FRESENIUS KABI

caring for life

Agilia VP MC WiFi

Volumetric Infusion Pump

For Healthcare Facilities

Instructions For Use

Valid for software version 2.6

Symbols Description

Symbols used in this document

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

Recommendations to be followed.

Labelling symbols

Warning
(Refer to the Instructions For Use)

Refer to the Instructions For Use

Product reference/part number

Product serial number

Input terminal - connector

Output terminal - connector

Electrical fuses

Alternating Current (AC)

Direct Current (DC)

MR Unsafe

IP22

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

Part included in a recycling process

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

Name and address of the manufacturer / Date of manufacture

Caution: Federal law restricts this device to sale by or on the order of a physician (See 21 CFR 801.109(b)(1))

Protection against electric shock: class II

Non-ionizing electromagnetic radiation

Medical Device

Unique Device Identifier

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

Cybersecurity recommendations

The Agilia VP Infusion System protects against wireless network and physical cable interface cybersecurity threats. It enforces WPA-2 Enterprise 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
- When not in use, the Agilia VP Infusion System is securely stored
- When not in use, the Agilia USB Cable is disconnected and securely stored
- Secure storage access is restricted to authorized personnel only
- You install the latest version of the pump firmware as soon as it is made available.

For more information about securing the Agilia VP Infusion System, see Data Communication on page 127 and Communication Port on page 179.

Should you have concerns with network connectivity or the loss of the pump maintenance access code, contact your biomedical department or your Fresenius-Kabi representative.

If you suspect a cybersecurity attack occurred or a vulnerability related to the Agilia VP Infusion System, please report this to your local Fresenius Kabi representative or submit a request to the Fresenius CERT (cert@fresenius.com).

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

- Practical cybersecurity guidelines for installation
- General cybersecurity recommendations
- Device cybersecurity features
- Detailed descriptions of potential risks and countermeasures
- Operation
- Disposal of devices.

Patient Safety

WARNING

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

- The software version of the device is displayed on the start-up screen.
- The software version described in this IFU is displayed in the Release Notes, page 220.

WARNING

- The Agilia VP MC WiFi should be used to deliver medications where it is clinically acceptable to be given using an infusion pump. Refer to the medication product insert for details on infusion routes for the adequate programming of the infusion pump (e.g.: rate, pressure thresholds…).
- Medications used outside of their approved labelling may result in serious injury to the patient.

Reminder

The Agilia VP Infusion is intended for adult and pediatric care for the intermittent or continuous delivery of parenteral fluids, medications, blood, and blood derivatives through clinically accepted parenteral routes of administration.

The Agilia VP Infusion System is intended for neonatal care for the intermittent or continuous delivery of parenteral fluids for hydration and nutrition, blood, and blood derivatives through clinically accepted parenteral routes of administration. These routes of administration include intravenous, intra-arterial, and subcutaneous using dedicated administration sets.

WARNING

Starting an infusion at a low flow rate (typically under 1mL/h) can cause a delay in medication delivery because it reduces the initial accuracy of the programmed flowrate which prolongs rate stabilization (for additional information, see section 15.9, **"Accuracy"** on page 161, and section 18.9, **"Trumpet, Start-up Curves and AAMI TIR101: 2020 Delivery Performance"** on page 182).

In order to ensure patient safety in high risk populations, close monitoring is recommended in low flow rate infusions.

WARNING

Do not use the pump in the following environments:

- Explosive or flammable environments
- Hyperbaric chamber
- High humidity environments (e.g. shower, bath, etc.)
- Agilia VP MC WiFi is MR Unsafe.

WARNING

- The functionality of the pump can be affected by pressure variations, mechanical shocks, heat ignition sources, and other unusual events.
- Direct exposure to ultrasound devices may damage the pump or its components.

WARNING

Apart from the described intended use and use environment, **Fresenius Kabi** does not guarantee the pump performances.

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.
- The pump is not tested for use in an ambulance in the US.

WARNING

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.

WARNING

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

WARNING

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

WARNING

- If you stop the pump prior to initiating a Programmed bolus, the pump will not resume after the Programmed Bolus has been delivered. The pump will remain in the stop mode until you resume the infusion. If the infusion is not resumed within 30 seconds the pump will alarm, **Waiting Start.**
- To ensure continuous infusion after completion of Bolus Delivery DO NOT STOP the pump before accessing the Bolus Function.

WARNING

- Air in the administration set presents the risk of injury, death or other serious adverse reactions.
- During priming, make sure that the administration set is not connected to the patient.
- The pump does not detect air bubbles when priming.

WARNING

- Air-in-line presents the risk of injury, death or other serious adverse reactions.
- Advancing an air bubble past the air detection sensor does not remove air from the line. Use clinical judgement to assess if air should be removed from the line per established facility protocols.

When addressing or clearing an occlusion:

WARNING

Ensure the fluid flow to the patient is clamped to prevent administering an unintended bolus. An occlusion may pressurize the infusion tubing, which can result in an unintended bolus of drug when the occlusion is cleared. In order to prevent this additional bolus, disconnect the tubing from patient to relieve the excess pressure or through a stopcock, if present. The healthcare professional should weigh the relative risks of disconnection with the risks of an unintended bolus of drug.

WARNING

- The pump should be protected against unauthorized physical access.
- The keypad automatic lock can be enabled to reduce the risk of unauthorized access, but is not a replacement for other facility access controls such as door lock, card access or security guards.

WARNING

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 1 mL per hour): consider occlusion pressure threshold setting and adjust it, as necessary. The lower the occlusion pressure threshold setting is, the shorter the occlusion detection time will be. However, when infusing viscous or thick fluids (e.g., lipids), the occlusion pressure threshold setting may need to be adjusted to a higher value to reduce false alarms.

Note: When infusing at flow rates of less than 1mL/h, the time to detect occlusion may be more than 5 minutes: monitor the patient and if there is a lack of patient clinical response, check for occlusion.

WARNING

- The pump should be protected against unauthorized physical access.
- The keypad automatic lock can be enabled to reduce the risk of unauthorized access, but is not a replacement for other facility access controls such as door lock, card access or security guards.

WARNING

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

WARNING

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

WARNING

When the pump is not connected to the power supply a Medium-Priority Battery Alarm will sound 30 minutes prior to a High-Priority Battery Alarm. If the pump is still not connected to the power supply after the High-Priority Battery Alarm the pump will turn OFF after 5 minutes.

WARNING

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

WARNING

- Only use recommended 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

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

WARNING

If the device is not used for an extended period (longer than 1 month), it is recommended that the battery be removed from the device and put in storage by authorized personnel. If the battery cannot be removed, or the device will be used in less than 1 month, charge the battery at least once a month by connecting the device to the AC power supply for at least 6 hours.

WARNING

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

WARNING

To avoid the risks of infection and microbial transmission, make sure to adequately clean and disinfect the equipment in case of dangerous spills such as blood, body fluids or chemotherapy, after each patient use, before any maintenance, on a routine basis when the pump is not in use and before storage. see section 16.5, page 173.

WARNING

Do not use the following cleaning agents and disinfectants:

- Trichloroethylene
- Abrasive detergents
- Undiluted alcohol.

These cleaning agents and disinfectants may damage plastic parts and cause the pump to malfunction.

WARNING

When the cleaning is performed while the infusion pump is running, the keyboard should be locked to avoid any unintended modification of the infusion parameters.

WARNING

- This cleaning at the patient bedside does not replace the need for a complete cleaning.
- At the end of the infusion, perform the complete cleaning protocol, see section 16.5, page 173.

WARNING

The disinfecting procedure must be done immediately after cleaning. Disinfecting the pump without prior cleaning is not effective.

WARNING

- Only trained staff can clean and disinfect the pump.
- Do not place the pump in an autoclave or immerse it in liquid.
- The pump is not intended to be sterilized.
- Do not spray liquids directly on connectors and pump surface. Instead, use a cleaning cloth or disposable wipes.
- Do not use the pump if the housing, keypad, or display is damaged or cracked.
- If sticky or high-viscosity fluids are spilled behind the pump door, replace the infusion pump as soon as possible so it can be thoroughly cleaned. These types of fluids can damage the pumping mechanism when dried.

WARNING

Ensure the air sensor is completely dry after cleaning to ensure air detection performance.

WARNING

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

WARNING

- The use of another cable may lead to PC / Agilia VP MC WiFi infusion pump malfunctions and electrical harm due to residual leakage currents.
- External wireless devices cannot be used with the Agilia USB cable or communication port.

WARNING

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

WARNING

- Use of the Agilia pump adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.
- Use of accessories, transducers and cables other than those specified or provided by the manufacturer of the Agilia pump could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.
- Portable RF communications equipment (including peripherals such as antenna cables, internal and external antennas) should be used no closer than 4 in (10 cm) for cell phones and 12 in (30 cm) for other equipments, to any part of the Agilia pump, including cables specified by the manufacturer. Otherwise, degradation of the essential performances of Agilia pump could result. Electrosurgical equipment (including base unit, cables, electrodes) should be used no closer than 12 in (30 cm) to any part of the Agilia pump, including cables specified by the manufacturer. Otherwise, degradation of the essential performance of Agilia pump could result.

WARNING

- Maintenance operations must be done while pumps are not infusing to a patient.
- Perform preventive maintenance at least once every 3 years. This includes replacing the battery and the pumping membrane.

WARNING

Only use recommended items that are compatible with the Agilia Connect Infusion System. Use of any other items may damage the pump.

Table of Contents

1 Introduction

1.1 Scope

These Instructions For Use (IFU) are applicable to the Agilia VP MC Volumetric Infusion Pump. The user must adhere to the instructions specified in this IFU or other accompanying documents including quick reference guide. Failure to adhere to these instructions may result in damage to the equipment, injury to patients or injury to users.

WARNING

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

- The software version of the device is displayed on the start-up screen.
- The software version described in this IFU is displayed in the Release Notes, page 220.

1.2 Intended Use

The Agilia VP Infusion System is intended for adult and pediatric care for the intermittent or continuous delivery of parenteral fluids, medications, blood and blood derivatives through clinically accepted parenteral routes of administration. These routes of administration include intravenous, intra-arterial, subcutaneous and intraosseous, using dedicated administration sets.

The Agilia VP Infusion System is also intended for neonatal care for the intermittent or continuous delivery of parenteral fluids for hydration and nutrition, blood and blood derivatives through clinically accepted parenteral routes of administration. These routes of administration include intravenous, intra-arterial, and subcutaneous, using dedicated administration sets.

It is intended for use by trained healthcare professionals in healthcare facilities.

1.2.1 Intended routes of administration

	Intravenous	Intra-arterial	Subcutaneous	Intraosseous
Adult care	Yes	Yes	Yes	Yes, when allowed by hospital policy
Pediatric care	Yes	Yes	Yes	Yes
Neonatal care	Yes	Yes	Yes	No

WARNING

- The Agilia VP MC WiFi should be used to deliver medications where it is clinically acceptable to be given using an infusion pump. Refer to the medication product insert for details on infusion routes for the adequate programming of the infusion pump (e.g.: rate, pressure thresholds…).
- Medications used outside of their approved labelling may result in serious injury to the patient.

1.3 Principles of Operation

The Agilia VP MC WiFi is a programmable electronic medical pump dedicated to administering a pre-determined volume of infusion product at a programmed rate. This peristaltic pump ensures fluid delivery by using pumping and alternating fingers (compressing and relaxing the pumping segment) to advance the liquid to the patient through the administration set.

Agilia VP MC WiFi is a portable and reusable device that can be used everyday.

Agilia VP MC WiFi can be used for intermittent or continuous infusions.

Agilia VP MC WiFi is intended for use on only one patient at a time. It can be reused indefinitely on multiple patients throughout its lifetime.

1.4 Intended Products to be Infused

The pump administers products through clinically accepted routes. These products include but are not limited to the following:

	Intended Products
Parenteral Fluids	▪ Standard solutions ▪ Colloids ▪ Parenteral nutrition.

Medication	▪ Diluted drugs ▪ Antibiotics ▪ Chemotherapy ▪ Catecholamines ▪ Short acting drugs ▪ Anesthesia drugs.
Transfusion	▪ Blood ▪ Red blood cells ▪ Platelets ▪ Plasma ▪ Albumin.

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

The Agilia VP MC WiFi should be used for only fluids intended for infusion pumps.

Do not use the pump for epidural use.

INFORMATION

The Volumat Lines cleared for use for transfusion are detailed in Administration Sets, page 211.

1.5 Intended Users

The pump must be used by qualified and trained healthcare professionals.

Typical initial training duration: approximately 2 hours 30 min.
It is recommended that users attend a refresher training session every year.

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

1.6 Patient Characteristics

WARNING

Starting an infusion at a low flow rate (typically under 1mL/h) can cause a delay in medication delivery because it reduces the initial accuracy of the programmed flowrate which prolongs rate stabilization (for additional information, see section 15.9, **"Accuracy"** on page 161, and section 18.9, **"Trumpet, Start-up Curves and AAMI TIR101: 2020 Delivery Performance"** on page 182).

In order to ensure patient safety in high risk populations, close monitoring is recommended in low flow rate infusions.

Agilia VP MC WiFi is intended for patients with the following characteristics:

	Patient Characteristics
Weight	0.25 kg to 350 kg
Body Surface Area	0.05 m² to 4.5 m²

Note: 1 kg = 2.2 lb

When using the pump with specific patients easily affected by light and noise like neonates, options are available to:

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

1.7 Contraindications

None known.

1.8 Inspection Requirements

Visually inspect the pump before and after each use:

- Check all surfaces on the device
- Check all moving parts on the device.

If you see discoloration, cracks or other damage, return the pump to Biomedical Engineering for repair.

1.9 Use Environment

Agilia VP MC WiFi is intended for use in healthcare facilities, under the supervision of trained healthcare personnel.

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

- Operating temperature range:
  41 °F (5 °C) to 104 °F (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 9842 ft (3000 m) above sea-level

WARNING

Do not use the pump in the following environments:

- Explosive or flammable environments
- Hyperbaric chamber
- High humidity environments (e.g. shower, bath, etc.)
- Agilia VP MC WiFi is MR Unsafe.

WARNING

- The functionality of the pump can be affected by pressure variations, mechanical shocks, heat ignition sources, and other unusual events.
- Direct exposure to ultrasound devices may damage the pump or its components.

WARNING

Apart from the described intended use and use environment, **Fresenius Kabi** does not guarantee the pump performances.

INFORMATION

Devices which may cause decreased downstream pressure in the IV set (i.e ECMO, dialyzer) may lead to flow rate inaccuracy. These devices should be used carefully with the pump and appropriate measures should be taken to avoid influence on the pump performances.

INFORMATION

For more information on using the device in specific conditions, contact your **Fresenius Kabi** representative.

INFORMATION

Please wear gloves when using Agilia VP MC WiFi.

2 Agilia Connect Infusion System

2.1 Agilia Connect Infusion System

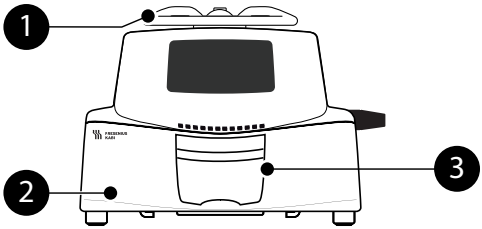
Agilia Range		Description
Pump	**Agilia VP MC WiFi**	**Volumetric Infusion Pump** Pumps designed to deliver the contents of a bag or bottle through a line connected to a patient.
Software	**Drug Library Software**	**Medication Safety Solution** Drug Library Software designed to create, customize and manage data sets to be uploaded to the Agilia VP MC WiFi infusion pump. **Server Software** Software intended to distribute data sets to Agilia infusion pumps and centralize information coming from infusion pumps for post analysis and reporting. **Infusion Data Reporting Software** Software provides reports designed to review the infusion parameters with in the Drug Library Software (Customer profiles).
	Agilia Partner	**Maintenance Software** Software designed to maintain, configure, test and calibrate the Agilia VP MC WiFi infusion pump.
Rack	**Agilia Link**	**Stacking rack systems** Rack systems designed to stack 4, 6 or 8 Agilia infusion pumps. Agilia Link is designed to centralize the power supply.
Disposables	**Volumat Lines (applied part)**	**Administration Sets** Dedicated administration sets for use with the Agilia VP MC WiFi pump.
Accessories	**Agilia Duo**	**Two Pump Accessory** Accessory designed to centralize the power supply when 2 Agilia infusion pumps are locked together.

2.2 Compatibility Matrix

For a list of devices compatible with your product refer to the Agilia Connect Infusion System Compatibility Guide. The matrix is provided along with each compatible device and is also available through your representative.

3 Description

3.1 Front View

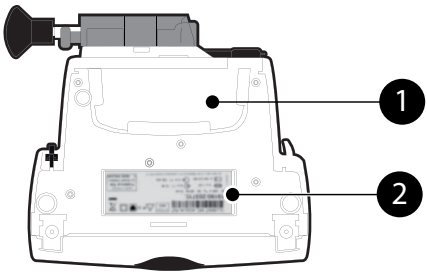


Legend

1. Handle
2. Pump Door
3. Door Lever

Figure 3.1: Front View

3.2 Bottom View



Legend

1. Slot for pump stacking
2. Device Identification Label

Figure 3.2: Bottom view

Device Identification Label:

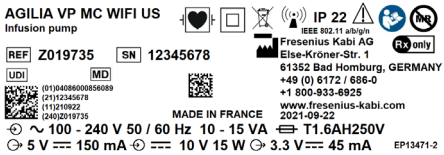


Figure 3.3: Example of Device Identification Label

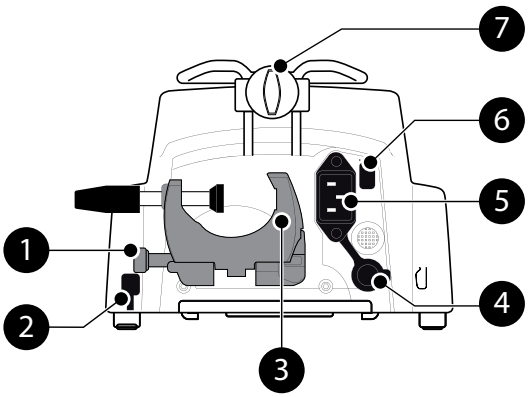
On the device identification label, the UDI (Unique Device Identifier) is presented in machine-readable form (AIDC - Automatic Identification and Data Capture - technology) and as text:

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 Labelling symbols, page 2.

3.3 Back View



Legend

1. Release Button
2. Drop Sensor Connection Socket (not available in the US)
3. Rotating Pole Clamp
4. RS232 Communication Port
5. Power Cord Inlet
6. Infrared Cell
7. Attachment Lock Knob

Figure 3.4: Back View

Symbol	Location	Description
	Near Power Cord Inlet	**WARNING** See section 18, page 178.
	Near RS232 Communication Port	**WARNING** See section 10, page 127.

3.4 Keypad

3.4.1 Keypad Description

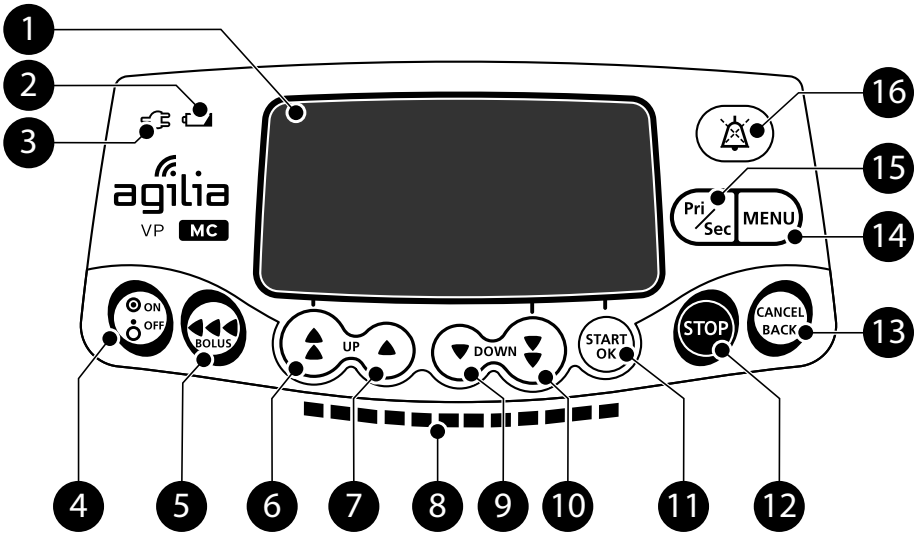


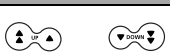
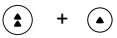
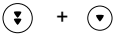
Figure 3.5: Keypad

Legend

1	Screen	7	Increment	13	Cancel Value / Move Back to Previous Field
2	Battery Charge Status Indicator (LED)	8	Infusion Indicator Lights (LED)	14	Menu
3	Power Supply Indicator (LED)	9	Decrement	15	Primary / Secondary
4	On / Off	10	Fast Decrement	16	Alarm Silence
5	Bolus / Prime / Advance Air	11	Confirm Value / Move to Next Field / Start infusion		
6	Fast Increment	12	Stop		

3.4.2 Keypad Details

3.4.2.1 Selection Keys

Key	Description
	**Arrow Keys** Keys for selecting values for 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 fast decrement keys have been programmed with different values corresponding to standardized volumes of bags and bottles.*
- *Pressing and holding any of the arrow keys results in faster increment or decrement.*

Pending on configuration the single arrow keys change the lowest programable value (0.01 or 0.1) while the double arrows keys will program values to the next increment (0.1 or 1).

3.4.2.2 Infusion Indicator Light (LEDs) Behavior

Indicator	Description
	Infusion in Progress (running green)
	Low-Priority Alarm (constant yellow)
	Medium-Priority Alarm (flashing yellow)
	High-Priority Alarm (flashing red)
	High-Priority Alarm State (flashing red LEDs and two ON green LEDs)
	Low-Priority Alarm State (ON yellow LEDs and two ON green LEDs)

Note:

- *Infusion indicator lights (LEDs) provide information about the infusion: in progress or alarm priority (low, medium or high).*
- *Green indicator lights will continuously run from right to left while the infusion is in progress.*
- *The higher the flow rate, the faster green indicator lights (LEDs) run.*
- *Low and medium-priority yellow lights will be combined with green running lights, which indicates infusion is still in progress during the alarm condition.*
- *High priority red lights will be combined with two ON green LEDs, which indicates infusion completed and KVO infusion in progress.*
- *Low priority yellow lights will be combined with two ON green LEDs, which indicates KVO mode after the VTBI is complete.*

3.4.2.3 Status Indicators

Indicator	Description
	Power Supply Indicator (LED) When the device is attached to an active power supply, the indicator light is a constant green. If the pump is not connected to the AC power, it does not light up.
	Battery Charge Status Indicator (LED) 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)** This symbol shows a drop falling into the drip chamber. The drop appears in the drip chamber when an infusion is in progress.
	**Infusion in Progress (custom profiles)** This symbol is displayed when the pump is infusing a drug within a custom profile.

3.5.2 Screen Options

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

Symbol	Description
	WiFi status ▪ WiFi signal strength: high ▪ WiFi signal strength: medium ▪ WiFi signal strength: low ▪ No WiFi signal (WiFi enabled). ▪ WiFi deactivated.

3.5.3 Navigation Buttons

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

3.5.4 Alarms and Safety Features

Symbol	Description
	Power Disconnection
	Alarm Silenced
	Pressure Increase
	Drop in Pressure

Note:
For more information on alarms, see section 12, page 132.

3.5.5 Infusion Features

Symbol	Description
	**Loading Dose** This symbol is displayed when programming a loading dose.
SEC	**Secondary Infusion** This symbol is displayed when programming and infusing a secondary infusion.
	**Ramp-up / Ramp-down Infusion** This symbol is displayed when programming and infusing a ramp-up / ramp-down infusion.
seq	**Sequential Infusion** This symbol is displayed when programming and infusing a sequential infusion.

3.5.6 Data Communication

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

3.6 Packaging

The Agilia VP MC WiFi packaging contains the following:

- 1 Agilia VP MC WiFi pump
- 1 Instructions For Use manual
- 1 Quick Reference Guide
- 1 Compatibility Guide
- 1 Power cord

Packaging weight: Approximately 1.16 lb (530 g).
Packaging consists of: Recycled cardboard.

INFORMATION

- It is the healthcare facility's responsibility to check the pump integrity upon receipt.
- If the packaging contents are incomplete or damaged, contact your **Fresenius Kabi** 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 using a compatible 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 with up to 200 drugs per profile

4.1.1 Basic Profile

Basic Profile allows programming of an infusion for which settings have not been pre-defined with a compatible Drug Library Software.

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

Basic Profile has the following characteristics:

- The infusion rate allowed is flow rate (mL/h) from 0.1 mL/h up to 1500 mL/h.
- 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.

INFORMATION

The Basic profile may not be adapted to suit the practices of a specific service. Before the device is deployed, the service must ensure the Basic profile is suitably adjusted.

4.1.2 Custom Profiles

Custom profiles can be configured and loaded to the pump using a compatible Drug Library Software.

A custom profile contains the following:

- a **specific device configuration** (pump settings that control the mechanical functions of the pump (i.e. alarm volume)
- a **drug library** (optional), see section 4.2, page 32.

Depending on the way it is pre-configured with Vigilant Master Med software, a custom profile may or may not include all of the functionalities described in this IFU.

Profile selection is only available at pump start up.

Once a profile is selected, you must power OFF and then ON the pump to switch from one profile to another. See more information in section 7.2, page 47.

INFORMATION

- We recommend using a custom profile when infusing critical drugs.
- We recommend creating and uploading profiles in order to limit usage errors and to maximize the safety features of the pump to mirror the approved practices of the specific units. For example limiting flow rates or dose rates for specific patient populations or infusions.
- We recommend creating a specific profile per patient population and/or care unit, therapy, protocol, or any relevant classification to ensure intuitive and safe use.
- We recommend when infusing pediatric and neonatal patients, using a dedicated custom profile to provide customized infusion parameters. Use the Basic profile only when a dedicated profile is unavailable.

Please use the recommended parameters specific to each patient category.

4.2 Drug Libraries

A drug library is a list of the facilities drugs with set values and limits that are created by the facility and their protocols.

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 care units (ward level).
- Drug settings may be adjusted on the pump according to pre-defined programming limits, such as dose limits.
- Infusion modes defined in a custom drug entry are not adjustable on the pump.

4.3 Drugs

4.3.1 Infusion Rates

A drug in a drug library must specify the infusion rate:

- **Flow rate**: Infusion of a volume over a period of time

or

- **Dose rate**: Infusion of a specific amount of a drug over a period of time

4.3.2 Drug X (mL/h)

Drug X is configurable in a compatible Drug Library Software by profile. The Drug X entry allows the clinician to deliver a drug or a concentration that is not in the drug library (i.e. medications new to formulary, research drugs, nonstandard concentrations etc.).

If Drug X is enabled, Drug X can be programmed on the pump as a flow rate (mL/h) infusion as one of following infusion modes: volume/time/rate, ramp-up / ramp-down mode and sequential infusion mode, loading dose and bolus (programmed and direct).

Drug X does not have the same safety limits as found within specific drug entries within the drug library.

Drug X flow rate max hard limit is configurable from 50 to 1,500 mL/h in primary infusion and from 50 to 1,000 mL/h in secondary infusion. The drug library entries can have max and min hard and soft limits around the rate, volume and time/duration. It is recommended to use the drug library and limit use of Drug X.

The position of Drug X is configurable by profile. Drug X may appear either as the first or last entry in the drug library. The position of Drug X supersedes the alphabetical order of the other drugs in the drug library.

4.3.3 Hard Limits and Soft Limits

Programming limits can be set for each drug in a drug library. 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.

4.3.4 Infusion Modes

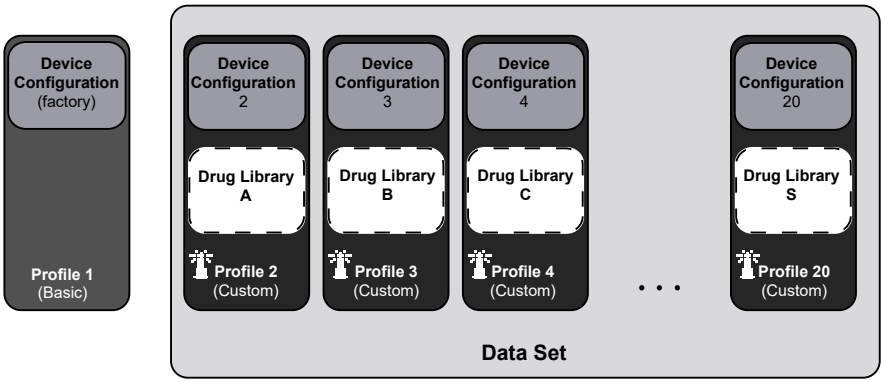
An infusion can be started according to the following modes:

Infusion Mode	Description	Infusion Rate	
		Flow Rate	Dose Rate
Volume / Time / Rate (V/T/R)	This infusion mode gives access to the 3 infusion parameters (V, T, R)	✓	✓
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.	✓	×
Sequential	Infusion by sequences (up to a maximum of 20) defined by volume to be infused and the infusion flow rate for each sequence.	✓	×

To program infusions, see Programming an Infusion on page 49. To program ramp and sequential modes, see Additional Infusion Modes on page 82.

4.4 Data Set

A **data set** can contain up to 19 custom profiles that can be uploaded to Agilia pumps with a compatible Drug Library Software.

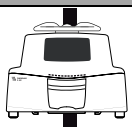
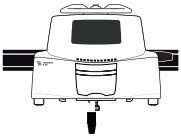
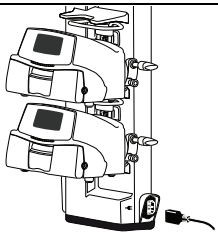
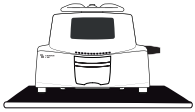
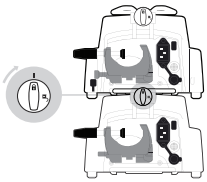


If there is no data set uploaded to the pump, the pump can be used with the Basic Profile.

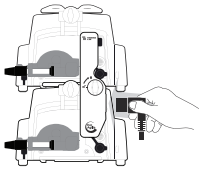
5 Installation

5.1 Accessory Installation

A pump can be installed on any of the following:

Location		Comments
Pole		☞ See section 5.3.1, page 38. **Pole specifications:** ▪ Diameter: from 0.6 to 1.6 in (15 to 40 mm)
Rail		☞ See section 5.3.2, page 38. **Rail specifications:** ▪ Height: from 1.0 to 1.4 in (25 to 35 mm) ▪ Depth: from 0.3 to 0.4 in (8 to 10 mm)
Agilia Link		☞ Refer to the Agilia Link accompanying documents.
Table		☞ See section 5.3.3, page 38. Only install a pump on a table if it is not possible to attach it to a pole, a rail or recommended Agilia accessory.
Another Pump		☞ See section 5.3.4, page 39.

Power two pumps with Agilia Duo:

Agilia Duo		☞ Refer to the Agilia Duo accompanying documents.

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

WARNING

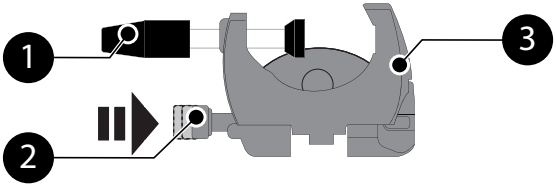
- The pump must be used in a horizontal and stable position to function properly.
- Use recommended Agilia accessories to ensure stability and prevent the pump from falling. Do not stack the pump with equipment other than those recommended.
- The pump is not tested for use in an ambulance in the US.

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



Legend

1. Screw clamp
2. Release button
3. Rotating pole clamp

Figure 5.1: Rotating Pole Clamp System

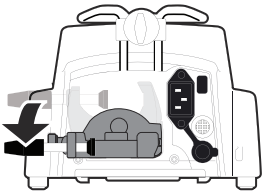
5.2.2 Using the Rotating Pole Clamp

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)

Fold the clamp down as follows:

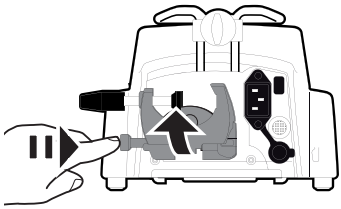
1. Push the release button.
2. Fold the clamp outward.



