FRESENIUS KABI

caring for life

# **Agilia** SP MC WiFi

## Syringe 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 SP 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 SP Infusion System against unauthorized access and its removal from the premises, you must ensure:

- Your premises are secured
- When not in use, the Agilia SP 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 SP Infusion System, see Data Communication on page 119 and Communication Port on page 169.

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 SP 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 SP 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.

**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 206.

**WARNING**

- The Agilia SP 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.

**WARNING**

Accuracy may be reduced when the infusion flow rate is below 1 mL/h.

**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 15.8, **"Accuracy"** on page 149 and section 18.9, **"Trumpet, Start-up Curves and AAMI TIR101: 2020 Delivery Performance"** on page 171). In order to ensure patient safety in high risk populations (e.g. neonates), close monitoring is recommended in low flow rate infusions.

**WARNING**

Specific attention for infusing high risk and life sustaining medication therapies : use the smallest compatible syringe size necessary to deliver the fluid or medication; this is especially important when infusing high risk or life-sustaining medications at low infusion rates (e.g., less than 5 mL per hour, and especially flow rates less than 0.5 mL per hour). Using a larger syringe when infusing at low rates can lead to inadequate syringe pump performance including delivery inaccuracies, delay of therapy, and delayed generation of occlusion alarms. This is due to the increased friction and compliance of the syringe plunger head with larger syringes.

**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 SP 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**

- 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**

Ideally, the syringe pump should be level with the distal tip of the catheter (e.g., the site of fluid delivery; if accessing a central line the syringe 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 syringe 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 syringe pump may result in a decrease in delivery or under-infusion until the flow rate stabilizes.

**WARNING**

During programming and prior to starting an infusion, verify that the syringe size and model on the syringe pump's display screen matches the syringe size and model loaded onto the syringe pump.

**WARNING**

- When connecting the syringe's extension set to the patient's access device, always use aseptic technique according to your healthcare facility's policy.
- During programming and prior to starting an infusion, verify that the syringe size and model on the syringe pump's display screen matches the syringe size and model loaded onto the syringe pump.

**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 Extension Set presents the risk of injury, death or other serious adverse reactions.

**WARNING**

- Electronically prime the syringe pump system before starting an infusion, or after replacing a near-empty syringe with a replacement syringe.
- Verify the fluid flow to the patient is OFF, and if available, use the prime function on the syringe pump to remove any mechanical slack in the system.
- Using the syringe pump's prime feature engages the mechanical components of the pump and decreases the syringe's friction and compliance (i.e., stiffness) to minimize startup delays and delivery inaccuracies, especially at low infusion rates.
- Failure to use the prime feature on the syringe pump after every syringe change and/or tubing change can significantly delay the infusion delivery startup time and lead to delivery inaccuracies.
- During priming, make sure that the extension set is not connected to the patient.

**WARNING**

When addressing or clearing an occlusion:

- Ensure the fluid flow to the patient is clamped to prevent administering an unintended bolus. An occlusion may pressurize the infusion tubing and syringe, 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.
- Larger size syringes combined with high pressure threshold settings may produce a larger post occlusion bolus.

**WARNING**

- During Occlusion, drug can accumulate prior to the occlusion resulting in an unintended bolus delivery after clearance. Use clinical judgement to assess if the bolus after occlusion release should be addressed prior to resuming the infusion.
- To minimize the amount of time it takes the pump to recognize an occlusion and generate an alarm while infusing at low rates (e.g., less than 5 mL per hour, and especially flow rates less than 0.5 mL per hour): Consider occlusion pressure threshold setting and adjust it, as necessary. The lower the occlusion pressure threshold setting, the shorter the occlusion detection time, the smaller the bolus after occlusion release (resulting bolus volumes are discussed in section 24.4, page 199.). 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.
- Use the smallest compatible syringe size necessary to deliver the fluid or medication. This minimizes the amount of friction and compliance (i.e., stiffness) of the syringe plunger head. Because syringe pumps infuse fluids by precisely controlling the plunger, smaller syringes provide more precise fluid delivery than larger syringes.
- Use the prime feature on the pump when changing a syringe and/or tubing. Make sure the patient is disconnected when priming.
- Use an extension set which has the smallest internal volume or deadspace (e.g., use microbore tubing when infusing at low rates, shorter length of tubing, etc.).

**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**

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**

- **Fresenius Kabi** cannot accept responsibility for any flow rate errors that are due to changes to syringe specifications introduced by the manufacturer.
- Ensure syringe sizes and models are compatible with the syringe pump, see section 24.4, page 199. Use of incompatible syringes can cause injury to the patient and improper pump operation resulting in inaccurate fluid delivery, insufficient occlusion sensing, and other potential problems.

**WARNING**

Prime the syringe and extension set with the pump after replacing a near-empty syringe with a replacement syringe. Make sure the patient is disconnected.

**WARNING**

- **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 will be impossible to detect patient-side occlusions. Such an occlusion could cause the pumped drug to back up into the gravity line, and later be infused in an uncontrolled manner when the occlusion is released.
- Be careful about drugs interactions and incompatibilites during a multi-line infusion. **Fresenius Kabi** recommends infusing the critical drugs first.

**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 syringe model, syringe configuration, extension 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, page 161.

**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, page 161.

**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.

**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 SP 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**

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

**WARNING**

- The Agilia SP MC WiFi 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 SP MC WiFi pump should ensure that it is used in such environments.
- The Agilia SP MC WiFi pump must not be used in the presence of intense electromagnetic fields, such as those generated by certain electrically powered medical devices. Agilia SP 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.

**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.

Table of Contents

# 1 Introduction

## 1.1 Scope

These Instructions For Use (IFU) are applicable to the Agilia SP MC WiFi Syringe 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 206.

## 1.2 Intended Use

### Agilia SP Infusion System

The Agilia SP Infusion System is intended for adult and pediatric care for the intermittent or continuous delivery of parenteral fluids, medication, 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 SP Infusion System is also intended for neonatal care for the intermittent or continuous delivery of parenteral fluids for hydration and nutrition, medication, blood, and blood derivatives through clinically accepted parenteral routes of administration and critical drugs under specific conditions. 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 | Intraosseus |
|---|---|---|---|---|
| **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 SP 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.

**WARNING**

Accuracy may be reduced when the infusion flow rate is below 1 mL/h.

## 1.3 Principles of Operation

Agilia SP MC WiFi is a programmable electronic medical pump dedicated to administering a pre-determined volume of a syringe at a programmed rate. This syringe pump ensures fluid delivery by pushing the syringe plunger and advancing the liquid to the patient through an extension set (applied part).

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

The size of a syringe can be minimum of 5 mL and maximum of 60 mL. For comprehensive list, see section 24.4, page 199.

Agilia SP 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<br>▪ Colloids<br>▪ Parenteral nutrition |
| **Medication** | ▪ Diluted drugs<br>▪ Antibiotics<br>▪ Chemotherapy<br>▪ Catecholamines<br>▪ Short acting drugs<br>▪ Anesthesia drugs |
| **Transfusion** | ▪ Blood<br>▪ Red blood cells<br>▪ Platelets<br>▪ Plasma<br>▪ Albumin |

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

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

Do not use the pump for epidural use.

## 1.5 Intended Users

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

Typical initial training duration: approximately 2 hours.
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 15.8, **"Accuracy"** on page 149 and section 18.9, **"Trumpet, Start-up Curves and AAMI TIR101: 2020 Delivery Performance"** on page 171). In order to ensure patient safety in high risk populations (e.g. neonates), close monitoring is recommended in low flow rate infusions.

It is recommended to use the smallest syringe possible to reduce the delay before the pump reaches the expected accuracy or stabilizes at the programmed flowrate.

Agilia SP MC WiFi is intended to be used on 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

**WARNING**

Specific attention for infusing high risk and life sustaining medication therapies : use the smallest compatible syringe size necessary to deliver the fluid or medication; this is especially important when infusing high risk or life-sustaining medications at low infusion rates (e.g., less than 5 mL per hour, and especially flow rates less than 0.5 mL per hour). Using a larger syringe when infusing at low rates can lead to inadequate syringe pump performance including delivery inaccuracies, delay of therapy, and delayed generation of occlusion alarms. This is due to the increased friction and compliance of the syringe plunger head with larger syringes.

## 1.7 Contraindications

None known.

## 1.8 Use Environment

Agilia SP 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 SP 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 pressure in the extension 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 SP MC WiFi.

# 2 Agilia Connect Infusion System

## 2.1 Agilia Connect Infusion System

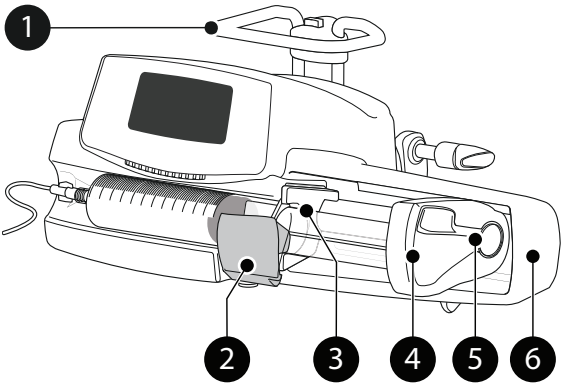
| Agilia Range | | Description |
|---|---|---|
| **Pump** | **Agilia SP MC WiFi** | **Syringe Infusion Pump**<br>Pumps designed to deliver the contents of a syringe through a line connected to a patient. |
| **Software** | **Drug Library Software** | **Medication Safety Solution**<br>Drug Library Software designed to create, customize and manage data sets to be uploaded to the Agilia SP MC WiFi infusion pump.<br>**Server Software**<br>Software intended to distribute data sets to Agilia infusion pumps and centralize information coming from infusion pumps for post analysis and reporting.<br>**Infusion Data Reporting Software**<br>Software provides reports designed to review the infusion parameters with in the Drug Library Software (Customer profiles). |
| | **Agilia Partner** | **Maintenance Software**<br>Software designed to maintain, configure, test and calibrate the Agilia SP MC WiFi infusion pump. |
| **Rack** | **Agilia Link** | **Stacking rack systems**<br>Rack systems designed to stack 4, 6 or 8 Agilia infusion pumps. Agilia Link is designed to centralize the power supply. |
| **Disposables** | **Syringes** | See section 13, page 138. |
| **Accessories** | **Agilia Duo** | **Two Pump Accessory**<br>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 **Fresenius Kabi** representative.

# 3 Description

## 3.1 Front View

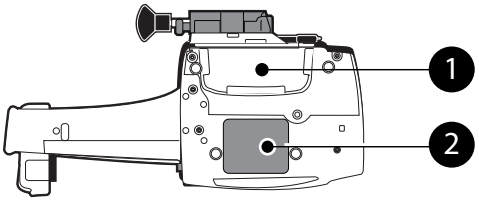



**Legend**

1. Handle
2. Syringe Barrel Clasp
3. Syringe Flange Cradle
4. Plunger Driver
5. Disengagement Lever
6. Syringe Guard

**Figure 3.1:** Front View

## 3.2 Bottom View (Device Identification Label)




**Legend**

1. Slot for pump stacking
2. Device Identification Label

**Figure 3.2:** Bottom view

Device Identification Label:

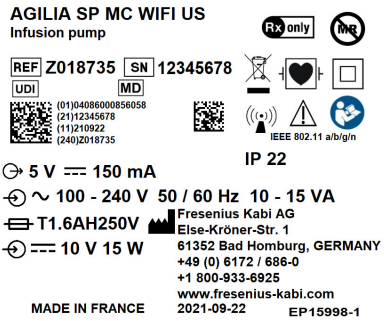


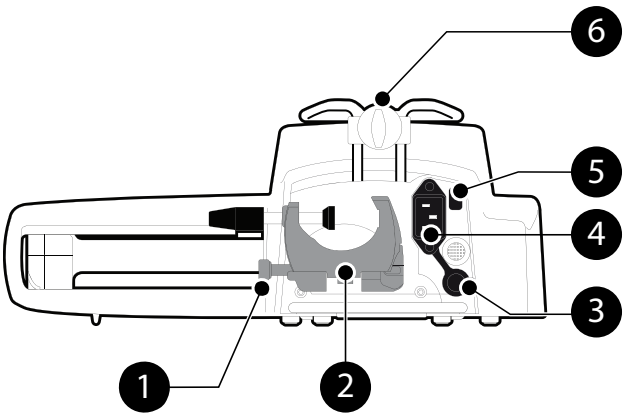

**Figure 3.3:** Example of Device Identification Label

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:

- (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 ii.

## 3.3 Back View




**Legend**

1. Release Button
2. Rotating Pole Clamp
3. RS232 Communication Port
4. Power Cord Inlet
5. Infrared Cell
6. Attachment Lock Knob

**Figure 3.4:** Back View

| Symbol | Location | Description |
|---|---|---|
|  | Near Power Cord Inlet | **WARNING**<br>See section 18, page 168. |
|  | Near RS232 Communication Port | **WARNING**<br>See section 10, page 119. |

## 3.4 Keypad

### 3.4.1 Keypad Description

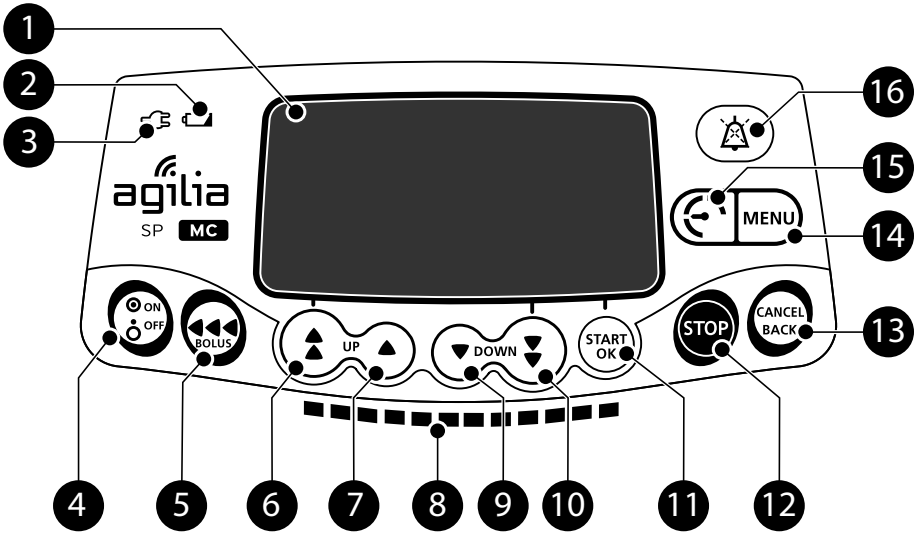


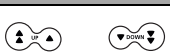
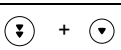

**Figure 3.5:** Keypad

**Legend**

| | | | | | |
|---|---|---|---|---|---|
| 1 | Screen | 7 | Increment | 13 | Cancel value / Return to previous field |
| 2 | Battery charge status indicator (LED) | 8 | Infusion indicator lights (LED) | 14 | Menu |
| 3 | Power supply indicator (LED) | 9 | Decrement | 15 | Pressure menu |
| 4 | ON/OFF switch | 10 | Fast decrement | 16 | Silence alarm |
| 5 | Bolus/Prime | 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**<br>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:*

- *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 (flashing 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 indicate infusion in progress at KVO flow rate. |
|  | Low-Priority Alarm State: ON Yellow LEDs and two ON Green LEDs indicating Infusion is complete and in progress at KVO flow rate. |

*Note:*

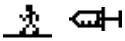
- *Infusion indicator lights (LEDs) provide information about the infusion: in progress or alarm priority (Low, Medium or High).*
- *Green indicator lights will continuously run from right to left while the infusion is in progress.*
- *The higher the flow rate, the faster green indicator lights (LEDs) flash.*
- *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)**<br>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)**<br>When the device is attached to an active power supply, the indicator light provides information about battery charge status:<br>▪ If the indicator is blinking, the battery is being charged.<br>▪ If the indicator is lit permanently, the battery is fully charged.<br>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 (Basic Profile)**<br>Symbols for infusion in progress. |
|  | **Infusion in Progress (custom profiles)**<br>This symbol is displayed when the pump is infusing a drug within a custom profile. |

### 3.5.2 Screen Options

| Symbol | Description |
|---|---|
|  | **Battery Logo**<br>▪ This symbol shows three different charge levels.<br>  < 30 % battery charge<br>  30 % - 70 % battery charge<br> > 70 % battery charge<br>▪ If the ‘Battery logo’ option is enabled, this symbol is displayed constantly.<br>▪ If the ‘Battery logo’ option is disabled, this symbol is only displayed when the pump is operating on battery. |
|  | **Pressure Logo**<br>This symbol gives information about pump pressure settings and measured pressure levels. |
|  | **Keypad locked symbol**<br>This symbol informs the user that the keypad is locked. |
|  | **Wi-Fi module status**<br>▪  The Wi-Fi signal strength is high.<br>▪  The Wi-Fi signal strength is medium.<br>▪  The Wi-Fi signal strength is low.<br>▪  No Wi-Fi signal (the Wi-Fi module is enabled).<br>▪  The Wi-Fi module is not enabled. |

### 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 |
|  | 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 124.*

### 3.5.5 Infusion Features

| Symbol | Description |
|---|---|
|  | **Loading Dose**<br>This symbol is displayed when programming a loading dose. |

### 3.5.6 Data Communication

| Symbol | Description |
|---|---|
|  | **Data Set Loaded**<br>A new data set has been loaded to the pump. |

## 3.6 Packaging

The Agilia SP MC WiFi packaging contains the following:

- 1 Agilia SP 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 1200 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 Drug Library 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 46.

**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: rate, Volume/Time, Dose/Time, Volume Limit, 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 1,200 mL/h. 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

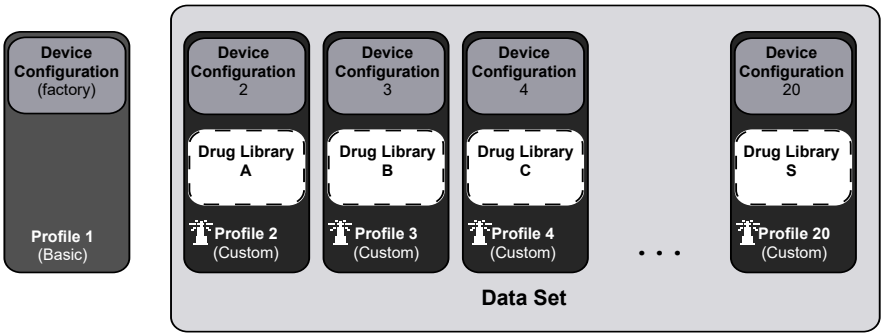
An infusion can be started according to the following modes:

| Infusion Mode | Description | Infusion Rate | |
|---|---|---|---|
| | | Flow Rate | Dose Rate |
| **Simple Rate** | Infusion with a programmed rate | ✓ | ✓ |
| **Volume/Time Dose/Time** | Infusion of a programmed volume or dose over a programmed period of time | ✓ | ✓ |
| **Volume Limit** | Infusion with a limitation on the volume or dose to be infused | ✓ | ✓ |

See: Infusion Modes, page 76.

