the same operational conditions as for the Agilia pump. See *Use Environment* on page 11.

25.3 Tag Compliance

CAUTION
Be sure that used RTLS tags are in compliance with latest local radio equipments and electrical safety directives and standards. Incompatible tags may impact pump performances.

Radio, EMC (Electromagnetic compatibility)	FCC Part 15 Subpart C class B subpart B EN/IEC 300-328, EN/IEC 301-489 Radio Equipment Directive 2014/53/EU (RED) Radio Equipment S.I2017/2016 (RED) RoHS 2 Directive 2011/65/EU, RoHS 2 Directive S.I.2012/3032 Safety: CE, UKCA
Safety	EN62368/UL62368/IEC62368, Japan 201-200209

A 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
ASA	American Society of Anesthesiologists
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
CVD	Coordinated Vulnerability Disclosure
dB(A)	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
DI	Dose Infused
DPS	Dynamic Pressure System
DSSS	Direct Sequence Spread Spectrum
DTBI	Dose to Be Infused
DUR	Duration

Term	Description
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	Intravascular
kg	Kilograms
KVO	Keep Vein Open
lb(s)	Pound(s)
LED	Light Emitting Diode
mA	Milliamperes
mEq	Milliequivalents

Term	Description
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
OR	Operating Room
OTS	Off-The-Shelf
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
RPC	Remote Procedure Call
RS232	Serial interface connector
SN	Serial Number
SELV	Safety Extra Low Voltage
SIR	Asynchronous Serial Infrared
SQL	Structured Query Language
TCP	Transmission Control Protocol

Term	Description
UDI	Unique Device Identifier
USB	Universal Serial Bus
Ut	Test specification level
V	Volts
V/m	Volts per meter
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
W	Watts
WPA	Wi-Fi Protected Access
XSS	Cross-Site Scripting

B Appendix: Factory Configuration

Menus

Feature	Availability	Feature	Availability
Profile	x	Ramp-up / Ramp-down	x
Pressure management	✓	Sequential	x
Volume to be infused	✓	Alarm volume	✓
Keypad lock status	✓	Call-back	✓
Battery life	✓	View flow rate history	x
Volume infused / Dose infused	✓	View pressure history	x
Pause	✓	View event log	✓
Drug	x	Date / Time	✓
Patient	✓	Maintenance	x
Day/Night mode	✓	Library information	x
Primary / Secondary	✓	Clinical information	x
Programmed bolus	x	Data Set	x
Infusion mode	✓		

Infusion Modes

Feature	Availability	Feature	Availability
V/T/R	✓	Ramp-up / Ramp-down	✓
V/R	✓	Sequential	✓
V/T	✓	Drops/min	x
T/R	x		

Infusion Features

Feature	Availability	Feature	Availability
Direct Bolus	✓	KVO	x
Programmed Bolus	✓	Prime Set	✓
Loading Dose	✓	Advance Air Bubble	✓
Secondary Infusion	✓	Dynamic Pressure System (DPS)	✓

✓ = Features activated with factory configuration (Basic Profile).

x = Features not activated with factory configuration. Can be enabled in the pump options or with Drug Library Software. Otherwise, they can be enabled on request.

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Release notes

Date	Software version	Description
October 2023	4.2	Creation
July 2024	4.3	Cover: Removed "Caring for life" from Fresenius Kabi logo § 1.8.2: Updated Cybersecurity recommendations § 18.6.2: Updated Alarms sound levels § 19: Updated WiFi specifications

Made in France

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CE 0123

First CE Mark:
Agilia VP MC WiFi: 2015 / Agilia VP MC: 2016

Local contacts for servicing

19185-0_ifu_agilia_vp_mc_eng

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