5.2.2.2 Folding the Clamp Up (inward toward the pump)

Fold the clamp up as follows:

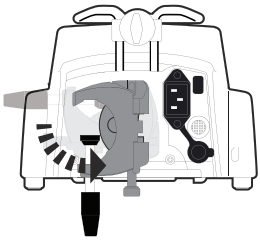
1. Push the release button.
2. Fold the pole clamp inward toward the pump.



5.2.2.3 Rotating the Clamp

Rotate the clamp as follows:

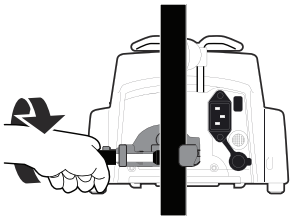
1. Fold the clamp up (see above).
2. Rotate the clamp to a vertical position.
3. Fold the clamp outward (see above) to attach to a rail.



5.3 Attaching the pump(s)

5.3.1 Attaching to a Pole

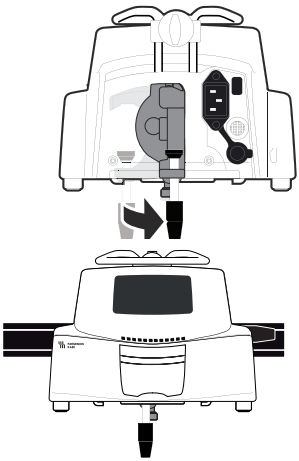
1. Fold the pole clamp down to the horizontal position:
see section 5.2.2.1, page 37.
2. Unscrew the clamp, attach to the pole, and screw the clamp until the pump is fully secured to the pole.
3. Make sure that the pump is securely attached.



5.3.2 Attaching to a Rail

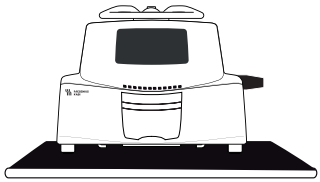
Only single pumps can be attached to a bed rail or gurney rail.

1. Rotate the pole clamp to the vertical position: see section 5.2.2.3, page 37.
2. Unscrew the clamp, attach to the rail, and screw the clamp until pump is fully secured to the rail.
3. Make sure that the pump is securely attached.



5.3.3 Using on a Flat Table

1. Fold the pole clamp up: see section 5.2.2.2, page 37.
2. Place the pump a safe distance from the edge, to prevent the pump from falling off.



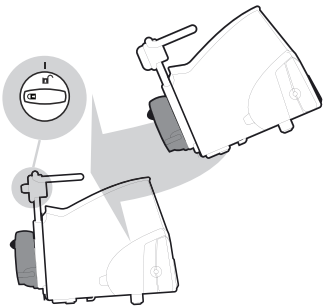
5.3.4 Attaching Pumps Together

You can attach up to

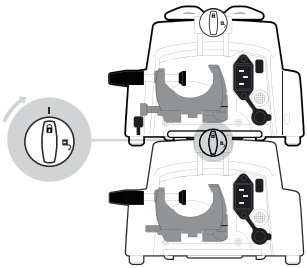
- three non-infusing pumps together for transport,
- two infusing pumps.

Note:
The diagram below describes attaching two pumps together.

1. Fold both pumps' pole clamps up: see section 5.2.2.2, page 37.
2. Slide the slot on the bottom of the upper pump onto the handle of the lower pump.
3. Make sure that the pump handle is fully seated in the slot of the pump above.



4. Turn the attachment lock knob on the lower pump handle clockwise until the locked symbol lines up with the mark.
5. Make sure the pumps are securely attached together by attempting to separate them.
6. If attaching to a pole, unfold both pole clamps and secure them tightly.



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

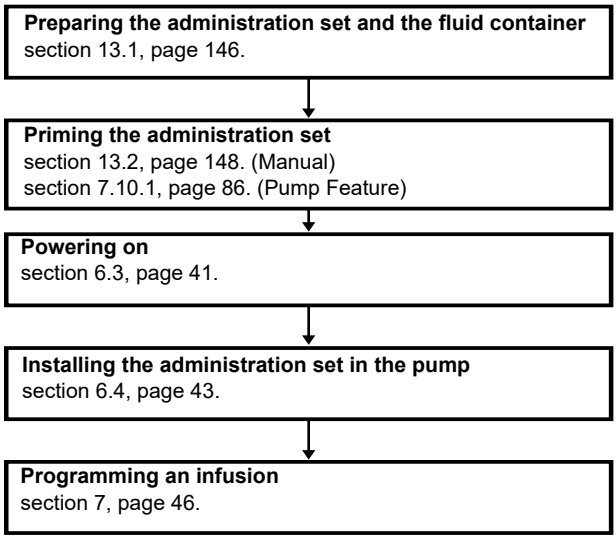
WARNING

The pump must be used in a horizontal and stable position to function properly.

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.



6.2 Using the Pump for the First Time

INFORMATION

- 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.

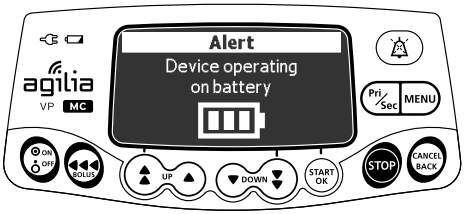
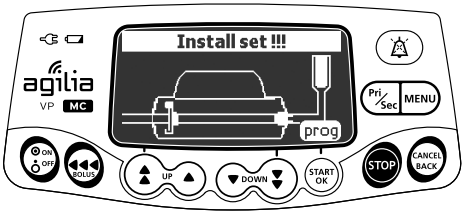
1. Make sure the pump is correctly installed at the bedside. See section 5, page 35.
2. Plug the pump into the AC power supply. See section 17.1, page 176.
3. Prepare the administration set. See section 13.1, page 146.
4. Power on the pump. See section 6.3, page 41.

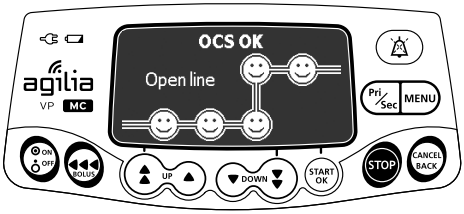
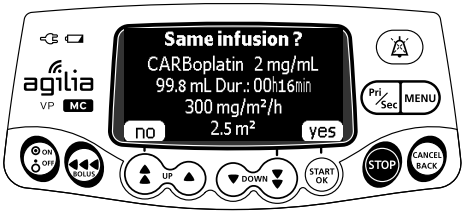
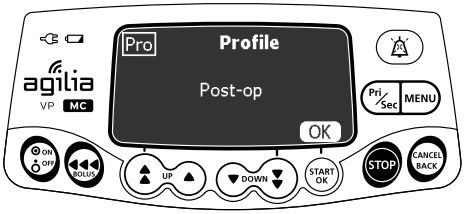
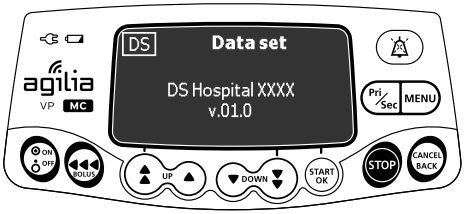
6.3 Powering on

INFORMATION

- The pump can operate using the battery; however, we recommend that the pump be connected to a power supply as often as possible during use in order to ensure that the battery remains charged.
- When the pump is connected to the power supply, check that the power supply indicator (LED) lights up green.
- When plugged into a power supply, the pump automatically powers on when the pump door is opened. You can disable this option in the pump options. For more information, refer to the technical manual.

1. Press 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. Acknowledge the different screens listed in the table below.

Screen After Powering on	Description
	Startup screen: upon startup, the following information is displayed: ▪ Product name ▪ Software version (2.6) ▪ (Optional - Ward name/Profile name) ▪ WiFi status ▪ Date and time.
	▪ The pump is operating on battery. The symbol shows three different charge levels: < 30 % battery charge 30 % - 70 % battery charge > 70 % battery charge
	▪ No administration set is installed on the pump and the door is closed or the administration set is not correctly installed and the door is closed. ▪ `Install set !!!` is displayed at the top of the screen. ☞ Install an administration set See section 6.4, page 43. or ☞ Press "prog" to pre-program the pump. See section , page 91.

Screen After Powering on	Description
	▪ The OCS checks and confirms the correct functionality of the pumping mechanism, pump door, pumping fingers, pumping membrane, downstream pressure sensor, and “SafeClip.” This system is the main mechanism for providing safety from free-flow.
	▪ Maintenance reminder message (optional).
	▪ Same infusion screen (optional). Press **yes** to resume previous infusion settings and same profile. Press **no** to program a different infusion and/or select a different profile.
	▪ Profile confirmation screen (optional). Press **OK** to confirm the profile. *Note:* *This screen is linked to the "same infusion" function above.*
	▪ Data Set information (optional)

Optional means that the feature can be configured in Basic Profile menu.

6.4 Installing the Administration Set in the Pump

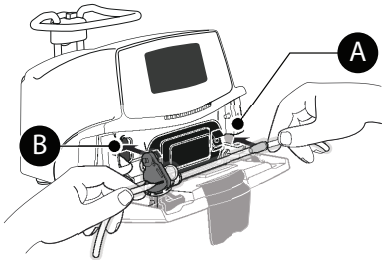
WARNING

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.

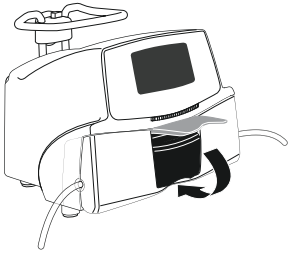
INFORMATION

Do not open the roller clamp until the OCS test has successfully completed.

1. Prepare the administration set and the fluid container, see section 13.1, page 146.
2. Prime the administration set manually (see section 13.2, page 148.) or using the pump (see section 7.10.1, page 86.)
3. Power on the pump, see section 6.3, page 41.
4. Open the pump door.
5. Align the fully primed administration set horizontally along the tubing guide 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 on the left (blue).
6. Insert the green connector into the green slot [A].
7. Guide the SafeClip (blue clamp) into the blue slot, with the spherical hinge on top [B].
8. Push the SafeClip to move the spherical hinge into place.
9. Check that the tubing is inserted in the left tubing guide.



10. 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.*

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

6.5 Pump Height

WARNING

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

Hang the container to 20 inches (50 cm) above the pump.

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

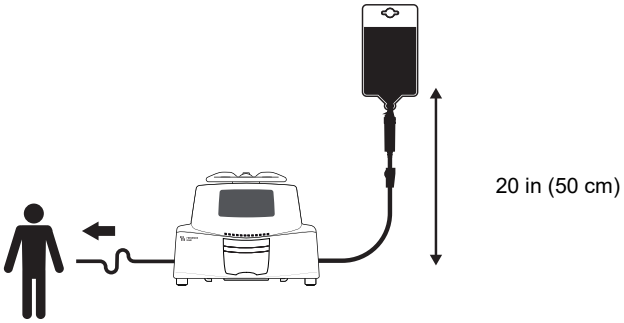
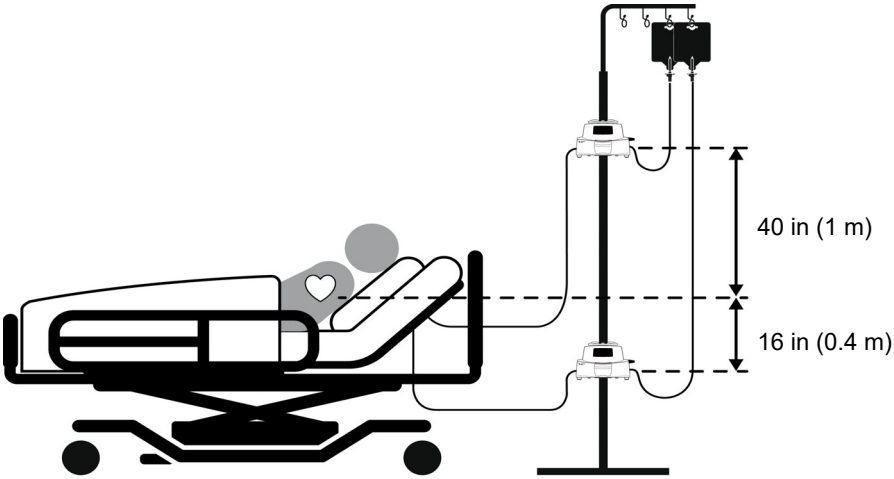


Figure 6.1: Global Installation

If the pump is used on an Agilia Link rack system, refer to the Agilia Link Instructions For Use manual.

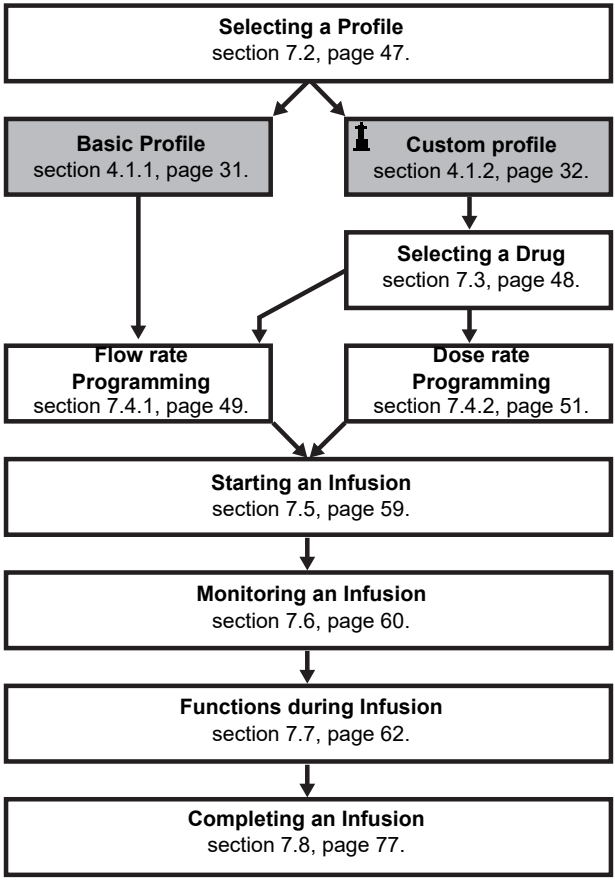
Precautions for pump position

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



7 Operation

7.1 Flowchart



7.2 Selecting a Profile

INFORMATION

Profile selection screen is displayed if more than one profile is available.

Profile selection step is only possible at pump start up.

Once a profile is selected, you must power OFF and then ON the pump to switch from one profile to another.

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

2. Press the arrow keys to select the appropriate profile.

   The ♜ (lighthouse) symbol indicates a profile as a drug library.

3. Press **OK** to confirm.
   The selected profile information is displayed.

4. Press **OK** to confirm the profile selection, or ✎ to change the profile.

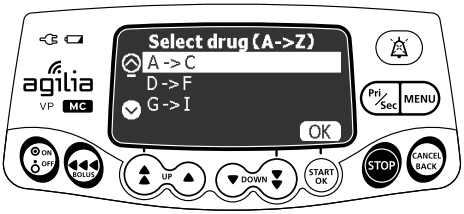
- *The drug library is loaded for the profile selected.*
- *The OCS test is performed.*

7.3 Selecting a Drug

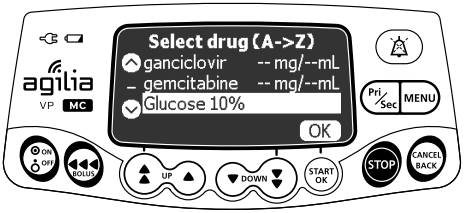
After selecting a custom profile, you must select a drug to infuse.

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)*



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



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

7.4 Programming an Infusion

Reminder

The Agilia VP Infusion System is intended for adult and pediatric care for the intermittent or continuous delivery of parenteral fluids, medications, blood and blood derivatives through clinically accepted parenteral routes of administration. These routes of administration include intravenous, intra-arterial, subcutaneous and intraosseous, using dedicated administration sets.

The Agilia VP Infusion System is also intended for neonatal care for the intermittent or continuous delivery of parenteral fluids for hydration and nutrition, blood and blood derivatives through clinically accepted parenteral routes of administration. These routes of administration include intravenous, intra-arterial, and subcutaneous, using dedicated administration sets.

It is intended for use by trained healthcare professionals in healthcare facilities.

WARNING

Starting an infusion at a low flow rate (typically under 1mL/h) can cause a delay in medication delivery because it reduces the initial accuracy of the programmed flowrate which prolongs rate stabilization (for additional information, see section "**15.9 Accuracy**" on page 161 and section "**18.9 Trumpet, Start-up Curves and AAMI TIR101: 2020 Delivery Performance**" on page 182).

In order to ensure patient safety in high risk populations, close monitoring is recommended in low flow rate infusions.

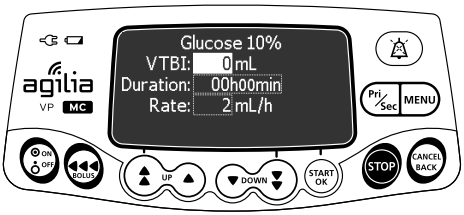
- This section describes the programming of an infusion with the **Volume / Time / Rate** (**V/T/R)** infusion mode.
- To change the infusion mode, see Mode on page 113.

7.4.1 Programming an Infusion by Flow Rate

WARNING

Starting an infusion at a low flow rate (typically under 1mL/h) can cause a delay in medication delivery because it reduces the initial accuracy of the programmed flowrate which prolongs rate stabilization (for additional information, see section "**15.9 Accuracy**" on page 161 and section "**18.9 Trumpet, Start-up Curves and AAMI TIR101: 2020 Delivery Performance**" on page 182).

In order to ensure patient safety in high risk populations, close monitoring is recommended in low flow rate infusions.



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

INFORMATION

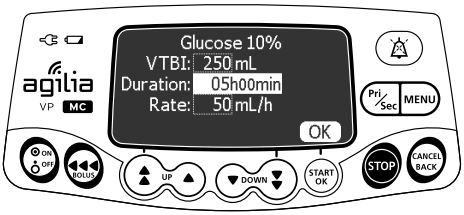
- Press (▲▲) to select the pre-defined VTBI from values: 0.1 mL, 10 mL, 20 mL, 50 mL, 100 mL, 250 mL, 500 mL, 1000 mL, 1500 mL.
- To program a VTBI between the pre-defined values: press the single (▲) or (▼)*.*

INFORMATION

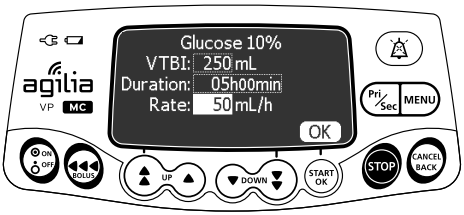
All volumes added or removed must be taken into consideration, including the volume of fluid contained in the administration set and lost during priming (priming volume varies by administration set; see the administration set package label for priming volumes).

INFORMATION

First you must program VTBI and then Duration or Rate. When Duration is programmed, the Rate is calculated automatically (Duration is not skipped automatically - see the following instructions). When Rate is programmed, the Duration is calculated automatically.



1. Press the arrow keys to program the infusion duration (_h_min), and press **OK**. *The flow rate is automatically calculated.*
   Duration programming can also be skipped by pressing **OK** to reach Rate field.



2. Press the arrow keys to program the flow rate, and press **OK**.
   Entry of a flow rate automatically calculates the duration.
   If duration has been programmed, you can press **OK** to confirm flow rate.
3. After confirming, you will reach Confirmation screen.
4. Press **OK** to confirm the infusion settings, or ✎ to change the settings.

7.4.2 Programming an Infusion by Dose Rate

WARNING

⚠ Starting an infusion at a low flow rate (typically under 1mL/h) can cause a delay in medication delivery because it reduces the initial accuracy of the programmed flowrate which prolongs rate stabilization (for additional information, see section "**15.9 Accuracy**" on page 161 and section "**18.9 Trumpet, Start-up Curves and AAMI TIR101: 2020 Delivery Performance**" on page 182).

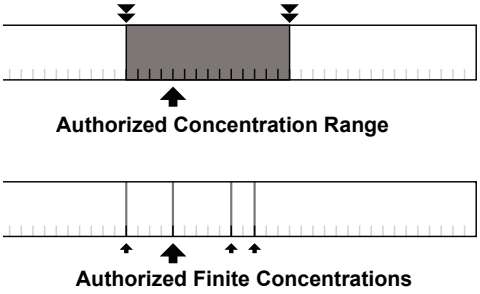
In order to ensure patient safety in high risk populations, close monitoring is recommended in low flow rate infusions.

7.4.2.1 Selecting the Drug Concentration

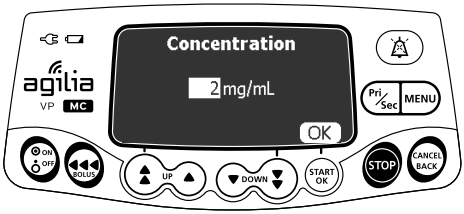
A drug selected from a drug library can allow adjustments of concentration in one of the following ways:

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

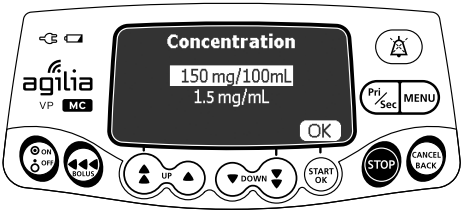
If no adjustment on the concentration is allowed, see section 7.4.2.2, page 52.



Selecting the Drug Concentration



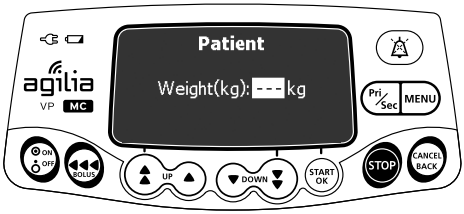
Range



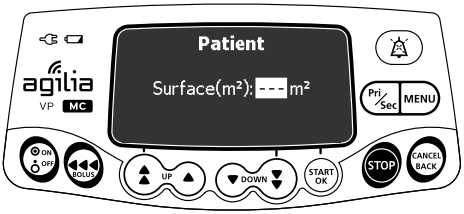
Finite values

1. Press the arrow keys to select the concentration.
2. Press **OK** to confirm.

7.4.2.2 Selecting the Patient's Characteristics



Weight



Body Surface Area

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

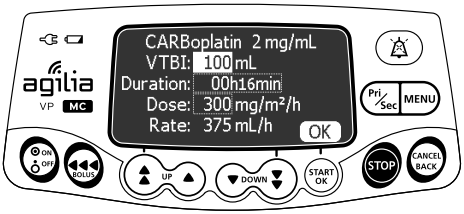
INFORMATION

- 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.
- Pre-populated default weight or body surface area are configured with a compatible Drug Library Software.

7.4.2.3 Programming the Infusion

INFORMATION

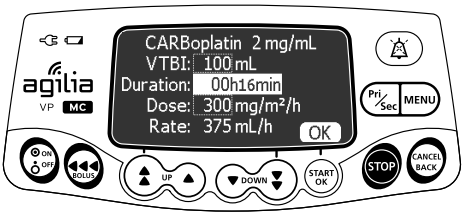
- Parameters that can be adjusted are displayed with an outlined dotted box. Parameters without the box are calculated values and are not adjustable.



- 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.
  To program a VTBI between the pre-defined values: use/press ▲ or ▼).

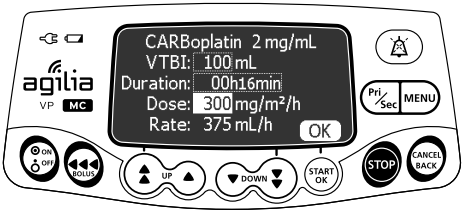
INFORMATION

- 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 package label for priming volumes).



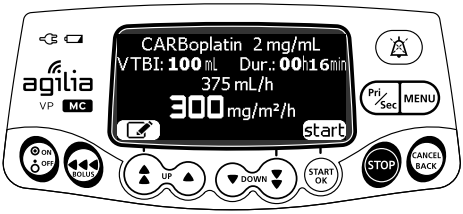
1. Press the arrow keys to program the infusion duration (_h_min), and press **OK**.
The dose rate is automatically calculated.

Duration programming can also be skipped by pressing **OK** to reach Dose field.

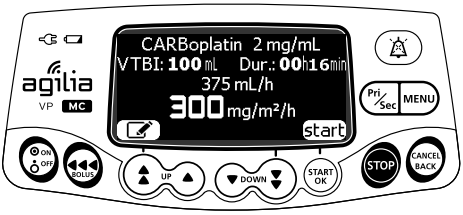


2. Press the arrow keys to program the dose rate, and press **OK**.
Entry of a flow rate automatically calculates the duration.
If duration has been programmed, you can press **OK** to confirm dose rate.

3. After confirming, you will reach Confirmation screen.



4. Press **OK** to confirm the infusion settings, or [✎] to change the settings.



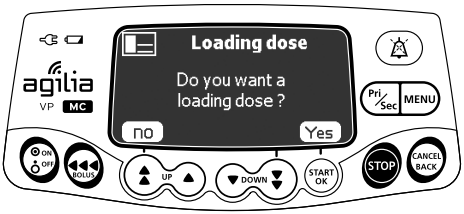
7.4.3 Programming a Loading Dose

Note:
This feature can be enabled or disabled with a compatible Drug Library Software.

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

The screens below will appear prior to starting the infusion.

Selecting a Loading Dose



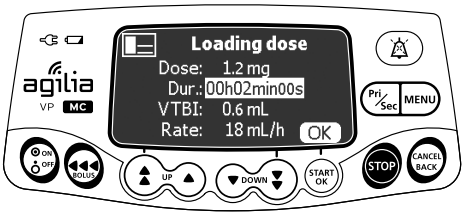
On the loading dose screen:

- Press **no** to return to the programming screen.
- Press **Yes** to program a loading dose prior to starting the primary infusion.

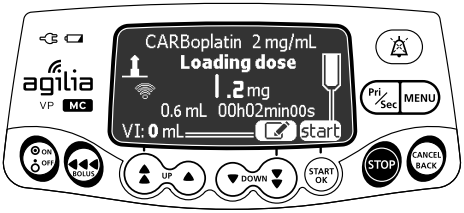
INFORMATION

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

Programming a Loading Dose

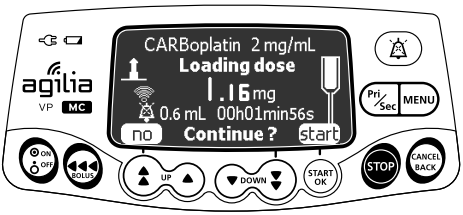


1. Press the arrow keys to enter a value for the dose, and press **OK** to confirm.
2. Press the arrow keys to program the loading dose duration (_h_min_s), and press **OK** to confirm. Single arrow increases seconds, double arrow increases minutes. Increasing to 60 minutes converts to 1 hour.
   The VTBI and the flow rate are automatically calculated based on dose and duration settings.
3. Press **OK** to confirm the loading dose settings.
   If needed, press ✎ *or* CANCEL/BACK *to change the loading dose settings before starting.*



4. Press **start** to initiate the loading dose.
   The screen displays the dose counting down and the VI increasing. Once the loading dose is finished, the pump automatically starts the programmed primary infusion.

Interrupting a Loading Dose

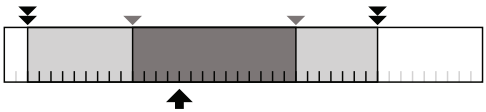


1. To Stop the loading dose, press STOP.
   The screen displays `Continue?`
2. Choose one of the following options:

- Press **no** or STOP to stop the loading dose and proceed to the programmed primary infusion.
- Press **start** to continue with the loading dose.

7.4.4 Programming Beyond Soft Limits

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



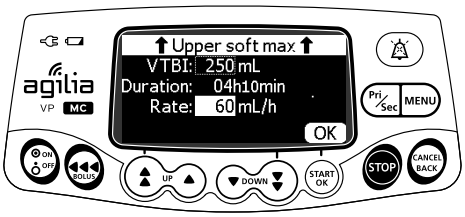
Legend

- Unauthorized Range
- Programmable Range (warning and confirmation)
- Authorized Range
- Hard Limits
- Soft Limits
- Default Value

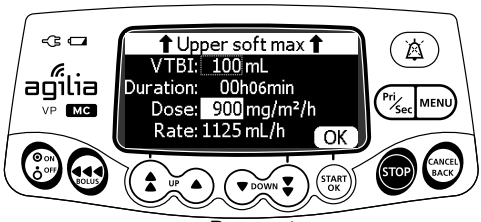
Overriding a Soft Limit

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

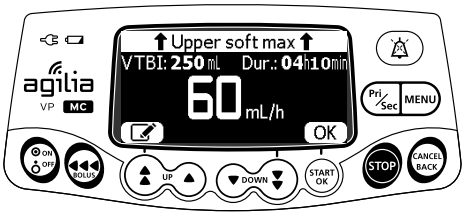


Flow rate

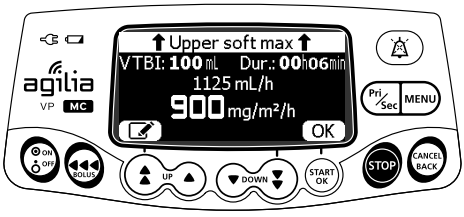


Dose rate

2. Press OK to confirm values.

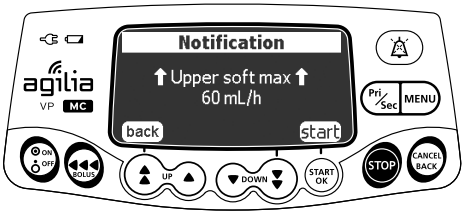


Flow rate

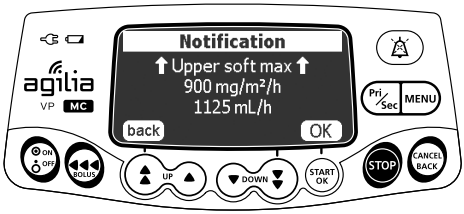


Dose rate

3. Carefully review the program settings.
4. If the displayed settings correspond to the intended flow rate or dose rate, press **OK**.

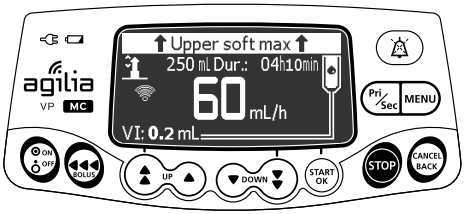


Flow rate

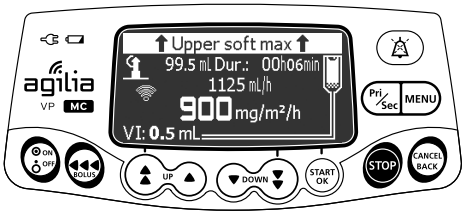


Dose rate

5. Press **OK** or **start** to confirm the soft limit override.



Flow rate

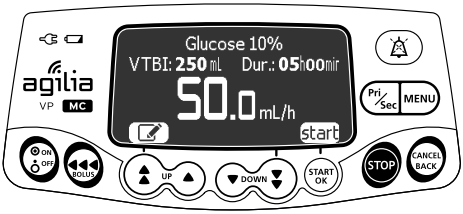


Dose rate

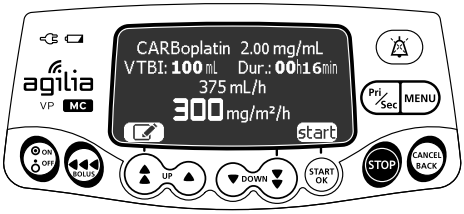
During infusion, the upper or lower soft limit message will alternate with the drug name and concentration at the top of the screen.

7.5 Starting an Infusion

1. Check the administration set integrity.
2. Check that no air remains in the administration set.
3. Confirm that the administration set is correctly installed in the pump.
4. Open the roller clamp.
5. Connect the administration set to the patient's access device.
6. Confirm infusion settings on confirmation screen.