## 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.

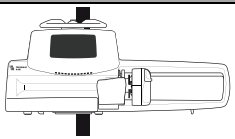
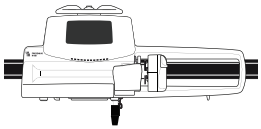
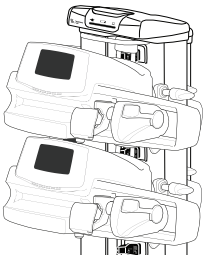
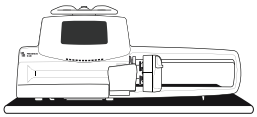
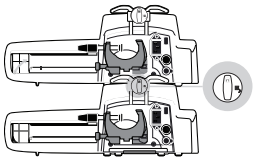



If there is no data set uploaded to the pump, the pump can be used with the Basic Profile.

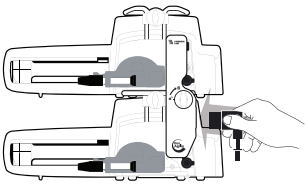
# 5 Installation

## 5.1 Accessory Installation

A pump can be installed on any of the following:

| Location | | Comments |
|---|---|---|
| **Pole** |  | ☞ See section 5.3.1, page 38.<br><br>**Pole specifications:**<br>▪ Diameter: from 0.6 to 1.6 in (15 to 40 mm) |
| **Rail** |  | ☞ See section 5.3.2, page 38.<br><br>**Rail specifications:**<br>▪ Height: from 1.0 to 1.4 in (25 to 35 mm)<br>▪ 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.<br><br>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**

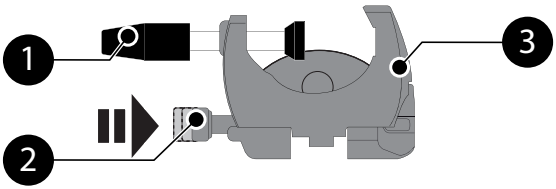
- The pump must be used in a horizontal and stable position to function properly.
- Use recommended Agilia accessories to ensure stability and prevent the pump from falling. Do not stack the pump with equipment other than those recommended.
- The pump is not tested for use in an ambulance in the US.

## 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

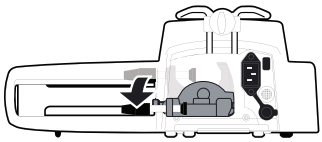
### 5.2.2 Using the Rotating Pole Clamp

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:

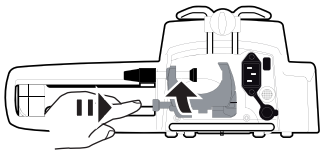
1. Push the release button.
2. Fold the clamp outward.



#### *5.2.2.2 Folding the Clamp Up (inward toward the pump)*

Fold the clamp up as follows:

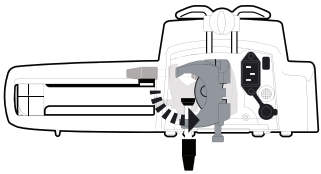
1. Push the release button.
2. Fold the pole clamp inward toward the pump.



#### *5.2.2.3 Rotating the Clamp*

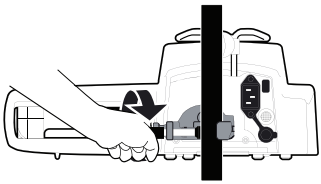
Rotate the clamp as follows:

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)

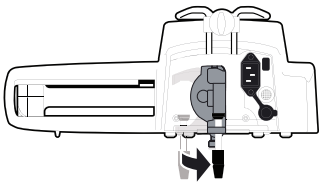
### 5.3.1 Attaching to a Pole



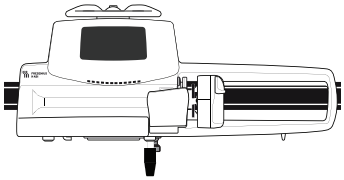
1. Fold the pole clamp down to the horizontal position: see section 5.2.2.1, page 37.
2. Unscrew the clamp, attach to the pole, and screw the clamp until the pump is fully secured to the pole.
3. Make sure that the pump is securely attached.

### 5.3.2 Attaching to a Rail

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



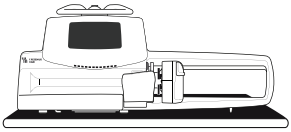
1. Rotate the pole clamp to the vertical position: see section 5.2.2.3, page 37.
2. Unscrew the clamp, attach to the rail, and screw the clamp until pump is fully secured to the rail.



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.



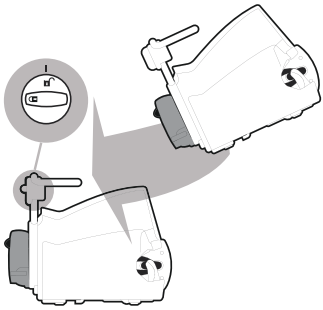
### 5.3.4 Attaching Pumps Together

You can attach up to

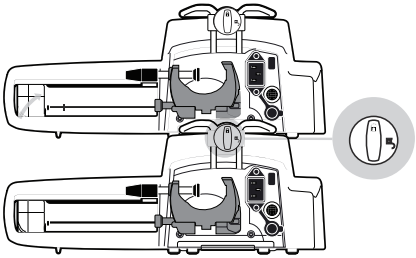
- three non-infusing pumps together for transport,
- two infusing pumps.

*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.

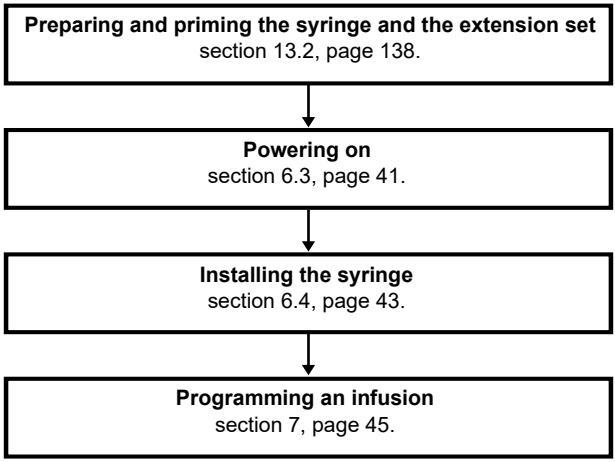


| Symbol | Location | Description |
|---|---|---|
|  | Attachment Lock Knob | Locked Position |
|  | Attachment Lock Knob | Unlocked Position |

# 6 Getting Started

## 6.1 Flowchart

Once the pump is installed at the bedside, you must follow the steps below in order to install a syringe 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.

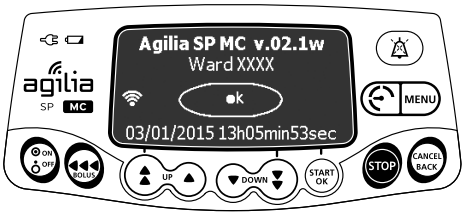
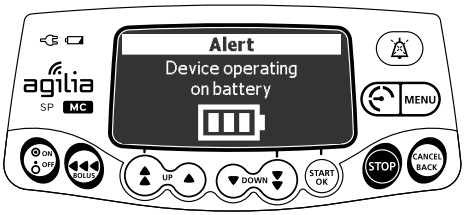
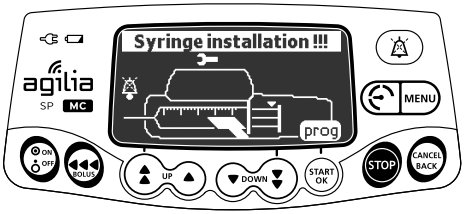
1. Make sure the pump is correctly installed at the bedside. See section 5, page 35.
2. Plug the pump into the AC power supply. See section 17.1, page 166.
3. Power on the pump. See section 6.3, page 41.
4. Install a syringe into the pump. See section 6.4, page 43.

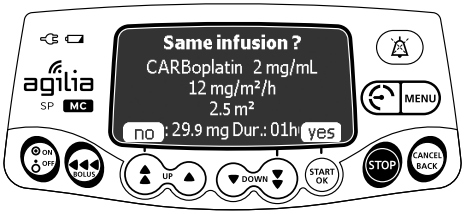
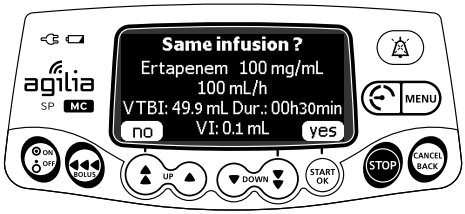
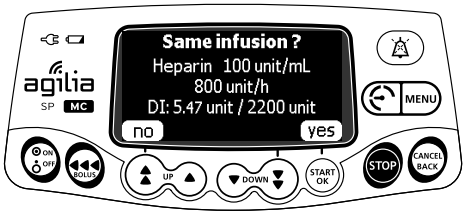
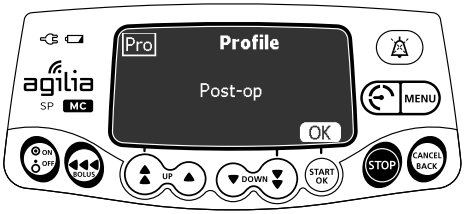
## 6.3 Powering on

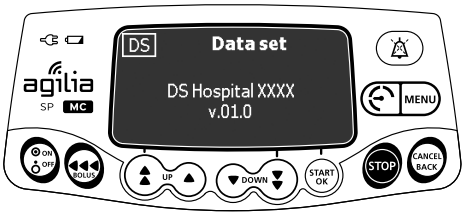
**INFORMATION**

- 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.

1. Press .
   *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: the following information is displayed:<br>▪ Product name / Care unit name (Ward level - optional)<br>▪ Wi-Fi module status (if applicable)<br>▪ Date & time |
|  | ▪ The pump is operating on battery.<br>The symbol shows three different charge levels:<br>< 30 % battery charge<br>30 % - 70 % battery charge<br>> 70 % battery charge |
|  | ▪ No syringe is installed on the pump.<br>▪ `Syringe installation !!!` is displayed at the top of the screen.<br>☞ Install a syringe.<br>See section 6.4, page 43.<br>or<br>☞ Press "prog" to pre-program the pump.<br>See section 7.11.2, page 81. |

| Screen After Powering on | Description |
|---|---|
|  | ▪ Maintenance reminder message (optional). |
|  <br>Same infusion - Simple rate | |
|  <br>Same infusion - Volume / Time | ▪ Same infusion screen (optional).<br>☞ Press **yes** to resume previous infusion settings and same profile.<br>or<br>☞ Press **no** to program a different infusion and/or select a different profile. |
|  <br>Same infusion - Simple rate with Volume Limit | |
|  | ▪ Profile confirmation screen (optional).<br>☞ Press **OK** to confirm the profile.<br>*<u>Note</u>: This screen is linked to the "same infusion" function above.* |

| Screen After Powering on | Description |
|---|---|
|  | ▪ Data Set information (optional) |

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

## 6.4 Installing a Syringe

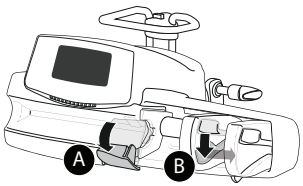
**WARNING**

This must only be done when the patient is not connected.

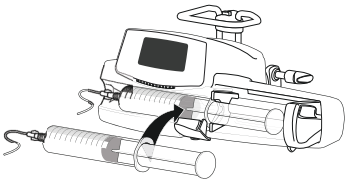
**INFORMATION**

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

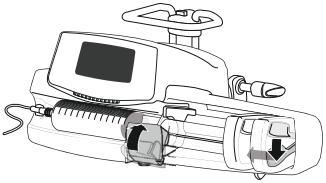
1. Open the syringe barrel clasp [A].
2. Push the disengagement lever [B] down and move the plunger driver to the right.




3. Place the syringe in its cradle, with the flanges correctly inserted in the provided slot.
4. Secure the syringe with the syringe barrel clasp [A].



5. Push the disengagement lever [B] down and move the plunger driver gently to the left until it is in contact with the plunger head.
6. Release the disengagement lever.
7. Check the general installation.



## 6.5 Pump Height

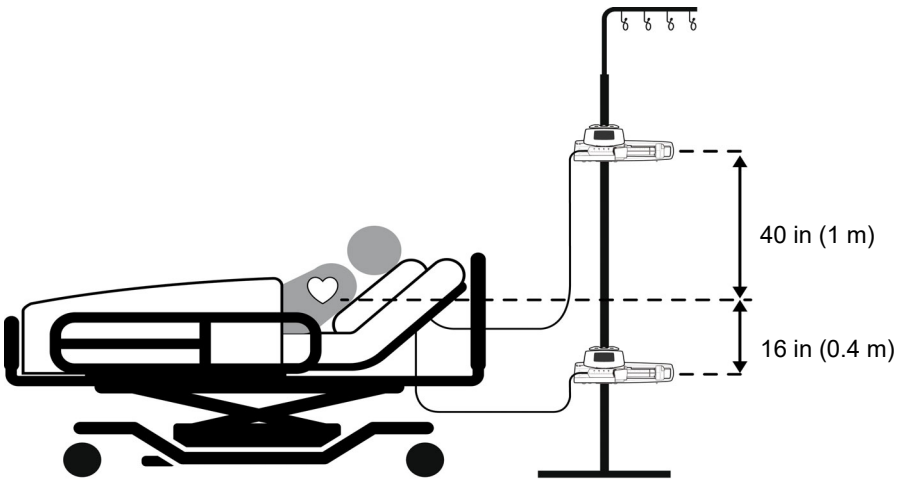
**WARNING**

Ideally, the syringe pump should be level with the distal tip of the catheter (e.g., the site of fluid delivery; if accessing a central line the syringe 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 syringe 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 syringe pump may result in a decrease in delivery or under-infusion until the flow rate stabilizes.

### Precautions for pump position

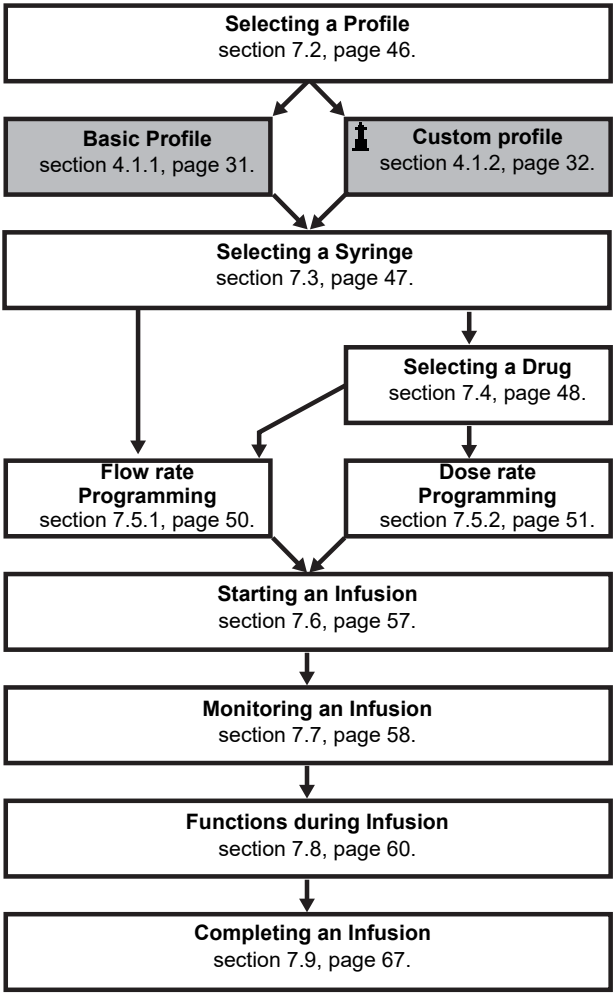
- If using multiple syringe pumps and it is not clinically feasible to have all pumps level with the distal tip of the catheter (or the site of fluid delivery), place the high risk or life-sustaining medications as close to level with the distal tip of the catheter as possible. When infusing multiple 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.

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



# 7 Operation

## 7.1 Flowchart



## 7.2 Selecting a Profile

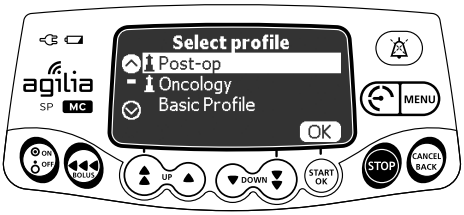
**INFORMATION**

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.

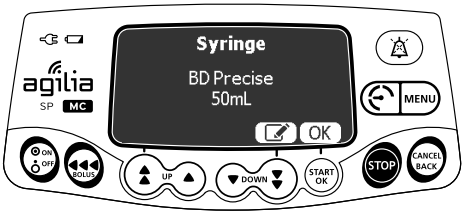



2. Press the arrow keys to select the appropriate profile.
   *The (lighthouse) symbol indicates a profile as a drug library.*
3. Press **OK** to confirm.
   *The selected profile information is displayed.*


4. Press **OK** to confirm the profile selection, or to change the profile.
   *The drug library is loaded for the profile selected.*

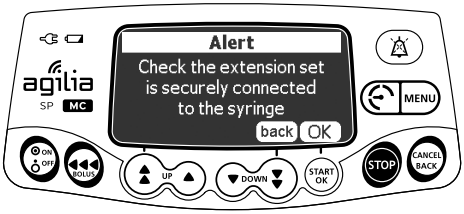
## 7.3 Selecting a Syringe

The pump automatically detects the size of the installed syringe.




1. Press **OK** to confirm the displayed syringe, or to change it.


2. If you have chosen to select another syringe, press the arrow keys to select a new syringe.
3. Press **OK** to confirm the new syringe.
   *A clinical advisory message may appear, if one is configured for the selected syringe.*




4. Press **OK** to acknowledge the clinical advisory message, or **back** to return to the syringe selection screen.

**WARNING**

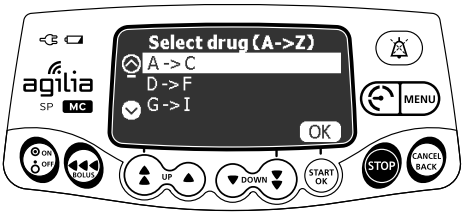
During programming and prior to starting an infusion, verify that the syringe size and model on the syringe pump's display screen matches the syringe size and model loaded onto the syringe pump.