Flow rate



Dose rate

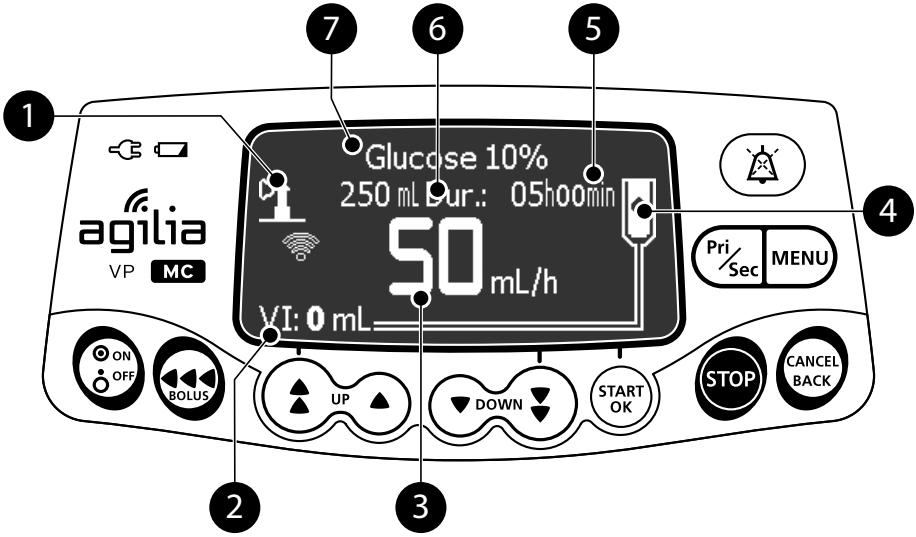
7. Press **start** to start the infusion, or [edit] to edit the infusion settings.

WARNING

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

7.6 Monitoring an Infusion

7.6.1 Monitoring an Infusion when Programmed by Flow Rate



Legend

1. **Custom Profile Icon**
   
   When infusing a drug selected from a drug library, this lighthouse icon is displayed on the screen continuously.

2. **VI** (Volume Infused).
   Will increase during the infusion. To clear VI, see section 8.8, page 104.

3. **Infusion Flow Rate (mL/h)**
   To change the flow rate during an infusion, see section 7.7.2, page 62. The flow rate is displayed with the largest font size.

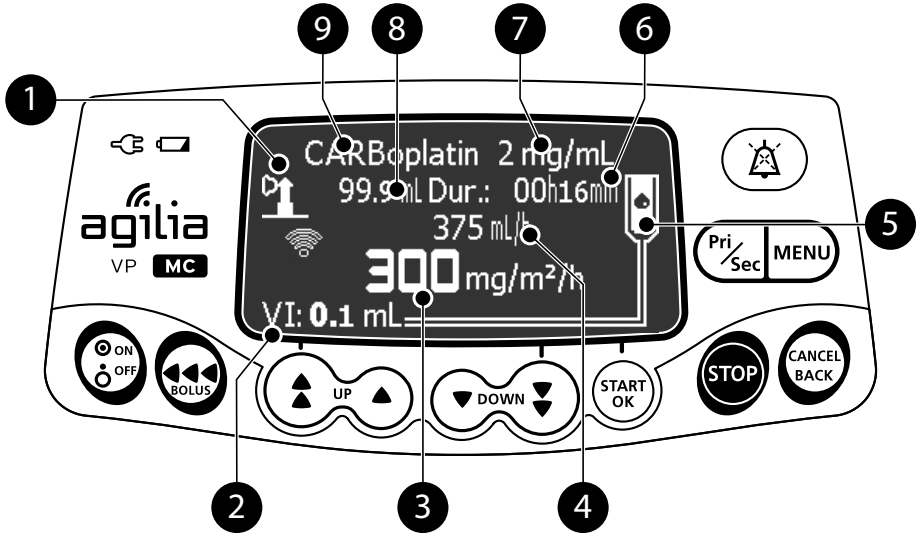
4. **Infusion in Progress**
   The infusion in progress indicator displays falling drops.

5. **Infusion Duration** (Dur.:)
   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 a compatible Drug Library Software for this drug.

6. **VTBI** (Volume To Be Infused).
   Will decrease during the infusion. To change VTBI during an infusion, see section 8.4, page 99.

7. **Drug Name (custom profiles only)**

7.6.2 Monitoring an Infusion when Programmed by Dose Rate



Legend

1. **Custom Profile Icon**
   When infusing a drug selected from a drug library, this lighthouse icon is displayed on the screen continuously.

2. **VI** (Volume Infused).
   Will increase during the infusion. To clear VI, see section 8.8, page 104.

3. **Dose Rate**
   To change the dose rate during an infusion, see section 7.7.2, page 62. Dose 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** (Dur.:)
   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 a compatible Drug Library Software for this drug.

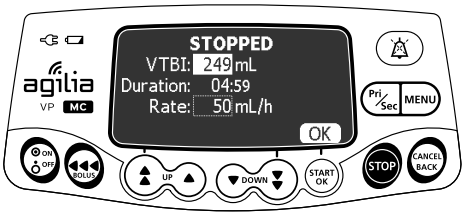
7. **Drug Concentration**

8. **VTBI** (Volume To Be Infused).
   Will decrease during the infusion. To change VTBI during an infusion, see section 8.4, page 99.

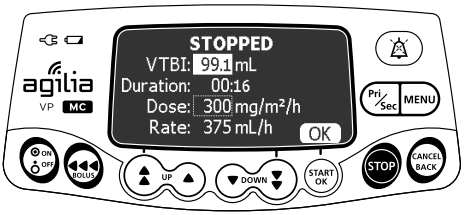
9. **Drug Name (custom profiles only)**

7.7 Functions During Infusion

7.7.1 Stop



Flow rate



Dose rate

To stop the infusion, press STOP.
After 30 seconds, an alarm is generated as a reminder that the infusion is stopped.

To restart the infusion, first confirm or modify the programming settings, then start the infusion. See section 7.4, page 49.

7.7.2 Rate Titration

You can adjust the infusion rate (flow rate or dose rate) during the infusion.

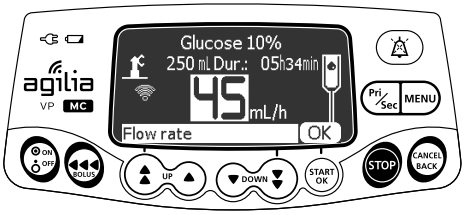
Depending on your pump configuration:

- You may be required to stop the infusion before modifying the infusion rate,

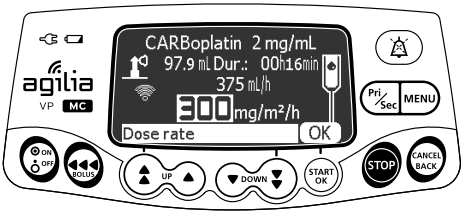
or

- You will be allowed to adjust the infusion rate while the pump is infusing or stopped.

1. If required, stop the infusion, see section 7.7.1, page 62.
2. Press the arrow keys to access and change the flow rate or dose rate.
3. Press **OK** when desired value is reached.



Flow rate



Dose rate

7.7.3 Secondary (Piggyback) Infusions

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 Basic profile configuration and Drug Library Software Profile settings.

Note:

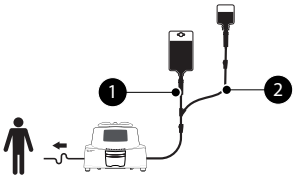
- *This feature can be enabled or disabled in Drug Library Software for custom profiles or in the pump options for Basic Profile.*
- *Secondary is only available if the primary drug selected is set up in the drug library to accept a secondary infusion.*

INFORMATION

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

7.7.3.1 Preparing the Secondary Line

1. Prime the secondary administration line, close roller clamp.
2. Hang the secondary container.
3. Lower the primary container approximately 12 inches (30 cm) lower than the secondary container.
4. If the primary infusion is already infusing, press STOP.
5. Connect the secondary line to the upstream access port of the primary line located above the pump (using aseptic technique).
6. Program secondary infusion (see section 7.7.3.2, page 64. and section 7.7.3.3, page 65.)
7. Open the roller clamp.



Legend

1 Primary Line

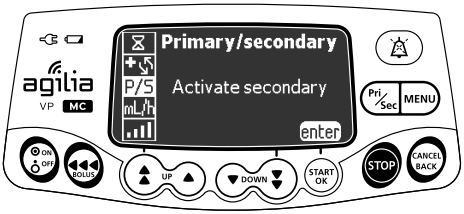
2 Secondary Line

Figure 7.1: Primary and Secondary Infusion

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.

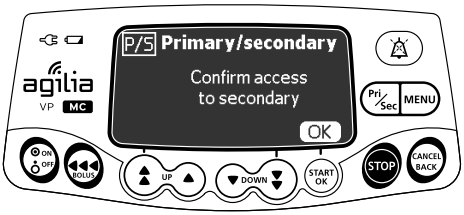
7.7.3.2 Accessing Secondary Infusion



1. Open the Primary / Secondary menu in one of the two following ways:

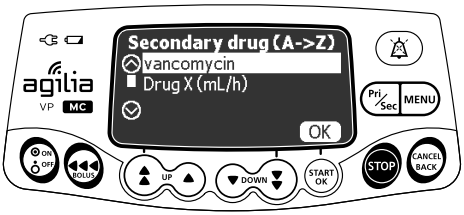
- Press Pri/Sec.
- Through the Menu:
  - Press MENU.
  - Press the arrow keys to select P/S .

2. Press **enter**.



3. Press **OK** to confirm access to the secondary infusion.

7.7.3.3 Programming Secondary Infusion

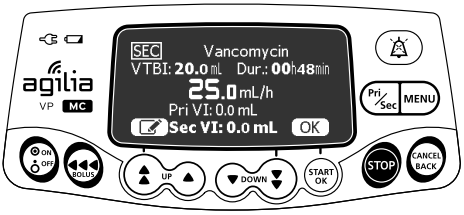


1. Select a secondary drug (only when using a custom profile) and press **OK**. Press the arrow keys to program the secondary VTBI, and press **OK**.

INFORMATION

The secondary infusion default soft and hard limits for flow rate as well as minimum, default and maximum limits for VTBI are defined for each medication.

2. Press the arrow keys to program the infusion duration, and press **OK**.
   The flow rate is automatically calculated.
   Duration programming can also be skipped by pressing **OK** to reach Rate field.
3. Press the arrow keys to program the secondary flow rate and press **OK**.
   Entry of a flow rate automatically calculates the duration.
   If duration has been programmed, you can press **OK** to confirm flow rate.

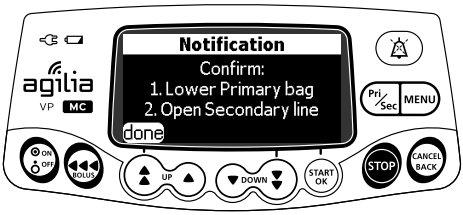


4. After confirming, you will reach Confirmation screen.
5. Press **OK** to confirm the infusion settings, or [✎] to change the settings.

INFORMATION

- **Pri VI** indicates the total primary volume infused since it was last cleared or since a new primary drug was started.
- **Sec VI** indicates the total secondary volume infused since it was last cleared or since a new secondary drug was started.

7.7.3.4 Secondary Infusion Start



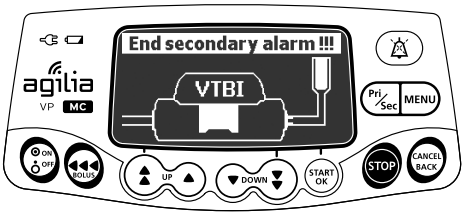
1. Confirm the following:
   - The secondary line is connected to the primary upstream port.
   - The roller clamp is open.
   - The primary container is hung approximately 12 inches (30 cm) below the secondary container.
2. Press **done** to confirm.
3. Press **start** to start the secondary infusion.

7.7.3.5 End of Secondary Infusion

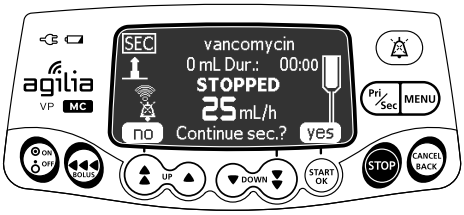
INFORMATION

The near end of infusion alert is not available in secondary infusion.

7.7.3.5.1 Manual Return to Primary Infusion

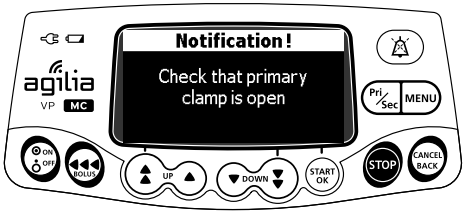


2. Press (🔔) to silence the alarm.



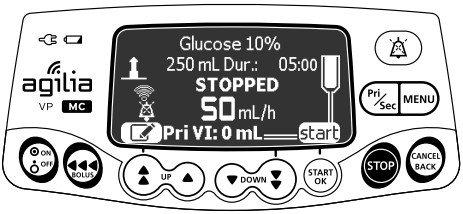
3. Answer the question `Continue sec ?`

- Press **Yes** to program another secondary infusion.
- Press **no** to return to primary infusion.
  A Notification message is displayed (optional).



4. Ensure that the primary line is open.

5. Press (🔔) to acknowledge the message.

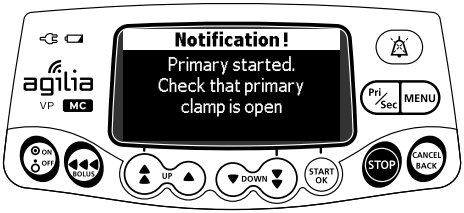


6. Press **start** to resume primary infusion.

7.7.3.5.2 Automatic Return to Primary Infusion

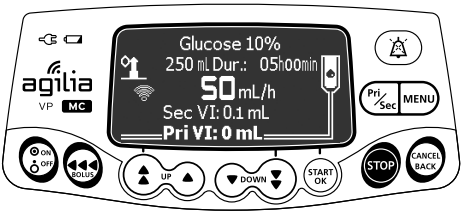
At the end of secondary infusion, a short beep is emitted.

A notification message is displayed (optional).



1. Ensure that the primary clamp is open.

2. Press (🔔) to acknowledge the message.

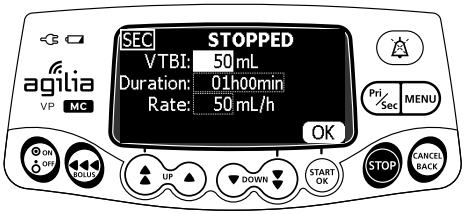


The infusion automatically returns to the programmed primary infusion.

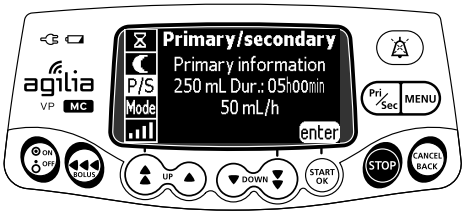
7.7.3.5.3 Discontinue Secondary

To manually return to primary infusion prior to the end of a Secondary infusion:

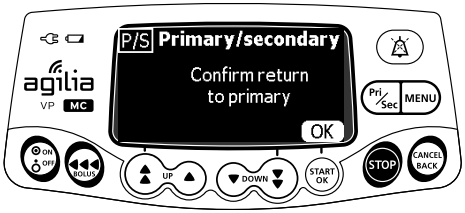
1. Stop Secondary infusion with **Stop** key.



2. Press Pri/Sec key or press Menu and scroll to find P/S menu.



3. Enter P/S menu.
4. Press **OK** to confirm return to primary infusion.



5. Clamp the Secondary line before pressing **Start** to restart primary infusion.

Optional means that the feature can be configured in Basic Profile menu.

7.7.4 Administering a Bolus

INFORMATION

For very low-volume boluses (less than 5 mL for sets with filters and less than 1 mL for sets without filters) at maximal sustainable flow rates, see section "**15.9.3 Bolus Volume Accuracy**" on page 164.

A **bolus** is an extra dose or volume that a pump can deliver from the current infusion.

There are two ways a pump can deliver a bolus during an infusion:

- Programmed bolus,
- Direct bolus.

Note:
These features are enabled within a compatible Drug Library Software. Not all profiles, therapies or drugs may have these features enabled. Check with your pharmacy for facility specific configurations.

INFORMATION

- The bolus volume is added to the Volume Infused (VI).
- Total volume infused (including bolus volume) will not exceed the VTBI of the programmed infusion.
- Both Programmed and Direct Boluses are available for primary infusions.
- Direct Bolus is not available in the Basic Profile.
- The BOLUS key is not enabled when the menu screen is displayed.
- The BOLUS key is not active when the following infusion modes are selected: Ramp-up / ramp-down, Sequential, Secondary.

A **bolus** is an extra dose or volume that a pump can deliver from the current infusion.

There are two ways a pump can deliver a bolus during an infusion:

- Programmed bolus,
- Direct bolus.

Note:
These features are enabled within a compatible Drug Library Software. Not all profiles, therapies or drugs may have these features enabled. Check with your pharmacy for facility specific configurations.

INFORMATION

- The bolus volume is added to the Volume Infused (VI).
- Total volume infused (including bolus volume) will not exceed the VTBI of the programmed infusion.
- Both Programmed and Direct Boluses are available for primary infusions.
- Direct Bolus is not available in the Basic Profile.
- The BOLUS key is not enabled when the menu screen is displayed.
- The BOLUS key is not active when the following infusion modes are selected: Ramp-up / ramp-down, Sequential, Secondary.

Feature	Definition	Configurable parameters		Access key
Programmed Bolus	Used when a specific dose/volume of drug is given over a specific amount of time. These limits are predefined in a compatible Drug Library Software by drug.	Default Dose or Volume (mL, mg, mg/kg*, etc.)	Default Duration (1 min - 24 h)	BOLUS or MENU
Direct Bolus	Used with drugs when titration to effect is needed (i.e. pain relief, sedation)	Maximum Volume (0.1-60 mL)	Flow Rate (50-1500 mL/h)	BOLUS

* For a complete list of dose units of measure, see Units and Conversion Rules, page 169.

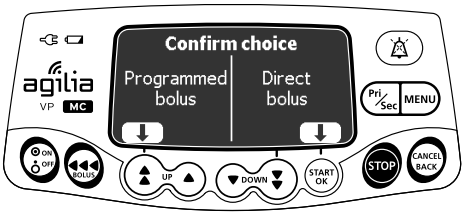


Figure 7.2: Bolus Delivery Screen with both Programmed Bolus and Direct Bolus enabled

Occlusion Pressure Level during a bolus is set to 750 mmHg/100 kPa/14.5 PSI.

INFORMATION

- Programmed Bolus parameters can be adjusted at the bedside within limits defined by a compatible Drug Library Software (Custom Profile).
- Basic Profile Programmed Bolus volume defaults to 0.1 mL on the pump, this can be adjusted at the bedside in accordance with the prescription.
- Direct Bolus parameters cannot be changed at the bedside to exceed the limits defined by a compatible Drug Library Software (Custom Profile).
- Direct Bolus is not available in the Basic Profile.
- Direct bolus is administered while the bolus key is depressed. Direct Bolus will stop when the key is no longer depressed or the volume limit for the Direct Bolus is reached (whichever occurs first).
- Once the volume limit of Direct Bolus is reached, a **Limit reached** message will display on the pump's screen.

7.7.4.1 Programmed Bolus

Note:
Programmed bolus can be enabled or disabled by a compatible Drug Library Software (for Custom Profile) or in the pump options (for Basic Profile).

WARNING

- If you stop the pump prior to initiating a Programmed bolus, the pump will not resume after the Programmed Bolus has been delivered. The pump will remain in the stop mode until you resume the infusion. If the infusion is not resumed within 30 seconds the pump will alarm, **Waiting Start.**
- To ensure continuous infusion after completion of Bolus Delivery DO NOT STOP the pump before accessing the Bolus Function.

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

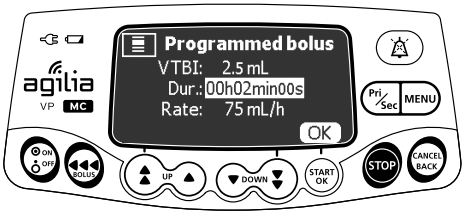
1. Press BOLUS, then ▲ to access Programmed bolus menu.

   Note: in case Direct Bolus is disabled, pressing BOLUS key brings you right to the programmed bolus menu.

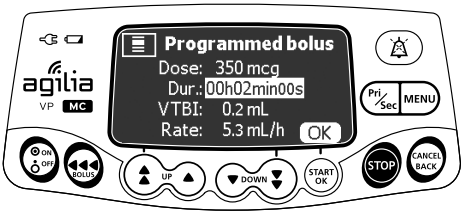
2. Press MENU, and select ☰ in the menu. Press **enter** to confirm.

Programming a Bolus

3. Press the arrow keys to program the bolus volume or dose, and press **OK**.
4. Press the arrow keys to program the bolus duration (_h_min_s), and press **OK**.
   The flow rate is calculated automatically.

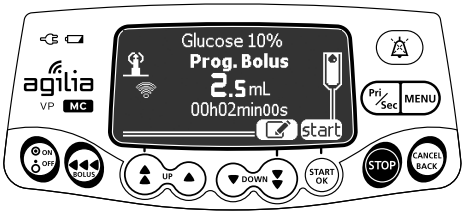


Flow rate

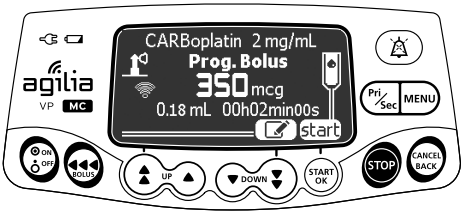


Dose rate

5. Press **START** to start the bolus.



Flow rate



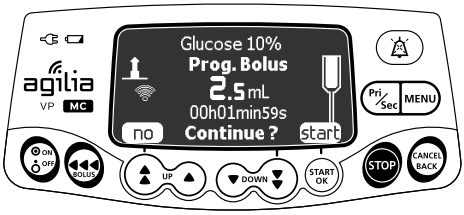
Dose rate

The infusion resumes its previous rate after the bolus is delivered.

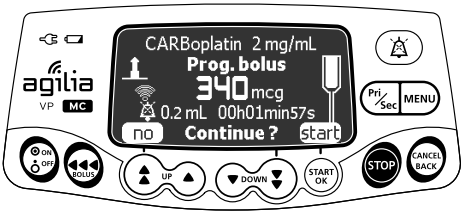
Press ✎ *to change the settings of the last bolus.*

Interrupting a Programmed Bolus

1. Press STOP to interrupt the bolus.



Flow rate



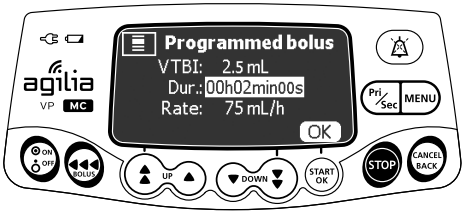
Dose rate

2. Answer the question: `Continue?`

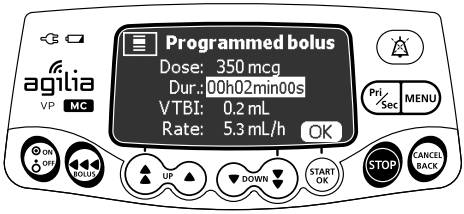
- Press **no** ▲▲ to return to the infusion.
- Press **START** to continue the bolus.

Initiating a Programmed Bolus without resuming the infusion

1. Stop the infusion. Press the key and select Programmed bolus.
2. Press the arrow keys to program the bolus volume or dose, and press **OK**.
3. Press the arrow keys to program the bolus duration (_h_min_s), and press **OK**.
   The flow rate is calculated automatically.

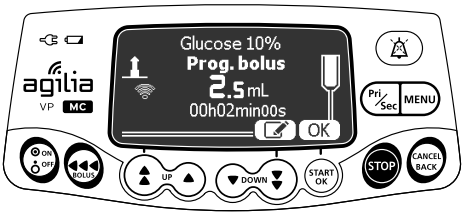


Flow rate

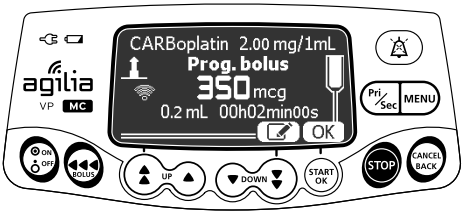


Dose rate

4. Check the right settings on confirmation screen.

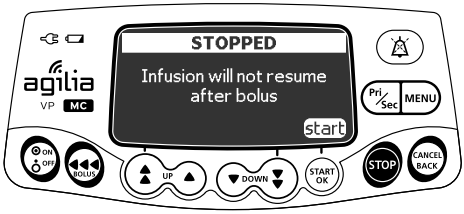


Flow rate



Dose rate

5. Screen displays the information that infusion will not resume after bolus. Press **START** to launch the bolus.



Note:
*If you want your infusion to restart after bolus press **Cancel/Back** or **STOP** key and restart infusion. Program and press **START** to start the bolus.*

6. Press ***START*** to restart infusion.

WARNING

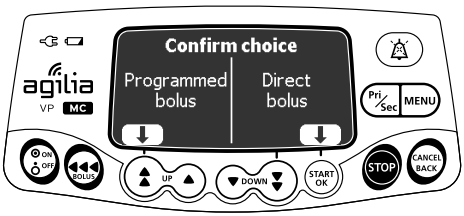
- If you stop the pump prior to initiating a Programmed Bolus, the pump will not resume after the Programmed Bolus has been delivered. The pump will remain in the stop mode until you resume the infusion. If the infusion is not resumed within 30 seconds the pump will alarm, **Waiting Start.**
- To ensure continuous infusion DO NOT STOP the pump before accessing the Bolus Function.

7.7.4.2 Direct Bolus

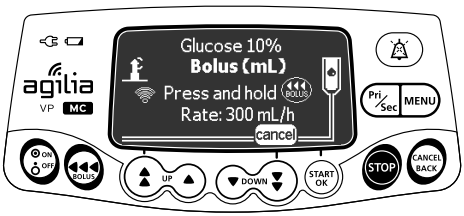
Note:
Direct Bolus can be enabled or disabled by a compatible Drug Library Software (for Custom profile). Direct Bolus is not available in Basic Profile.

To deliver a Direct Bolus

1. During the infusion, press BOLUS.



2. Press START/OK to confirm access to the Direct Bolus function.



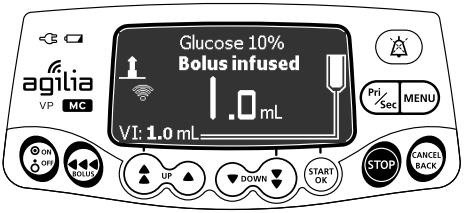
3. Press and hold the BOLUS key to administer the bolus.

4. Monitor the patient until the desired effect is reached.

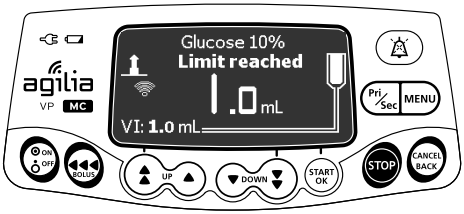
5. Release the BOLUS key to stop the Direct Bolus.

Notes:

- *The bolus volume infused will be displayed on the pump's screen.*



- The infusion resumes its programmed rate after the bolus key is released.
- *Direct bolus is administered while the bolus key is depressed. Direct Bolus will stop when the key is no longer depressed or the volume limit for the Direct Bolus is reached (whichever occurs first).*
- *Once the volume limit is reached, a "Limit reached" message will display on the pump's screen.*



7.8 Completing an Infusion

7.8.1 Near End of Infusion Alert

Note:
This feature can be enabled or disabled with a compatible Drug Library Software (custom profiles) or in the pump options (Basic Profile). For more information, refer to the technical manual.

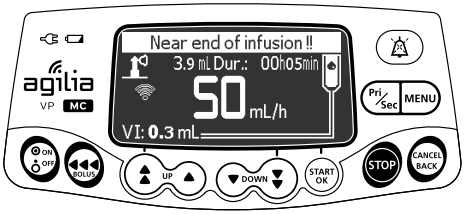
Prior to the end of an infusion, a **near end of infusion** alert is automatically triggered. The following happens:

- An audible alarm is triggered.
- An alarm message appears on the pump's screen.
- The infusion indicator lights (LEDs) flash yellow with green running lights.

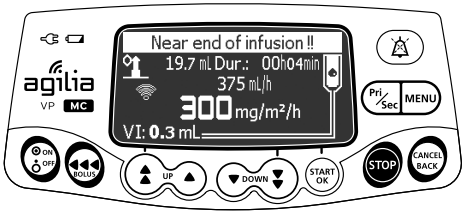
Near end of infusion alert is triggered when the first of the three criteria below is reached.

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 %	0 (disabled)
Remaining VTBI	From 0 to 50 mL	0 (disabled)

Silencing Near End of Infusion Alert



Flow rate



Dose rate

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

7.8.2 End of Infusion

After completion of the VTBI, the pump alarms and issues End of Infusion alarm.

1. End of Infusion with KVO disabled
2. End of Infusion with KVO enabled

Keep Vein Open (KVO) - KVO rate starts at the completion of a primary infusion (VTBI to zero), the infusion will continue at the KVO rate configured or whichever is lower.

The KVO rate is configurable with a compatible Drug Library Software (Custom profiles), or in the pump options (Basic Profile); configured between 0-20 mL/h (defaults zero).

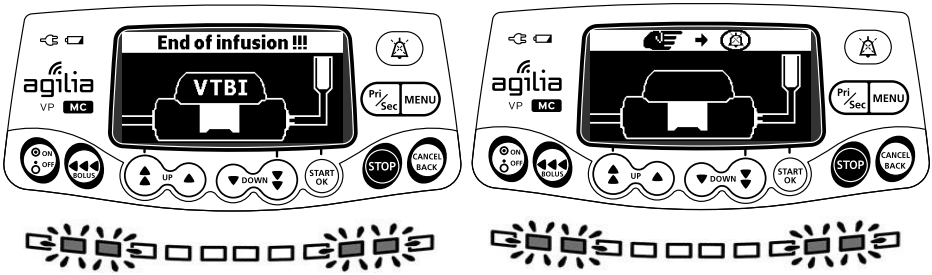
INFORMATION

- For more information, refer to the pump's Technical manual or Drug Library Software User's Guide.

7.8.2.1 End of Infusion (KVO Disabled)

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

- Pump Stops infusing.
- An audible High-Priority Alarm is triggered.
- An alarm message appears on the pump's screen.
- The infusion indicator lights (LEDs) flash red.



Addressing End of Infusion with KVO disabled

1. Press (🔔) to silence the alarm.
   Pump is silenced for:
   - 15 seconds when using a compatible Drug Library Software (Custom Profiles)
   - 2 minutes in Basic Profile.
2. Pump displays programming screen:
   - Drug selection when using a compatible Drug Library Software (Custom Profiles)
   - Infusion programming in Basic Profile.
3. Prepare the new container and adjust the settings for a new Infusion OR power off the pump.

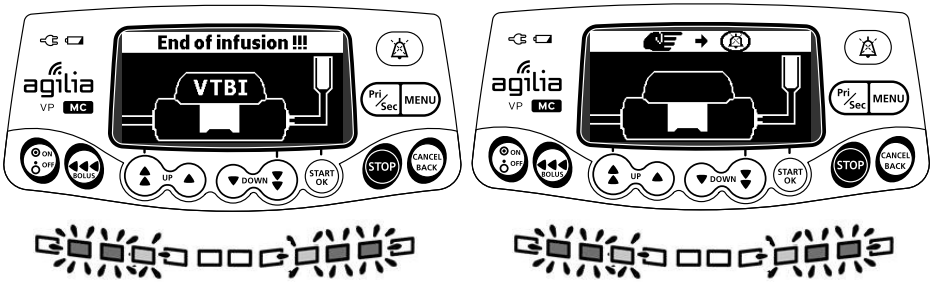
7.8.2.2 End of Infusion (KVO Enabled)

INFORMATION

- End of Infusion settings: KVO rate and silence duration are configurable with a compatible Drug Library Software (Custom Profiles).
- The end of Infusion alarm behavior will be consistent with or without KVO enabled. An audible and visual high priority alarm will occur at the End of Infusion and reoccur per configuration between 1 - 5 min (factory default 2 min).
- For more information, refer to the pump Technical manual or Drug Library Software User's Guide.