## 7.4 Selecting a Drug

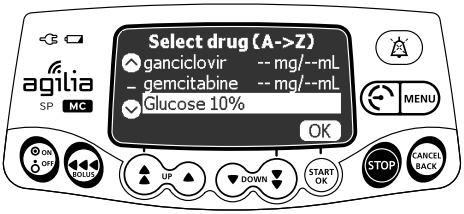
After selecting a syringe, you must select a drug to infuse.

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.

## 7.5 Programming an Infusion

**Reminder**

The Agilia SP Infusion System is intended for adult and pediatric care for the intermittent or continuous delivery of parenteral fluids, medication, 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 SP Infusion System is also intended for neonatal care for the intermittent or continuous delivery of parenteral fluids for hydration and nutrition, medication, blood, and blood derivatives through clinically accepted parenteral routes of administration and critical drugs under specific conditions. 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 15.8, **"Accuracy"** on page 149 and section 18.9, **"Trumpet, Start-up Curves and AAMI TIR101: 2020 Delivery Performance"** on page 171). In order to ensure patient safety in high risk populations (e.g. neonates), close monitoring is recommended in low flow rate infusions.

It is recommended to use the smallest syringe possible to reduce the delay before the pump reaches the expected accuracy or stabilizes at the programmed flowrate.

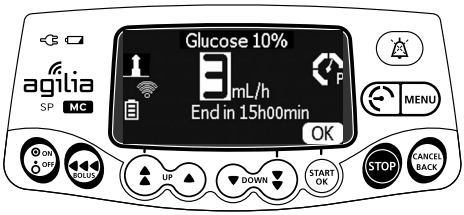
- This section describes the programming of an infusion with the **Simple Rate** infusion mode.
- You can also program an infusion with the following modes:
  - Volume/Time (or Dose/Time), see section 7.10.2, page 76.
  - Volume Limit, see section 7.10.3, page 77.

### 7.5.1 Programming an Infusion by Flow Rate

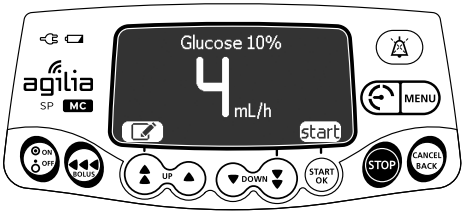
**WARNING**

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 15.8, **"Accuracy"** on page 149 and section 18.9, **"Trumpet, Start-up Curves and AAMI TIR101: 2020 Delivery Performance"** on page 171). In order to ensure patient safety in high risk populations (e.g. neonates), close monitoring is recommended in low flow rate infusions.

It is recommended to use the smallest syringe possible to reduce the delay before the pump reaches the expected accuracy or stabilizes at the programmed flowrate.




1. Press the arrow keys to program the flow rate.
2. Press **OK** to confirm.
3. Check infusion programming on the Confirmation screen.
4. Press **Start/OK** to start infusion.



## 7.5.2 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 15.8, **"Accuracy"** on page 149 and section 18.9, **"Trumpet, Start-up Curves and AAMI TIR101: 2020 Delivery Performance"** on page 171). In order to ensure patient safety in high risk populations (e.g. neonates), close monitoring is recommended in low flow rate infusions.

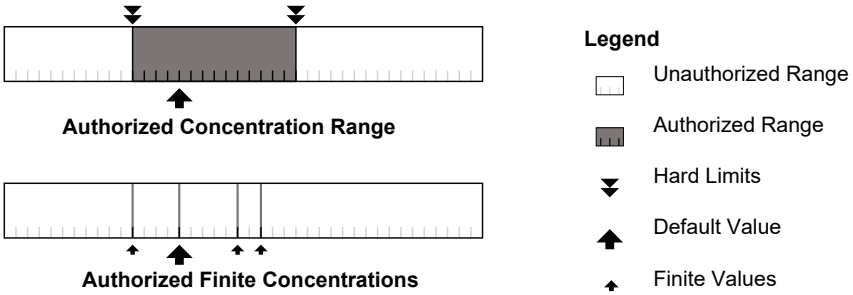
It is recommended to use the smallest syringe possible to reduce the delay before the pump reaches the expected accuracy or stabilizes at the programmed flowrate.

### *7.5.2.1 Selecting the Drug Concentration*

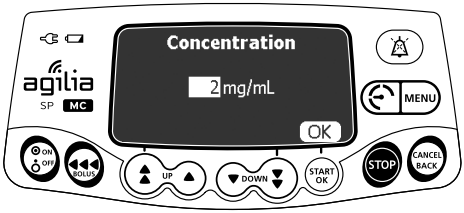
A drug selected from a drug library can allow adjustments of concentration in one of the following ways:

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

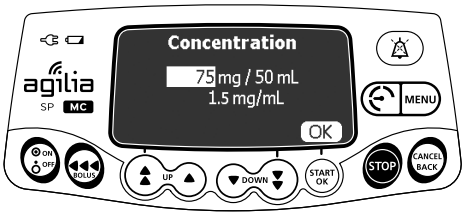
If no adjustment on the concentration is allowed, see section 7.5.2.2, page 52.



### Selecting the Drug Concentration



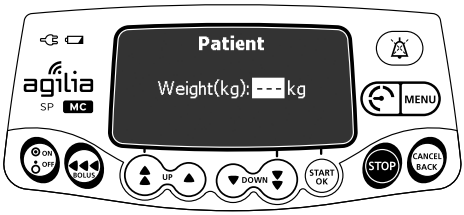

**Range**



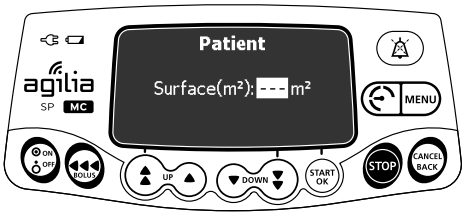

**Finite values**

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

*7.5.2.2 Selecting the Patient's Characteristics*




**Weight**



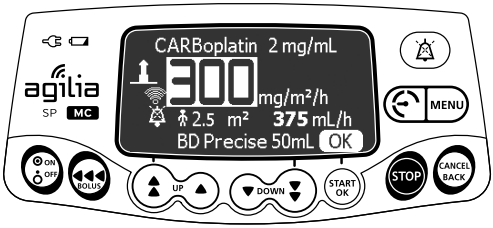

**Body Surface Area**

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.

### *7.5.2.3 Programming the Infusion*




1. Press the arrow keys to program the dose rate value.
2. Press **OK** to confirm.
3. Check infusion programming on the Confirmation screen.
4. Press **Start/OK** to start the infusion.


### *7.5.2.4 Programming a Loading Dose*

*Note: This feature can be enabled or disabled with a compatible Drug Library Software (custom profiles).*

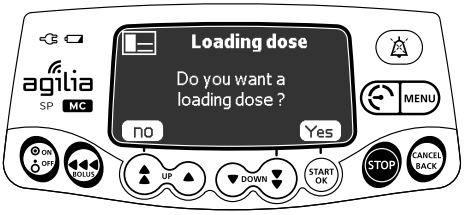
**INFORMATION**

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.

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.

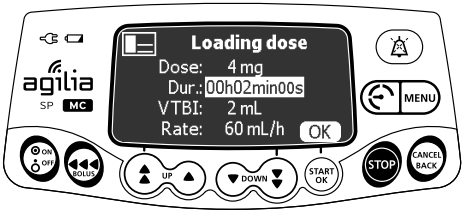
## Selecting a Loading Dose



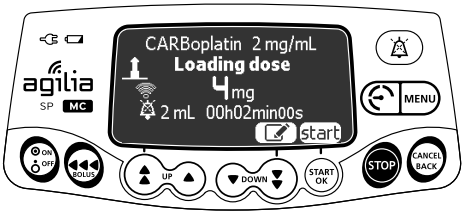

On the loading dose screen:

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

## Programming a Loading Dose

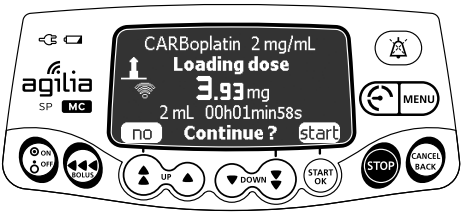



1. Press the arrow keys to enter a value for the dose, and press **OK** to confirm.
2. Press the arrow keys to program the loading dose duration (_h_min_s), and press **OK** to confirm. Single arrow increases seconds, double arrow increases minutes. Increasing to 60 minutes converts to 1 hour.
   *The 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 infusion.*

### Interrupting a Loading Dose

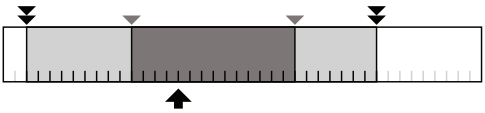



1. To stop the loading dose, press STOP.
   *The screen displays* `Continue?`
2. Choose one of the following options:

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

## *7.5.2.5 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.



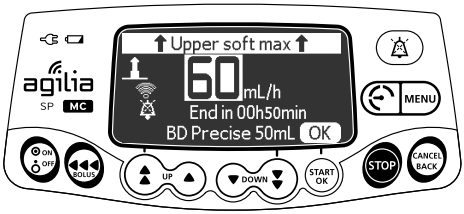
**Legend**

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

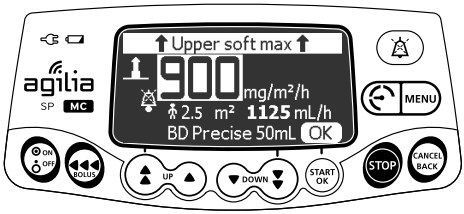
## Overriding a Soft Limit

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

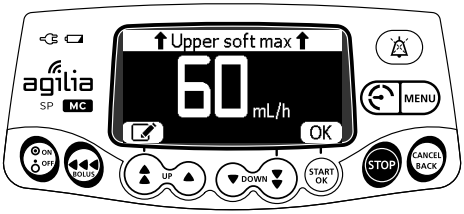



**Flow rate**

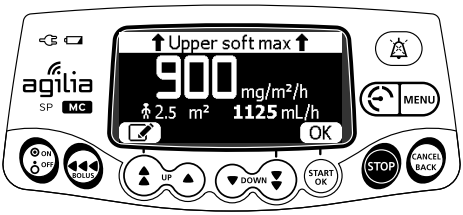



**Dose rate**

2. Press OK to confirm values.

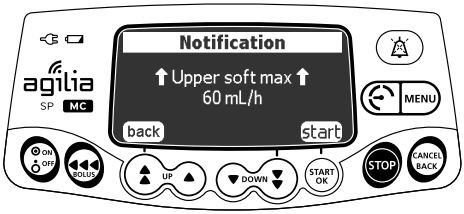



**Flow rate**

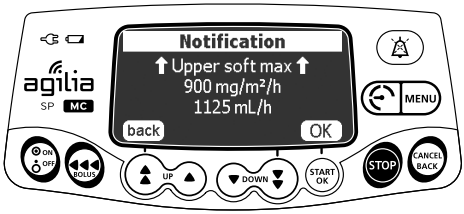



**Dose rate**

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

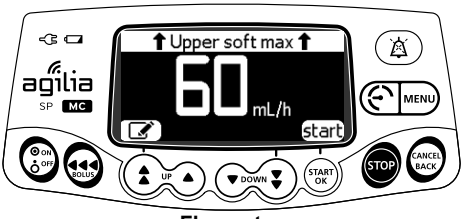



**Flow rate**

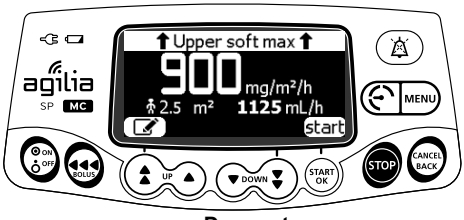



**Dose rate**

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




**Flow rate**

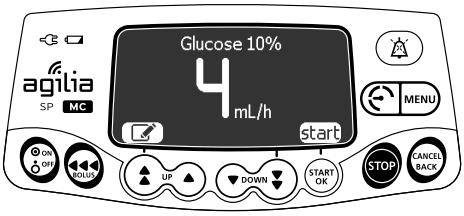



**Dose rate**

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

## 7.6 Starting an Infusion

1. Check the delivery path integrity.
2. Check that there is no air in the syringe or in the extension set.
3. Confirm that the syringe is correctly installed in the pump.
4. Connect the syringe's extension set to the patient's access device.
5. Check the infusion settings prior to starting the infusion.




**Flow rate**


**Dose rate**

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

**WARNING**

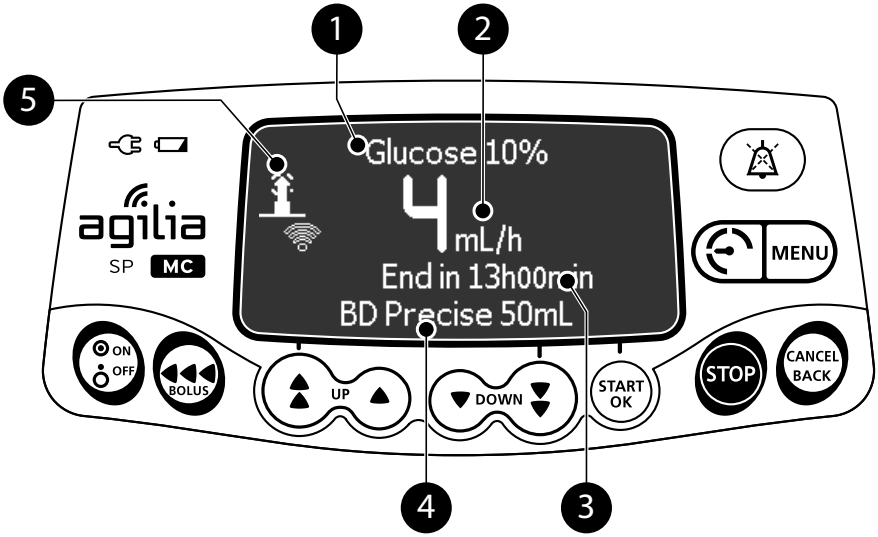
- When connecting the syringe's extension set to the patient's access device, always use aseptic technique according to your healthcare facility's policy.
- During programming and prior to starting an infusion, verify that the syringe size and model on the syringe pump's display screen matches the syringe size and model loaded onto the syringe pump.

**INFORMATION**

If the syringe is not correctly positioned in the pump, we recommend clamping, closing or disconnecting the extension set from the patient's access device before repositioning the syringe.

## 7.7 Monitoring an Infusion

### 7.7.1 Monitoring an Infusion when Programmed by Flow Rate




**Legend**

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

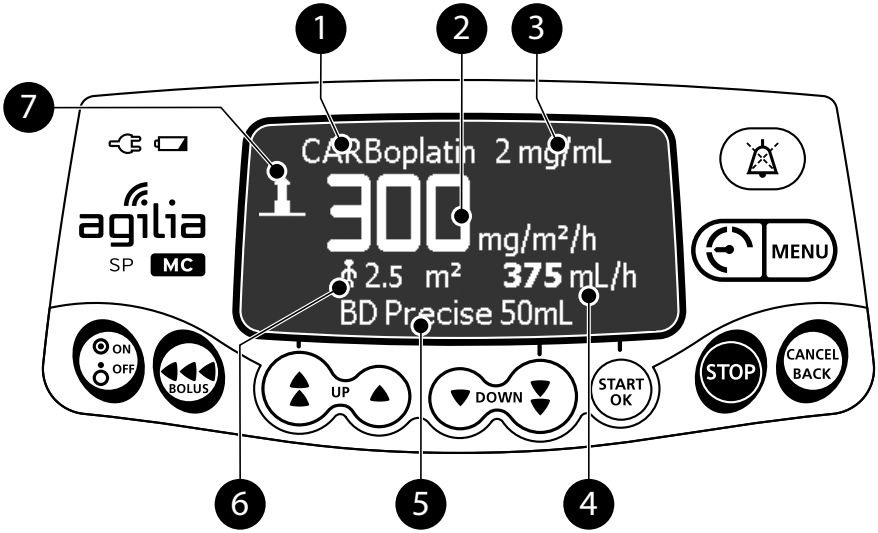
2. **Infusion Flow Rate (mL/h)**
   To change the flow rate during an infusion, see section 7.8.2, page 60. The flow rate is displayed with the largest font size.

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

4. **Syringe Name**

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

### 7.7.2 Monitoring an Infusion when Programmed by Dose Rate

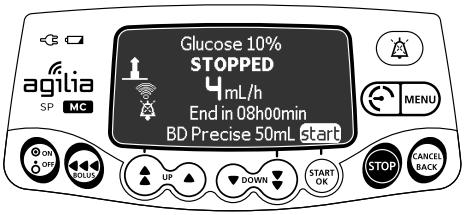



**Legend**

1. **Drug Name (custom profiles only)**
2. **Dose Rate**
   To change the dose rate during an infusion, see section 7.8.2, page 60. Dose rate is displayed with the largest font size.
3. **Drug Concentration**
4. **Infusion Flow Rate**
5. **Syringe Name**
6. **Patient Characteristics**
7. **Custom Profile Icon**
   
   When infusing a drug selected from a drug library, this lighthouse icon is displayed on the screen continuously.

## 7.8 Functions During Infusion

### 7.8.1 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 7.5, page 49.

### 7.8.2 Rate Titration

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

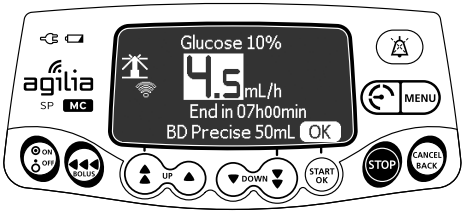
Depending on your pump configuration:

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

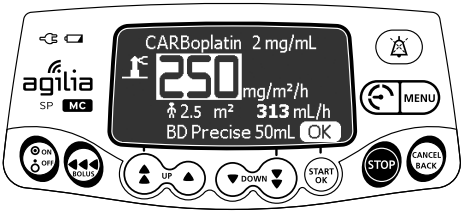
or

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

1. If required, stop the infusion, see section 7.8.1, page 60.
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**

### 7.8.3 Administering a Bolus

**INFORMATION**

For very low-volume boluses (less than 0.3 mL) at maximal sustainable flow rate, please refer to section 15.8.2, **"Bolus Volume Accuracy"** on page 155.