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

- An audible alarm is triggered.
- An alarm message appears on the pump's screen.
- The infusion indicator lights (LEDs) flashing red with two ON green (LEDs) indicating the high priority alarm with KVO infusing.
- KVO rate is infusing at the configured or the current infusion rate, whichever is lower. If the programmed infusion rate is lower than the configured KVO rate, the pump continues infusing at the programmed rate.



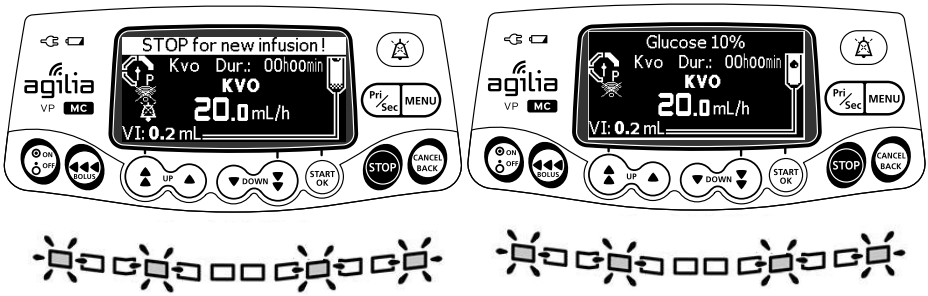
KVO Specifications	Basic Profile	Custom Profile(s)
Configurable	Yes, pump menu	Yes, by profile in the compatible Drug Library Software
Default Setting	Disabled/OFF	Disabled/OFF
Flow rate	1-20 mL/h (mandatory field)	1-20 mL/h (mandatory field)
Silence Key Duration	1 to 5 minutes (default 2 minutes)	1 to 5 minutes (default 2 minutes)
End of Infusion Alarm	High priority audible alarm with flashing red LEDs and ON green LEDs	High priority audible alarm with flashing red LEDs and ON green LEDs
During KVO Infusion	Pump Status: ON yellow LEDs and ON green LEDs	Pump Status: ON yellow LEDs and ON green LEDs
Reminder Alarm	High priority audible alarm with flashing red LEDs and ON green LEDs	High priority audible alarm with flashing red LEDs and ON green LEDs

Refer to the compatible Drug Library Software User's Guide to configure the profiles.

Addressing End of Infusion with KVO enabled

Infusion complete, VTBI is zero.

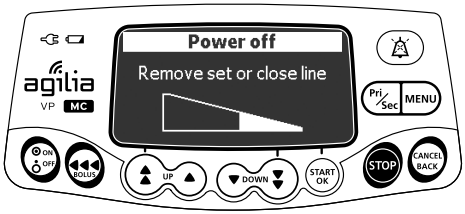
1. Press (🔔) to silence the alarm.
2. When alarm silenced, the pump transitions to the KVO Infusing screen.



The infusion indicator lights (LEDS) display 2 ON yellow and 2 ON green.

If **No User Action** is taken, the high priority audible/visual alarm recurs in configured silenced time (default 2 minutes, maximum 5 minutes).

7.8.3 Powering off



You can power off the pump as follows:

1. Press (STOP) to stop the infusion.
2. Close the roller clamp.
3. Press and hold (⏻) until the pump powers off.

7.9 Additional 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 section 8.15, page 113.
For more information on calculation rules, see section 15.10, page 168.

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

For more information, see section 7.4, page 49.

7.9.2 Ramp-up / Ramp-down

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

- Ramp-up: the flow rate gradually increases up to a programmed value
- Plateau: the flow rate remains constant
- Ramp-down: the flow rate gradually decreases to 0.

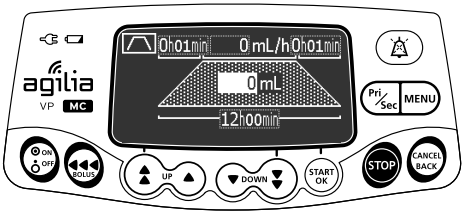
INFORMATION

Ramp-up / Ramp Down is used for Total Parenteral Nutrition (TPN) or other therapies that require a ramp-up period to a plateau rate in mL/h and a ramp down period until the total prescribed period of time has elapsed.

7.9.2.1 Programming the Ramp-up / Ramp-down Infusion

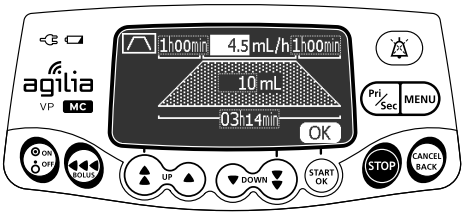
Program an infusion with the ramp-up / ramp-down infusion mode as follows:

1. In the "Mode" menu, select the ramp-up / ramp-down infusion mode, see section 8.15, page 113.
2. Press **OK** to confirm the new infusion mode.

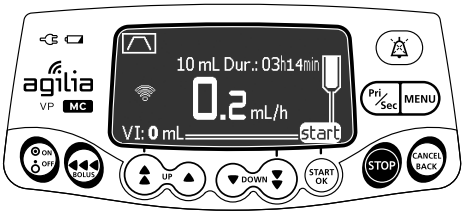


3. Press the arrow keys to program the VTBI, and press **OK**.
4. Press the arrow keys to program the total infusion duration (_h_min), and press **OK**.
5. Press the arrow keys to program the ramp-up duration (_h_min), and press **OK**.
6. Press the arrow keys to program the ramp-down duration (_h_min),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

Note: The plateau flow rate is calculated automatically during steps 3 to 6. Review and adjust the plateau flow rate if needed. Adjusting the plateau flow rate changes the overall infusion time while maintaining the VTBI and ramp-up and ramp-down durations.



8. Press **OK** to confirm, or to cancel the settings.

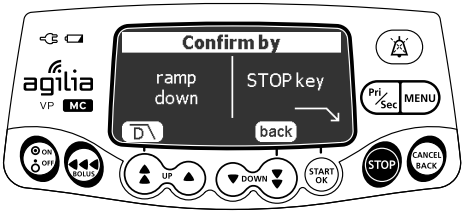


9. Press **start** to start the infusion.

INFORMATION

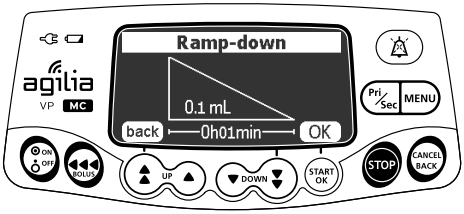
During the infusion, a part of the ramp symbol blinks. This part corresponds to the current infusion phase.

7.9.2.2 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 **back** 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.**

7.9.3 Sequential Infusion

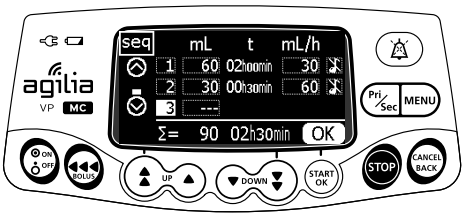
You can program up to 20 infusion sequences with the sequential infusion mode, each with their own VTBI and flow rate.

You can also program the following sequences:

- ***Hold**:* programming of a pause between two sequences
- ***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:

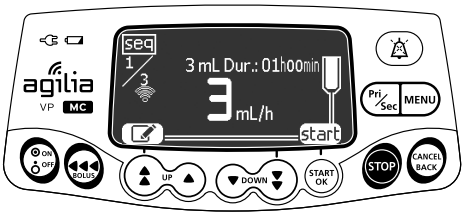
1. In the "Mode" menu, select the sequential infusion mode, see section 8.15, page 113.
2. Press **OK** to confirm the new infusion mode.



3. Press **OK** to program sequence 1, or the down arrow key to move to sequence 2.
4. 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 enable or mute the end of sequence beep, and press **OK**.
Hold	▪ Press the arrow keys to select **Hold**, and press **OK**. ▪ Press the arrow keys to select the pause duration, and press **OK**. ▪ Press the arrow keys to enable or mute the end of sequence beep, and press **OK**. ☞ *Other sequences can be programmed after a "Hold" 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 an "End" sequence.*



5. Press **start** to start the infusion.

INFORMATION

To modify a sequential infusion, see section 8.17, page 115.
You can only modify a sequence that has not started yet.

7.10 Other Functions

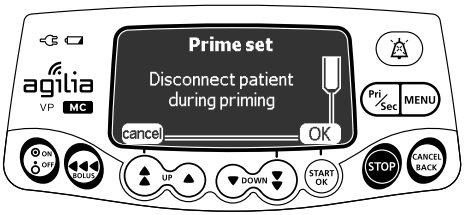
7.10.1 Priming the Administration Set

Note:
This feature can be enabled or disabled with a compatible Drug Library Software (custom profiles) or in the pump options (Basic Profile).

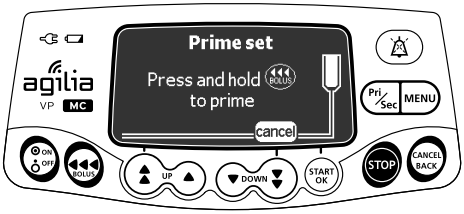
WARNING

- Air in the administration set presents the risk of injury, death or other serious adverse reactions.
- During priming, make sure that the administration set is not connected to the patient.
- The pump does not detect air bubbles when priming.

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 **OK** to proceed.



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

INFORMATION

- Priming is only accessible prior to starting the infusion.
- User can repeat priming as needed.
- 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 repeat priming.
- When using the pump to prime the volume is subtracted from the VTBI.

7.10.2 Air-in-line Conditions

- Incorrect or incomplete priming (either manually or using the pump).
- Fluid outgassing resulting from infusing chilled fluids or certain medications known to routinely outgas. To prevent outgassing allow fluid to warm to room temperature.
- Damage to administration set may cause ingress of air into the system.

In cases where air in the administration set is a concern, use of an air eliminating filter may be clinically appropriate.

Use clinical judgment to assess if air should be removed from the line per established facility protocols. Air can be removed by re-priming the administration set, replacing and re-priming administration set, or removing the air at a lower access site.

7.10.3 Advancing an Air Bubble

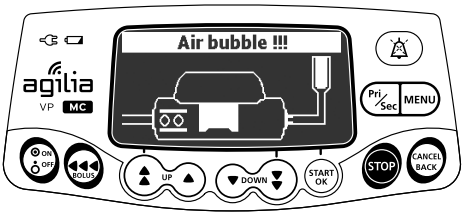
Note:
This feature can be enabled or disabled with a compatible Drug Library Software (custom profiles) or in the pump options (Basic Profile).

An air-in-line alarm is triggered when an air bubble is detected by the air sensor. The air sensor is located behind the pump door downstream from the SafeClip (blue anti-free-flow clamp).

If enabled, you can use the Advance Air Bubble function to advance the air bubble beyond the air detector to view the size of the air bubble.

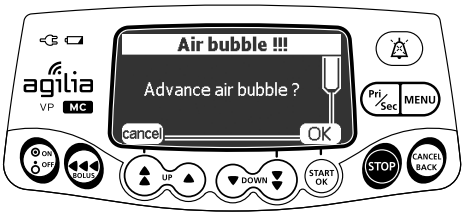
WARNING

- Air-in-line presents the risk of injury, death or other serious adverse reactions.
- Advancing an air bubble past the air detection sensor does not remove air from the line. Use clinical judgement to assess if air should be removed from the line per established facility protocols.

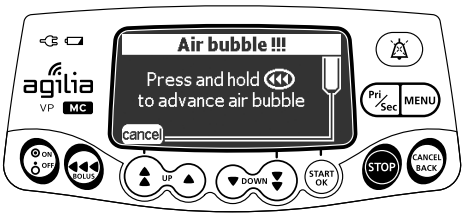


1. Press (🔔) to silence the audible signal for up to 2 minutes.

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 **cancel** to cancel the advance air bubble function.

INFORMATION

- Use of the Advance Air Bubble function is intended to allow the clinician to view the size of the air bubble in the administration set. Use clinical judgement to assess if air should be removed from the administration set per established facility protocols.
- The air bubble advances at the programmed rate. The maximum volume of air advanced equals the configured air bubble detection setting.

7.10.4 Auto-restart

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

The auto-restart feature can be enabled or disabled with compatible Drug Library Software (custom profiles) or by using the pump options (Basic Profile).

INFORMATION

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.

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

- Audible and visual alerts are generated to inform the user that the pressure threshold has been reached.
- The infusion is stopped.
- The pressure sensor continuously measures the downstream line-pressure for a configurable period of time:
  - If the pressure decreases below a configurable value, the infusion automatically restarts.
  - If the pressure does not decrease, the downstream occlusion alarm is generated.

When addressing or clearing an occlusion:

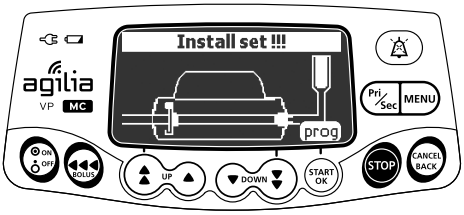
WARNING

Ensure the fluid flow to the patient is clamped to prevent administering an unintended bolus. An occlusion may pressurize the infusion tubing, which can result in an unintended bolus of drug when the occlusion is cleared. In order to prevent this additional bolus, disconnect the tubing from patient to relieve the excess pressure or through a stopcock, if present. The healthcare professional should weigh the relative risks of disconnection with the risks of an unintended bolus of drug.

INFORMATION

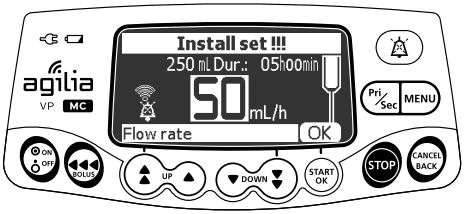
When infusing with critical drugs or on vulnerable patients (such as young pediatric patients), pay special attention to configuring Auto-restart to meet clinical requirements.

7.10.5 Pre-programming the Pump



You can program the pump before installing the administration set.

1. Press ⏻ to power on the pump.
   `Install set !!!` *is displayed on top of the pump's screen.*
2. Make sure the pump door is closed.
   *The **prog** symbol is displayed.*
3. Press **prog**.
4. Program the infusion.
   See section 7.4, page 49.



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

8 Menus

8.1 Overview

8.1.1 Commands

Operation	Key
Access menu or exit menu	MENU
Select	⏫ 🔼 🔽 ⏬
Confirm	START OK (corresponds to **enter** on the screen)
Select ☑ / Deselect ☐	⏫

8.1.2 Menu Description

Menu	Symbol	Stop Infusion Required	Associated Procedure
Profile	Pro	NO	▪ Displaying active profile information, page 94.
Pressure		NO	▪ Pressure, page 95. ▪ Enabling / Desabling Auto-restart, page 90.
Volume to be infused	VTBI	NO	▪ Changing VTBI, page 99.
Keypad lock status		NO	▪ Locking / Unlocking the keypad, page 100.
Keypad automatic lock	AUTO	NO	▪ Keypad Automatic Lock, page 102.
Battery life		NO	▪ Viewing the battery life, page 104.
Volume Infused Dose Infused	mL?	NO	▪ Viewing and clearing the volume or dose infused, page 104.
Pause		YES	▪ Programming a pause, page 106.
Drug		YES	▪ Changing the drug selection, page 108.
Patient		NO	▪ Changing a patient's weight or body surface area, page 109.

Menu	Symbol	Stop Infusion Required	Associated Procedure
Day/Night mode		NO	▪ Switching between day mode and night mode, page 110.
Primary / Secondary	P/S	YES	▪ Programming a secondary infusion or returning to a Primary infusion, page 112.
Programmed bolus		NO	▪ Programming a bolus, page 112.
Infusion mode	Mode	YES	▪ Changing the infusion mode, page 113.
Ramp-up / Ramp-down		YES	▪ Modifying a ramp-up/ramp-down infusion, page 114.
Sequential	seq	YES	▪ Modifying a sequential infusion, page 115.
Alarm volume		NO	▪ Adjusting the alarm volume, page 116.
View flow rate history		NO	▪ Viewing flow rate history, page 117.
View pressure history		NO	▪ Viewing pressure history, page 118.
View event log		NO	▪ Viewing the event log, page 119.
Date/Time		NO	▪ Setting up the date and time, page 120.
Maintenance		NO	▪ Displaying maintenance information, page 121.
Library information		NO	▪ Displaying drug library information, page 122.
Clinical information		NO	▪ Viewing remaining time before clinical information display, page 123.
Data Set	DS	NO	▪ Displaying active data set information, page 124.

<u>Note</u>:

The displayed menu may change depending on the pump configuration.

Some menu items are optional (optional) and may not be available depending on the pump configuration.

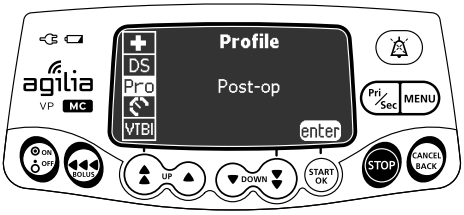
For more information on factory configuration, refer to Appendix: Factory Configuration, page 216.

8.2 Profile

Symbol	Pro
Procedure	Displaying active profile information
Stop Infusion Required	No

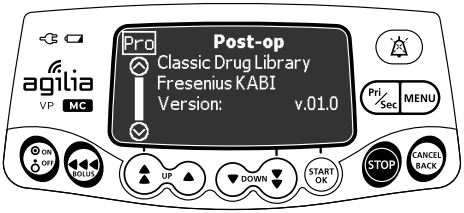
INFORMATION

If current Profile is not correct, turn the pump OFF and ON again to access Profile selection.



You can display the active profile name as follows:

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



8.3 Pressure

Symbol	
Procedure	Modifying the pressure threshold (occlusion alarm) and pressure threshold modes
Stop Infusion Required	No

8.3.1 Configuring the Pressure Threshold Mode Prior to Use

When the downstream line pressure exceeds the pressure threshold, the pump triggers a downstream occlusion alarm. The pump offers one of two user modes for setting pressure thresholds:

- **Variable** mode  : provides an extended range of pressure thresholds to optimize pump performance. This is the default mode for the factory-delivered Basic Profile
- **3 levels** mode: allows rapid selection by displaying only three preset values: low  , medium  , and high  .

To change and configure the pressure threshold mode, use either:

- The pump options to modify the factory delivered Basic Profile. See Options on page 125.
- Compatible drug library software (such as Vigilant Master Med (VMM)) to create and modify custom drug library profiles.

The Pressure Threshold Mode may only be changed by technical users.

8.3.2 Configuring the Pressure Threshold During Use

Clinical users (including at the bedside) can change the occlusion alarm pressure threshold settings before and during an infusion. The choice of pressure thresholds is set by the drug library profile (Basic Profile or a Custom Profile).

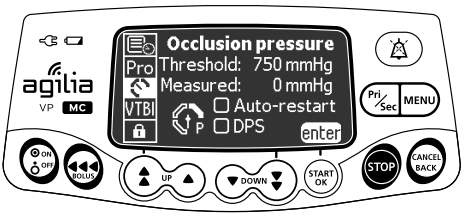
8.3.2.1 Recommended Initial Pressure Threshold Settings

The following table shows the initial recommended Pressure Threshold settings for different infusion flow rates:

Target Infusion Flow Rate	Recommended Pressure Threshold	Expected Time to Detect Downstream Occlusion
0.1 mL/h	50 mmHg	46.5 ± 9 minutes
0.5 mL/h	50 mmHg	7.0 ± 1.7 minutes
1 mL/h	50 mmHg	4.5 ± 0.6 minutes
1.5 mL/h	100 mmHg	3.8 ± 1.7 minutes
2 mL/h	150 mmHg	5.0 ± 0.2 minutes
5 mL/h	200 mmHg	3.0 ± 0.9 minutes
10 mL/h	200 mmHg	1.7 ± 0.3 minutes
10.1 to 1,500 mL/h	200 to 750 mmHg	Less than 5 minutes
1,500 mL/h	750 mmHg	12.6 ± 4.9 seconds

8.3.2.2 Setting the Pressure Threshold

To view the pressure threshold setting and the downstream pressure measured during an active infusion, use the Occlusion pressure screen shown here:

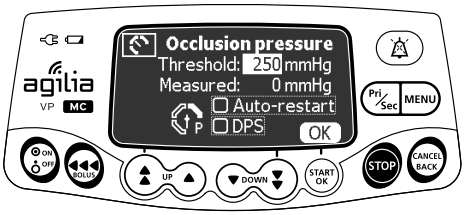


You can modify the pressure threshold as follows:

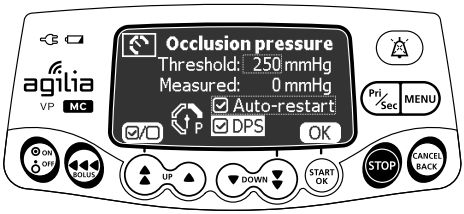
1. Press MENU.

2. Press the arrow keys to select .

3. Press **enter** to access the **Occlusion pressure** screen.



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



6. Press ☑/☐ to enable or disable the Auto-restart function (optional). Press **OK** to confirm.
   To review the Auto-restart setting, see section 15.8, page 159.
7. Press ☑/☐ to enable or disable the DPS function (optional).
8. Press **OK** to confirm.

To review the pressure settings, see section 15.8, page 159. For additional information, see Pressure Alarms on page 139.

8.3.2.3 Adjusting the Pressure Threshold Settings During an Active Infusion

WARNING

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 1 mL per hour): consider occlusion pressure threshold setting and adjust it, as necessary. The lower the occlusion pressure threshold setting is, the shorter the occlusion detection time will be. However, when infusing viscous or thick fluids (e.g., lipids), the occlusion pressure threshold setting may need to be adjusted to a higher value to reduce false alarms.

Note: When infusing at flow rates of less than 1mL/h, the time to detect occlusion may be more than 5 minutes: monitor the patient and if there is a lack of patient clinical response, check for occlusion.

8.3.2.4 Responding to Occlusion Alarms

When the alarm pressure threshold is reached, an occlusion alarm is triggered: you must silence the alarm, resolve the occlusion and restart the infusion. If there is no occlusion, see on page 98.

When addressing or clearing an occlusion:

WARNING

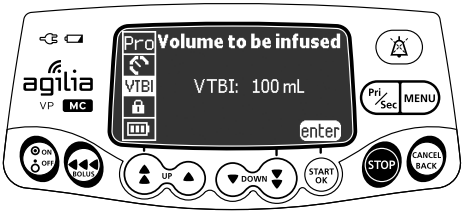
Ensure the fluid flow to the patient is clamped to prevent administering an unintended bolus. An occlusion may pressurize the infusion tubing, which can result in an unintended bolus of drug when the occlusion is cleared. In order to prevent this additional bolus, disconnect the tubing from patient to relieve the excess pressure or through a stopcock, if present. The healthcare professional should weigh the relative risks of disconnection with the risks of an unintended bolus of drug.

INFORMATION

- For more information on the Auto-restart function, see section 7.10.4, page 90.
- To review the Auto-restart setting, see section 15.8, page 159.
- The Dynamic Pressure System (DPS) informs the user of any sudden rise or drop in pressure before the pressure threshold 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 thresholds be adjusted to the same level.

8.4 Volume To Be Infused (VTBI)

Symbol	VTBI
Procedure	Changing VTBI
Stop Infusion Required	No



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** to confirm.

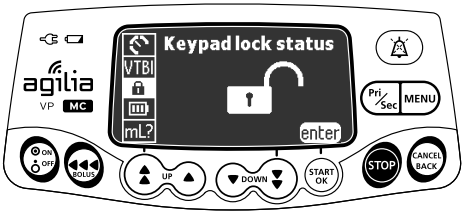
8.5 Keypad Lock Status

Note:
This feature can be enabled or disabled with a compatible Drug Library Software (custom profiles) or in the pump options (Basic Profile).

Symbol	
Procedure	Locking / Unlocking the keypad
Stop Infusion Required	No

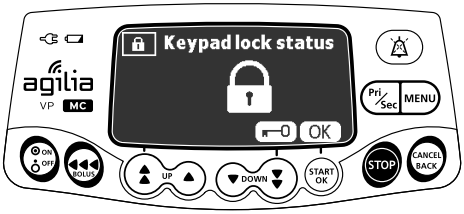
You can use this feature to avoid inadvertent key presses. Depending on the device configuration the keypad lock and unlock code can be enabled or disabled.

Locking the Keypad



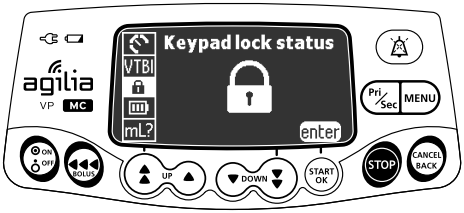
You can lock the keypad as follows:

1. Press MENU.
2. Press the arrow keys to select .
3. Press **enter**.
4. Press to lock the keypad.
   The keypad is locked and the screen displays .



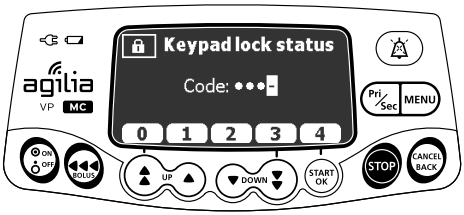
5. Press **OK** to confirm.

Unlocking the Keypad

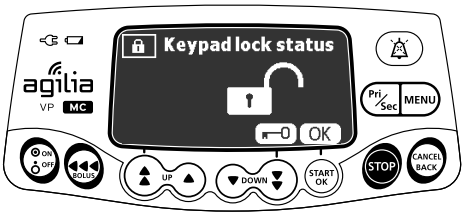


You can unlock the keypad as follows:

1. Press MENU.
2. Press the arrow keys to select 🔒 .
3. Press **enter**.
4. If a code is required, press the keys to enter the unlock code.
   The keypad is unlocked.



5. If no code is required, press 🔑 .
   The keypad is unlocked and the screen displays 🔓.



6. Press **OK** to confirm.

INFORMATION

- The STOP and ⚠ keys remain functional when the keypad is locked.
- During keypad lock, the START/OK 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 retained when the pump is powered off and powered back on.
- In case of forgotten unlock code, contact your biomedical department or the drug library representative at your facility.

8.6 Keypad Automatic Lock

WARNING

- The pump should be protected against unauthorized physical access.
- The keypad automatic lock can be enabled to reduce the risk of unauthorized access, but is not a replacement for other facility access controls such as door lock, card access or security guards.

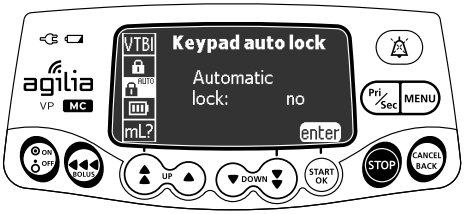
Note:
This feature can be enabled or disabled with a compatible Drug Library Software (custom profiles) or in the pump options (Basic Profile).

Symbol	AUTO
Procedure	Enabling / Disabling the keypad automatic lock
Stop Infusion Required	No

You can use this feature to avoid inadvertent key presses. Depending on the device configuration the keypad lock and unlock code is available or not.

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 enable the Keypad Automatic Lock as follows:

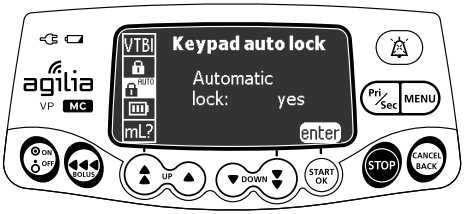
1. Press MENU.
2. Press the arrow keys to select AUTO.
3. Press **enter**.
4. Press the arrow keys to set the Automatic lock to "yes".

5. Press **OK**.
   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.

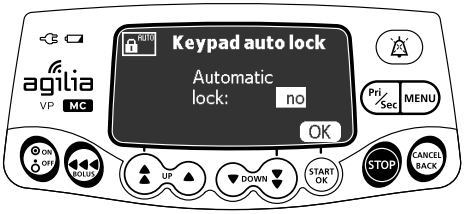
Deactivating the Keypad Automatic Lock

You can disable the Keypad Automatic Lock as follows:

1. Unlock the keypad: see Unlocking the Keypad, page 101.
2. Press MENU.
3. Press the arrow keys to select AUTO.



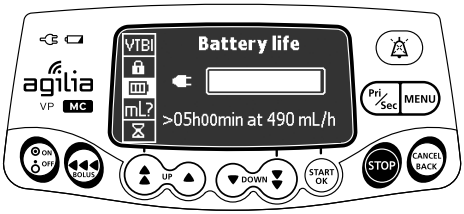
4. Press **enter**.
5. Press the arrow keys to set the Automatic lock to "no".



6. Press **OK**.

8.7 Battery Life

Symbol	
Procedure	Viewing the battery life
Stop Infusion Required	No



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 symbols displayed on the screen indicate the following:

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

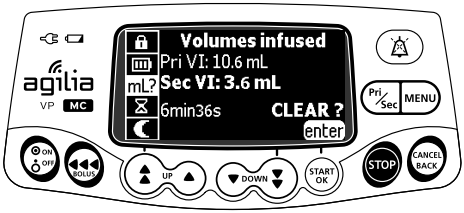
8.8 Volume Infused / Dose Infused

Symbol	mL?
Procedure	Viewing and clearing the volume or dose infused
Stop Infusion Required	No

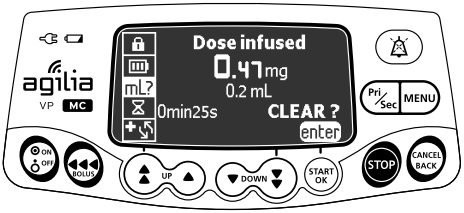
The screen displays the time (lower left) since last VI or DI clearance.

The total volume or total dose infused includes primary and secondary.

User can clear VI or DI and related time as follows:

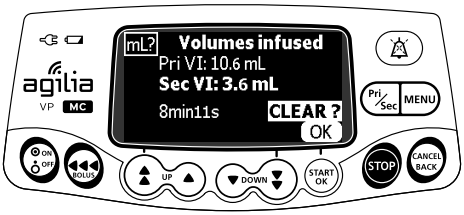


Pri/Sec



Dose rate

1. Press MENU to enter the menu list. This action can be done during an active infusion or when the infusion is stopped.
2. Scroll with arrow keys to select mL? .
3. To access the VI / DI information, press **enter**.



4. To clear the volume infused or dose infused and related time, press **OK**.

INFORMATION

Primary cumulative amount of drug infused since last cleared is displayed by Volume Infused (VI) in Flow Rate or Dose Infused (DI) in Dose Rate.

Changing a primary drug resets the infusion settings.

Loading doses and bolus doses are added to the related infusion.

Secondary volume infused is cleared at each different secondary drug infusion.

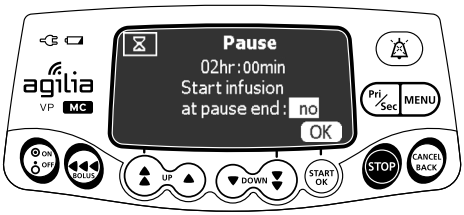
To view the volume or dose infused after clearing, enter the View event log menu.

The volume or dose infused is kept when "Same Infusion" and "Same Therapy" are retained when turning back on the pump.

If the "Same Infusion" and "Same Therapy" are not retained, the VI and DI can be retrieved after Profile selection and before starting a new infusion in View event log menu (see section 8.21, page 119).