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.
- Direct Bolus is not available in the Basic Profile.
- The BOLUS key is not enabled when the menu screen is displayed.

| 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 (50-1200 mL/h) | BOLUS |

* For a complete list of dose units of measure, see section 15.9, page 158.

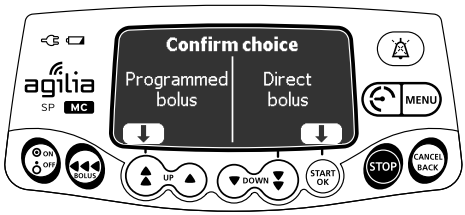



**Figure 7.1:** Bolus Delivery Screen with both Programmed Bolus and Direct Bolus enabled.

Occlusion Pressure Level during a bolus is set to 900 mmHg / 120 kPa / 17.4 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.

### *7.8.3.1 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**

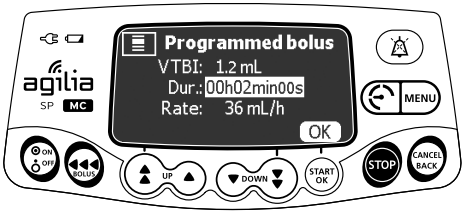
- If you stop the pump prior to initiating a Programmed bolus, the pump will not resume after the Programmed Bolus has been delivered. The pump will remain in the stop mode until you resume the infusion. If the infusion is not resumed within 30 seconds the pump will alarm, **Waiting Start.**
- To ensure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

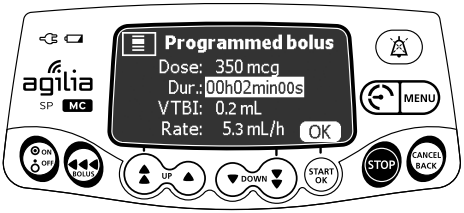
- Press BOLUS, then ▲▼ "Prog" to access Programmed bolus menu.
  Note: in case Direct Bolus is disabled, pressing BOLUS key brings you right to the programmed bolus menu.
- Press MENU, and select ☰ in the menu. Press **enter** to confirm.

## Programming a Bolus

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

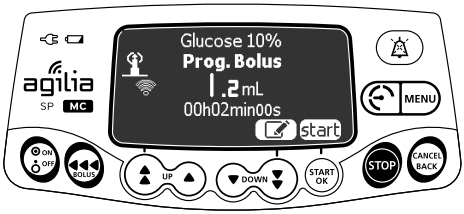



**Flow rate**

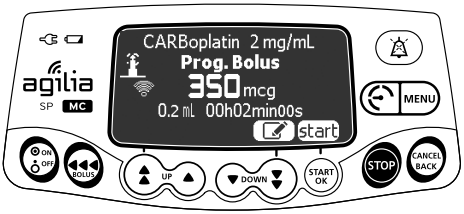



**Dose rate**

3. Press **start** to start the bolus.




**Flow rate**

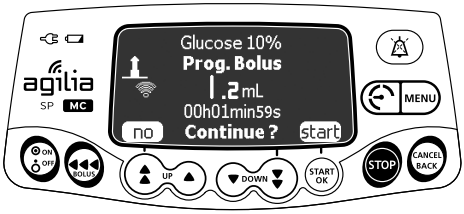



**Dose rate**

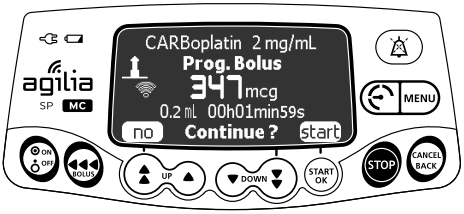
*The infusion resumes its previous rate after the bolus is delivered.*
*Press [✎] to change the settings of the last bolus.*

## Interrupting a Programmed Bolus

1. Press STOP to interrupt the bolus.




Flow rate



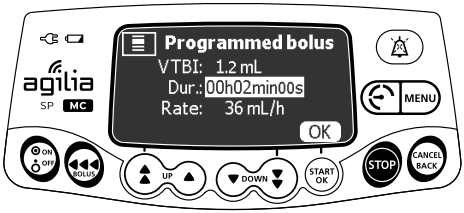

Dose rate

2. Answer the question: `Continue?`

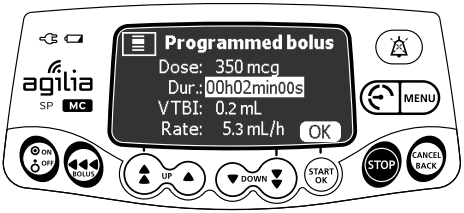
- Press **no** ▲ to return to the infusion.
- Press **START** to continue the bolus.

## Initiating a Programmed Bolus without resuming the infusion

1. Stop the infusion. Press the ◀◀◀ BOLUS 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.*

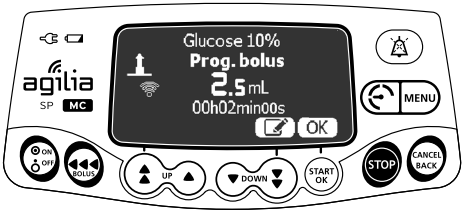



Flow rate

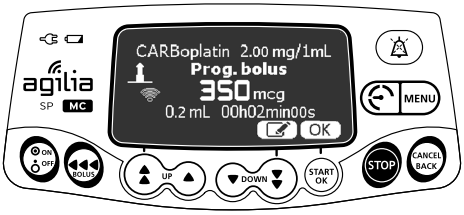



Dose rate

4. Check the right settings on confirmation screen.

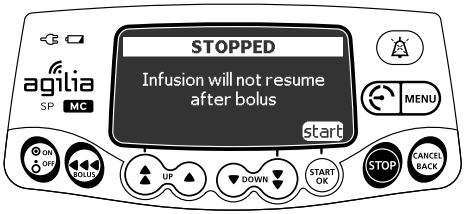



Flow rate




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**

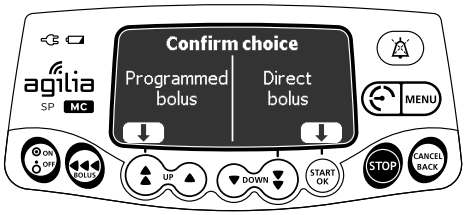
- If you stop the pump prior to initiating a Programmed Bolus, the pump will not resume after the Programmed Bolus has been delivered. The pump will remain in the stop mode until you resume the infusion. If the infusion is not resumed within 30 seconds the pump will alarm, **Waiting Start.**
- To ensure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

### *7.8.3.2 Direct Bolus*

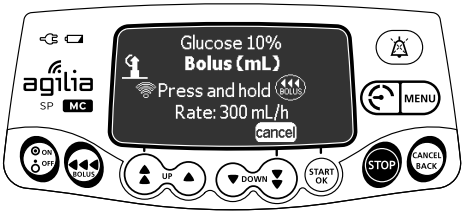
*Note: Direct Bolus can be enabled or disabled by a compatible Drug Library Software (for Custom profile). Direct Bolus is not available in Basic Profile.*

#### To deliver a Direct Bolus

1. During the infusion, press BOLUS.




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



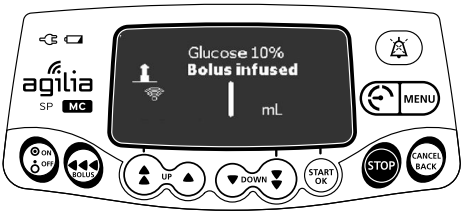

**3.** Press and hold the key to administer the bolus.

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

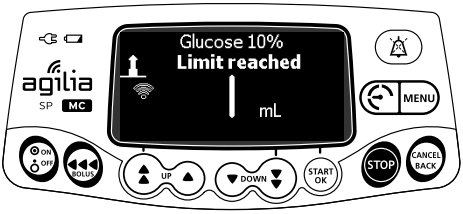
**5.** Release the key to stop the Direct Bolus.

*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.*



## 7.9 Completing an Infusion

### 7.9.1 Near End of Infusion Alert

*Note: This feature can be configured 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:

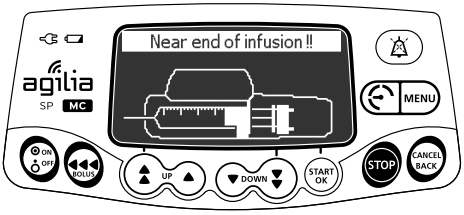
- An audible alarm is triggered.
- An alarm message appears on the pump's screen.
- The infusion indicator lights (LEDs) flash yellow with green running lights.

Near end of infusion alert is triggered when the two criteria below are reached simultaneously.

| Setting | Range of Values | Default Pump Setting |
|---|---|---|
| **Time Before the End of the Infusion** | From 1 to 30 minutes | 5 minutes |
| **The remaining volume of fluid in the syringe < 10 % of the syringe capacity** | N/A | N/A |

Near end of infusion alert settings are configurable with a compatible Drug Library Software (custom profiles), or in the pump options (Basic Profile).

#### Silencing Near End of Infusion Alert



1. Press (🔔) to silence the alarm.
2. If required, press **OK** to confirm the **empty syringe** mode.

*Depending on the pump configuration, the following happens:*

- *The infusion continues at the programmed rate until the plunger almost reaches the tip of the syringe. The syringe is not completely emptied so that the rate to the patient is continuous until the end of infusion (regular end of infusion).*
- *The infusion continues until the syringe is completely emptied. During the very last mm of the arm movements, the plunger is in contact with the tip of the syringe thus ensuring the syringe is completely emptied, but the flow rate to the patient is decreasing. (empty syringe - only in Simple Rate mode).*

### 7.9.2 End of Infusion

End of infusion occurs at the completion of the defined VTBI, DTBI, or Volume Limit (completion of the syringe volume).

Keep Vein Open (KVO) - KVO rate or Continuous mode starts at the completion of Volume/Time and Dose/Time or simple rate with Volume Limit infusions, the infusion will continue at the KVO rate configured or whichever is lower or will continue at last programmed rate if Continuous mode is enabled.

The KVO rate is configurable with a compatible Drug Library Software (Custom profiles), or in the pump options (Basic Profile); configured between 0-5 mL/h (defaults zero).

The Continuous mode availability is defined in a compatible Drug Library Software or in the pump options (Basic Profile). When programming Volume/Time or Volume Limit, user must choose between the configurable options for the End of Infusion between three possible options: Stop, Continuous and KVO.

Depending on the configuration, there are three possible End of Infusion settings:

1. For Volume/Time, Dose/Time, or Simple rate with Volume Limit, the pump issues an End of Infusion alarm.
2. End of Infusion with KVO Disabled, Continuous Disabled, or in Simple rate without Volume Limit (see section 7.9.2.1, page 69.)
3. End of Infusion with Continuous enabled (see section 7.9.2.2, page 71.) or KVO enabled (see section 7.9.2.3, page 73.)

**INFORMATION**

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

### *7.9.2.1 End of Infusion with KVO Disabled, Continuous Disabled or Simple rate without Volume Limit*

When the Volume Infused equals the defined Volume Limit (VL) or when the VTBI of Volume/Time & Dose/Time reaches zero and at syringe end in Simple rate without Volume Limit, 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.

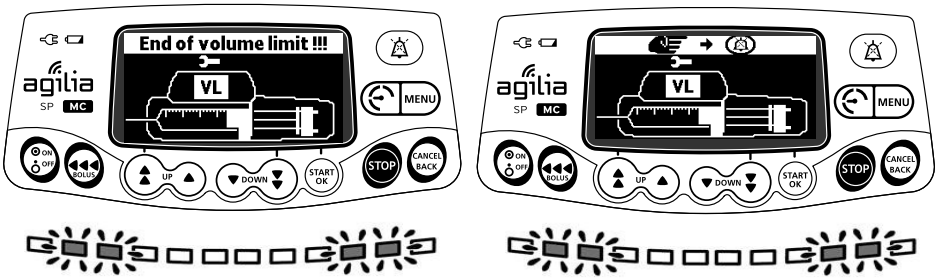



**Figure 7.2:** End of Infusion with KVO Disabled, Continuous Disabled (End of Volume Limit)

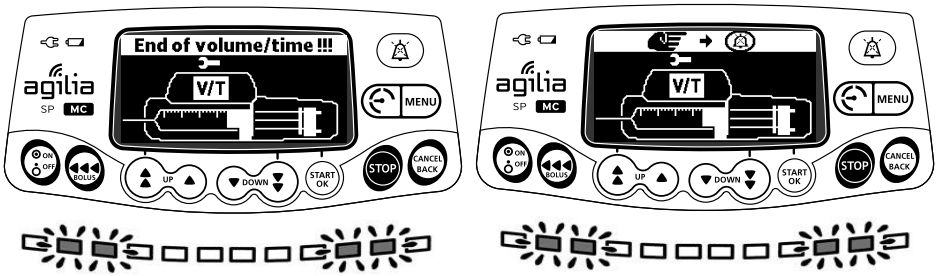



**Figure 7.3:** End of Infusion with KVO Disabled, Continuous Disabled (End of Volume/Time)

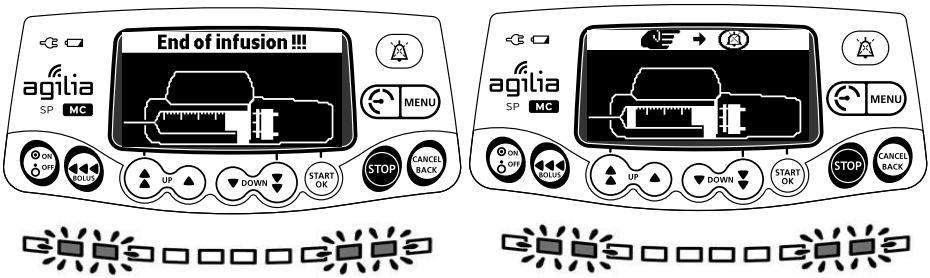



**Figure 7.4:** End of Infusion with Simple rate without Volume Limit

### Addressing End of Infusion with KVO or Continuous Disabled

1. Press (🔔) to silence the alarm.
   Pump is silenced for:
   - 15 seconds when using drug library
   - 2 minutes without drug library.
2. Pump displays programming screen:
   - Drug selection when using drug library
   - Infusion programming without drug library.
3. Prepare the new syringe and adjust the settings for a new Infusion OR power off the pump.

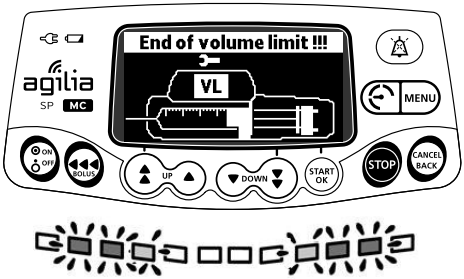
### *7.9.2.2 End of Infusion with Continuous enabled*

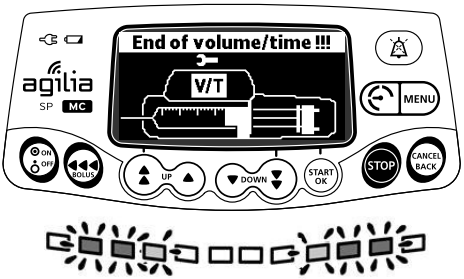
**INFORMATION**

- End of Infusion settings: Continuous 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 Continuous enabled. An audible High-Priority Alarm is triggered at the End of Infusion and reoccurs per configuration between 1 - 5 min (default 2 min).
- For more information, refer to the Technical manual or compatible Drug Library Software User's Guide.

When the Volume Limit or Volume/Time & Dose/Time reaches zero, the infusion is complete. The following happens:

- An audible High-Priority Alarm is triggered.
- An alarm message appears on the pump's screen.
- The infusion indicator lights (LEDs) are flashing red with two ON green (LEDs) indicating the High-Priority Alarm with Continuous infusing.
- The pump continues infusing at the programmed rate.




**INFORMATION**

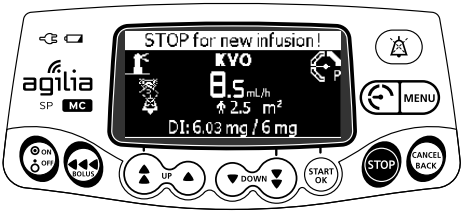
- Refer to the compatible Drug Library Software User's Guide to configure the profiles.

| Continuous Specifications | Basic Profile | Custom Profile(s) |
|---|---|---|
| Configurable | N/A | Yes, by profile in the Drug Library Software |
| Default Setting | Disabled/OFF | Disabled/OFF |
| Flow rate | Current programmed flow rate | Current programmed flow rate |
| 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 two ON green LEDs | High-Priority audible Alarm with flashing red LEDs and two ON green LEDs |
| During Continuous Infusion | Pump Status: ON yellow LEDs and two ON green LEDs | Pump Status: ON yellow LEDs and two ON green LEDs |
| Reminder Alarm | High-Priority audible Alarm with flashing red LEDs and two ON green LEDs | High-Priority audible Alarm with flashing red LEDs and two ON green LEDs |

### Addressing End of Infusion with Continuous enabled

Infusion complete, Volume Limit is zero.

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




If **No User Action** is taken, the High-Priority Alarm recurs in configured silenced time (default 2 minutes, maximum 5 minutes).

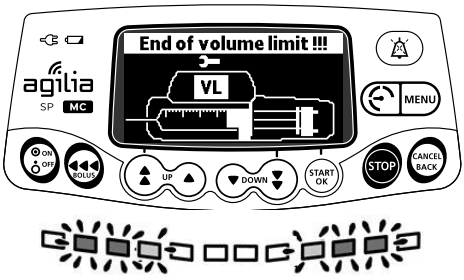
### *7.9.2.3 End of Infusion with KVO enabled*

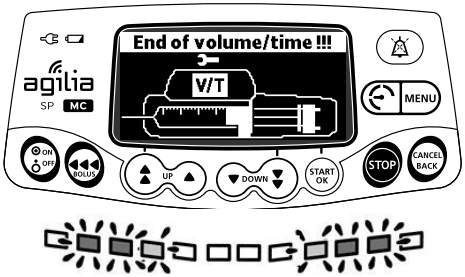
**INFORMATION**

- 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 High-Priority Alarm is triggered at the End of Infusion and reoccurs per configuration between 1 - 5 min (default 2 min).
- For more information, refer to the Technical manual or compatible Drug Library Software User's Guide.