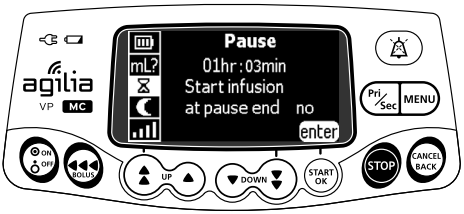
8.9 Pause

Symbol	⧖
Procedure	Programming a pause
Stop Infusion Required	Yes

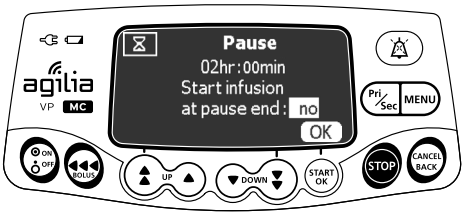


You can program a pause as follows:

1. Press STOP to stop the infusion.
2. Press MENU.
3. Scroll the menu list with the arrow keys to select ⧖ .
4. Press **enter**.



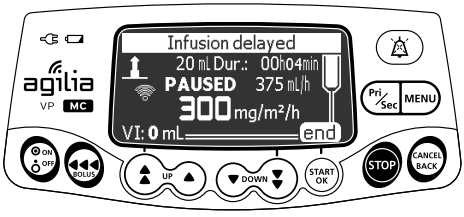
5. Press the arrow keys to program the pause duration in hours and minutes, and press **OK**.



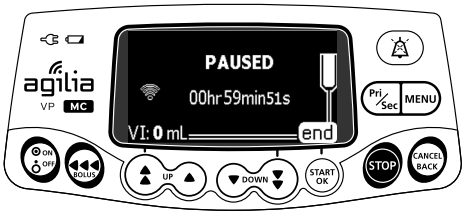
*The default value is **no**.*
Arrow keys allow to switch between **no** and **yes**.

6. Select **yes** with any arrow key to automatically restart infusion at pause end**.**
   OR
   Keep **no** for the pump to wait for user action at pause end**.**
7. Press **OK** to begin the programmed pause.

To restart the infusion before the end of the pause period.



Infusion delayed - Automatic resume



Pause - Manual resume

INFORMATION

If the "start infusion at pause end" is enabled, there will be an audible alert then the infusion will start automatically.

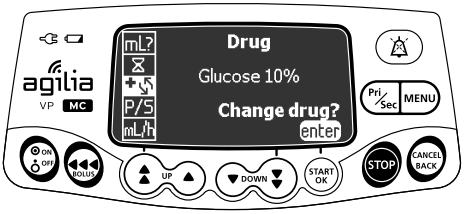
1. Press **end.**
2. Restart infusion pressing **start**.

INFORMATION

If you do not enable the "start infusion at pause end" option, an audible information signal is generated at the end of the pause. The infusion must be started manually to continue the infusion.

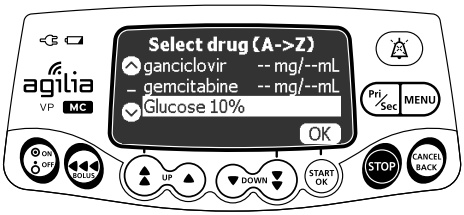
8.10 Drug

Symbol	✚↺
Procedure	Changing the drug selection
Stop Infusion Required	Yes



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** 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 CANCEL/BACK then ✎ to select another drug.
10. Program the infusion for the new drug.

INFORMATION

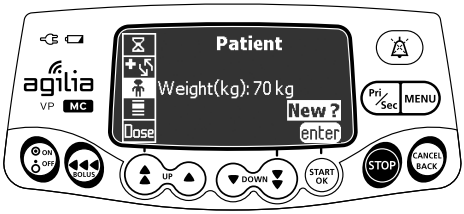
- Changing a drug resets the infusion settings.
- If the previous infusion was programmed by flow rate, the new drug's confirmation screen will display VI (Volume Infused).
- If the previous infusion was programmed by dose rate, the new drug's confirmation screen will display DI (Dose Infused).

8.11 Patient

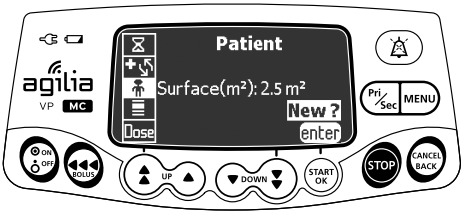
Symbol	
Procedure	Changing a patient's weight or body surface area
Stop Infusion Required	No

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. The screen will read **New?**. Press **enter**.
4. Press **OK** to change the patient's weight or body surface area.
5. Press **OK** to confirm the infusion settings: drug selection, clinical indicator (if configured) and concentration.
6. Enter new patient weight or body surface area.
7. Press **OK** to verify the rate or dose rate.
8. Press **START**.

8.12 Day/Night Mode

Note:
This feature can be enabled or disabled with a compatible Drug Library Software (custom profiles) or in the pump options (Basic Profile).

Symbol	
Procedure	Switching between day mode and night mode
Stop Infusion Required	No

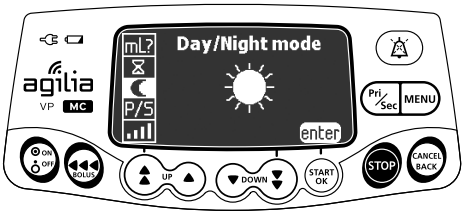
This function switches between day mode ☀ and night mode ☾.

The default night mode settings are as follows:

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

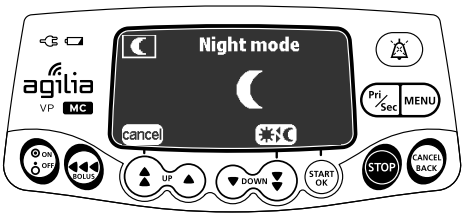
Depending on your pump configuration, the switch between day and night mode may be managed either through this menu (manual mode), or according to pre-defined settings (auto mode).
For more information, reach out your biomed technician.

Switching from Day Mode to Night Mode



You can switch to night mode as follows:

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

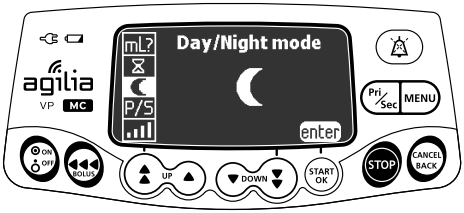


4. Press ☀/☾ to enable night mode.
   The screen displays ☾.
5. Press **OK** to confirm.

Note:
Pressing any key when the pump is in night mode will illuminate the screen display for 30 seconds.

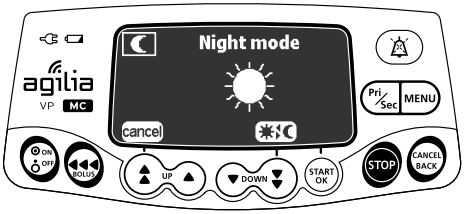
In case of alarm, pump will automatically switch from night to day mode.

Switching from Night Mode to Day Mode



You can switch to day mode as follows:

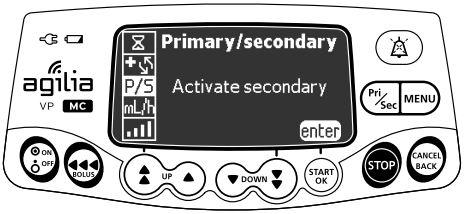
1. Press MENU.
2. Press the arrow keys to select ☾.
3. Press **enter**.



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

8.13 Primary / Secondary

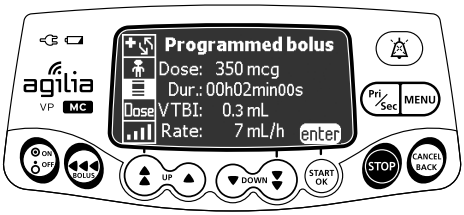
Symbol	P/S
Procedure	Programming a secondary infusion or returning to a Primary infusion
Stop Infusion Required	Yes



To program a secondary infusion, see section 7.7.3, page 63.

8.14 Programmed Bolus

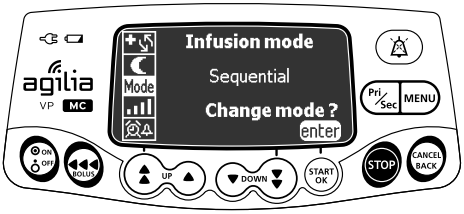
Symbol	
Procedure	Programming a bolus
Stop Infusion Required	Yes



To program a bolus, see section 7.7.4, page 70.

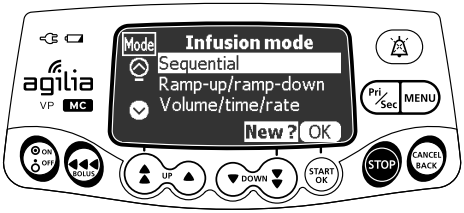
8.15 Mode

Symbols	Mode
Procedure	Changing the infusion mode
Stop Infusion Required	Yes



You can change the infusion mode as follows:

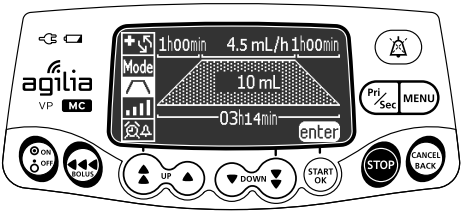
1. Press MENU.
2. Press the arrow keys to select Mode.
   The infusion mode currently applied is displayed.
3. Press **enter**.
   The available infusion modes are displayed.



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

8.16 Ramp-up / Ramp-down

Symbol	
Procedure	Modifying a ramp-up/ramp-down infusion
Prerequisite	Ramp-up/ramp-down infusion mode must be selected, see section 8.15, page 113.
Stop Infusion Required	Yes

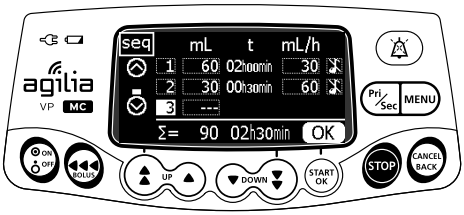


You can modify the ramp-up /ramp-down infusion settings as follows:

1. Press MENU.
2. Press the arrow keys to select .
3. Press **enter**.
4. Modify the infusion settings, see section 7.9.2, page 82.

8.17 Sequential Infusion

Symbol	seq
Procedure	Modifying a sequential infusion
Prerequisite	Sequential infusion mode must be selected, see section 8.15, page 113.
Stop Infusion Required	No

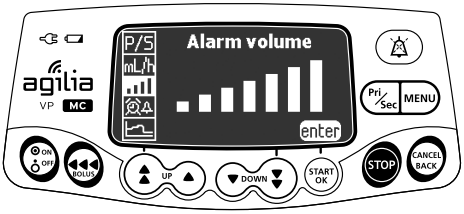


You can modify the sequential infusion settings as follows:

1. Press MENU.
2. Press the arrow keys to select seq.
3. Press **enter**.
4. Modify the infusion settings, see section 7.9.3, page 84.

8.18 Alarm Volume

Symbol	
Procedure	Adjusting the alarm volume
Stop Infusion Required	No



You can adjust the alarm volume as follows:

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

Note:

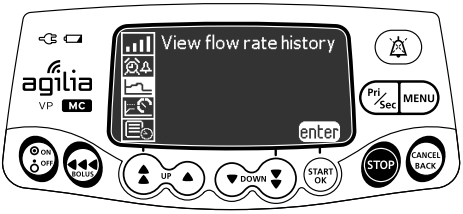
An alarm volume change applies to all alarm levels simultaneously. Whatever the alarm volume is set to:

- Medium-Priority alarm sounds are always louder than Low-Priority alarms.
- High-Priority alarm sounds are always louder than Medium-Priority alarms.

8.19 View Flow Rate History

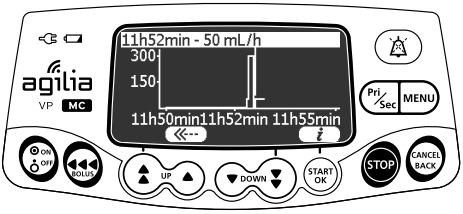
Symbol	
Procedure	Viewing flow rate history
Stop Infusion Required	No

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 **enter**.
   The following information is displayed:
   - An event marker (cursor)
   - The event details (time and flow rate)
   - The measured flow rate (solid line)



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

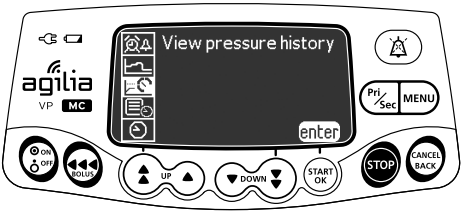
INFORMATION

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

8.20 View Pressure History

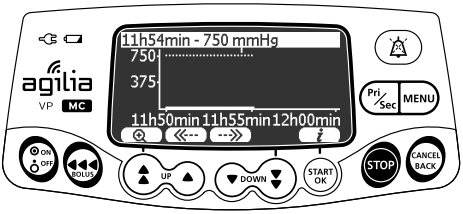
Symbol	
Procedure	Viewing pressure history
Stop Infusion Required	No

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 **enter**.
   The following information is displayed:
   - An event marker (cursor)
   - The event details (time and pressure threshold)
   - The pressure threshold (dotted line)
   - The measured pressure (solid line)



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

INFORMATION

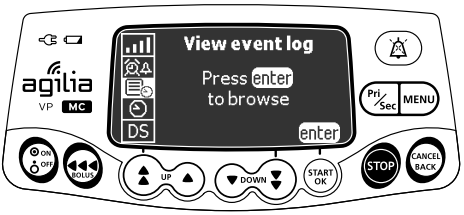
- The history is not refreshed while the history screen is displayed. To refresh the history data, exit and select the history again.
- Pressure history is not stored after powering off.

8.21 View Event Log

Symbol	
Procedure	Viewing the event log
Stop Infusion Required	No

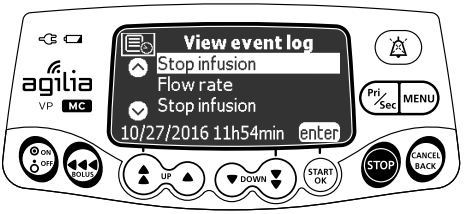
The event log displays details of the last events that occurred on the pump. Events are stored in the log even after the pump is powered off and on again. The log can store up to 1500 events. Older events are overwritten.

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.

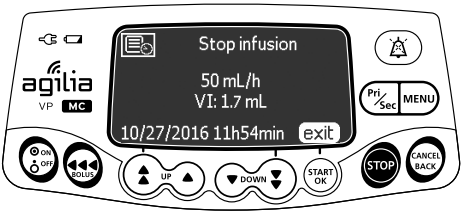


You can view the event log as follows:

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



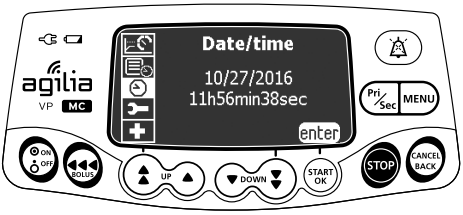
4. Press the arrow keys to select the desired event.
5. Press **enter**. *The details of the event are displayed.*



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

8.22 Date/Time

Symbol	
Procedure	Setting up the date and time
Stop Infusion Required	No

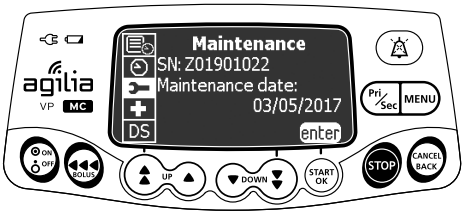


You can set the date and time as follows:

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

8.23 Maintenance

Symbol	
Procedure	Displaying maintenance information
Stop Infusion Required	No



You can display maintenance information as follows:

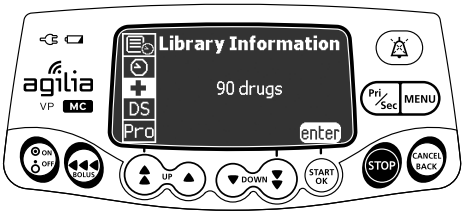
1. Press MENU.
2. Press the arrow keys to select .
3. Press **enter**.
4. Press the arrow keys to scroll through the maintenance information.

The following information is displayed:

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

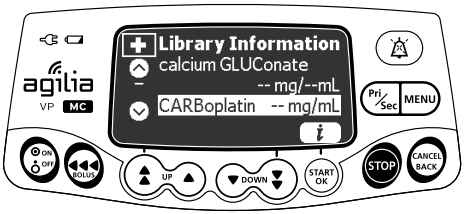
8.24 Library Information

Symbol	✚
Procedure	Displaying drug library information
Stop Infusion Required	No



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 **enter**.
   All the drugs contained in the drug library are displayed.

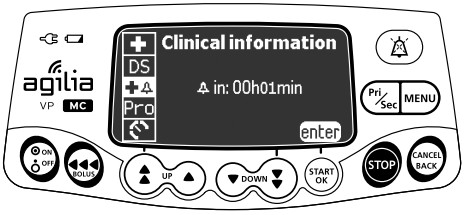


4. Press the arrow keys to select a drug.
5. Press (i) to view information on the selected drug (concentration, flow rate, vol/time).
6. Press **Exit** to move to the next line of information.

8.25 Clinical Information

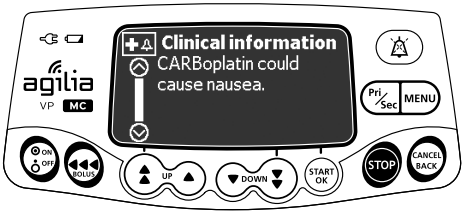
Symbol	✚🔔
Procedure	Viewing remaining time before clinical information display
Stop Infusion Required	No

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



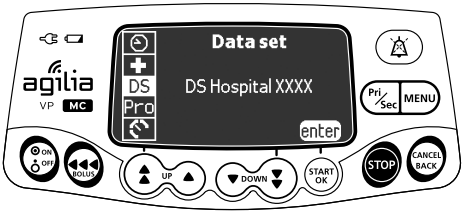
You can view the remaining time before clinical information display as follows:

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



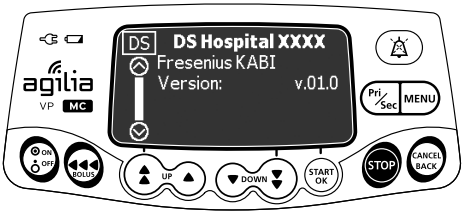
8.26 Data Set

Symbol	DS
Procedure	Displaying active data set information
Stop Infusion Required	No



You can display active data set information as follows:

1. Press MENU.
2. Press the arrow keys to select DS.
3. Press **enter**.
   The active data set information is displayed.



9 Options

9.1 Commands

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

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

9.2 Option Descriptions

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

Option	Access Code?	Description
Profile	Yes	Technical manual
Pump Settings	Yes	Technical manual
Basic Profile Configuration	Yes	Technical manual
Maintenance	Yes	Technical manual

INFORMATION

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

9.3 Pump Settings

The following options have different functions that you can enable or disable to customize your Agilia VP MC WiFi.

Function	Choice	Default Pump Setting
[User 2]: Menu items	▪ Maintenance: display or hide maintenance menu	Disabled
	▪ Date/Time: display or hide date/time menu	Enabled
[User 3]: Contrast	▪ Adjustment of screen contrast using the fast increment and decrement keys	Medium level
[User 7]: Date/Time	▪ Date selection: mm/dd/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]: WiFi module	▪ Enable/Disable the WiFi module	Enabled
[Par 7]: Prime mode	▪ Advised prime: enable/disable the display of the "Check set prime" screen at power on.	Disabled
[Par 13]: AC power disconnection	▪ Enable/Disable "AC power disconnection" message and "Device operating on battery" message at power on	Disabled
[Par 28]: Auto power on at door opening	▪ Enable/Disable automatic device powering on at door opening when the pump is connected to the power supply	Disabled
[Par 35]: Dose display format	▪ Enable/Disable display of the decimal "0" after a dose value	Remove trailing 0 / Remove trailing 0 during programming
[Par 38]: Keypad unlock code	▪ Set or disable keypad unlock code (4-digit). Disable value: 0000	0000

10 Data Communication

Important cybersecurity recommendations

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

10.1 Overview

Cable Communication	WiFi Communication
Connection of 1 pump to a PC for the following purposes: ▪ Data set upload ▪ Maintenance.	Communication between a hospital information system and a number of identified pumps for the following purposes: ▪ Data set upload ▪ Pump history retrieval.

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 WiFi Volumetric Infusion Pump (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

WARNING

- The pump should be protected against unauthorized physical access.
- The keypad automatic lock can be enabled to reduce the risk of unauthorized access, but is not a replacement for other facility access controls such as door lock, card access or security guards.

Serial connection to the infusion pump should only be established using secured computers that have been verified malware/virus free.

10.2.1 Data Communication Cables

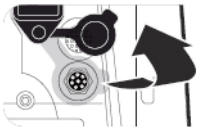
INFORMATION

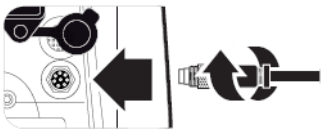
- Only use recommended Agilia cables. See section 18.4, page 179.
- All connections and disconnections must be performed by authorized and appropriately trained staff.
- All IT devices (including computers, hubs and switches) inside the patient area (< 4.92 ft or < 1.5 m) must comply with IEC/EN 60601-1 (leakage current).
- IT devices connected outside the patient area (> 4.92 ft or > 1.5 m) must be at least IEC/EN 60950 compliant.
- The RS232 communication port is disabled by default. The port must be enabled by the pump software to successfully connect. For more information, refer to the technical manual or contact your Fresenius Kabi Representative.

10.2.2 Using the Communication Port

How to connect the cable:

1. Remove the protective cap from the Agilia VP MC WiFi infusion pump's RS232 communication port.
2. Connect the cable to the RS232 communication port by tightening the cable nut completely. Make sure the connector is correctly locked in place.
3. Connect the USB end of the cable to the PC USB port.





INFORMATION

Do not disconnect communication cables while data is being transferred.

10.3 Communication via WiFi

The WiFi option allows the pump to connect to a hospital information system.

To enable or disable the WiFi, see section 9.3, page 126. ([User 14]: WiFi Module).

INFORMATION

- WiFi pumps can be configured with WiFi enabled or disabled.
- WiFi connection to infusion pump should only be established using secured WiFi networks.

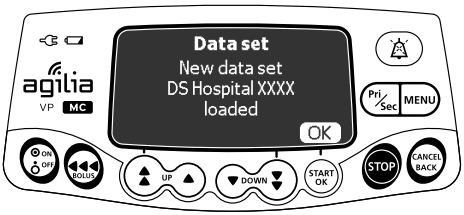
10.4 Data Set Upload

A new data set may be uploaded to the pump while it is infusing.

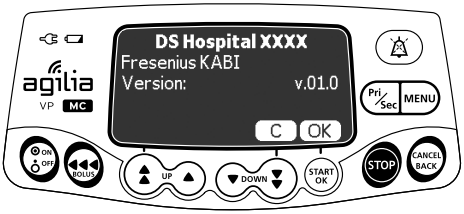
When a new data set has been uploaded since the last start-up of the pump, the ⬇ symbol is displayed on the screen.

At the next pump start-up, this new data set will be installed.

1. Power on the pump.



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



3. Press **OK** to acknowledge this information, or **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.

10.5 Infrared Communication

The Infrared Communication option is not available in the US.

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 press sound (if key press sound is enabled).

12 Alarms and Safety Features

12.1 Introduction

Agilia VP MC WiFi has a continuous monitoring system that begins when the pump is started.
When an alarm is triggered, a message is displayed on the pump's screen.

WARNING

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

12.2 Alarm Descriptions

There are several 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 or switches to KVO infusion. ▪ The infusion indicator lights (LEDs) flash **red**. ▪ The pump emits audible alarm signals. ▪ An alarm description is displayed on the pump's screen. ▪ Depending on the alarm, except end of infusion with KVO, the (🔕) key silences the pump for 30 seconds or 2 minutes. For end of infusion with KVO: the (🔕) key silences the pump for 1 minute to 5 minutes, configurable. For detailed description of each alarm, please refer to List of Alarms, page 134.
Medium (!!)	Prompt response	▪ The infusion continues. ▪ The infusion indicator lights (LEDs) flash **yellow**. ▪ The pump emits audible alarm signals. ▪ Depending on the alarm, the (🔕) key silences the alarm for no time limit or for a defined duration. For detailed description of each alarm, please refer to List of Alarms, page 134.

Alarm Priority	Required Operator Response	Description
Low (!)	Awareness	▪ The infusion continues. ▪ The infusion indicator lights (LEDs) **yellow** are ON. ▪ The pump emits audible alarm signals. ▪ Depending on the alarm, the (🔔) key silences the alarm for no time limit or for a defined duration. For detailed description of each alarm, please refer to List of Alarms, page 134.
Information Signals	Awareness	▪ The infusion continues. ▪ An information message is displayed on the pump's screen. For detailed description of each Information Signal, please refer to List of Alarms, page 134.

12.3 General Remarks

- 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, if the alarm was triggered during infusion, the message remains displayed at the top of the screen as a reminder of the cause of the alarm until the infusion is resumed.
- The highest priority alarms override lower priority alarms.
- 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	Alarm Trigger	Stops Infusion?	Problem / Resolution
`Install set !!!`	High (!!!)	When a set is properly installed, 4 sensors (door, air, clamp and pressure sensors) should send information compatible with a set installed One or more sensor did not detect the set	Yes	At start-up, the administration set is not loaded or the door is open. ☞ Install the administration set and close the door. There is no administration set in front of the upstream or downstream sensor. ☞ Check the administration set installation. 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.
`Door opened !!!`	High (!!!)	Door presence sensor does not detect the door	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.

Message	Priority	Alarm Trigger	Stops Infusion?	Problem / Resolution
`Air bubble !!!` `Air alarm !!!`	High (!!!)	Air bubble: detection of air stops infusion Air alarm: while infusion is running, configured cumulated air volume limit has been reached during the last 15 minutes (10 to 2000 microliters) Note: user can configure the device	Yes	An air bubble has been detected (at start-up, during the infusion, or while the infusion is stopped). ☞ Remove the air from the administration set. Note: the (🔔) key silences the pump for 2 minutes.

12.4.2 OCS Alarms

Message	Priority	Alarm Trigger	Stops Infusion?	Problem / Resolution
`OCS failure !!!`	High (!!!)	Pumping mechanism failure is detected	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, discontinue use of the pump, tag for repair. Do not use until checked by a biomed person or technician. Note: the (🔔) key silences the alarm for 2 minutes.
`Open and close door for OCS test`	Information Signal	Last OCS test was not completed properly and the pump was switched off without performing the test	No	Under specific conditions, the pump asks you to open and close the door to perform the OCS test. ☞ Open and close the door.

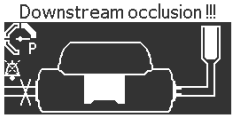
12.4.3 Infusion Alarms

Message	Priority	Alarm Trigger	Stops Infusion?	Problem / Resolution
`Near end of infusion !!`	Medium (!!)	Remaining VTBI (0 to 50 mL) or remaining infusion duration at current flow rate (0 to 30 minutes) or % of VTBI remaining (0 to 15 %) reached configured near end of infusion alarm value Note: when all triggering conditions are configured to 0, near end of infusion alarm is disabled	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. Note: the (🔔) key silences the alarm for no time limit.
`End of infusion !!!`	High (!!!)	Pumps detects end of primary VTBI or silenced time during KVO elapsed	Yes	The VTBI is completed. Note: the (🔔) key silences the alarm.
			No, starts KVO infusion	The VTBI is completed and the KVO starts. Note: the (🔔) key silences the alarm for a time duration from 1 minute to 5 minutes (default 2 minutes).
`Stop for new infusion !`	Low (!)	End of infusion alarm with KVO was silenced by user	No	KVO infusion in progress. ☞ Press STOP to select new infusion settings (if required).
`End secondary alarm !!!`	High (!!!)	Pump detects end of secondary VTBI while manual return to primary is configured	Yes	The secondary infusion is completed (only with manual return to primary). ☞ Restart the primary infusion. Note: the (🔔) key silences the alarm.

Message	Priority	Alarm Trigger	Stops Infusion?	Problem / Resolution
`Check settings !!`	Medium (!!)	User reprogrammed / modified an infusion parameter, but did not confirm the change	No	The flow rate (or dose rate) has been modified using the keys, but has not been confirmed. ☞ Check the flow rate (or dose rate) and press **OK** to confirm. Note: the (🔔) key silences the alarm for 2 minutes.
`Waiting settings !!`	Medium (!!)	User selected an infusion parameter to program, but did not input or reprogram the parameter	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 (!!)	Infusion programmation is completed and user did not start the infusion	No	The infusion settings have been entered, but have not been confirmed with **start**. ☞ Check the infusion settings, and press **start** to start the infusion. Note: the (🔔) key silences the alarm for 2 minutes.
`Primary started Check that primary clamp is open`	Low (!)	Pump reaches end of secondary VTBI Note: this low priority alarm if configured on will display when the pump is configured to switch to primary automatically	No	End of secondary infusion with automatic return to primary infusion. ☞ Press (🔔) to silence the alarm.

Message	Priority	Alarm Trigger	Stops Infusion?	Problem / Resolution
`Check that primary clamp is open`	Low (!)	Pump reaches end of secondary VTBI and user silenced the end of secondary alarm Note: pump is configured in manual switch to primary and this low priority alarm is configured to be displayed	No	End of secondary infusion with manual return to primary infusion. ☞ Press (🔔) to silence the alarm.
`1. Lower Primary bag` `2. Open Secondary line`	Information signal	Secondary infusion workflow	No	Secondary programming is completed, press **OK**. ☞ Confirm, press **done**. ☞ Press **start** to start the Secondary infusion.
`Upper soft max`	Information signal	User programmed above max soft limit	No	The upper soft limit is exceeded, according to the drug settings defined in the drug library.
`Lower soft min`	Information signal	User programmed below min soft limit	No	The lower soft limit is exceeded, according to the drug settings defined in the drug library.
`Reached hard limit`	Information signal	User reached hard limit	No	The upper or lower hard limit is reached. Hard limits cannot be overridden.
`Limit reached`	Information signal	Max bolus volume reached	Stops bolus delivery	Maximum volume for Direct Bolus is reached.
`Infusion will not resume after bolus`	Information signal	User starts a bolus while infusion is stopped	N/A	Press **start** to restart infusion after Programmed Bolus delivery.

12.4.4 Pressure Alarms

Message	Priority	Alarm Trigger	Stops Infusion?	Problem / Resolution
`Upstream occlusion !!!`	High (!!!)	Sensor detects that upstream blockage reaches pressure limit (infusion pressure is getting closer to pressure value measured while door is open)	Yes	The pressure in the upstream line is too low. "X" indicates an upstream occlusion.  ☞ Check line for closed clamps or kinks. ☞ Check the container height. ☞ Check air vent (if a bottle is used). Note: the (⚠) key silences the alarm for 2 minutes.
`Wait during pressure measurement checking !!!`	High (!!!)	Sensor detects that down-stream blockage exceeds pressure limit and auto-restart is enabled	Yes	A downstream occlusion has been detected by the device. ▪ See Auto-restart on page 90 ▪ Otherwise, a downstream occlusion alarm is triggered.
`Downstream occlusion !!!`	High (!!!)	Sensor detects that down-stream blockage exceeds pressure limit (50 mmHg to 750 mmHg) and auto-restart is disabled or restart conditions were not satisfied	Yes	The pressure in the infusion line has reached the threshold level. "X" indicates a downstream occlusion.  ☞ Check infusion line for closed clamps, kinks or other occlusions. ☞ If necessary, readjust the pressure threshold. See section 8.3, page 95. Note: the (⚠) key silences the alarm for 2 minutes if the pressure condition is still present.

Message	Priority	Alarm Trigger	Stops Infusion?	Problem / Resolution
`Occlusion pre alarm !!`	Medium (!!)	Sensor detects that down-stream blockage reached pre-alarm pressure limit: - alarm threshold between 76 mmHg and 750 mmHg, 50 mmHg below the current downstream occlusion alarm threshold - alarm threshold between 50 mmHg and 75 mmHg, 25 mmHg below the current downstream occlusion alarm threshold	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 (!)	Measured pressure value represents configured value added to average infusion pressure (added value goes from 50 to 415 mmHg) Note: alarm only available when activated and for flow rate below 150 mL/h	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 silences the alarm.

Message	Priority	Alarm Trigger	Stops Infusion?	Problem / Resolution
`Drop in pressure !`	Low (!)	Measured pressure value is inferior to configured limit (from 100 to 415 mmHg)	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 silences the alarm.

12.4.5 Battery Alarms

WARNING

When the pump is not connected to the power supply a Medium-Priority Battery Alarm will sound 30 minutes prior to a High-Priority Battery Alarm. If the pump is still not connected to the power supply after the High-Priority Battery Alarm the pump will turn OFF after 5 minutes.

Message	Priority	Alarm Trigger	Stops Infusion?	Problem / Resolution

`Battery pre alarm !!`
 	
`Very low battery Connect to AC power and wait`
	Medium (!!)	Battery detects low charge
		
		Occurs at least 35 minutes prior to depleted battery
			No	Low battery.
				☞ Connect the pump to a power supply.
				
				Note: The (🔔) key silences the alarm for no time limit.

`Alert !!!`
 	
`Very low battery Connect to AC power and wait`
	High (!!!)	Battery detects low charge
		
		Occurs 5 minutes prior to fully depleted battery
			Yes	The battery is discharged.
				
				If the pump is not connected to the power supply, the pump will power OFF automatically within 5 minutes.
				☞ Connect the pump to the power supply immediately.
				
				If the pump is connected to the power supply:
				☞ Check that the pump is well connected to a power supply and allow time to charge.
				
				Note: the (🔔) key silences the alarm for 2 minutes.

	Low (!)	Battery detects low charge Occurs when powering on the pump when battery has a low charge	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	Alarm Trigger	Stops Infusion?	Problem / Resolution
`AC power failure !`	Low (!)	Power supply failure: multiple interruptions	No	The power supply is inconsistent. ☞ Contact your technical support. Note: the (🔔) key silences the alarm.
`Power disconnection`	Information signal	Power supply source disconnected	No	The pump is disconnected from the AC power. A single beep is emitted. ☞ Press (🔔) to silence the alarm. ☞ 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 Technical Error Alarms

WARNING

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

Message	Priority	Alarm Trigger	Stops Infusion?	Problem / Resolution
`Erxx(yyyy) !!!`	High (!!!)	Pump malfunction	Yes	Technical alarm. ☞ Contact your qualified technician or your **Fresenius Kabi** representative. Note: the (🔔) key silences the alarm for 30 seconds. In the case of a system malfunction, the alarm sounds and an error message `Erxx(yyyy) !!!` is displayed. ☞ Record the error message `Erxx(yyyy) !!!`. ☞ Close the roller clamp. ☞ Disconnect the pump from the power supply. ☞ Switch the pump off by pressing the (ON/OFF) key.

12.4.9 Technical Low Priority Alarm

Message	Priority	Alarm Trigger	Stops Infusion?	Problem / Resolution
`High internal temperature !`	Low (!)	Temperature limit exceeded (≥ to 65 °C)	No	Temperature increase. ☞ Check the environment, move from direct sun light or other heat sources. Note: the (🔔) key silences the alarm for 2 minutes.

12.5 Audio-only Information Signals

Type	Comment	Stops Infusion ?	Activation
Inactive key	Beep until key is released	No	Beep occurs when action is not allowed
Return to primary infusion	Depends on configuration	No	At the end of secondary infusion
Pressure measurement checking	4 beeps	Yes	When auto-restart is enabled and a downstream occlusion is detected
End of secondary	3 beeps	No	At the end of secondary when automatic mode is enabled
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 programmed bolus
End of sequence	3 beeps	No	At the end of each sequence (if programmed)
AC power connection	1 beep	No	When power is connected
Forbidden key	1 beep	No	Repeated until key is released
Key press sound	1 beep	No	For each key pressed
Other non validation beep	1 beep	No	For each key pressed
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
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
Incomplete programming of settings	1 beep	No	One or several settings have not been defined or confirmed

13 Volumat Lines

13.1 Preparing the Administration Set and the Fluid Container

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

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

Refer to Volumat Line label for more information on the following elements: name, description, expiration date, length, priming volume ("dead space"), intended use and contraindications.

To use the SafeClip with gravity infusions, see section 13.2, page 148.

WARNING

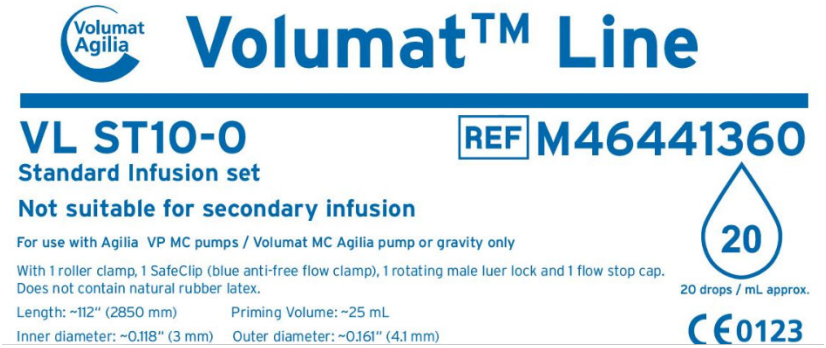
- Only use recommended Volumat Lines. Use of any other administration sets may affect the accuracy of the infusion, and result in injury to the patient and damage to the pump.
- Do not use an administration set if its packaging appears to be damaged or opened.

INFORMATION

- The pump does not have an internal chamber and does not contribute to "dead space".
- The administration set priming volume is indicated on the set labeling.
- The fluid in the administration set, the administration set and the bag or bottle must be within normal operating temperature conditions: 64.4 °F (18 °C) to 86 °F (30 °C).
- Do not use in conjunction with positive pressure infusion devices that could generate back pressure higher than 2000 hPa (1500 mmHg): doing so will damage the administration set and the pump.
- Some administration sets may have components such as a burette or filter that require special instructions.
- For administration sets with two spikes, only open one line at a time.
- Certain drugs may require specific administration sets for infusion or transfusion.
- When using an administration set with a filter, verify that the fluid to be infused is compatible with the size of the filter.
- Follow your healthcare facility's protocol for installing and replacing the fluid container.

Precautions for the use of administration sets

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



13.2 Priming the Administration Set Manually 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 Volumat Line label.

WARNING

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

INFORMATION

- Priming can be done manually or with the pump feature. This chapter describes manual priming. For pump priming feature, see section 7.10.1, page 86.
- For manual priming, ensure that the SafeClip is opened (see a).
- If it is necessary to prime after the set has been loaded into the pump, please note that the safe clip is closed (see b) and need to be opened (see a).

a *Open position after removing from packaging (allows flow from gravity)*

b *Closed position after removing from the pump (stops flow)*

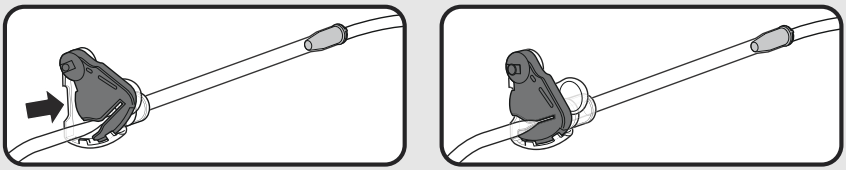
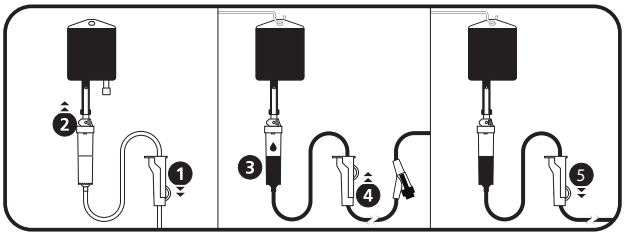


Figure 13.1: Operation of the SafeClip (blue anti-free flow clamp)

13.2.1 With a Bag

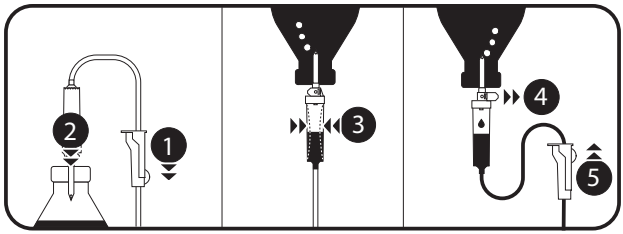
The following diagram shows how to prime the administration set with a bag:



1. Close roller clamp.
2. Remove cap from spike, insert spike into bag
3. Hang bag and fill drip chamber to approx. 1/2 full.
4. Open roller clamp slowly for priming.
   Invert needle-free port while priming and gently tap valve to remove all air and prime set.
5. When set is fully primed, close roller clamp, and check carefully for the absence of air bubbles.

13.2.2 With a Bottle

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



1. Close the roller clamp.
2. Check that the air vent is closed and push the spike down into the bottle.
3. Hang the bottle upside down, then squeeze and release the drip chamber in order to fill it approximately 1/2 full.
4. 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.
5. Slowly open the roller clamp for priming.
6. When the administration set is fully primed, close the roller clamp and check carefully for the absence of air bubbles.
   For gravity infusions, the flow rate is regulated by the roller clamp.

13.3 Other Uses of Administration Sets

13.3.1 Access Ports

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

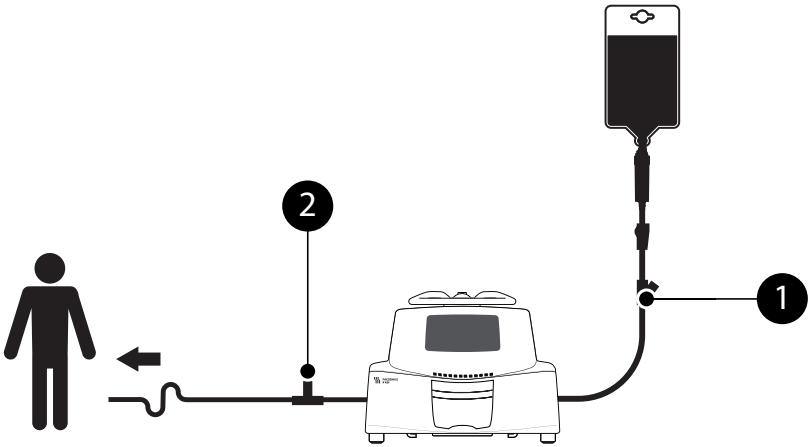


Figure 13.2: Needle-Free Ports

Legend	
1	Upstream port (before the pump)
2	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.

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). Flushing with neutral solution may be necessary (in case of incompatibility of drugs).

13.3.2 Use of Administration Sets for Gravity Infusion

13.3.2.1Gravity Infusion (without pump)

In order to use the administration set to infuse via gravity, make sure that the SafeClip is opened, see section 13.2, page 148.

1. Ensure that the set is primed, roller clamp is closed and SafeClip opened.
2. Adjust the roller clamp on the administration set to regulate gravity flow.

13.3.2.2Gravity Infusion in Parallel with a Pump

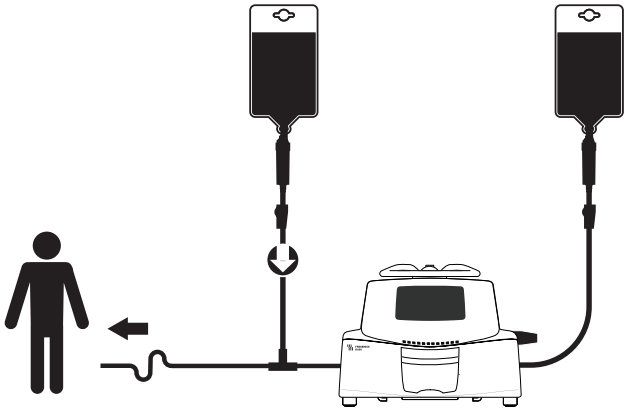


Figure 13.3: Gravity Infusion (in parallel with a pump)

INFORMATION

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

13.4 Removal and Replacement of Administration Sets

13.4.1 Removing an Administration Set

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

13.4.2 Changing an Administration Set

1. Remove the administration set.
   See section 13.4.1, page 153.
2. Install another administration set, and follow the steps described in the flowchart.
   See section 6.1, page 40.

INFORMATION

Properly dispose of used administration sets as per medical healthcare guidelines.

13.4.3 Administration Set Replacement Interval

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

Replace the administration set according to your established medical protocol.

14 Device Storage, Transport, and Recycling

14.1 Precautions for Storage

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

WARNING

If the device is not used for an extended period (longer than 1 month), it is recommended that the battery be removed from the device and put in storage by authorized personnel. If the battery cannot be removed, or the device will be used in less than 1 month, charge the battery at least once a month by connecting the device to the AC power supply for at least 6 hours.

14.2 Storage and Transport Conditions

Observe the following conditions for storage and transport:

- Temperature: 14 °F (-10 °C) to 140 °F (+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 9842.52 ft (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. If necessary (long-term storage), disconnect the pump's power cord and all data communication cables.
2. Remove the pump from its mounting point.
3. Clean and disinfect the pump.
4. 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

We recommend charging the battery for at least 6 hours.

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

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

When using the device after storage, software version should be checked to ensure that the latest version is installed.

We recommend that the "User test" is performed when the device is installed after storage, and before being used on a patient, see section 11, page 131.

14.5 Recycling at End of Life

Before disposal, remove the battery from the device. Batteries and devices with this label must not be disposed of with the general waste. They must be collected separately and disposed of according to local regulations.

INFORMATION

- For more information on waste processing regulations, contact your **Fresenius Kabi** representative or the local distributor.
- Follow healthcare facility policy regarding proper disposal, at end of pump life.

15 Specifications

INFORMATION

The range of settings and default values described in this section corresponds to the factory configuration. Range of settings and default values may be adjusted in the pump options (Basic Profile) or a compatible Drug Library Software (custom profiles). Increment rules may be modified with a compatible 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	section 15.9.1, page 162. section 18.9, page 182.
Time to Detect Occlusion	section 18.10, page 191.
Bolus Volume After Occlusion Release	section 18.10, page 191.
Management of High-Priority Alarms	section 12, page 132.

15.2 Flow Rate

Reminder

The Agilia VP Infusion is intended for adult and pediatric care for the intermittent or continuous delivery of parenteral fluids, medications, blood, and blood derivatives through clinically accepted parenteral routes of administration.

The Agilia VP Infusion System is intended for neonatal care for the intermittent or continuous delivery of parenteral fluids for hydration and nutrition, blood, and blood derivatives through clinically accepted parenteral routes of administration. These routes of administration include intravenous, intra-arterial, and subcutaneous using dedicated administration sets.

WARNING

Starting an infusion at a low flow rate (typically under 1mL/h) can cause a delay in medication delivery because it reduces the initial accuracy of the programmed flowrate which prolongs rate stabilization (for additional information, see section 15.9, **"Accuracy"** on page 161, and section 18.9, **"Trumpet, Start-up Curves and AAMI TIR101: 2020 Delivery Performance"** on page 182).

In order to ensure patient safety in high risk populations, close monitoring is recommended in low flow rate infusions.

	Format	Range of Settings	Default Value	Minimum Increment
Primary Infusion	mL/h	0.1 ➔ 1500*	N/A	0.01 (0.10 ➔ 9.99) 0.1 (10.0 ➔ 99.9) 1 (100 ➔ 1500)
Direct Bolus	mL/h	50 ➔ 1500	1500	50
Programmed Bolus	mL/h	0.1 ➔ 1500	N/A	0.01 (0.10 ➔ 9.99) 0.1 (10.0 ➔ 99.9) 1 (100 ➔ 1500)
Secondary Infusion	mL/h	0.1 ➔ 1000	N/A	0.01 (0.10 ➔ 9.99) 0.1 (10.0 ➔ 99.9) 1 (100 ➔ 1000)
KVO	mL/h	0 ➔ 20	0	1
Loading Dose	mL/h	0.1 ➔ 1500	N/A	0.01 (0.10 ➔ 9.99) 0.1 (10.0 ➔ 99.9) 1 (100 ➔ 1500)
Ramp (plateau)	mL/h	2 ➔ 1500	N/A	0.1 (2.0 ➔ 99.9) 1 (100 ➔ 1500)
Sequential	mL/h	0.1 ➔ 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). 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	0.1
Programmed Bolus	mL	0.1 ➔ 1000	0.1	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

15.4 Dose To Be Infused (DTBI)

	Format	Range of Settings	Default Value	Minimum Increment
Dose	Unit	0.01 ➔ 9999	N/A	0.001 (0.010 ➔ 4.999) 0.01 (5.00 ➔ 9.99) 0.1 (10.0 ➔ 99.9) 1 (100 ➔ 9999)
Programmed Bolus	Unit	0.01 ➔ 9999	N/A	0.01 (0.01 ➔ 9.99) 0.1 (10.0 ➔ 99.9) 1 (100 ➔ 9999)
Loading Dose	Unit	0.01 ➔ 9999	N/A	0.01 (0.01 ➔ 9.99) 0.1 (10.0 ➔ 99.9) 1 (100 ➔ 9999)

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	00h00min01s ➔ 24h00min00s	00h02min00s	00h00min01s
Loading Dose	_h_min_s	00h00min01s ➔ 24h00min00s	00h02min00s	00h00min01s
KVO Silence Alarm Duration	_h_min	00h01min ➔ 00h05min	00h02min	00h01min
Pause	_h_min	00h01min ➔ 24h00min	00h01min	00h01min
Ramp (Total Duration)	_h_min	00h01min ➔ 48h00min**	12h00min	00h01min
Ramp (Ramp-up / Ramp-down)	_h_min	00h00min ➔ 06h00min	00h30min	00h01min

* If the calculated infusion time exceeds this value, ↑ 168h00min will be displayed on the pump.
** If the calculated infusion time exceeds this value, ↑ 48h00min will be displayed on the pump.

15.6 Concentration

	Format	Range of Settings	Default Value	Minimum Increment
Concentration	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

15.7 Air Detection

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

15.8 Pressure Management

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

		Format	Range of Settings	Default Value	Minimum Increment
3 Levels	**Low**	mmHg	50 ➔ 300	200	50
	Medium	mmHg	150 ➔ 600	450	50
	High	mmHg	250 ➔ 750	550	50
Variable	**Full Range**	mmHg	50 ➔ 750	200	25 (50 ➔ 250) 50 (250 ➔ 750)
	Maximum Limit	mmHg	300 ➔ 750	750	50
DPS	**Raise Threshold**	mmHg	50 ➔ 400	200	50
	Drop Threshold	mmHg	100 ➔ 400	100	50

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

Settings	Description	Range of settings	Default Value
Auto Restart After Occlusion: Allow User Option to Enable/Disable Alert	When enabled, the device startup setting is to automatically restart the current infusion when occlusion condition clears.	Enabled/Disabled	Disabled
Allow User Option to Enable/Disable Alert	When enabled, the user can enable/disable the auto restart after occlusion on the pump.	Enabled/Disabled	Disabled
Sliding Duration for Number of Restarts	Determines the sliding period during which the pump can auto restart up to the max number before triggering an alarm.	1 minute to 5 hours	60 mins (1h)
Maximum Number of Auto Restarts	Specifies the maximum number of auto restart that the pump can attempt before triggering an alarm.	1-10	5
Maximum Low-Pressure Duration Before Auto Restart	Specifies the waiting time for the Pressure to reach low enough point.	5-30 secs	10 secs
Infusion Restart Threshold	Specifies the threshold of pressure under which the pump can attempt to auto restart.	25 to 500 mmHg	50 mmHg
Maximum Pressure for Disabling Auto Restart	Specifies the maximum pressure under which the auto restart feature is prohibited.	25-500 mmHg	Disabled
Maximum Flow Rate for Disabling Auto Restart	Specifies the maximum Flow rate under which the auto restart feature is prohibited.	0.1-1500 mL/h	Disabled

15.9 Accuracy

Reminder

The Agilia VP Infusion is intended for adult and pediatric care for the intermittent or continuous delivery of parenteral fluids, medications, blood, and blood derivatives through clinically accepted parenteral routes of administration.

The Agilia VP Infusion System is intended for neonatal care for the intermittent or continuous delivery of parenteral fluids for hydration and nutrition, blood, and blood derivatives through clinically accepted parenteral routes of administration. These routes of administration include intravenous, intra-arterial, and subcutaneous using dedicated administration sets.

WARNING

Starting an infusion at a low flow rate (typically under 1mL/h) can cause a delay in medication delivery because it reduces the initial accuracy of the programmed flowrate which prolongs rate stabilization (for additional information, see section 15.9, **"Accuracy"** on page 161, and section 18.9, **"Trumpet, Start-up Curves and AAMI TIR101: 2020 Delivery Performance"** on page 182).

In order to ensure patient safety in high risk populations, close monitoring is recommended in low flow rate infusions.

WARNING

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

INFORMATION

Occlusion alarms might be triggered when using administration sets with filters at flow rates higher than 250 mL/h. If this happens, check the set and filter for occlusions. If there are no occlusions, dismiss the alarm and restart infusion. Despite these occlusion alarms, accuracy remains guaranteed during infusion.

15.9.1 Flow Rate Accuracy

Delivery Performance Disclosure in Standard Operational Conditions (SOC)

Tested Sets	Mean Flow Error Initial (T_B) %				
	MinSR 0.1 mL/h	LTR 1 mL/h	MTR 10 mL/h	HTR 100 mL/h	MaxSR 1500 mL/h
Sets without filters	0.4 ± 2.2	0.4 ± 1.2	-0.2 ± 1.3	0.9 ± 1.6	2.1 ± 2.2
Sets with filters	0.33 ± 3.9	-0.3 ± 1.5	-0.9 ± 1.3	-0.11 ± 1	3.33 ± 1.9

Tested Sets	Mean Flow Error End (T_E) %				
	MinSR 0.1 mL/h	LTR 1 mL/h	MTR 10 mL/h	HTR 100 mL/h	MaxSR 1500 mL/h
Sets without filters	1.6 ± 1.8	0.5 ± 1.2	1.3 ± 1.3	-0.2 ± 1.6	0.3 ± 3.1
Sets with filters	1.1 ± 2.6	-0.3 ± 1.4	2 ± 1.1	-0.8 ± 1	2 ± 2.4

Tested Sets	Start-up Delay Time Minutes				
	MinSR 0.1 mL/h	LTR 1 mL/h	MTR 10 mL/h	HTR 100 mL/h	MaxSR 1500 mL/h
Sets without filters	0.1 ± 8	0.2 ± 0.5	± 0.2	-0.4 ± 0.1	< 0.1
Sets with filters	-129 ± 376	-9 ± 30	-2.5 ± 4	-0.1 ± 0.6	< 0.1

Notes:

- Variations in atmospheric pressure and changes in altitude between new infusions does not impact flow rate accuracy.
- SR = Selectable rate; LTR = Low Test Rate ; MTR = Medium Test Rate: HTR = High Test Rate.
- Mean and standard deviation were established with 10 tested pumps per set. Six representative administration sets (with 10 samples each) were tested: VL ST10, VL SP22, VL PA92, VL PR42, VL ON72, and VL PN02.
- A negative value for start-up delay time is indicative that the infusion initially starts at a higher rate before setting into steady-state flow.
- **Test conditions:**
  - Flow rate: 0.1 to 1500 mL/h* Back-pressure: 0 mmHg
  - Inlet Pressure: 50cm (height of fluid supply container relative to pump)
  - Viscosity: Distilled Water (grad 3)
  - Ambient Temperature: 17°C to 23°C
  - Relative Humidity: 45% to 80 %
  - Ambient Pressure: 1000 hPa.

15.9.2 Effects of Negative Backpressure On Accuracy

Delivery Performance Disclosure in Back Pressure Conditions

Tested Sets	Mean Flow Error Initial (T_B) %			Start-up Delay Time Minutes		
	MinSR 0.1 mL/h	MTR 10 mL/h	MaxSR 1500 mL/h	MinSR 0.1 mL/h	MTR 10 mL/h	MaxSR 1500 mL/h
Sets without filters	31 ± 9	-1.5 ± 1.4	0.6 ± 1.7	-10 ± 43	-0.3 ± 0.3	< 0.1
Sets with filters	19 ± 8	-2.3 ± 1.1	0.7 ± 1.2	-86 ± 257	-3.6 ± 4.5	< 0.1

Test conditions:

- Inlet pressure: 50cm
- Back pressure: -100 mmHg

(the pump is raised above the patient 1.33m to attain -100mmHg downstream line pressure)

Delivery Performance Disclosure in Inlet Pressure Conditions

Tested Sets	Mean Flow Error Initial (T_B) %			Start-up Delay Time Minutes		
	MinSR 0.1 mL/h	MTR 10 mL/h	MaxSR 1500 mL/h	MinSR 0.1 mL/h	MTR 10 mL/h	MaxSR 1500 mL/h
Sets without filters	-1.1 ± 6.6	-1.3 ± 4.9	1.2 ± 5.6	3.8 ± 39	-0.2 ± 0.2	< 0.1
Sets with filters	-3.9 ± 7	-2.8 ± 5.3	1.2 ± 5.8	-384 ± 436	-1.5 ± 3.2	< 0.1

Test conditions:

- Back pressure: 0 mmHg
- Inlet pressures: -50cm, 120cm (height of fluid supply container relative to pump)

Notes:

- Variations in atmospheric pressure and changes in altitude between new infusions does not impact flow rate accuracy.
- Mean and standard deviation established with 10 tested pumps per set.
- Six representative administration sets (with 10 samples each) were tested: VL ST10, VL SP22, VL PA92, VL PR42, VL ON72, and VL PN02
- A negative value for start-up delay time is indicative that the infusion initially starts at a higher rate before setting into steady-state flow.
- **Test conditions:**
    - Flow rate: 0.1 to 1500 mL/h
    - Viscosity: Distilled Water (grad 3)
    - Ambient Temperature: 17°C to 23°C
    - Relative Humidity: 45% to 80 %
    - Ambient Pressure: 1000 hPa.

15.9.3 Bolus Volume Accuracy

	Volume
Direct Bolus*	± 10 %

* Test condition: *Back pressure:* 0 mmHg, *Container height:* 20 in (50 cm)

Bolus Dose Volumetric Accuracy Disclosure in Standard Operational Conditions (SOC)

Tested Sets	Bolus dose Volume mL	Bolus dose rate mL/h	Volumetric Accuracy %
Sets without filters	0.1	360	9.7 ± 51
	1	1200	5.4 ± 4.1
	5	1500	2.9 ± 2.2
Sets with filters	0.1	360	20 ± 111
	1	1200	4.6 ± 12
	5	1500	3.8 ± 2.8

NOTE Mean and standard deviation established with 10 tested pumps per set.

NOTE Six representative administration sets (with 10 samples each) were tested: VL ST10, VL SP22, VL PA92, VL PR42, VL ON72, and VL PN02

NOTE Conditions tested:

* Basal Flow rate: None
* Backpressure: 0 mmHg
* InletPressure: 50cm (height of fluid supply container relative to pump)
* Viscosity: Distilled Water (grad 3)
* Ambient Temperature: 17°C to 23°C
* Relative Humidity: 45% to 80 %

Bolus Dose Volumetric Accuracy Disclosure in Back Pressure Conditions

Tested Sets	Bolus dose Volume mL	Bolus dose rate mL/h	Volumetric Accuracy %
Sets without filters	0.1	360	10.3 ± 50
	1	1200	4.5 ± 4.1
Sets with filters	0.1	360	20 ± 109
	1	1200	5.3 ± 11.1

NOTE Mean and standard deviation established with 10 tested pumps per set.
NOTE Six representative administration sets (with 10 samples each) were tested:
VL ST10, VL SP22, VL PA92, VL PR42, VL ON72, and VL PN02

NOTE Conditions tested:
* Basal Flow rate: None
* Backpressure: -100 to +100 mmHg
* InletPressure: 50cm (height of fluid supply container relative to pump)
* Viscosity: Distilled Water (grad 3)
* Ambient Temperature: 17°C to 23°C
* Relative Humidity: 45% to 80 %
* Ambient Pressure: 1000 hPa

Bolus Dose Volumetric Accuracy Disclosure in Viscosity Conditions

Tested Sets	Bolus dose Volume mL	Bolus dose rate mL/h	Volumetric Accuracy %
Sets without filters	0.1	360	8.7 ± 50
	1	1200	6.2 ± 4.3
Sets with filters	0.1	360	16 ± 49
	1	1200	7.8 ± 14

NOTE Mean and standard deviation established with 10 tested pumps per set.
NOTE Six representative administration sets (with 10 samples each) were tested:
VL ST10, VL SP22, VL PA92, VL PR42, VL ON72, and VL PN02

NOTE Conditions tested:
* Basal Flow rate: None
* Backpressure: 0 mmHg
* InletPressure: 50cm (height of fluid supply container relative to pump)
* Viscosity: 20% Dextrose solution
* Ambient Temperature: 17°C to 23°C
* Relative Humidity: 45% to 80 %
* Ambient Pressure: 1000 hPa

15.9.4 Pressure Accuracy

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

* Test condition: *Back pressure:* 0 mmHg, *Container height:* 20 in (50 cm)

15.9.5 Effects of Temperature on Accuracy

Delivery Performance disclosure in Temperature conditions

Tested Sets	Mean Flow Error Initial (T_B) %			Mean Flow Error End (T_E) %		
	MinSR 0.1 mL/h	MTR 10 mL/h	MaxSR 1500 mL/h	MinSR 0.1 mL/h	MTR 10 mL/h	MaxSR 1500 mL/h
Sets without filters	4.8 ± 6.9	1.9 ± 1.6	2.4 ± 3.5	3.0 ± 4.9	0.9 ± 1.9	1.0 ± 3.9
Sets with filters	0.3 ± 5.3	0.4 ± 2.3	2.2 ± 3.1	-3.8 ± 6.6	-0.5 ± 2.7	0.5 ± 3

Notes:

- The accuracy is inclusive of the effects of temperature variations
- SR = Selectable rate; MTR = Medium Test Rate.
- Mean and standard deviation established with 10 tested pumps per set, per temperature, at 10 mL/h and 3 tested pumps at 0.1 and 1500 mL/h
- Six representative administration sets (with 10 or 3 samples each) were tested: VL ST10, VL SP22, VL PA92, VL PR42, VL ON72, and VL PN02
- A negative value for start-up delay time is indicative that the infusion initially starts at a higher rate before setting into steady-state flow.

Test conditions:

- Inlet Pressure: 50cm (height of fluid supply container relative to pump)
- Back pressure: 0 mmHg
- Flow rate: 0.1 to 1500 mL/h
- Viscosity: Distilled Water (grad 3)
- Ambient Temperature: 5°C to 40°C
- Ambient Pressure: 1000 hPa.

15.9.6 Effects of Viscosity on Accuracy

Delivery Performance disclosure in Viscosity conditions

Tested Sets	Mean Flow Error Initial (T_B) %			Start-up Delay Time Minutes		
	MinSR 0.1 mL/h	MTR 10 mL/h	MaxSR 1500 mL/h	MinSR 0.1 mL/h	MTR 10 mL/h	MaxSR 1500 mL/h
Sets without filters	-0.7 ± 1.9	0.3 ± 1.3	0.8 ± 6.2	3 ± 8	-0.1 ± 0.12	< 0.1
Sets with filters	-4.2 ± 1.9	-0.17 ± 1.3	4.8 ± 1.6	-373 ± 462	-2.8 ± 4.3	< 0.1

Notes:

- SR = Selectable rate; MTR = Medium Test Rate.
- Mean and standard deviation established with 10 tested pumps per set.
- Six representative administration sets (with 10 samples each) were tested: VL ST10, VL SP22, VL PA92, VL PR42, VL ON72, and VL PN02
- A negative value for start-up delay time is indicative that the infusion initially starts at a higher rate before setting into steady-state flow.

Test conditions:

- Inlet pressure: 50cm (height of fluid supply container relative to pump)
- Back pressure: 0 mmHg
- Flow rate: 0.1 to 1500 mL/h
- Viscosity: 50% Dextrose solution
- Ambient Temperature: 17°C to 23°C
- Relative Humidity: 45% to 80 %
- Ambient Pressure: 1000 hPa.