When the Volume Limit or Volume/Time & Dose/Time reaches zero, the infusion is complete. The following happens:

- An audible High-Priority Alarm is triggered.
- An alarm message appears on the pump's screen.
- The infusion indicator lights (LEDs) are 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 | N/A | Yes, by profile in the Drug Library Software |
| Default Setting | Disabled/OFF | Disabled/OFF |
| Flow rate | 1-5 mL/h<br>(mandatory field) | 1-5 mL/h<br>(mandatory field) |
| Silence Key Duration | 1 to 5 minutes<br>(default 2 minutes) | 1 to 5 minutes<br>(default 2 minutes) |
| End of Infusion Alarm | High-Priority audible Alarm with flashing red LEDs and two ON green LEDs | High-Priority audible Alarm with flashing red LEDs and two ON green LEDs |
| During KVO Infusion | Pump Status: ON yellow LEDs and two ON green LEDs | Pump Status: ON yellow LEDs and two ON green LEDs |
| Reminder Alarm | High-Priority audible Alarm with flashing red LEDs and two ON green LEDs | High-Priority audible Alarm with flashing red LEDs and two ON green LEDs |

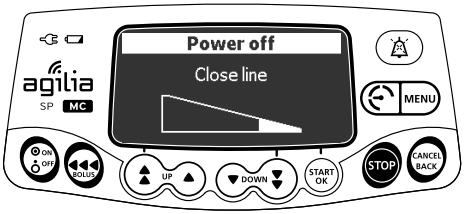
### Addressing End of Infusion with KVO enabled

Infusion complete, Volume Limit is zero.

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


If **No User Action** is taken, the High-Priority Alarm recurs in configured silenced time (default 2 minutes, maximum 5 minutes).

### 7.9.3 Powering off




You can power off the pump as follows:

1. Press STOP to stop the infusion.
2. Press and hold ON/OFF until the pump powers off.

## 7.10 Infusion Modes

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

### 7.10.1 Simple Rate

This infusion mode allows user to program a flow rate or a dose rate.

For more information, see section 7.5, page 49.

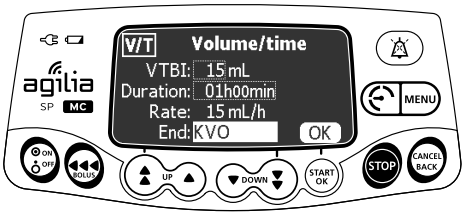
### 7.10.2 Volume/Time & Dose/Time

This infusion mode allows user to program a volume to be infused (VTBI) over a programmed period of time.

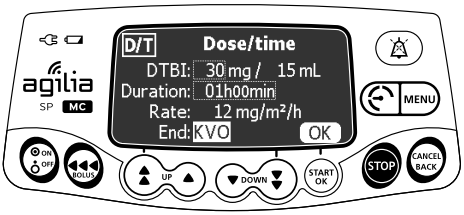
The End of Infusion settings allow the infusion pump to infuse at a KVO rate or infuse at the current rate (Continuous) or stop.

When the VTBI is reached, a High Priority alarm is triggered.

1. For information on how to access the **Volume/Time** or **Dose/Time** menu, see section 8.12, page 104.




**Volume/Time**




**Dose/Time**

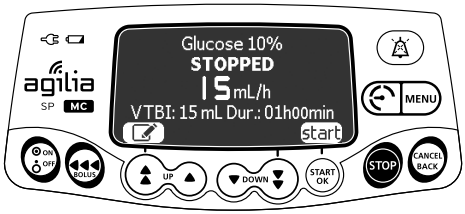
2. Press the arrow keys to set the volume or dose to be infused (VTBI / DTBI), and press **OK**.
   *The infusion rate is automatically calculated.*

**INFORMATION**

If you program a volume to be infused that is greater than the actual volume in the syringe, make sure to replace the syringe when it is empty, see section 13.3.2, page 141.

3. Press the arrow keys to set the infusion time, and press **OK**.
   *The infusion rate is automatically readjusted.*
4. Press the arrow keys to configure the end of infusion settings and press **OK** to confirm.

- *Stop:* The infusion stops when the VTBI is completed.
- *Keep Vein Open (KVO):* After the VTBI is completed, the infusion continues at a preset flow rate to keep the access device open.
- *Continuous:* After the VTBI is completed, the infusion continues at the programmed flow rate.



**Volume/Time**

**Dose/Time**

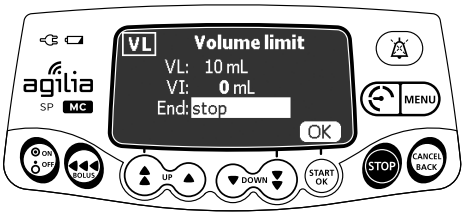
5. Press **start** to start the infusion.

## 7.10.3 Volume Limit

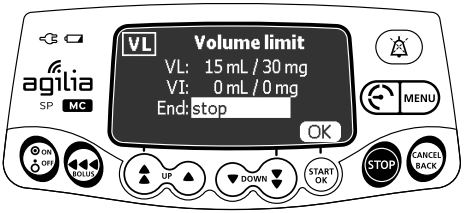
This function allows user to define a Volume Limit for a simple rate infusion.
Infusion is complete when Volume Infused (VI) reaches defined Volume Limit.
The End of Infusion settings allow either the infusion to stop, KVO or Continuous.

When the limit is reached, an alarm is triggered.

1. Access the **Volume Limit** menu, see section 8.13, page 105.



**Flow rate**



**Dose rate**

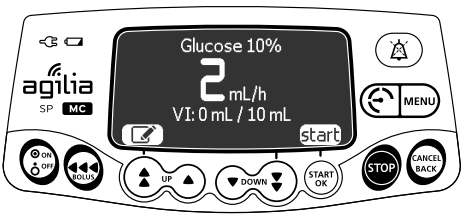
2. Press the arrow keys to set the volume limit, and press **OK**.

**INFORMATION**

- If you program a volume limit that exceeds the actual volume in the syringe, make sure to replace the syringe when it is empty, see section 13.3.2, page 141.
- The volume already infused (VI) before accessing the volume limit mode is taken into account.

**3.** Press the arrow keys to configure the end of infusion settings and press **OK** to confirm.

- *Stop:* The infusion stops when the volume limit is reached.
- *Keep Vein Open (KVO):* After the volume limit is reached, the infusion continues at a preset flow rate to keep the access device open.
- *Continuous:* After the volume limit is reached, the infusion continues at the programmed flow rate.




**Flow rate**


**Dose rate**

**4.** Press **start** to start the infusion.

## 7.11 Other Functions

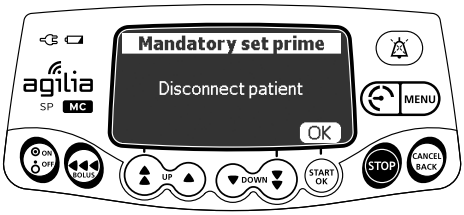
### 7.11.1 Priming the Syringe and the Extension Set

*Note: The prime function can be configured with a compatible Drug Library Software (custom profiles) or in the pump options (Basic Profile):*

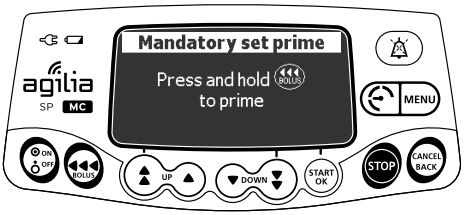
- ***Mandatory**: A message is displayed and the user is required to prime the line before infusion.*
- ***Advised**: A message is displayed to encourage the user to prime the line before infusion.*
- ***Not displayed**: The pump does not remind the user to prime the line before infusion.*

**WARNING**

- Air in the Extension Set presents the risk of injury, death or other serious adverse reactions.




1. Press ⏻ to power on the pump.
2. Press ◀◀◀ BOLUS.
3. Make sure the extension set is not connected to the patient, as indicated on the screen.
4. Press **OK** to confirm.




5. Press and hold the ◀◀◀ BOLUS key to prime.
6. To end priming, release the ◀◀◀ BOLUS key.
7. Make sure there is no air in the extension set.

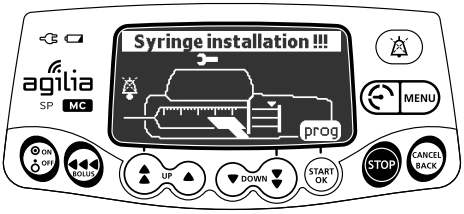
**WARNING**

- Electronically prime the syringe pump system before starting an infusion, or after replacing a near-empty syringe with a replacement syringe.
- Verify the fluid flow to the patient is OFF, and if available, use the prime function on the syringe pump to remove any mechanical slack in the system.
- Using the syringe pump's prime feature engages the mechanical components of the pump and decreases the syringe's friction and compliance (i.e., stiffness) to minimize startup delays and delivery inaccuracies, especially at low infusion rates.
- Failure to use the prime feature on the syringe pump after every syringe change and/or tubing change can significantly delay the infusion delivery startup time and lead to delivery inaccuracies.
- During priming, make sure that the extension set is not connected to the patient.

**INFORMATION**

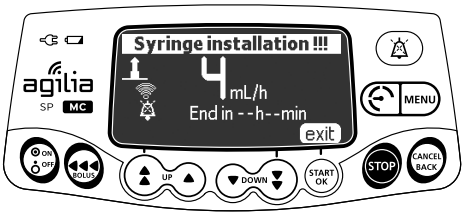
- Priming is only accessible prior to starting the infusion.
- User can repeat priming as needed.
- The BOLUS key is not active when the menu screen is displayed.
- During priming, the occlusion pressure level is set to its maximum value 900 mmHg / 120 kPa / 17.4 PSI.
- Priming is limited to 5 mL maximum. Above 5 mL, you must release and press the BOLUS key again to repeat priming.

### 7.11.2 Pre-programming the Pump




You can program the pump before installing the syringe.

1. Press (ON OFF) to power on the pump.
   *`Syringe installation !!!` is displayed on top of the pump's screen.*
2. Make sure the syringe barrel clasp is folded up.
   *The **prog** symbol is displayed.*
3. Press **prog**.
4. Program the infusion.
   See section 7.5, page 49.




5. Press **exit** to confirm.
6. When ready, install the syringe.
7. Press **start** to start the infusion.

# 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 84. |
| Pressure | | NO | ▪ Modifying the pressure threshold (occlusion alarm) and pressure threshold modes, page 85. |
| Keypad lock status | | NO | ▪ Keypad Lock Status, page 90. |
| Keypad automatic lock | AUTO | NO | ▪ Keypad Automatic Lock, page 92. |
| Battery life | | NO | ▪ Viewing the battery life, page 95. |
| Volume Infused<br>Dose Infused | mL? | NO | ▪ Viewing and clearing the volume or dose infused, page 96. |
| Pause | | YES | ▪ Programming a pause, page 98. |
| Programmed bolus | | NO | ▪ Programming a bolus, page 100. |
| Patient | | NO | ▪ Changing a patient's weight or body surface area, page 101. |
| Day/Night mode | | NO | ▪ Switching between day mode and night mode, page 102. |
| Volume/Time | V/T | YES | ▪ Programming a Volume/Time or Dose/Time infusion, page 104. |
| Dose/Time | D/T | YES | |
| Volume limit | VL | YES | ▪ Volume Limit, page 77. |
| Alarm volume | | NO | ▪ Adjusting the alarm volume, page 106. |
| Volume-Dose history | | YES | ▪ Viewing the infusion history, page 107. |
| View flow rate history | | NO | ▪ Viewing flow rate history, page 108. |
| View pressure history | | NO | ▪ Viewing pressure history, page 109. |

| Menu | Symbol | Stop Infusion Required | Associated Procedure |
|---|---|---|---|
| Syringe |  | NO | ▪ Displaying on-pump syringe information, page 110. |
| View event log |  | NO | ▪ Viewing the event log, page 111. |
| Date/Time |  | NO | ▪ Setting the date and time, page 112. |
| Maintenance |  | NO | ▪ Displaying maintenance information, page 113. |
| Library information |  | NO | ▪ Displaying drug library information, page 114. |
| Clinical information |  | NO | ▪ Viewing remaining time before clinical information display, page 115. |
| Data Set | DS | NO | ▪ Displaying active data set information, page 116. |

*Note:*

*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.*

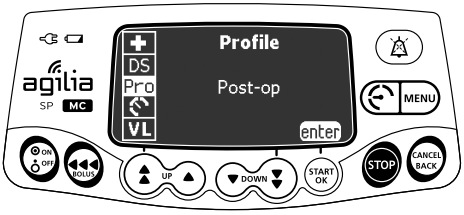
*For more information on factory configuration, refer to Appendix: Factory Configuration, page 202.*

## 8.2 Profile

| Symbol | Pro |
|---|---|
| **Procedure** | Displaying active profile information |
| **Stop Infusion Required** | No |

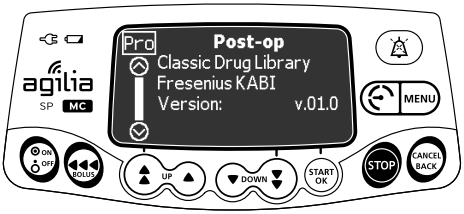
**INFORMATION**

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 section 9, **"Options"** on page 117.
- 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

**WARNING**

- Use the smallest compatible syringe size necessary to deliver the fluid or medication. This minimizes the amount of friction and compliance (i.e., stiffness) of the syringe plunger head. Because syringe pumps infuse fluids by precisely controlling the plunger, smaller syringes provide more precise fluid delivery than larger syringes.
- Use the prime feature on the pump when changing a syringe and/or tubing. Make sure the patient is disconnected when priming.
- Use an extension set which has the smallest internal volume or deadspace (e.g., use microbore tubing when infusing at low rates, shorter length of tubing, etc.).

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 Pressure Threshold Settings (Expected Time to Detect Downstream Occlusion)*

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

For 6cc syringes:

| Target Infusion Flow Rate | Recommended Pressure Threshold | Expected Time to Detect Downstream Occlusion |
|---|---|---|
| 0.1 mL/h | 50 mmHg | 21.4 ± 7.2 minutes |
| 0.5 mL/h | 50 mmHg | 5.6 ± 1.9 minutes |
| 1 mL/h | 50 mmHg | 1.3 ± 0.5 minutes |
| 1.5 mL/h | 100 mmHg | 1.6 ± 0.6 minutes |
| 2 mL/h | 150 mmHg | 1.4 ± 0.5 minutes |
| 5 mL/h | 200 mmHg | 1 ± 0.5 minute |
| 10 mL/h | 200 mmHg | 0.6 ± 0.1 minutes |
| 10.1 to 250 mL/h | 200 to 900 mmHg | Less than 3 minutes |
| 250 mL/h | 900 mmHg | 19.9 ± 1.9 seconds |

*Note: When using Agilia SP with 6cc syringes to infuse critical drugs, prefer programmed flow rates equal to or greater than 1 mL/hr*

For 60cc syringes:

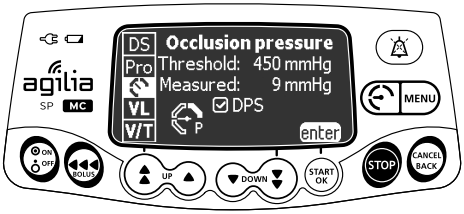
| Target Infusion Flow Rate | Recommended Pressure Threshold | Expected Time to Detect Downstream Occlusion |
|---|---|---|
| 0.1 mL/h | 50 mmHg | 2.3 ± 0.8 hours |
| 1 mL/h | 100 mmHg | 19.6 ± 5.9 minutes |
| 2 mL/h | 200 mmHg | 14 ± 2 minutes |
| 5 mL/h | 100 mmHg | 3.7 ± 0.6 minutes |
| 10 mL/h | 200 mmHg | 2.7 ± 0.6 minutes |
| 10.1 to 25 mL/h | 200 mmHg | Less than 5 minutes |
| 25 to 1200 mL/h | 200 to 900 mmHg | Less than 5 minutes |
| 1200 mL/h | 900 mmHg | 35.7 ± 5.1 seconds |

*Note: When using Agilia SP with 60cc syringes to infuse critical drugs, prefer programmed flow rates equal to or greater than 5 mL/hr.*

### *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:

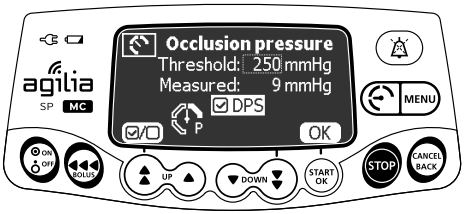
To resolve an occlusion, see section 12.4.5, page 131.




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 DPS function (optional).
7. Press **OK** to confirm.

To review the pressure settings, see section 15.7, **"Pressure Management for Downstream Occlusion Detection"** on page 148.

For more detailed information, see section 12.4.5, **"Pressure Alarms"** on page 131.

### *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 5 mL per hour, and especially flow rates less than 0.5 mL per hour, see section 8.3.2.1, **"Recommended Pressure Threshold Settings (Expected Time to Detect Downstream Occlusion)"** on page 86): Consider occlusion pressure threshold setting and adjust it, as necessary. The lower the occlusion pressure threshold setting, the shorter the occlusion detection time, the smaller the bolus after occlusion release (resulting bolus volumes are discussed in section 18.10, **"Occlusion Alarm Accuracy and Bolus Volume at Occlusion Release"** on page 179). 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 1 mL/h with a 6cc syringe and 5mL/h with a 60cc syringe, 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*

**WARNING**

When addressing or clearing an occlusion:

- Ensure the fluid flow to the patient is clamped to prevent administering an unintended bolus. An occlusion may pressurize the infusion tubing and syringe, 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**

- During Occlusion, drug can accumulate prior to the occlusion resulting in an unintended bolus delivery after clearance. Use clinical judgement to assess if the bolus after occlusion release should be addressed prior to resuming the infusion.
- Larger size syringes combined with high pressure threshold settings may produce a larger post occlusion bolus.

**INFORMATION**

- 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.

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 section 8.3.2.3, **"Adjusting the Pressure Threshold Settings During an Active Infusion"** on page 88.

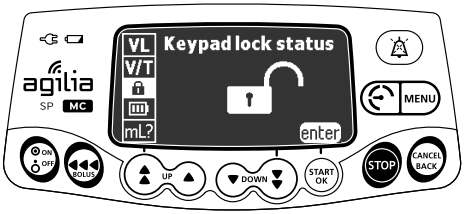
## 8.4 Keypad Lock Status

*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 |

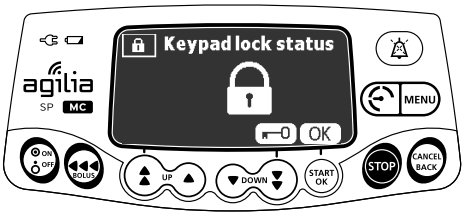
You can use this feature to avoid inadvertent key presses. Depending on the device configuration the keypad lock and unlock code can be enabled or disabled.

### Locking the Keypad



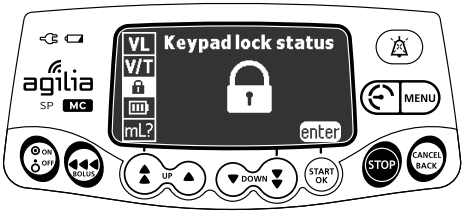

You can lock the keypad as follows:

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 🔒 .*



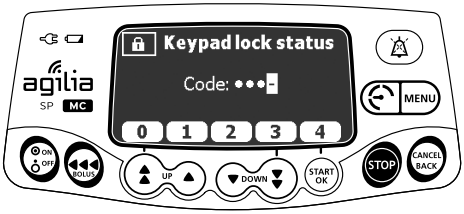

5. Press **OK** to confirm.

## Unlocking the Keypad

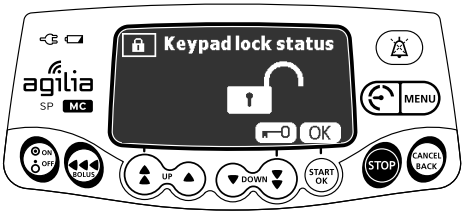



You can unlock the keypad as follows:

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 alarm 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.

## 8.5 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.

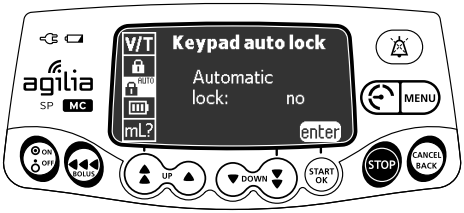
*Note: This feature can be enabled or disabled with a compatible Drug Library Software (custom profiles) or in the pump options (Basic Profile).*

| | |
|---|---|
| **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.

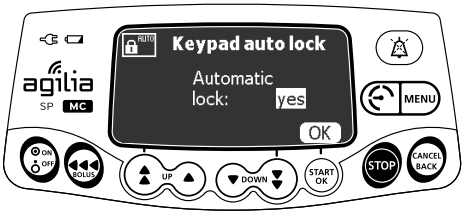
If keypad automatic lock is selected, the keypad will lock automatically at infusion start, or after a time-out.

## 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".

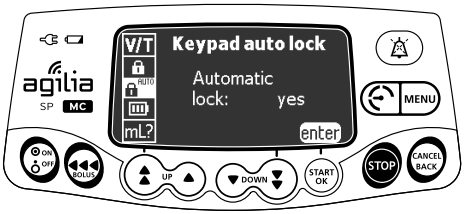



5. Press **OK**.
   *The keypad will lock automatically at infusion start. If the keypad is unlocked during the infusion, it will lock again automatically after a configured time-out.*

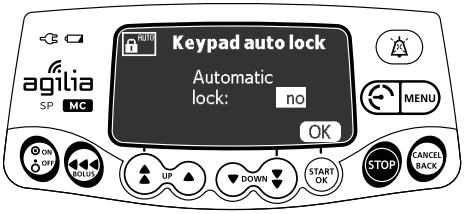
## Deactivating the Keypad Automatic Lock

You can disable the Keypad Automatic Lock as follows:

1. Unlock the keypad: see Unlocking the Keypad, page 91.
2. Press MENU.
3. Press the arrow keys to select AUTO.



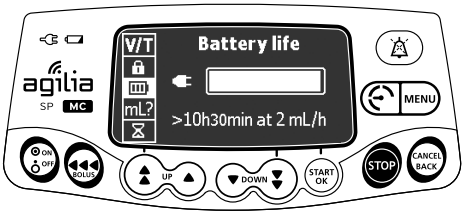

4. Press **enter**.
5. Press the arrow keys to set the Automatic lock to "no".




6. Press **OK**.

## 8.6 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.

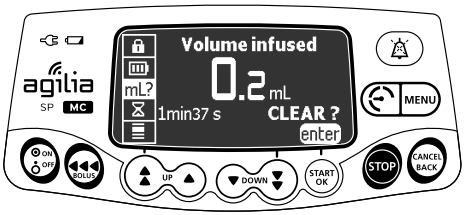
## 8.7 Volume Infused / Dose Infused

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

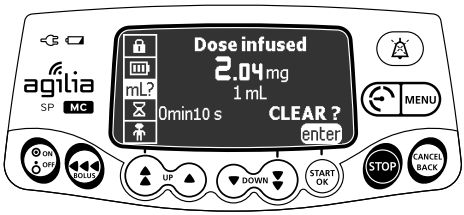
The screen displays the time (lower left) since last VI or DI clearance.

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

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**.

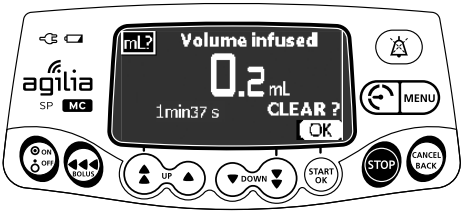



**Flow rate**

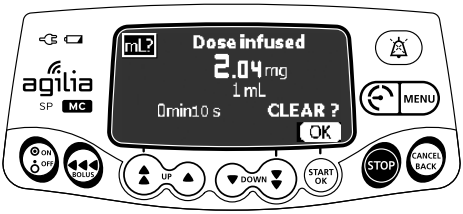



**Dose rate**

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




**Flow rate**




**Dose rate**

**INFORMATION**

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

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

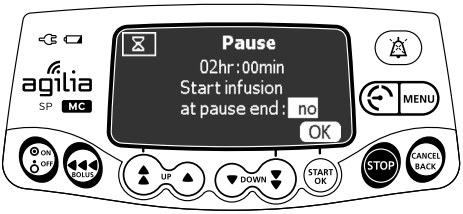
To view the volume or dose infused after clearing, enter the View event log menu.

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 8.15, page 107).

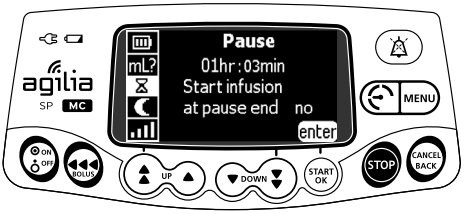
## 8.8 Pause

| | |
|---|---|
| **Symbol** | ⧖ |
| **Procedure** | Programming a pause |
| **Stop Infusion Required** | Yes |

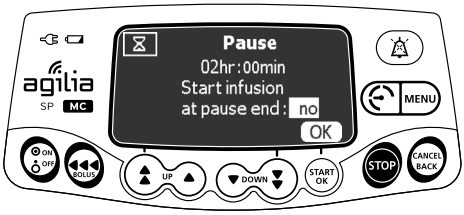


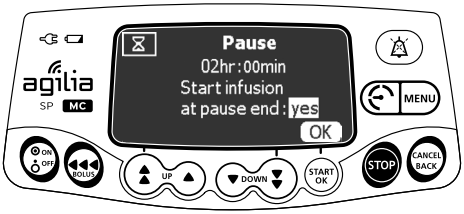

You can program a pause as follows:

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**.

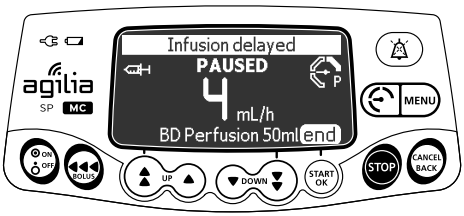


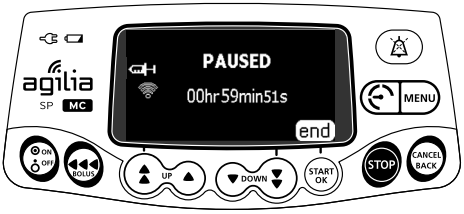
*The default value is **no**.*
Arrow keys allow to switch between **no** and **yes**.

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.

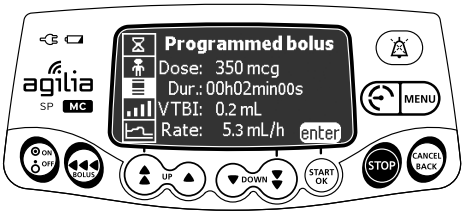
1. Press **end**.
2. Restart infusion pressing **start**.

**INFORMATION**

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

## 8.9 Programmed Bolus

| | |
|---|---|
| **Symbol** | |
| **Procedure** | Programming a bolus |
| **Stop Infusion Required** | No |



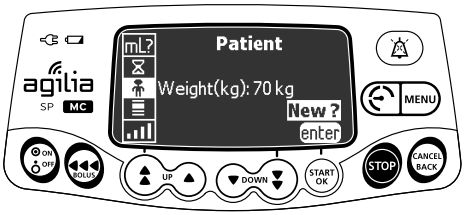

To program a bolus, see section 7.8.3.1, page 62.

## 8.10 Patient

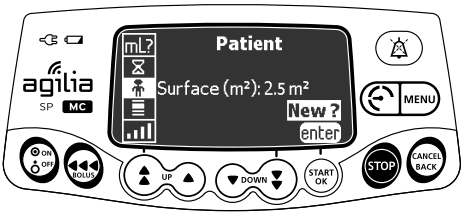
| | |
|---|---|
| **Symbol** | |
| **Procedure** | Changing a patient's weight or body surface area |
| **Stop Infusion Required** | No |

**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**.

## 8.11 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 |

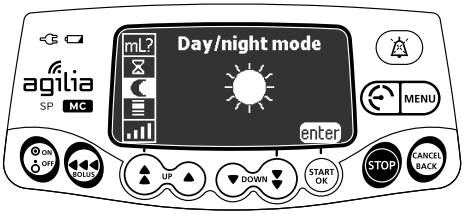
This function switches between day mode and night mode .

The default night mode settings are as follows:

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

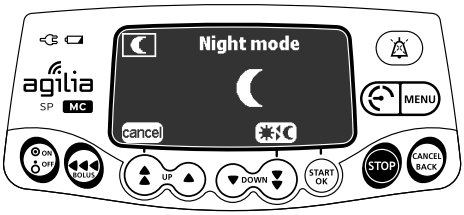
Depending on your pump configuration, the switch between day and night mode may be managed either through this menu (manual mode), or according to pre-defined settings (auto mode).
For more information, reach out your biomed technician.

### Switching from Day Mode to Night Mode




You can switch to night mode as follows:

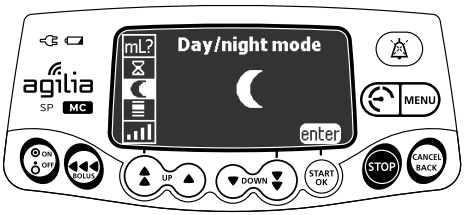
1. Press MENU.
2. Press the arrow keys to select .
3. Press **enter**.



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

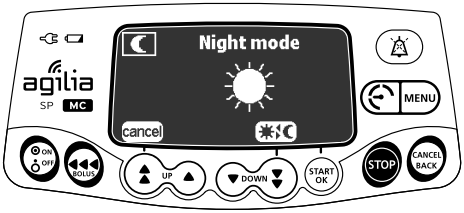
*Note:*
*Pressing any key when the pump is in night mode will illuminate the screen display for 30 seconds.*
*In case of alarm, pump will automatically switch from night to day mode.*

## Switching from Night Mode to Day Mode




You can switch to day mode as follows:

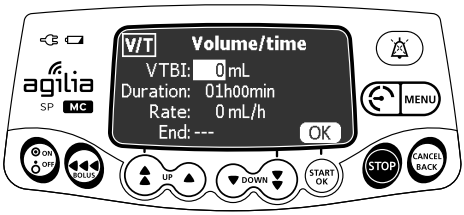
1. Press MENU.
2. Press the arrow keys to select ☾.
3. Press **enter**.



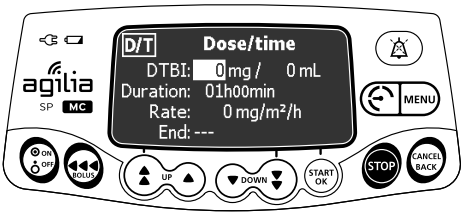

4. Press ☀/☾ to enable day mode.
   *The screen displays ☀.*
5. Press **OK** to confirm.

## 8.12 Volume/Time & Dose/Time

| | |
|---|---|
| **Symbols** | V/T<br>D/T |
| **Procedure** | Programming a Volume/Time or Dose/Time infusion |
| **Stop Infusion Required** | Yes |




**Volume/Time**



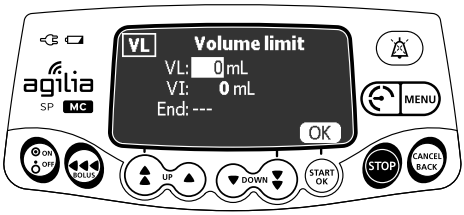

**Dose/Time**

1. Press MENU.
2. Press the arrow keys to select V/T(or D/T).
3. Press **enter** to enable a Volume/Time or Dose/Time infusion.

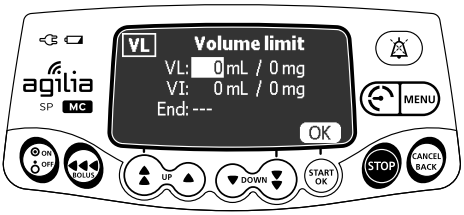
For more information on how to program a Volume/Time or Dose/Time infusion, see section 7.10.2, page 76.

## 8.13 Volume Limit

| | |
|---|---|
| **Symbol** | VL |
| **Procedure** | Adding a Volume Limit to simple rate infusion |
| **Stop Infusion Required** | Yes |




**Flow rate**



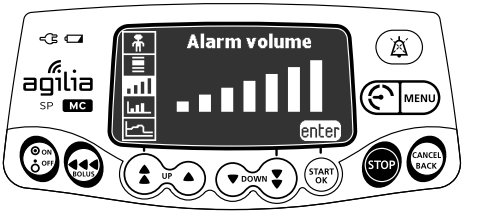

**Dose rate**

1. Press MENU.
2. Press the arrow keys to select VL.
3. Press **enter** to enable a Volume Limit infusion.

For more information on how to program a Volume Limit infusion, see section 7.10.3, page 77.

## 8.14 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:

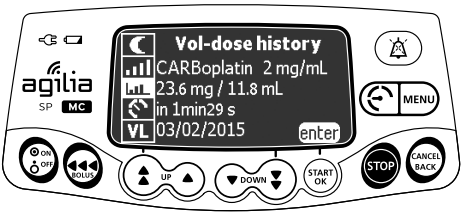
An alarm volume change applies to all alarm levels simultaneously. Whatever the alarm volume is set to:

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

## 8.15 Volume-Dose History

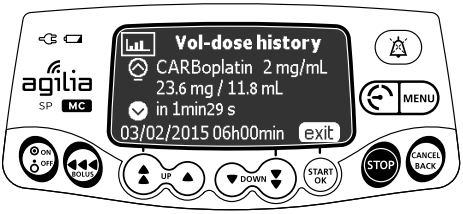
| | |
|---|---|
| **Symbol** | |
| **Procedure** | Viewing the infusion history |
| **Stop Infusion Required** | Yes |

This function allows the user to view the infusion history on the pump.




You can view the infusion history as follows:

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

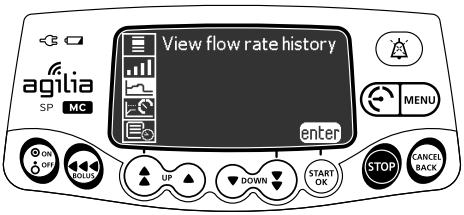



4. Press the arrow keys to select the desired infusion.
   *The selected infusion's details are displayed:*
   *- Drug name*
   *- Drug concentration*
   *- Volume or dose infused*
   *- Infusion total duration*
   *- Infusion date & time*
5. Press **exit** to return to the menu.

## 8.16 View Flow Rate History

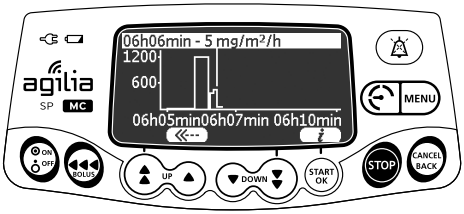
| | |
|---|---|
| **Symbol** | |
| **Procedure** | Viewing flow rate history |
| **Stop Infusion Required** | No |

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.

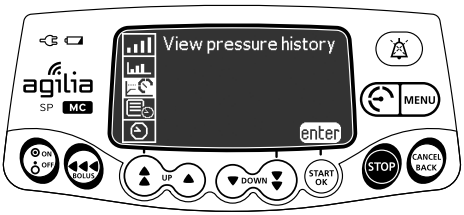
**INFORMATION**

- 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.

## 8.17 View Pressure History

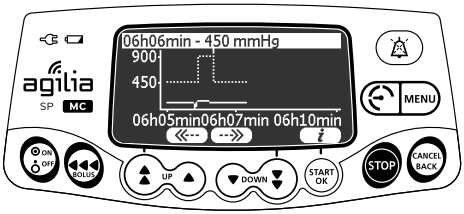
| | |
|---|---|
| **Symbol** | |
| **Procedure** | Viewing pressure history |
| **Stop Infusion Required** | No |

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)*



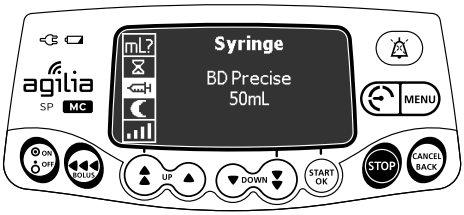

4. Press the «--- and ---» buttons to browse the events.
5. Press i to view details on the selected event.

**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.

## 8.18 Syringe

| | |
|---|---|
| **Symbol** | |
| **Procedure** | Displaying on-pump syringe information |
| **Stop Infusion Required** | No |




You can display on-pump syringe information as follows:

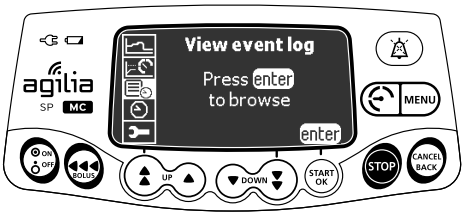
1. Press MENU.
2. Use the arrow keys to select .
3. Press **enter**.
   *The following information is displayed:*
   *- Syringe capacity*
   *- Syringe brand / name*

## 8.19 View Event Log

| | |
|---|---|
| **Symbol** |  |
| **Procedure** | Viewing the event log |
| **Stop Infusion Required** | No |

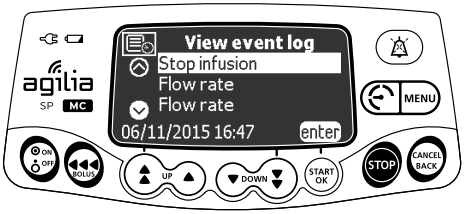
The event log displays details of the last events that occurred on the pump. Events are stored in the log even after the pump is powered off and on again. The log can store up to 1500 events. Older events are overwritten.