15.9.7 Loading Dose Volumetric Accuracy

Loading Dose Volumetric Accuracy Disclosure

Tested sets reference	Loading dose Volume mL	Loading dose rate mL/h	Loading Dose Volumetric Accuracy %	
			With Startup Delay Reduction	Without Startup Delay reduction
VL ST10 reference	0.1	360	6.4 ± 47	-20 ± 51
	1	1200	7.8 ± 3.7	6.2 ± 4.4
VLON72 reference	0.1	360	15 ± 55	-24 ± 50
	1	1200	6.6 ± 4.2	4.8 ± 4.7

NOTE Mean and standard deviation established with 10 tested pumps per set.

NOTE VL ST10 reference is considered as standard infusion set (set without filter)
VL ON72 reference is considered as representative reference for sets with filter

NOTE Conditions tested:
* Backpressure: 0 mmHg
* Inlet Pressure: 50cm (height of fluid supply container relative to pump)
* Viscosity: Distilled Water (grad 3)
* Ambient Temperature: 17°C to 23°C
* Relative Humidity: 45% to 80 %
* Ambient Pressure: 1010 hPa

15.9.8 Effects of Pumping on Fluid Temperature

	Impact on Fluid Temperature	
	Ambient Temperature	Temperature increase
Effects of Ambient Temperature on Infusion	~ 22 °C	< 2 °C (max. difference: 0.33 °C)
Test at maximum operating temperature	40 °C	< 1 °C

15.10 Infusion of blood and blood derivatives

15.10.1 Test results

Testing was performed under three different test conditions:

- Worst-case Rapid Infusion,
- Nominal Infusion,
- Worst-case Long Infusion,

to determine if the Agilia VP MC WiFi pump meets the requirements for acceptable limits of hemolysis, see Table below for test conditions.

Each scenario was performed 10 times on 5 Agilia VP MC WiFi pumps.

Condition	Flow rate (in mL/h)	Back Pressure (in mmHg)	Blood age (in day)	Blood Temperature (in °F) (1)	Needle Size (in Gauge	% hemolysis generated by the pump 95% confidence 99% of the population
Worst-case Rapid Infusion	1500	Close to 750	Close to 42	37.4°F	21	0.316%
Nominal Infusion	250	~ 300 - 550	Random	71.6 °F	21	0.086%
Worst-case Long Infusion	62.5	Close to 750	Close to 42	71.6 °F	21	0.206%

(1) 37.4°F = Cold ; 71.6°F = Room Temperature.

The test consists in the infusion of one unit of aged human blood within four hours (62.5 mL/h) or as rapidly as possible (1500 mL/h).

Transfusion set used for testing M46443160.

15.10.2 Infusion sets for infusion of blood and blood derivatives

Several transfusion sets are available. Please refer to section 24.1, page 211.

15.11 Calculation Rules

		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 = 01h13min
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, mcg, mg, g	/mL, /--mL
	mmol	
	mUnit, Unit	
	cal, kcal	
	mEq	

15.12.2 Dose Rate Units

	Units
Dose Rate Units	nanog/h, nanog/kg/min, nanog/kg/h
	mcg/min, mcg/h, mcg/kg/min, mcg/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	$mL/h = \frac{unit/kg/h\ (dose\ rate) \times kg\ (weight)}{unit/mL\ (concentration)}$	Conversion of a dose rate including the unit/kg into volume flow rate (mL/h)
	$mL/h = \frac{unit/m^2/h\ (dose\ rate) \times m^2\ (body\ surface\ area)}{unit/mL\ (concentration)}$	Conversion of a dose rate including the unit/m² into volume flow rate (mL/h)
	$mL/h = \frac{unit/h\ (dose\ rate)}{unit/mL\ (concentration)}$	Expression of a volumetric flow rate
	$mL = \frac{unit/kg\ (dose) \times kg\ (weight)}{unit/mL\ (concentration)}$	Conversion of a dose including the unit/kg into volume (mL)
	$mL = \frac{unit/m^2\ (dose) \times m^2\ (body\ surface\ area)}{unit/mL\ (concentration)}$	Conversion of a dose including the unit/m² into volume (mL)
	$mL = \frac{unit\ (dose)}{unit/mL\ (concentration)}$	Expression of a volume (mL)

16 Cleaning and Low Level Disinfection

Low level disinfection as per AAMI TIR 12.

WARNING

To avoid the risks of infection and microbial transmission, make sure to adequately clean and disinfect the equipment in case of dangerous spills such as blood, body fluids or chemotherapy, after each patient use, before any maintenance, on a routine basis when the pump is not in use and before storage. See section 16.5, page 173.

To clean non-dangerous spills or soil that may occur while preparing or operating the Agilia infusion pump, follow your facilities policies and procedures. See section 16.4, page 172.

16.1 Inspection Requirements

Before and after each use of the pump, and before and after cleaning and disinfecting it, you must perform a visual inspection as follows:

- Inspect all surfaces
- Check all moving parts.

If you see discoloration, cracks or other damage, return the pump to your biomedical engineering department for repair.

16.2 Recommended Cleaning Products and Disinfectants

- For cleaning, we recommend using Enzol (an enzymatic detergent) by Advanced Sterilization Products.
- For disinfection, we recommend using Caviwipes (active ingredients: isopropyl alcohol and benzethonium chloride) by Metrex Research Corporation.

16.3 Prohibited Cleaning Agents and Disinfectants

WARNING

Do not use the following cleaning agents and disinfectants:

- Trichloroethylene
- Abrasive detergents
- Undiluted alcohol.

These cleaning agents and disinfectants may damage plastic parts and cause the pump to malfunction.

16.4 Clean the Pump at the Patient Bedside

WARNING

When the cleaning is performed while the infusion pump is running, the keyboard should be locked to avoid any unintended modification of the infusion parameters.

INFORMATION

Non-dangerous fluid spills should be wiped up as soon as possible, and are not allowed to dry on the pump.

To clean non-dangerous spills or soil at the patient bedside:

1. Check the pump for visible cracks or damage that may allow fluid to reach internal components.
2. Check that the keypad is locked in order to avoid unintended modification of the infusion parameters.
3. Use ready-to-use wipes to thoroughly wipe down all exposed surfaces (housing, keyboard, pump door, door lever, etc.) of the pump, moving from the inner to outer edges of each surface.
   - When wiping down the sides, avoid wetting the connector sockets.
   - Do not allow liquids to run, leak, or drip into the pump housing.
   - Change wipes as needed to avoid spreading the spill from one area of the pump to another.

WARNING

- This cleaning at the patient bedside does not replace the need for a complete cleaning.
- At the end of the infusion, perform the complete cleaning protocol, See section 16.5, page 173.

16.5 Instructions for Cleaning and Disinfecting

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

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

Cleaning	Disinfecting
Enzol	Caviwipes

WARNING

The disinfecting procedure must be done immediately after cleaning. Disinfecting the pump without prior cleaning is not effective.

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

WARNING

- Only trained staff can clean and disinfect the pump.
- Do not place the pump in an autoclave or immerse it in liquid.
- The pump is not intended to be sterilized.
- Do not spray liquids directly on connectors and pump surface. Instead, use a cleaning cloth or disposable wipes.
- Do not use the pump if the housing, keypad, or display is damaged or cracked.
- If sticky or high-viscosity fluids are spilled behind the pump door, replace the infusion pump as soon as possible so it can be thoroughly cleaned. These types of fluids can damage the pumping mechanism when dried.

The use of certain cleaning or disinfecting agents may affect the service life of some operable parts, in particular parts that are seldom used.

16.5.1 How to Clean the Pump

Before cleaning, ensure that:

- The pump is at ambient room temperature between 68 °F and 77 °F (20 to 25 °C).
- You are wearing suitable protective equipment.

Cleaning procedure using Enzol product
1. Make sure the pump is turned off, unplug the power cord.
2. Place the pump on a clean surface or disposable underlay.
3. Prepare the cleaning solution according to the manufacturer's recommendations: - Add one ounce (1 pump action) of ENZOL Enzymatic Detergent liquid concentrate per gallon of water. - Wet a fresh piece of gauze or a soft cloth with the diluted cleaning agent and wring out any excess moisture.
4. Use the piece of gauze to remove any major grime.
5. Thoroughly wipe down all exposed surfaces (housing, keyboard, pump door, door lever…) of the pump from top to bottom. Use the metal handle to lift and move the pump as required. - When wiping down the sides of the pump, avoid wetting the connector sockets. - Do not allow liquids to run, leak, or drip into the pump housing.
6. Make sure the pump remains damp for at least 1 minute.
7. Set down the pump, and wipe down the metal handle, the attachment lock knob, the screw clamp and the release button.
8. Open the pump door, and gently wipe down the exposed surfaces (blue clamp, tube guides) and the back of the door lever.
9. Use a clean swab to gently scrub the exposed surfaces of the pump. Be sure to scrub along the seams and edges of the control panel (screen and keypad), and the narrow or hard-to-reach areas.
10. Using a fresh piece of gauze or a soft cloth dampened with cleaning agent, thoroughly wipe down again all exposed surfaces, including the tube guides and the back of the door lever.
11. Make sure the pump remains damp for at least 1 minute to dissolve all organic matter.
12. Complete the cleaning by wiping down the power cord, and any pump accessories.
13. Dampen a fresh piece of gauze with tap water, and rinse all exposed surfaces of the pump.
14. Allow the pump to dry completely at room temperature.
15. Inspect the device for any visible soil to ensure that the pump is completely clean prior to disinfection. If the device has remaining visible soil, repeat the cleaning steps.

WARNING
Ensure the air sensor is completely dry after cleaning to ensure air detection performance.

16.5.2 How to Disinfect the Pump

Before disinfecting the pump, ensure that:

- You first clean the pump according to the cleaning protocol, see How to Clean the Pump on page 174
- The pump is at ambient room temperature between 68 °F and 77 °F (20 to 25 °C)
- You are wearing suitable protective equipment
- That you use the appropriate disinfecting product: see Instructions for Cleaning and Disinfecting on page 173.

Disinfection procedure using Caviwipes product
1. Make sure the pump is turned off, unplug the power cord.
2. Place the previously cleaned pump on a clean surface or disposable underlay.
3. Use a fresh 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 (same surfaces as cleaned in the cleaning procedure). You can use the metal 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. Set down the pump and wipe down the metal handle, the attachment lock knob, the screw clamp and the release button.
5. Open the pump door, and gently wipe down the exposed surfaces (blue clamp, tube guides) and the back of the door lever.
6. Using a fresh ready-to-use wipe, repeat steps 3 to 5.
7. Leave the disinfecting product on the pump for at least 3 minutes.
8. Wipe down the power cord and any pump accessories.
9. Allow the pump to dry completely at room temperature.

WARNING
Ensure the air sensor is completely dry after cleaning to ensure air detection performance.

17 Power Management

17.1 AC Power Supply Precautions

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

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

WARNING

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

17.2 Battery Precautions

The device uses a Lithium-ion rechargeable battery.

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

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

Refer to section 18.2, page 178. for more information about battery characteristics.

INFORMATION

- Do not replace with a battery other than the one provided by **Fresenius Kabi**.
- Do not use the pump without the battery connected.
- Do not disconnect the battery when the device is operating on AC or battery power. Disconnect the power cord and power off the device before disconnecting the battery.
- Do not incinerate or place near a flame.
- Do not drop, crush, puncture, modify or disassemble the battery.
- Do not use a battery that is severely scratched or damaged.
- Do not short the terminals.
- Do not expose to high temperatures or very low temperatures: refer to the operating conditions for use, and the storage instructions.
- Do not try to charge or discharge the battery outside of the device.
- For more information on replacing the battery, refer to the technical manual.

17.3 Battery Operating Mode

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

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

INFORMATION

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

18 Technical Characteristics

18.1 Power Supply

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

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

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

18.2 Battery

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

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

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

✓ = WiFi enabled
✗ = WiFi 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 using a serial RS232 protocol.

You must use an Agilia USB cable (shown below) to connect the pump to a computer:

To pump
(proprietary serial RS232 male connector)

To computer
(USB male connector)

When not using the Agilia USB Cable, disconnect it from both the pump and the PC. Securely store the cable and restrict its access to authorized personnel only.

WARNING

- The use of another cable may lead to PC / Agilia VP MC WiFi infusion pump malfunctions and electrical harm due to residual leakage currents.
- External wireless devices cannot be used with the Agilia USB cable or communication port.

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*

* power output is only used to power the Agilia USB cable.

18.5 Infrared Communication

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

The Infrared Communication is not available in the US.

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 Sound Levels

18.6.1 Operating Pump Sound Levels (without alarms)

Flow Rate (mL/h)	Sound Level (dBA)
0	21
1	30
100	37
400	33
1500	46

Note:
These values are provided for information purposes only.

18.6.2 Alarms Sound Levels

Alarm Priority	Sound Level (dB)	
	min	Max
High-Priority	55 ±6	67 ±6
Medium-Priority	51 ±6	63 ±6
Low-Priority	50 ±6	58 ±6

As per the measuring method defined in IEC60601-1-8: ed 2006; Am.1: 2012

18.7 Compliance

Electro-Medical Equipment Safety	Compliant with the following standards: ▪ IEC 60601-1 ▪ IEC 60601-1-8	**IP22**	Index of protection against ingress of water or particulate matter
EMC (Electro-Magnetic Compatibility)	Compliant with the following standard: ▪ IEC 60601-1-2		Protection against leakage current: defibrillation-proof type CF applied part*
			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.*

18.8 Dimensions and Weight

H / W / D	5.3 x 7.5 x 6.7 in (135 x 190 x 170 mm)
Weight	Approximately 4.4 lbs (2 kg)
Screen Size	2.7 x 1.4 in (70 x 35 mm)

18.9 Trumpet, Start-up Curves and AAMI TIR101: 2020 Delivery Performance

Reminder

The Agilia VP Infusion is intended for adult and pediatric care for the intermittent or continuous delivery of parenteral fluids, medications, blood, and blood derivatives through clinically accepted parenteral routes of administration.

The Agilia VP Infusion System is intended for neonatal care for the intermittent or continuous delivery of parenteral fluids for hydration and nutrition, blood, and blood derivatives through clinically accepted parenteral routes of administration. These routes of administration include intravenous, intra-arterial, and subcutaneous using dedicated administration sets.

WARNING

Starting an infusion at a low flow rate (typically under 1mL/h) can cause a delay in medication delivery because it reduces the initial accuracy of the programmed flowrate which prolongs rate stabilization (for additional information, see section 15.9, **"Accuracy"** on page 161, and section 18.9, **"Trumpet, Start-up Curves and AAMI TIR101: 2020 Delivery Performance"** on page 182).

In order to ensure patient safety in high risk populations, close monitoring is recommended in low flow rate infusions.

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

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 threshold in order to gain in time to detect occlusion.
- For the infusion of very short half-life at flow rate below 5 mL/h, we recommend using syringe pumps that usually offer better performances of instant flow rates.

WARNING

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 1 mL per hour): consider occlusion pressure threshold setting and adjust it, as necessary. The lower the occlusion pressure threshold setting is, the shorter the occlusion detection time will be. However, when infusing viscous or thick fluids (e.g., lipids), the occlusion pressure threshold setting may need to be adjusted to a higher value to reduce false alarms.

Note: When infusing at flow rates of less than 1mL/h, the time to detect occlusion may be more than 5 minutes: monitor the patient and if there is a lack of patient clinical response, check for occlusion.

18.9.1 Flow Rate: 0.1 mL/h

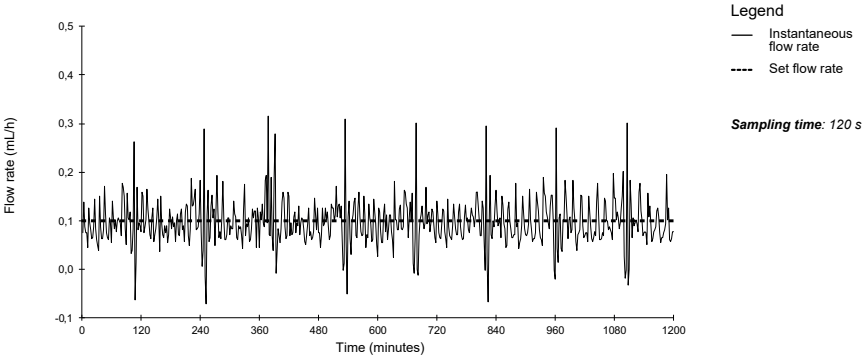


Figure 18.1: Start-up and instantaneous flow rate
(0.1 mL/h over first 20 hours on 96 hours)

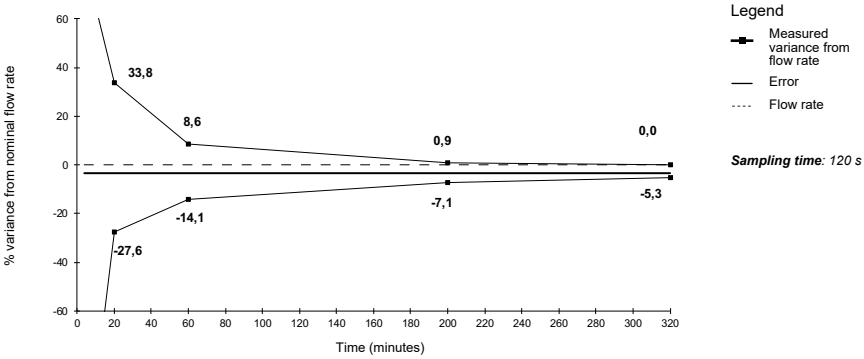


Figure 18.2: Trumpet curves for 4, 20, 60, 200, 320 minutes observation windows
(0.1 mL/h over first 20 hours on 96 hours)

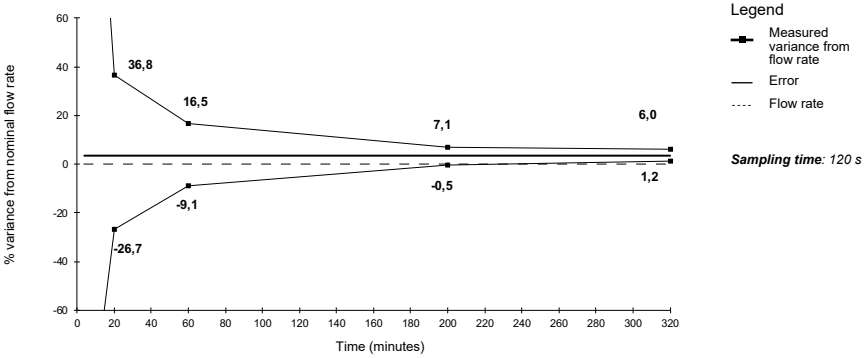


Figure 18.3: Trumpet curves for 4, 20, 60, 200, 320 minutes observation windows
(0.1 mL/h over last 20 hours on 96 hours)

18.9.2 Flow Rate: 1 mL/h

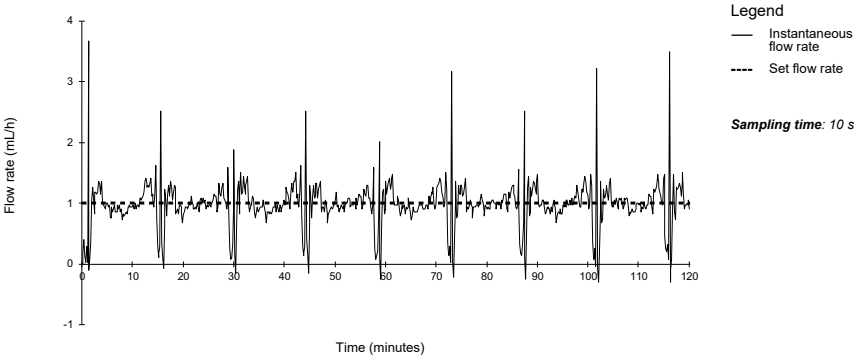


Figure 18.4: Start-up and instantaneous flow rate
(1 mL/h over first 2 hours on 96 hours)

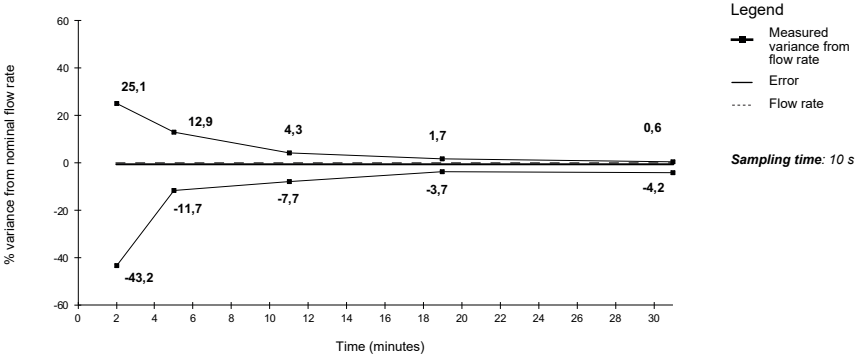


Figure 18.5: Trumpet curves for 2, 5, 11, 19, 31 minutes observation windows
(1 mL/h over first 2 hours on 96 hours)

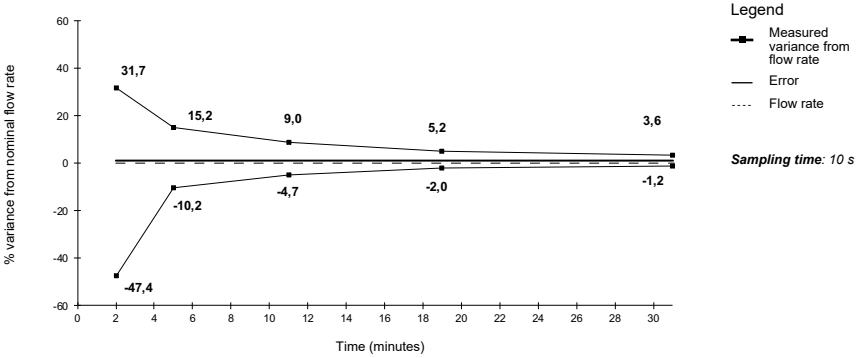


Figure 18.6: Trumpet curves for 2, 5, 11, 19, 31 minutes observation windows
(1 mL/h over last 2 hours on 96 hours)

18.9.3 Flow Rate: 25 mL/h

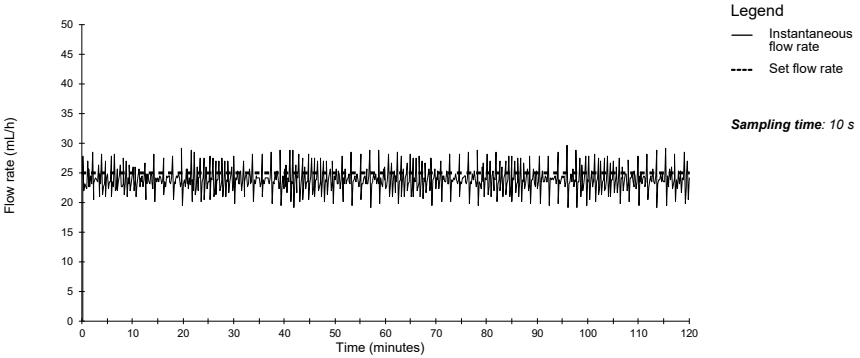


Figure 18.7: Start-up and instantaneous flow rate
(25 mL/h over first 2 hours on 96 hours)

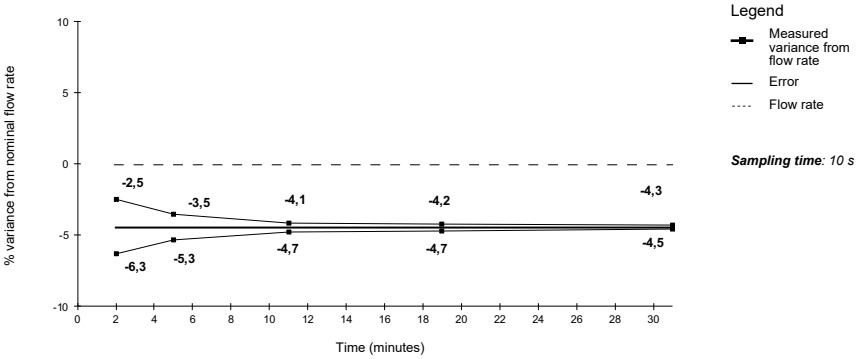


Figure 18.8: Trumpet curves for 2, 5, 11, 19, 31 minutes observation windows
(25 mL/h over first 2 hours on 96 hours)

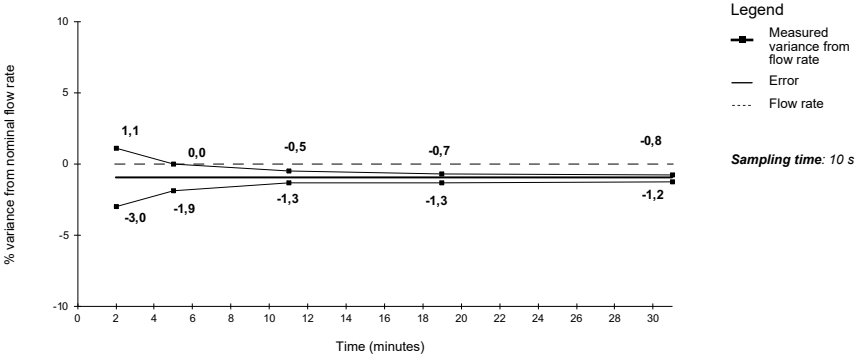


Figure 18.9: Trumpet curves for 2, 5, 11, 19, 31 minutes observation windows
(25 mL/h over last 2 hours on 96 hours)

18.9.4 Flow Rate: 1500 mL/h

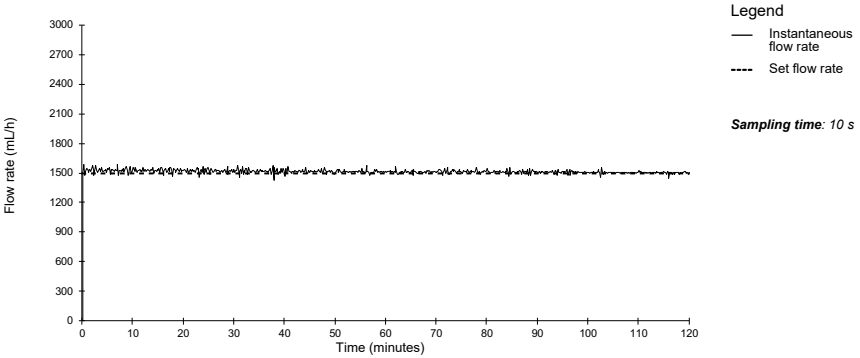


Figure 18.10: Start-up and instantaneous flow rate (1500 mL/h over first 2 hours on 10 liters)

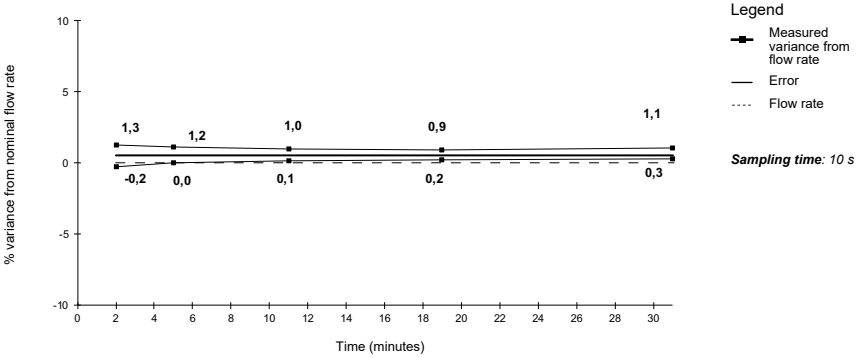
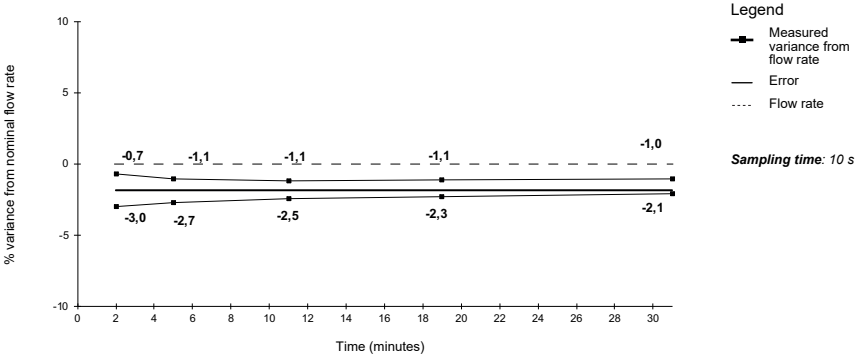
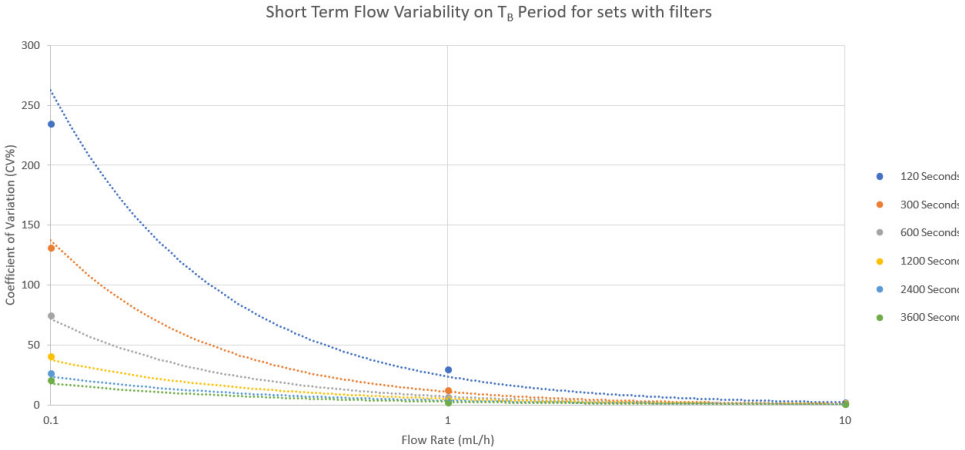


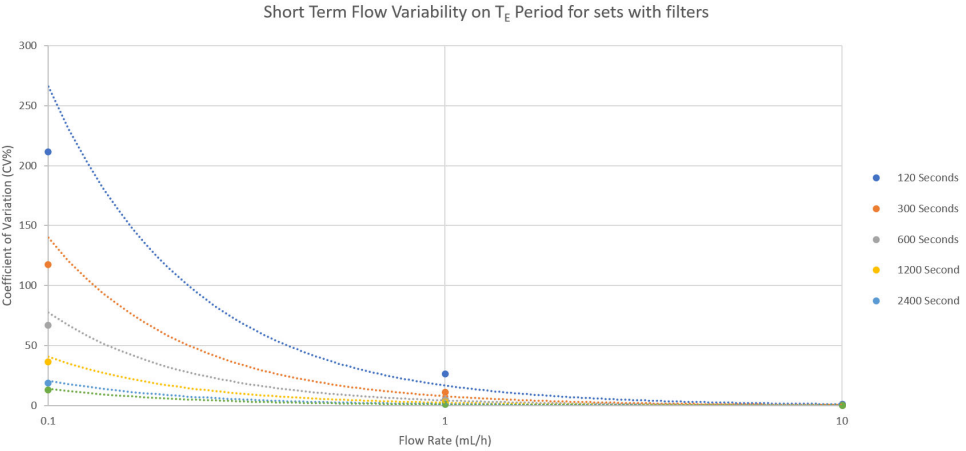
Figure 18.11: Trumpet curves for 2, 5, 11, 19, 31 minutes observation windows (1500 mL/h over first 2 hours on 10 liters)