*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.*

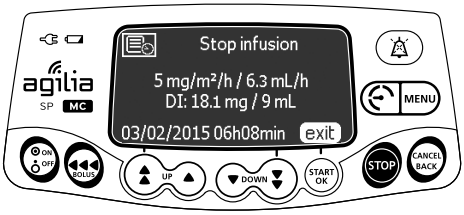



You can view the event log as follows:

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



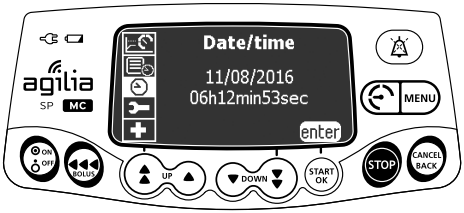

4. Press the arrow keys to select the desired event.
5. Press **enter**. *The details of the event are displayed.*




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

## 8.20 Date/time

| | |
|---|---|
| **Symbol** | |
| **Procedure** | Setting the date and time |
| **Stop Infusion Required** | No |




The Agilia Infusion Pump automatically sets its date and time to the date and time of the VSS server each time it connects wirelessly to the server.

Set the date and time manually as follows:

**1.** Press MENU.

**2.** Press the arrow keys to select .

**3.** Press **enter**.

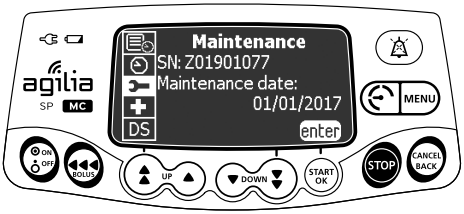
**4.** Press the arrow keys to set the following:

- Month
- Day
- Year
- Hours
- Minutes

**5.** Press **OK** to confirm.

## 8.21 Maintenance

| | |
|---|---|
| **Symbol** | |
| **Procedure** | Displaying maintenance information |
| **Stop Infusion Required** | No |




You can display maintenance information as follows:

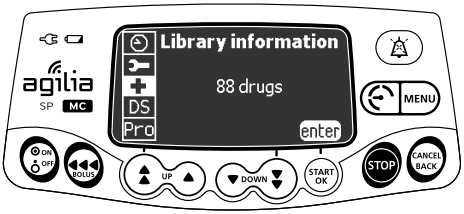
1. Press MENU.
2. Press the arrow keys to select .
3. Press **enter**.
4. Press the arrow keys to scroll through the maintenance information.

*The following information is displayed:*

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

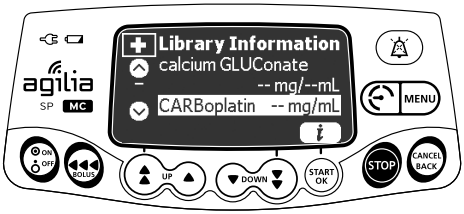
## 8.22 Library Information

| 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.*

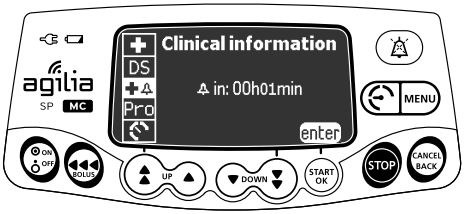



4. Press the arrow keys to select a drug.
5. Press ( i ) to view information on the selected drug (concentration, flow rate, vol/time).
6. Press **Exit** to move to the next line of information.

## 8.23 Clinical Information

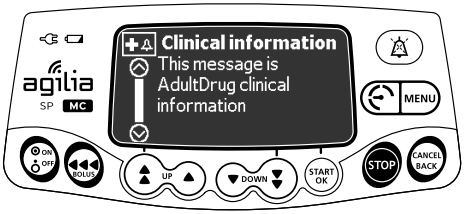
| | |
|---|---|
| **Symbol** | ✚🔔 |
| **Procedure** | Viewing remaining time before clinical information display |
| **Stop Infusion Required** | No |

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.



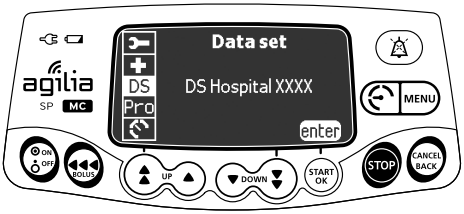

You can view the remaining time before clinical information display as follows:

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.*
   *Example of clinical information message that can be configured: "Time to change syringe reached."*



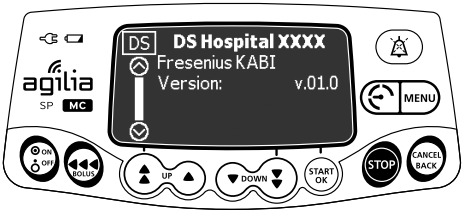
## 8.24 Data Set

| | |
|---|---|
| **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 Location |
|---|---|---|
| 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 SP MC WiFi.

| Function | Choice | Default Pump Setting |
|---|---|---|
| [User 2]: Menu items | ▪ Maintenance: display or hide maintenance | 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]: Wi-Fi module | ▪ Enable/Disable the Wi-Fi module | Enabled |
| [Par 5]: Syringe selection | ▪ Enable/Disable selected syringe confirmation screen | Enabled |
| [Par 6]: Syringes | ▪ Checkbox list with the names of available syringes, and other syringes sizes | section 13.1, page 138. |
| [Par 13]: AC power disconnection alert | ▪ Enable/Disable "AC power disconnection" message and "Device operating on battery" message at power on | Disabled |
| [Par 28]: Automatic power on with disengagement | ▪ Enable/Disable automatic device powering on at syringe disengagement 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 (Disabled) |

# 10 Data Communication

## 10.1 Overview

### Important cybersecurity recommendations

The Agilia SP 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 SP 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 SP Infusion System when not in use.

| Cable Communication | Wi-Fi Communication |
|---|---|
| Connection of 1 pump to a PC for the following purposes:<br>▪ Data set upload<br>▪ Maintenance | Communication between a hospital information system and a number of identified pumps for the following purposes:<br>▪ Data set upload<br>▪ 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 SP MC WiFi Syringe 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

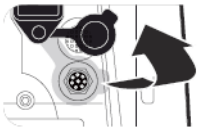
**INFORMATION**

- Only use recommended Agilia cables. See section 18.4, page 169.
- 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.
- RS232 communication port is disabled by default. Port must be enabled by pump software to successfully connect. For more information, refer to the technical manual or contact your Fresenius Kabi Representative.

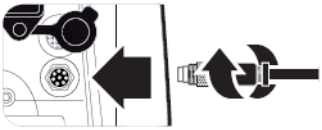
### 10.2.2 Using the Communication Port

How to connect the cable:

1. Remove the protective cap from the Agilia SP 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 Wi-Fi

The Wi-Fi option allows the pump to connect to a hospital information system.

To enable or disable the Wi-Fi module, see section 9.3, page 118.([User 14] : Wi-Fi Module).

**INFORMATION**

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

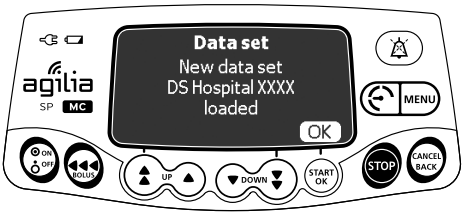
## 10.4 Data Set Upload

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

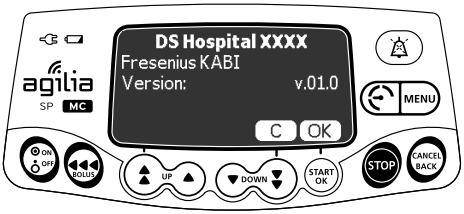
When a new data set has been uploaded since the last start-up of the pump, the ⬇ symbol is displayed on the screen.

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 Port 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 the key press sound (if key press sound is enabled in the pump configurations).

# 12 Alarms and Safety Features

## 12.1 Introduction

Agilia SP 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.<br>▪ The infusion indicator lights (LEDs) flash **red**.<br>▪ The pump emits audible alarm signals.<br>▪ An alarm description is displayed on the pump's screen.<br>▪ Depending on the alarm, except end of infusion with KVO, the (🔔) key silences the pump for 30 seconds or 2 minutes.<br>For end of infusion with KVO: the (🔔) key silences the pump for 1 minute to 5 minutes, configurable.<br>End of infusion is acknowledged.<br>For detailed description of each alarm, please refer to List of Alarms, page 126. |
| **Medium (!!)** | Prompt response | ▪ The infusion continues.<br>▪ The infusion indicator lights (LEDs) flash **yellow**.<br>▪ The pump emits audible alarm signals.<br>▪ 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 126. |

| Alarm Priority | Required Operator Response | Description |
|---|---|---|
| **Low (!)** | Awareness | ▪ The infusion continues.<br>▪ The infusion indicator lights (LEDs) **yellow** are ON.<br>▪ The pump emits audible alarm signals.<br>▪ 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 126. |
| **Information Signals** | Awareness | ▪ The infusion continues.<br>▪ An information message is displayed on the pump's screen.<br>For detailed description of each information signal, please refer to List of Alarms, page 126. |

## 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 (1 mL can be reached in the worst operating condition: biggest syringe model and highest flow rate).
- 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 Syringe Alarms

| Message | Priority | Alarm Trigger | Stops Infusion? | Problem / Resolution |
|---|---|---|---|---|
| `Syringe installation !!!` | High (!!!) | No syringe detected: incompatible syringe diameter or syringe incompletely/ incorrectly installed | Yes | The syringe is not installed correctly (plunger driver, syringe barrel clasp or flange detection).<br>☞ Check the syringe installation.<br><br>Note: The (🔔) key silences the alarm for 2 minutes. |
| `Plunger head alarm !!!` | High (!!!) | No syringe detected: plunger head no longer detected after correct syringe installation | Yes | The plunger head is missing or incorrectly inserted.<br>☞ Check the syringe installation.<br><br>Note: The (🔔) key silences the alarm for 2 minutes. |
| `Disengagement mechanism !!!` | High (!!!) | Disengagement lever activated | Yes | Disengaged mechanism.<br>☞ Check the syringe installation.<br><br>Note: The (🔔) key silences the alarm for 2 minutes. |
| `Remove completely syringe !` | Low (!) | Pump was started with syringe installed while risk mitigation requires a full installation process to be checked from time to time | No | Preventive auto-test on potential failure of plunger head.<br>☞ Remove and reinstall the syringe.<br><br>Note: The (🔔) key silences the alarm for 2 minutes. |

## 12.4.2 Volume Limit Alarms

| Message | Priority | Alarm Trigger | Stops Infusion? | Problem / Resolution |
|---|---|---|---|---|
| `Near end of volume limit !!` | Medium (!!) | Pump detects end of infusion<br><br>Remaining volume represents less than 10 % of syringe nominal volume and configured remaining infusion duration at current flow rate (1 to 30 minutes) is reached | No | Note: The (🔔) key silences the alarm for no time limit. |
| `End of volume limit !!!` | High (!!!) | Volume infused reached programmed volume limit or silenced time during KVO elapsed | Yes | The volume limit is reached.<br><br>Note: The (🔔) key silences the alarm. |
| | | | No, starts KVO infusion or continuous infusion | The volume limit is reached and the end of infusion setting is set as "KVO" or "continuous".<br><br>Note: The (🔔) key silences the alarm for a time duration from 1 minute to 5 minutes (default 2 minutes). |

## 12.4.3 Volume/Time & Dose/Time Alarms

| Message | Priority | Alarm Trigger | Stops Infusion? | Problem / Resolution |
|---|---|---|---|---|
| `Near end of volume/time !!` | Medium (!!) | Pump detects end of infusion<br><br>Remaining volume to be infused represents less than 10 % of syringe nominal volume and configured remaining infusion duration at current flow rate (1 to 30 minutes) is reached | No | The time remaining is less than the defined time duration (adjustable between 1 and 30 minutes), and the remaining VTBI has dropped to less than 10 % of the syringe capacity.<br><br>Note: The (🔔) key silences the alarm for no time limit. |
| `Near end of dose/time !!` | | | | |
| `End of volume/time !!!` | High (!!!) | Pump detects end of infusion<br><br>Volume infused reached programmed volume to be infused or silenced time during KVO elapsed | Yes | The VTBI is completed.<br><br>Note: The (🔔) key silences the alarm. |
| `End of dose/time !!!` | | | No starts KVO infusion or continuous infusion | The VTBI is completed and the end of infusion setting is set as "KVO" or "continuous".<br><br>Note: The (🔔) key silences the alarm for a time duration from 1 minute to 5 minutes (default 2 minutes). |

## 12.4.4 Infusion Alarms

| Message | Priority | Alarm Trigger | Stops Infusion? | Problem / Resolution |
|---|---|---|---|---|
| `Near end of infusion !!` | Medium (!!) | Pump detects near end of infusion<br><br>Remaining volume to be infused represents less than 10 % of syringe nominal volume and configured remaining infusion duration at current flow rate (1 to 30 minutes) is reached | No | The time remaining is less than the defined time duration (adjustable between 1 and 30 minutes), and the remaining volume of fluid in the syringe has dropped to less than 10 % of the syringe capacity.<br><br>Note: The (🔔) key silences the alarm for no time limit. |
| `End of infusion !!!` | High (!!!) | Pump detects end of infusion<br><br>The plunger reached the end of the syringe or the force sensor detected that the syringe is empty | Yes | ☞ The infusion is completed (Simple Rate).<br><br>Note: The (🔔) key silences the alarm for 2 minutes. |
| `Check settings !!` | Medium (!!) | User did not complete infusion parameter modification | No | The flow rate (or dose rate) has been modified using the keys, but has not been confirmed.<br>☞ Check the flow rate (or dose rate) and press **OK** to confirm.<br><br>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.<br>☞ Enter a value and press **OK** to confirm.<br><br>Note: The (🔔) key silences the alarm for 2 minutes. |

| Message | Priority | Alarm Trigger | Stops Infusion? | Problem / Resolution |
|---|---|---|---|---|
| `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**.<br>☞ Check the infusion settings, and press **start** to start the infusion.<br><br>Note: The (🔔) key silences the alarm for 2 minutes. |
| `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.<br>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. |

## 12.4.5 Pressure Alarms

| Message | Priority | Alarm Trigger | Stops Infusion? | Problem / Resolution |
|---|---|---|---|---|
| `Occlusion pre alarm !!` | Medium (!!) | Sensor detects that down-stream blockage reached prealarm pressure limit:<br><br>- alarm threshold between 76 mmHg and 900 mmHg, 50 mmHg below the current downstream occlusion alarm threshold<br><br>- alarm threshold between 50 mmHg and 75 mmHg, 25 mmHg below the current downstream occlusion alarm threshold | No | In-line pressure has reached the following value:<br>▪ 25 mmHg / 2.5 kPa / 0.5 PSI below the programmed threshold (from 50 to 250 mmHg).<br>or<br>▪ 50 mmHg / 5 kPa / 1 PSI below the programmed threshold (over 250 mmHg).<br>☞ Check the infusion line.<br>☞ Set the correct pressure threshold.<br><br>Note: The (🔔) key silences the alarm for no time limit. |

| Message | Priority | Alarm Trigger | Stops Infusion? | Problem / Resolution |
|---|---|---|---|---|
| `Occlusion alarm !!!` | High (!!!) | Sensor detects that down-stream blockage reaches pressure limit (50 mmHg to 900 mmHg) | Yes | The pressure in the infusion line has reached the threshold level. "X" indicates an occlusion.<br>  <br>☞ Check infusion line for an occlusion without disengaging the syringe, releasing the barrel clasp or disengagement lever. If necessary, readjust the pressure threshold. See section 8.3, page 85.<br>☞ If alarm continues, clamp patient tubing and disconnect from patient.<br>☞ Remove the syringe by fully extending the plunger driver and opening the syringe barrel clasp.<br><br>Note: The (🔔) key silences the alarm for 2 minutes. |
| `Pressure increase !` | Low (!) | Measured pressure value represents configured value added to average infusion pressure (added value goes from 50 to 415 mmHg)<br><br>Note: alarm only available when activated and for flow rate below 20 mL/h | No | The pressure is increasing in the infusion line.<br>☞ Check for occlusions in the infusion line.<br><br>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.<br>☞ Check the downstream Luer lock connection and the integrity of the entire line.<br><br>Note: The (🔔) key silences the alarm. |

### 12.4.6 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 !!`<br><br>`Very low battery Connect to AC power and wait` | Medium (!!) | Battery detects low charge<br><br>Occurs at least 35 minutes prior to fully depleted battery | No | Low battery.<br>☞ Connect the pump to a power supply.<br><br>Note: The (🔔) key silences the alarm for no time limit. |
| `Alert !!!`<br><br>`Very low battery Connect to AC power and wait` | High (!!!) | Battery detects low charge<br><br>Occurs 5 minutes prior to fully depleted battery | Yes | The battery is discharged.<br><br>If the pump is not connected to the power supply, the pump will power OFF automatically within 5 minutes.<br>☞ Connect the pump to a power supply immediately.<br><br>If the pump is connected to the power supply:<br>☞ Check that the pump is well connected to a power supply and allow time to charge.<br><br>Note: The (🔔) key silences the alarm for 2 minutes. |
|  | Low (!) | Battery detects low charge<br><br>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. |

## 12.4.7 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.<br>☞ Contact your technical support.<br>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.<br>☞ Press (🔔) to silence the alarm.<br>☞ Check that the battery life is sufficient for the expected infusion duration.<br>☞ If the disconnection was unintentional, check the power connection. |

## 12.4.8 Keypad Alarms

| Message | Priority | Stops Infusion? | Problem / Resolution |
|---|---|---|---|
| `Keypad lock status` | Information signal | No | The keypad is locked.<br>☞ Unlock the keypad. |
| `Keypad locked`<br>`Unlock keypad to continue` | Information signal | No | The keypad is locked and the syringe barrel clasp was opened and closed.<br>☞ Unlock the keypad. |

## 12.4.9 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.<br>☞ Contact your qualified technician or your **Fresenius Kabi** representative.<br><br>Note: The (🔔) key silences the alarm for 30 seconds.<br><br>In the case of a system malfunction, the alarm sounds and an error message `Erxx(yyyy) !!!` is displayed.<br>☞ Record the error message `Erxx(yyyy) !!!`.<br>☞ Disconnect the pump from the power supply.<br>☞ Switch the pump off by pressing the (ON/OFF) key. |

## 12.4.10 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.<br>☞ Check the environment, move from direct sun light or other heat sources.<br><br>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 |
| End of loading dose | 3 beeps | No | At the end of the loading dose |
| End of programmed bolus | 3 beeps | No | At the end of a programmed bolus |
| 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 |
| Syringe prime | 1 beep | N/A | When purge reached end after 5 mL |
| 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 Syringes

## 13.1 Syringe List

**WARNING**

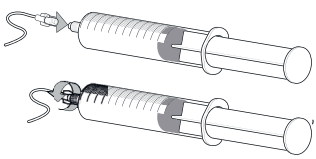
- **Fresenius Kabi** cannot accept responsibility for any flow rate errors that are due to changes to syringe specifications introduced by the manufacturer.
- Ensure syringe sizes and models are compatible with the syringe pump, see section 24.4, page 199. Use of incompatible syringes can cause injury to the patient and improper pump operation resulting in inaccurate fluid delivery, insufficient occlusion sensing, and other potential problems.