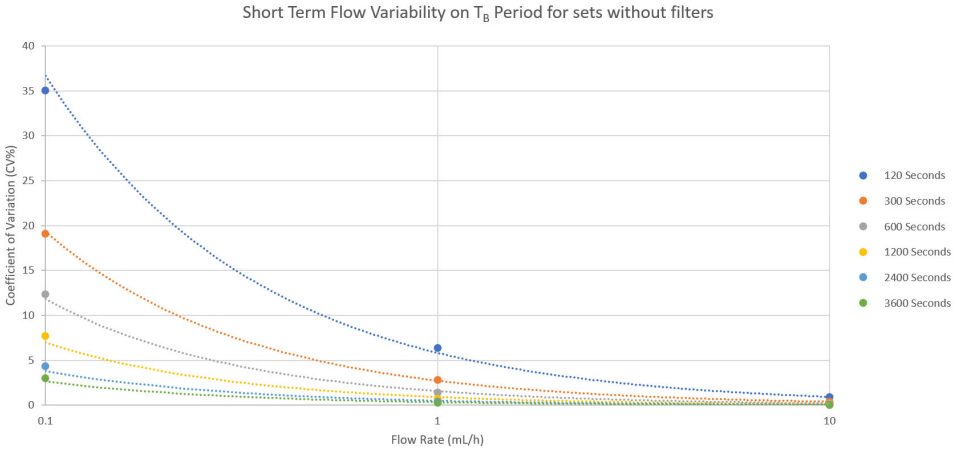


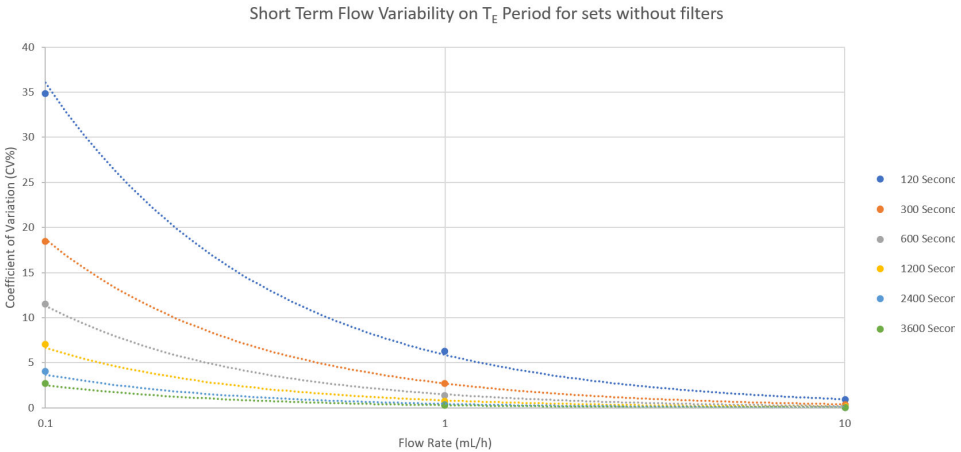
Trumpet curves for 2, 5, 11, 19, 31 minutes observation windows (1500 mL/h over last 2 hours on 10 liters)

18.9.5 AAMI TIR101:2020 Coefficient of Variability (CV%)

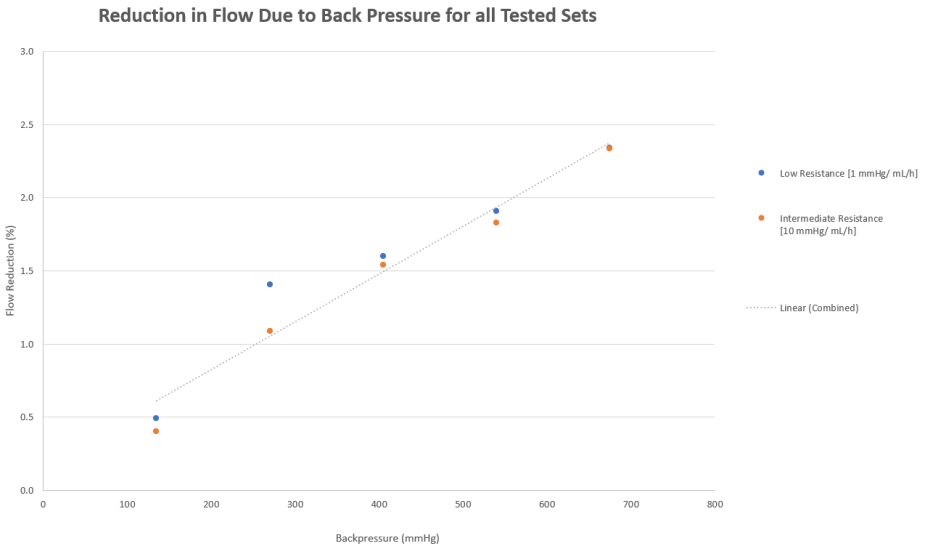





Short Term Flow Variability on T_B Period for sets without filters
Coefficient of Variation (CV%)
40
35
30
25
20
15
10
5
0
0.1
1
10
Flow Rate (mL/h)
120 Seconds
300 Seconds
600 Seconds
1200 Seconds
2400 Seconds
3600 Seconds


Short Term Flow Variability on T_E Period for sets without filters
Coefficient of Variation (CV%)
40
35
30
25
20
15
10
5
0
0.1
1
10
Flow Rate (mL/h)
120 Seconc
300 Seconc
600 Seconc
1200 Secor
2400 Secor
3600 Secor

18.9.6 AAMI TIR101:2020
Reduction in Flow Due to Back Pressure



18.10 Occlusion Alarm Accuracy and Bolus Volume at Occlusion Release

The following tables show the initial recommended Pressure Threshold settings for different infusion flow rates.

Target Infusion Flow Rate	Recommended Occlusion Pressure Threshold	Expected Time to Detect Downstream Occlusion	Post-occlusion unintended bolus (average per minute over 5 minutes)
0.1 mL/h	50 mmHg	46.5 ± 9 minutes	0.00453 ± 0.00705 mL/min
0.5 mL/h	50 mmHg	7.0 ± 1.7 minutes	-0.00100 ± 0.00291 mL/min
1 mL/h	50 mmHg	4.5 ± 0.6 minutes	-0.00103 ± 0.00617 mL/min
1.5 mL/h	100 mmHg	3.8 ± 1.7 minutes	0.00556 ± 0.00634 mL/min
2 mL/h	150 mmHg	5.0 ± 0.2 minutes	0.00905 ± 0.00669 mL/min
5 mL/h	200 mmHg	3.0 ± 0.9 minutes	0.00425 ± 0.00265 mL/min
10 mL/h	200 mmHg	1.7 ± 0.3 minutes	0.00392 ± 0.00689 mL/min
10.1 to 1,500 mL/h	200 to 750 mmHg	Less than 5 minutes	< +10% of the intended volume over one minute
1,500 mL/h	750 mmHg	12.6 ± 4.9 seconds	0.01699 ± 0.00586 mL/min

* **Test conditions**: *Tests were performed using distilled water (and using a USA market equivalent administration set). Temperature: 68° F (20 °C). Administration set length: 105 in (270 cm).*

Note:
The maximum values of the occlusion alarm response time specified above do not take into account the auto-restart feature when it is enabled. When auto-restart is triggered, a period of 30 seconds maximum is added depending on the configurable period of pressure measurement. See section 7.10.4, page 90. It is the healthcare professional's responsibility to define whether the auto-restart feature should be enabled or not depending on the clinical practices.

Upstream occlusion alarm response *	Upstream occlusion is detected in less than 1ml of infusion

** Test condition: Back pressure: 0 mmHg, Container height: 20 in (50 cm)*

19 WiFi

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 and 5 GHz Frequency Band.

The Agilia infusion pump transmitter IDs are:

- FCC ID: XF6-RSWC301
- IC ID: 8407A-RSWC301.

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.

WARNING

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

19.1.1 WiFi functionalities

The built-in WiFi communicates periodically with the server software to perform the following tasks:

- Receive downloads of data sets (from the server software to the pump)
- Upload pump history (from the pump to the server)
- Communicate the operating status of the pump.

INFORMATION

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

INFORMATION

Agilia WiFi pump functions as a wireless client only using a 2.4 GHz or 5 GHz network.

No other wireless product can connect to our device.

19.2 Specifications

19.2.1 Technical Specifications

	Description
Technology	IEEE 802.11 a/b/g/n
Frequency Band	▪ 2.400 ➔ 2.500 GHz (2.4 GHz is ISM band) ▪ 4.900 ➔ 5.850 GHz (High Band)
Modulation	OFDM with BPSK, QPSK, 16-QAM, and 64-QAM 802.11b with CCK and DSSS
Wireless Security	▪ WPA2 Enterprise ▪ WPA2 Enterprise TLS ▪ WPA2 Enterprise TTLS The use of Radius authentication is recommended for all protocols.
Network Protocols	TCP, IPv4, DHCP, HTTPS
Typical Transmit Power (± 2 dBm)	▪ 17 dBm for 802.11b DSSS ▪ 17 dBm for 802.11b CCK ▪ 15 dBm for 802.11g/n OFDM ▪ 12 dBm in 802.11a mode

Note:
WPA2-Entreprise is the minimum recommended level of security to secure the wireless network.

19.2.2 Electromagnetic Compatibility

For information on electromagnetic compatibility, see section 22, page 199.

19.2.2.1 USA - FCC Notice

INFORMATION

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 Outside North America

This product is designed to function only in USA, and shall not be used outside the USA, as frequencies and power levels can be in violation with local regulation.

19.2.3 Protocols and Standards

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

- IEEE 802.11a/b/g/n standard
- WPA2 Enterprise, WPA2 Enterprise TLS, WPA2 Enterprise TTLS (Radius authentication recommended) is a long-term security solution for wireless networks. For more information, refer to the IEEE 802.11.
- TCP/IP (Transmission Control Protocol / Internet Protocol), IPv4 (Internet Protocol Version 4), DHCP (Dynamic Host Configuration Protocol) and HTTPS (Hypertext Transfer Protocol Secure) are standard data transport protocol used for the internet and other similar networks.

19.2.4 WiFi Quality of Service

The wireless functionality does not require a specific level of WiFi quality of service:

Agilia infusion pumps do not require an active wireless communication to function safely and 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's ability to infuse.

INFORMATION

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

19.2.5 WiFi Data Integrity

Data integrity is inherent in the design:

- Data that is transported through WiFi, or Data that is pending to be transported through WiFi, is stored locally in the pump, and can be automatically re-transmitted when the connection becomes available again.
- The system should be serviced and maintained by a qualified and trained technical user, or a Fresenius Kabi representative.

19.2.6 WiFi Troubleshooting guide

Issue	Recommended Actions
Data set are not transmitted to the pump or pump history is not transmitted to the server.	Biomedical department shall check pump WiFi settings in Agilia Partner Maintenance software.
WiFi icon is displayed as follow:  .	WiFi is disabled: biomedical department shall turn on the WiFi in pump dedicated menu and/or in Agilia Partner Maintenance software.
WiFi icon is displayed as follow:  .	No WiFi signal is received by the pump: biomedical department shall check the WiFi access points localization.
Battery is low, and WiFi is automatically turned off.	Connect the pump to the AC power supply.
Pump internal temperature is too high, and WiFi is automatically turned off.	Wait until temperature decreases, and WiFi will turn on automatically.

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).	▪ Do not use the pump. ▪ Remove the power cord. ▪ Contact your biomedical department or your **Fresenius Kabi** 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** representative.
The pump cannot be installed or removed from the Agilia Link.	▪ Check the rotating pole clamp position. ▪ Contact your biomedical department or your **Fresenius Kabi** 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** 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** 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** representative.
Keypad problem (keys, LEDs).	▪ Check the general condition of the keypad. ▪ Check the contrast. ▪ Contact your biomedical department or your **Fresenius Kabi** representative.
The power supply indicator (LED) does not light up.	▪ Connect the pump to the AC power supply. ▪ Contact your biomedical department or your **Fresenius Kabi** representative.
The pump powers off on its own.	▪ Connect the pump to the AC power supply. ▪ Contact your biomedical department or your **Fresenius Kabi** 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** representative.
The pump powers off when it is disconnected from the AC power supply.	▪ The battery is completely discharged: charge the battery. ▪ Contact your biomedical department or your **Fresenius Kabi** representative.
WiFi communication error.	▪ Contact your IT or biomedical department, or your **Fresenius Kabi** representative.

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

21 Warranty

21.1 General Warranty Conditions

Fresenius Kabi guarantees that this product is free from defects in material and workmanship during the period defined by the accepted sales conditions, except for the batteries and the accessories.

21.2 Limited Warranty

To benefit by the materials and workmanship guarantee from authorized agent or **Fresenius Kabi** representative, 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** representative.

21.3 Warranty Conditions for Accessories

Batteries and accessories may have specific warranty conditions.

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

22 Guidance and Manufacturer's Declaration on EMC

22.1 Electromagnetic Compatibility

WARNING

- The Agilia pump and its accessories are intended to be used in the electromagnetic environments specified in the technical manual.
- The customer or the user of the Agilia VP MC WiFi pump should ensure that it is used in such environments.
- The Agilia pump must not be used in the presence of intense electromagnetic fields, such as those generated by certain electrically powered medical devices. Agilia VP MC WiFi is MR Unsafe.
- Prolonged exposure to X-ray and CT Scan environments can damage the electronic components of the device and influence the flow rate accuracy. For a safe usage, we recommend to:
  - always put the device at the maximum distance from the patient and the source
  - limit the presence of the device in such environments.

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

Outside the normal use described in this IFU, 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 or battery contacts) and surfaces that are only accessible for maintenance also require precautions.

22.2 Electrostatic Discharge (ESD) and Precautions To Be Taken

INFORMATION

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

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

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

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

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

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

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

22.3 EMC and Essential Performance

In standard operating conditions (see section 1.9, page 21), the essential performance of the Agilia pump is defined in section 15.1, page 156.

In the event of electromagnetic disturbances above the limits defined in the applicable EMC standards, if the essential performance is lost or degraded, the consequences for the patient are: overdose, underdose, delay of therapy, electric shock.

It is the responsibility of the customer or user to check the equipment before use as described in section 11, page 131, and to consider the EMC guidance of Section 22.4.

22.4 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.

Agilia VP MC WiFi is classified as a Class B device according to CISPR 11 emitted radiation.

WARNING

- The functionality of the pump can be affected by pressure variations, mechanical shocks, heat ignition sources, and other unusual events.
- Direct exposure to ultrasound devices may damage the pump or its components.

WARNING

- Use of the Agilia pump adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.
- Use of accessories, transducers and cables other than those specified or provided by the manufacturer of the Agilia pump could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.
- Portable RF communications equipment (including peripherals such as antenna cables, internal and external antennas) should be used no closer than 4 in (10 cm) for cell phones and 12 in (30 cm) for other equipments, to any part of the Agilia pump, including cables specified by the manufacturer. Otherwise, degradation of the essential performances of Agilia pump could result. Electrosurgical equipment (including base unit, cables, electrodes) should be used no closer than 12 in (30 cm) to any part of the Agilia pump, including cables specified by the manufacturer. Otherwise, degradation of the essential performance of Agilia pump could result.

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

If the Agilia pump is placed near RF communication equipment such as cell phones, DECT phones or wireless access points, portable RFID reader, large scale RFID reader and RFID tags, it is essential to observe a minimum distance between the Agilia pump and this equipment.

If the Agilia pump causes harmful interference, or if it is disrupted by external interference, try the following:

- 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.

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

For further information on EMC compliance, please refer to the Agilia pump technical manual.

22.4.1 EMC compliance results

Electromagnetic emissions

Emission test	Compliance obtained by the device	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The Agilia pump uses RF energy only for its internal function. Therefore its RF emissions are 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, including domestic and hospital establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Complies Class A	
Voltage fluctuations Flicker emissions IEC 61000-3-3	Complies	

Electromagnetic immunity

Immunity test	IEC 60601-1-2 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 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 and 10 cm (see below)

Immunity test	IEC 60601-1-2 Test level	Compliance level obtained by the device	Electromagnetic environment – guidance
Near field radiated RF IEC 61000-4-3 test method	385 MHz, PM 18 Hz, 27 V/m 450 MHz, PM 18 Hz, 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, PM 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, PM 18 Hz, 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, PM 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

Immunity test	IEC 60601-1-2 Test level	Compliance level obtained by the device	Electromagnetic environment – guidance
Electrical Fast transient / Burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input output lines 100 kHz repetition	± 2 kV for power supply lines ± 1 kV for input output lines 100 kHz repetition	Electricity power quality should be that of a typical domestic, commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV differential mode ± 2 kV common mode	± 1 kV differential mode ± 2 kV common mode	Electricity power quality should be that of a typical domestic, commercial or hospital environment. For very exposed establishments or buildings with the lightning, a protection must be installed on electricity power. Class II product and no earth connection.
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.
Power frequency (50 / 60 Hz) magnetic field IEC 61000-4-8	30 A / m 400 A / m	400 A / m	If necessary, the power magnetic field should be measured in the intended installation location to make sure it is lower than the compliance level. If the measured field in the location where the Agilia pump is used exceeds the applicable magnetic field compliance level above, the Agilia pump should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Agilia pump, or installing magnetic shielding.

Immunity test	IEC 60601-1-2 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 0,5 cycle at 0°, 45°, 90°, 135°,180°, 225°, 270° and 315°	Electricity power quality should be that of a typical domestic, commercial or hospital environment.
	0% Ut (100% dip in Ut) for 1 cycle	0% Ut (100% dip in Ut) for 1 cycle	For short and long interruptions (< than battery autonomy) of electricity power supply, the internal battery provides the continuity of service.
	70% Ut (30% dip in Ut) for 25 cycles at 50 Hz for 30 cycles at 60 Hz at 0°	70% Ut (30% dip in Ut) for 25 cycles at 50 Hz for 30 cycles at 60 Hz at 0°	For very long (> than battery autonomy) interruptions of electricity power supply, the Agilia pump must be powered from an external Uninterruptible Power Supply (UPS).
	0% Ut (100% dip in Ut) for 250 cycles at 50 Hz for 300 cycles at 60 Hz	0% Ut (100% dip in Ut) for 250 cycles at 50 Hz for 300 cycles at 60 Hz	<u>Note:</u> *Ut is the a/c mains voltage prior to application of the test level.*

Additional immunity test and specific tests level

Immunity test	Specific test method / level	Compliance level obtained by the device	Electromagnetic environment – guidance
Near field radiated RF Special test IEC 61000-4-39 Test method	450 MHz, PM 217 Hz, 28 V/m 710 MHz, PM 217 Hz, 28 V/m 787 MHz, PM 217 Hz, 28 V/m 810 MHz, PM 217 Hz, 44 V/m 830 MHz, PM 217 Hz, 44 V/m 870 MHz, PM 217 Hz, 44 V/m 1750 MHz, PM 217 Hz, 28 V/m 1875 MHz, PM 217 Hz, 28 V/m 1970 MHz, PM 217 Hz, 28 V/m 2560 MHz, PM 217 Hz, 28 V/m 2655 MHz, PM 217 Hz, 28 V/m	28 V/m 28 V/m 28 V/m 44 V/m 44 V/m 44 V/m 28 V/m 28 V/m 28 V/m 28 V/m 28 V/m	For minimal distance approach 10 cm (4 inches). Portable and mobile RF communications equipment should be used no closer to any part of the device, including cables, than the recommended minimal separation distance (10 cm - 4 inches) for these frequencies.
RFID Special test AIM 7351731 Test methods	ISO 14223 – 134.2 kHz 65 A/m	65 A/m	The test level at 134.2 kHz are based on 2.5 cm (0.8 inches) distance.
	ISO/IEC 14443-3 (type A) – 13.56 MHz 7.5 A/m	7.5 A/m	The test level at 13.56 MHz are based on direct antenna contact with the device.
	ISO/IEC 14443-4 (type B) – 13.56 MHz 7.5 A/m	7.5 A/m	
	ISO/IEC 15693 (ISO 18000-3 Mode 1) – 13.56 MHz 5 A/m	5 A/m	
	ISO 18000-3 Mode 3 - 13.56 MHz 12 A/m	(*)	
	ISO/IEC 18000-7 – 433 MHz 3 V/m	3 V/m	The test levels at 433 MHz, 915 MHz and 2.4 GHz are based on the maximum allowed power under FCC part 15 and a typical distance of 20 cm (8 inches)
	ISO/IEC 18000-63 (DSB-ASK + PR-ASK) 860-960 MHz 54 V/m	50 V/m	
	ISO/IEC 18000-4 Mode 1 - 2,45 GHz 54 V/m	54 V/m	

(*): While ISO 18000-3:2010, 6.3.3.1 specifies a maximum value of 12 A/m, 5 A/m RMS is used for this test because it is the maximum value specified in the authoritative standards for the physical layer and air interface (ISO 15693-1 and ISO 15693-2) – ref. Annex J of AIM standard, rationale for test level. This mode is not described in the AIM test setup appendix: the test is not performed. Test and result of Annex D must be referred to, with the same test level and similar modulation: ISO/IEC 15693 (ISO 18000-3 Mode 1) – 13,56 MHz 5 A/m.

23 Servicing

23.1 Information on Device Servicing

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

1. Clean and disinfect the device.
2. Pack the device in appropriate packaging.
3. 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** representative.

23.2 Maintenance Requirements

WARNING

- Maintenance operations must be done while pumps are not infusing to a patient.
- Perform preventive maintenance at least once every 3 years. This includes replacing the battery and the pumping membrane.

To ensure the device continues to operate normally, preventive maintenance should be performed. 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.
- Failure to comply with these maintenance procedures could damage the device and lead to a functional failure. Internal inspection of the device requires compliance with special procedures to avoid damage to the device.
- When replacing components, only use spare parts from **Fresenius Kabi**.
- Do not modify the pump (except in the case of operations recommended by **Fresenius Kabi**).

The pump is expected to continue to function according to specifications for up to 10 years (end of life) with recommended preventive maintenance at least every 3 years.

INFORMATION

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

23.3 Inspection Requirements

Before and after each use of the pump, you must visually inspect it as follows:

- Inspect all visible surfaces.
- Check all moving parts on the device.

If you observe discoloration, cracking or other damage, return the pump to your biomedical engineering department for repair.

23.4 Calibration

INFORMATION

- The device remains calibrated so long as the preventive maintenance window has not elapsed and the device is not otherwise damaged or tampered with.
- To check the calibration date, follow instructions for accessing maintenance in section 8.23, page 121.

To ensure the device calibration is not affected by damage or tampering, follow the instructions below:

- Do not drop the device.
- If the device is dropped or other technical malfunctions occur, do not use the device. Immediately notify qualified personnel (i.e. biomedical engineering) to check calibration/re-calibrate device per technical manual instruction before returning device to use.
- Failure to comply with these instructions could damage the device and lead to a functional failure, including calibration failure and inaccurate fluid delivery.

23.5 Quality Control

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

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

INFORMATION

- These control checks must be performed by trained technical personnel, and are not covered by any contract or agreement provided by **Fresenius Kabi**.
- For more information, refer to the technical manual, or contact your **Fresenius Kabi** representative.

23.6 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: +1 800-933-6925 / +49 (0) 6172 / 686-0

www.fresenius-kabi.com

24 Ordering Information

The items listed below are compatible with the pump.
For more information, contact your **Fresenius Kabi** representative.

WARNING

Only use recommended items that are compatible with the Agilia Connect Infusion System. Use of any other items may damage the pump.

INFORMATION

Additional power cords and 'Instructions For Use' documents must be ordered separately. Contact your **Fresenius Kabi** representative for ordering.

24.1 Administration Sets

INFORMATION

- All Volumat Lines are sterile single used devices. They are all free from DEHP. For more information, refer to the individual administration set labelling.
- The flow rate accuracy of an infusion made with the Agilia VP MC WiFi and any of the administration sets listed below is ± 5%.
- Other administration sets available from **Fresenius Kabi** are listed in Fresenius's Medical Devices Product Catalog. Get in contact with your sales representative to get the website where this information is available.

VL ST10-0	**Primary Pump Set** with convertible piercing pin, non-DEHP tubing, roller clamp, calibrated silicone pumping segment with SafeClip, rotating male luer lock. Not made with natural rubber latex. PV 25 mL, 112 inch.	M46441360
VL ST02-0	**Primary Pump Set** with convertible piercing pin, non-DEHP tubing, roller clamp, calibrated silicone pumping segment with SafeClip, downstream pinch clamp, needle-free port, rotating male luer lock. Not made with natural rubber latex. PV 25 mL, 112 inch.	M46441960
VL PR42-11	**Primary Pump Set** with convertible piercing pin, non-DEHP tubing, pinch clamp, backcheck valve, needle free port, roller clamp, calibrated silicone pumping segment with SafeClip, downstream pinch clamp, needle-free port, rotating male luer lock. Not made with natural rubber latex. PV 25 mL, 112 inch.	M46445660

VL PR42-21	**Primary Pump Set** with convertible piercing pin, non-DEHP tubing, pinch clamp, backcheck valve, 2 needle free ports, roller clamp, calibrated silicone pumping segment with SafeClip, downstream pinch clamp, needle-free port, rotating male luer lock. Not made with natural rubber latex. PV 25 mL,1 12 inch.	M46445670
VL PR42-12	**Primary Pump Set** with convertible piercing pin, non-DEHP tubing, pinch clamp, backcheck valve, needle free port, roller clamp, calibrated silicone pumping segment with SafeClip, downstream pinch clamp, 2 needle-free ports, rotating male luer lock. Not made with natural rubber latex. PV 25 mL, 112 inch.	M46445690
VL PR72-11	**Primary Filter Pump Set** with convertible piercing pin, non-DEHP tubing, pinch clamp, backcheck valve, needle-free port, roller clamp, calibrated silicone pumping segment with SafeClip, downstream 0.2 micron filter, pinch clamp, needle-free port, rotating male luer lock. Not made with natural rubber latex. PV 27 mL, 112 inch.	M46445860
VL TR00-0	**Transfusion Pump Set** with dingle nonvented spike, non-DEHP tubing, upstream 200 micron filter, roller clamp, calibrated silicone pumping segment with SafeClip, downstream pinch clamp, rotating male luer lock. Not made with natural rubber latex. PV 25 mL, 124 inch.	M46442860
VL SP22-0	**Transfusion Pump Set** with dual nonvented spikes, non-DEHP tubing, upstream 200 micron filter, roller clamp, calibrated silicone pumping segment with SafeClip, downstream pinch clamp, needle free port, rotating male luer lock. Not made with natural rubber latex. PV 30 mL, 114 inch.	M46443160
VL SP62-1	**Primary Pump Set** with convertible piercing pin, PVC free, roller clamp, calibrated silicone pumping segment with SafeClip, downstream pinch clamp, needle-free port, rotating male luer lock. Not made with natural rubber latex. PV 25 mL, 112 inch.	M46443450
VL PN02-1	**Standard Filter Pump Set** with convertible piercing pin, non-DEHP tubing, roller clamp, calibrated silicone pumping segment with SafeClip, downstream 1.2 micron filter, pinch clamp, needle-free port, rotating male luer lock. Not made with natural rubber latex. PV 25 mL, 114 inch.	M46442460
VL ON72-1	**Standard Pump Set** with convertible piercing pin, PVC Free, roller clamp, calibrated silicone pumping segment with SafeClip, downstream 0.2 micron filter, pinch clamp, needle-free port, rotating male luer lock. Not made with natural rubber latex. PV 26 mL, 114 inch.	M46444160
VL PA92-1	**Burette Pump Set** with convertible piercing pin, non-DEHP tubing, 150 mL burette, 20 drops/mL, needle free port, roller clamp, calibrated silicone pumping segment with SafeClip, downstream pinch clamp, needle-free port, rotating male luer lock. Not made with natural rubber latex. PV 25 mL, 118 inch.	M46445260

VL PA 92-2	Burette Pump Set with convertible piercing pin, non-DEHP tubing, 150 mL burette, 60 drops/mL, needle free port, roller clamp, calibrated silicone pumping segment with SafeClip, downstream pinch clamp, needle-free port, rotating male luer lock. Not made with natural rubber latex. PV 25 mL, 118 inch.	M46445270
VL SL00-0	**Secondary Set** with convertible piercing pin, non-DEHP tubing, roller clamp, rotating male luer lock, Hanger. PV 12 mL, 35 inch.	M77460030

24.2 Data Management Cables

Agilia USB Cable	Communication cable for USB connection	Z073550

24.3 Associated Software

Agilia Partner	Maintenance Software (CD) Maintenance Software (eDownload)	Z067048 ZK267048

For more information, contact your Fresenius Kabi sales representative.

For a list of software compatible with your product refer to the Agilia Connect Infusion System Compatibility Guide.

24.4 Racks and Accessories

Agilia Link 4	4-slot rack for power centralization	Z074135
Agilia Link 6	6-slot rack for power centralization	Z076135
Agilia Link 8	8-slot rack for power centralization	Z078135
Agilia Duo	2 pump accessory for power supply centralization	Z073607

25 Glossary of Terms

A

A	Amperes
AC	Alternating Current
Ah	Ampere-hours
AIDC	Automatic Identification and Data Capture
AM	Amplitude Modulation
A/m	Amperes per meter

B

BPSK	Binary Phase Shift Keying

C

cal	Calorie
CCK	Complementary Code Keying
CISPR	Special International Committee on Radio Interference
CT Scan	Computed Tomography

D

dBA	Decibels
dBm	Decibels-Milliwatts
DC	Direct Current
DECT	Digital Enhanced Cordless Telecommunications
DEHP	Di(2-ethylhexyl) phthalate
DHCP	Dynamic Host Configuration Protocol
DI	Dose Infused
DPS	Dynamic Pressure System
DSSS	Direct Sequence Spread Spectrum
DTBI	Dose to Be Infused
DUR	Duration

E

ECG	Electrocardiogram
ECMO	ExtraCorporeal Membrane Oxygenation
EEG	Electroencephalogram
EMC	Electromagnetic compatibility
ErXX	Error message
ESD	Electrostatic Discharge

F

FCC	Federal Communications Commission
ft	Feet

G

GPL	General Public License
GTIN	Global Trade Item Number

H

H/W/D	Height / Width / Depth
hPa	Hectopascals
HTTPS	HyperText Transfer Protocol Secure
Hz	Hertz

I

IC	Industry Canada
IEC	International Electrotechnical Commission
IEEE	Institute of Electrical and Electronics Engineers
IFU	Instructions For Use
in	Inches
IT	Information Technology
IV	Intravenous

K

kg	Kilograms
KVO	Keep Vein Open

L

lb(s)	Pound(s)
LED	Light Emitting Diode

M

mA	Milliamperes
mEq	Milliequivalents
mL/h	Milliliters per hour
mmHg	Millimeters of mercury
mmol	Millimole
MOS	Metal Oxyde Semiconductor
MR	Magnetic Resonance
mW/sr	Milliwatts per steradian

N

N/A	Not Applicable

O

OCS	Occlusivity Check System
OFDM	Orthogonal Frequency Division Multiplexing

P

PC	Personal Computer
PSI	Pounds per Square Inch
PSK	Phase Shift Keying

Q

QAM	Quadrature Amplitude Modulation
QPSK	Quadrature Phase Shift Keying

R

REF	Product reference / part number
RF	Radio Frequency
RFID	Radio Frequency IDentification
RS232	Serial interface connector

S

SN	Serial Number
SIR	Asynchronous Serial Infrared

T

TCP	Transmission Control Protocol

U

UDI	Unique Device Identifier
USB	Universal Serial Bus
Ut	Test specification level

V

V	Volts
V/m	Volts per meter
VA	Volt-Amperes
VDC	Volts Direct Current
VI	Volume Infused
Vrms	Root Mean Square Voltage
VTBI	Volume to Be Infused

W

W	Watts
WPA2	WiFi Protected Access 2

Appendix: Factory Configuration

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

	Feature	Availability
Infusion Modes	V/T/R	✓
	Ramp-up / Ramp-down	✓
	Sequential	✓
Infusion Features	Auto-restart	× disabled
		✓ in menu for user to enable
	Direct Bolus	× (1)
	Programmed Bolus	✓
	Loading Dose	×
	Secondary Infusion	✓
	KVO	×
	Prime Set	✓
	Advance Air Bubble	✓
	Dynamic Pressure System (DPS)	× disabled
		✓ in menu for user to enable

✓ = Enabled with factory configuration (Basic Profile).
× = Not enabled with factory configuration. Can be enabled in the pump options or with a compatible Drug Library Software. Otherwise can be enabled on request.
(1) = available only with a compatible Drug Library Software.

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U

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W

Release Notes

Date	Software Version	Description
October 2021	2.6	Creation

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

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

Product manufactured in France
Document revision date: January 2022
www.fresenius-kabi.com

Local Contacts for Servicing

10919-16_Master_IFU_Agilia_VP_MC_WiFi_Eng-US

Rx only

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