**INFORMATION**

- Agilia SP MC WiFi is compatible with different types, brands and sizes of syringes. For a list of compatible syringes, and for ordering information, see section 24.4, page 199.
- The list of available syringes on your pump is accessible from the pump options.
- For general information on syringes (expiration date, storage, sterility, and so on), refer to the syringe manufacturer's instructions.

## 13.2 Preparing a Syringe

1. Prepare the fluid to be infused according to your healthcare facility's protocol.
2. Select a syringe.
3. Check the syringe and access device integrity.
4. Connect the extension set to the syringe according to your practices.
5. If syringe leakage is noticed, Do Not Use. Dispose per facility policy and procedure.
6. Manually prime the extension set according to your healthcare facility's protocol.



7. Confirm that there is no air in the syringe or in the extension set.

**INFORMATION**

- The fluid in the syringe and the syringe must be within normal operating temperature conditions: 64.4 °/ 71.6 °F (+18 °/+22 °C).
- It is recommended to prime the set immediately before starting the infusion.
- Do not use in conjunction with positive pressure infusion devices that could generate back pressure higher than 2000 hPa (1500 mmHg): doing so will damage the administration set and the pump.
- Connect the infusion line in accordance with healthcare facility's protocol. It is recommended to use a Luer lock system to reduce the risk of disconnection, leakage, air-in-line, or contamination.
- Manually prime the syringe and extension set to remove all air, before loading the syringe into the pump.

## Precautions for the use of extension sets

- Use extension sets which have the smallest internal volume or "deadspace" to minimize residual volumes between the syringe and the patient when administering medications or fluids at low infusion rates (e.g., less than 5 mL 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:
  - Tubing internal diameter: Small bore or microbore tubing is recommended when infusing at low rates
  - Tubing length: Tubing 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 extension sets 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).

**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.
- Some extension sets may have components such as a filter that require special instructions.
- Certain drugs may require specific extension sets.

## 13.3 Operations for Syringes

### 13.3.1 Removing a Syringe

1. Press STOP to stop the infusion.
2. Disconnect the extension set from the patient's access device in accordance with healthcare facility protocol.
3. Open the syringe barrel clasp.
4. Press (🔔) to silence the audible signal for 2 minutes.
5. Push the disengagement lever down and remove the syringe from its cradle.
6. Disconnect the syringe from its extension set.

### 13.3.2 Changing a Syringe

1. Press STOP to stop the infusion.
2. Clamp the extension set
3. Open the syringe barrel clasp.
4. Press (🔔) to silence the audible signal for 2 minutes.
5. Push the disengagement lever down and remove the syringe from its cradle.
6. Disconnect the syringe from its extension set.
7. Prepare a new syringe and follow the steps described in the flowchart. See section 6.1, page 40.
8. After the new syringe is installed, acknowledge the "same therapy" screen (optional screen) by pressing NO or YES at the CONFIRM prompt.

**WARNING**

Prime the syringe and extension set with the pump after replacing a near-empty syringe with a replacement syringe. Make sure the patient is disconnected.

**INFORMATION**

Properly dispose of used syringes.

### 13.3.3 Syringe Replacement Interval

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

## 13.4 Gravity Infusion in Parallel with a Pump

You can infuse the contents of a fluid container via gravity, in parallel with the pump.

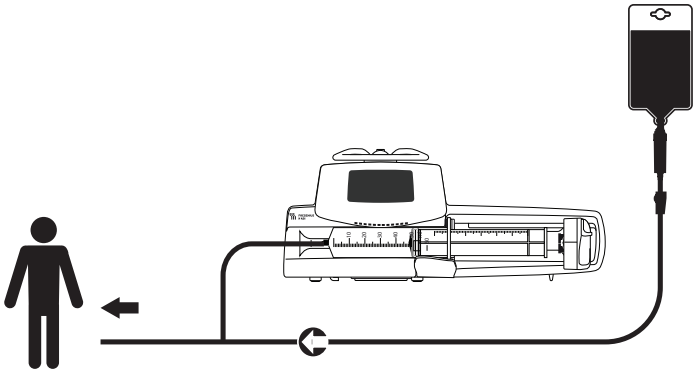


**Figure 13.1:** Gravity Infusion (in parallel with a pump)

**WARNING**

- **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 will be impossible to detect patient-side occlusions. Such an occlusion could cause the pumped drug to back up into the gravity line, and later be infused in an uncontrolled manner when the occlusion is released.
- Be careful about drugs interactions and incompatibilites during a multi-line infusion. **Fresenius Kabi** recommends infusing the critical drugs first.

# 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 106 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. 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. To minimize pump damage and wear, slide the syringe pusher head completely to the left side of the carriage (to the storage position).
5. Handle the pump with care, and store it in a compliant area.

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

## 14.4 Using the Device After Storage

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 123.

## 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 15.8.1, page 150.<br>section 18.9, page 171. |
| Time to Detect Occlusion | section 18.9.5, page 178. |
| Bolus Volume After Occlusion Release | section 18.9.5, page 178. |
| Management of High-Priority Alarms | section 12, page 124. |

## 15.2 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 15.8, **"Accuracy"** on page 149 and section 18.9, **"Trumpet, Start-up Curves and AAMI TIR101: 2020 Delivery Performance"** on page 171). In order to ensure patient safety in high risk populations (e.g. neonates), close monitoring is recommended in low flow rate infusions.

It is recommended to use the smallest syringe possible to reduce the delay before the pump reaches the expected accuracy or stabilizes at the programmed flowrate.

| | Format | Syringe | | | | | Minimum Increment |
|---|---|---|---|---|---|---|---|
| | | 50 mL/ 60 mL | 30 mL | 20 mL | 10 mL | 5 mL | |
| **Infusion Rate** | mL/h | 0.1 → 1200 | 0.1 → 600 | 0.1 → 600 | 0.1 → 350 | 0.1 → 250 | 0.01 (0.10 → 9.99)<br>0.1 (10.0 → 99.9)<br>1 (100 → 1200) |
| **Direct Bolus*** | mL/h | 50 → 1200 | 50 → 600 | 50 → 600 | 50 → 350 | 50 → 250 | 50 |
| **Priming** | mL/h | 1200 | 600 | 600 | 350 | 250 | N/A |
| **Programmed Bolus** | mL/h | 0.1 → 1200 | 0.1 → 600 | 0.1 → 600 | 0.1 → 350 | 0.1 → 250 | 0.01 (0.10 → 9.99)<br>0.1 (10.0 → 99.9)<br>1 (100 → 1200) |
| **KVO**** | mL/h | 0.1 → 5 | 0.1 → 5 | 0.1 → 5 | 0.1 → 5 | 0.1 → 5 | 0.1 |
| **Loading Dose** | mL/h | 0.1 → 1200 | 0.1 → 600 | 0.1 → 600 | 0.1 → 350 | 0.1 → 250 | 0.01 (0.10 → 9.99)<br>0.1 (10.0 → 99.9)<br>1 (100 → 1200) |

* Direct bolus default value = Upper flow rate value for each syringe size.
** KVO defaut value = Disabled.

## 15.3 Volume To Be Infused (VTBI)

| | Format | Range of Settings | Default Value | Minimum Increment |
|---|---|---|---|---|
| **Volume Limit** | mL | 0.1 → 999 | 0.1 | 0.1 (0.1 → 99.9)<br>1 (100 → 999) |
| **Volume/Time** | mL | 0.1 → 99.9 | 0.1 | 0.1 |
| **Direct Bolus** | mL | 0.1 → 60 | N/A | 0.1 |
| **Programmed Bolus** | mL | 0.1 → 99.9 | 0.1 | 0.1 |

Applicable for all syringe sizes.

## 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)<br>0.01 (5.00 ➔ 9.99)<br>0.1 (10.0 ➔ 99.9)<br>1 (100 ➔ 9999) |
| **Programmed Bolus** | Unit | 0.01 ➔ 9999 | N/A | 0.01 (0.01 ➔ 9.99)<br>0.1 (10 ➔ 99.9)<br>1 (100 ➔ 9999) |
| **Loading Dose** | Unit | 0.01 ➔ 9999 | N/A | 0.01 (0.01 ➔ 9.99)<br>0.1 (10.0 ➔ 99.9)<br>1 (100 ➔ 9999) |

Applicable for all syringe sizes.

## 15.5 Infusion Time

| | Format | Range of Settings | Default Value | Minimum Increment |
|---|---|---|---|---|
| **Infusion Rate** | _h_min_s | 00h00min01s ➔ 96h00min00s | N/A | 00h00min01s |
| **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 |

Applicable for all syringe sizes.

## 15.6 Concentration

| | Format | Range of Settings | Default Value | Minimum Increment |
|---|---|---|---|---|
| **Concentration** | Unit | 0.01 ➔ 70000 | 0.01 | 0.01 (0.01 ➔ 9.99)<br>0.1 (10.0 ➔ 99.9)<br>1 (100 ➔ 70000) |
| **Volume of Diluent** | mL | 1 ➔ 60 | 1 | 1 |

Applicable for all syringe sizes.

## 15.7 Pressure Management for Downstream Occlusion Detection

| | Setting Description | Setting Format | Default Value |
|---|---|---|---|
| **Mode** | Infusion pressure mode. | 3 levels / Variable | Variable |
| **DPS** | Allows DPS option activation on the pump pressure menu. | Yes / No | Yes |
| **Unit** | Pressure unit selection. | mmHg / kPa / PSI | mmHg |
| **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 ➔ 700 | 450 | 50 |
| | **High** | mmHg | 250 ➔ 900 | 550 | 50 |
| **Variable** | **Full Range** | mmHg | 50 ➔ 900 | 200 | 25 (50 ➔ 250)<br>50 (250 ➔ 900) |
| | **Maximum Limit** | mmHg | 500 ➔ 900 | 900 | 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.*

## 15.8 Accuracy

**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 15.8, **"Accuracy"** on page 149 and section 18.9, **"Trumpet, Start-up Curves and AAMI TIR101: 2020 Delivery Performance"** on page 171). In order to ensure patient safety in high risk populations (e.g. neonates), close monitoring is recommended in low flow rate infusions.

It is recommended to use the smallest syringe possible to reduce the delay before the pump reaches the expected accuracy or stabilizes at the programmed flowrate.

**WARNING**

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

**Note**: *Tests were performed using Covidien/Monoject 60 mL syringe and distilled water.*

### 15.8.1 Flow Rate Accuracy

**Reminder**

The Agilia SP Infusion System is intended for adult and pediatric care for the intermittent or continuous delivery of parenteral fluids, medication, 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 SP Infusion System is also intended for neonatal care for the intermittent or continuous delivery of parenteral fluids for hydration and nutrition, medication, blood, and blood derivatives through clinically accepted parenteral routes of administration and critical drugs under specific conditions. 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**

Accuracy may be reduced when the infusion flow rate is below 1 mL/h.

**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 15.8, **"Accuracy"** on page 149 and section 18.9, **"Trumpet, Start-up Curves and AAMI TIR101: 2020 Delivery Performance"** on page 171). In order to ensure patient safety in high risk populations (e.g. neonates), close monitoring is recommended in low flow rate infusions.

### *15.8.1.1 Delivery Performance Disclosure in Standard Operational Conditions (SOC)*

| Tested syringes | Mean Flow Error Initial (TB) % | | | |
|---|---|---|---|---|
| | MinSR=LTR 0.1 mL/h | MTR 1 mL/h | HTR 10 mL/h | MaxSR[1] 1200 mL/h or 250 mL/h |
| **Covidien 60cc** | 0.1 ± 0.8 | -0.4 ± 0.7 | 0.8 ± 0.4 | 0.6 ± 0.1 |
| **Covidien 6cc** | ± 1.4 | ± 0.5 | ± 0.9 | -0.6 ± 0.7[2] |

| Tested syringes | Mean Flow Error End (TE) % | | |
|---|---|---|---|
| | MinSR=LTR 0.1 mL/h | MTR 1 mL/h | MaxSR[1] 1200 mL/h or 250 mL/h |
| **Covidien 60cc** | -2.0 ± 0.5 | -1.0 ± 1.6 | 0.4 ± 0.3 |
| **Covidien 6cc** | -0.8 ± 0.5 | 1.4 ± 0.3 | -0.6 ± 0.7[2] |

| Tested syringes | Start-up Delay Time minutes | | | |
|---|---|---|---|---|
| | MinSR=LTR 0.1 mL/h | MTR 1 mL/h | HTR 10 mL/h | MaxSR[1] 1200 mL/h or 250 mL/h |
| **Covidien 60cc** | 52 ± 22 | 3.6 ± 1.4 | 0.8 ± 0.4 | < 0.1 |
| **Covidien 6cc** | 22 ± 21 | 3.7 ± 2.5 | 0.3 ± 0.3 | < 0.1 |

***Notes***:

- *(1) Flow rate at maximum selectable rate (MaxSR) depends of the syringe size: for a 6cc syringe: 250 mL/h; for a 60cc syringe: 1200 mL/h.*
- *(2) For 6cc syringe, the same accuracy data represents both beginning and end flow rates because the limited volume allows only one analysis time period.*
- ***Variations in atmospheric pressure and changes in altitude between new infusions does not impact flow rate accuracy.***
- TB: *analysis interval from the beginning of syringe use but after initial stabilization.*
- TE: *analysis period at the end of the recommendation time of the syringe.*
- *The maximum duration of accuracy tests was 96h.*
- *Mean and standard deviations were established with 10 tested pumps.*
- *SR = Selectable Rate; LTR = Low Test Rate; MTR = Medium Test Rate; HTR = High Test Rate.*
- *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 1200 mL/h; Back-pressure: 0 mmHg;*
  *- Viscosity: Distilled Water (grad 3); Ambient Temperature: 17°C to 23°C*
  *- Relative Humidity: 45 % to 80 % ; Ambient Pressure: 1000 hPa*
  *- Extension set tested: in PVC, length 150 cm, internal diameter 1.5 mm, external diameter 2.7 mm.*

### *15.8.1.2 Delivery Performance Disclosure in Temperature Conditions*

| Tested syringes reference | Mean Flow Error Initial (TB) % | | |
|---|---|---|---|
| | MinSR=LTR 0.1 mL/h | MTR 1 mL/h | MaxSR[1] 1200 mL/h or 250 mL/h |
| Covidien 60cc | ± 1.5 | 0.7 ± 1.4 | 0.9 ± 0.7 |
| Covidien 6cc | ± 2.7 | 0.1 ± 0.9 | 0.6 ± 0.5 |

| Tested syringes reference | Start-up Delay Time minutes | | |
|---|---|---|---|
| | MinSR=LTR 0.1 mL/h | MTR 1 mL/h | MaxSR[1] 1200 mL/h or 250 mL/h |
| Covidien 60cc | 92 ± 76 | 3.3 ± 1.5 | < 0.1 |
| Covidien 6cc | 30 ± 19 | 2.9 ± 1.5 | < 0.1 |

***Notes:***

- *(1) Flow rate at maximum selectable rate (MaxSR) depends of the syringe size: for a 6cc syringe: 250 mL/h; for a 60cc syringe: 1200 mL/h.*
- *Mean and standard deviations were established with 10 tested pumps per temperature, at 10 mL/h and 3 tested pumps at 0.1 and 1500 mL/h.*
- *SR = Selectable Rate; LTR = Low Test Rate; MTR = Medium Test Rate.*
- *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.*
- TB: *analysis interval from the start of syringe use but after initial stabilization.*
- *Test conditions:*
  - *Flow rate: 0.1 to 1200 mL/h*
  - *Back-pressure: 0 mmHg*
  - *Viscosity: Distilled Water (grad 3)*
  - *Ambient Temperature: 5°C to 40°C*
  - *Ambient Pressure: 1000 hPa*
  - *Extension set tested: in PVC, length 150 cm, internal diameter 1.5 mm, external diameter 2.7 mm.*

### *15.8.1.3 Delivery Performance Disclosure in Viscosity Conditions*

| Tested syringes reference | Mean Flow Error Initial (TB) % | | |
|---|---|---|---|
| | MinSR=LTR 0.1 mL/h | MTR 1 mL/h | MaxSR[1] 1200 mL/h or 250 mL/h |
| Covidien 60cc | 0.1 ± 1.6 | 0.5 ± 0.5 | 0.6 ± 0.2 |
| Covidien 6cc | 0.3 ± 1.3 | -0.3 ± 1.0 | -0.6 ± 1.0 |

| Tested syringes reference | Start-up Delay Time minutes | | |
|---|---|---|---|
| | MinSR=LTR 0.1 mL/h | MTR 1 mL/h | MaxSR[1] 1200 mL/h or 250 mL/h |
| Covidien 60cc | 41.2 ± 11.9 | 4.3 ± 2.5 | < 0.1 |
| Covidien 6cc | 20.4 ± 8.3 | 2.4 ± 1.2 | < 0.1 |

***Notes:***

- *(1) Flow rate at maximum selectable rate (MaxSR) depends of the syringe size: for a 6cc syringe: 250 mL/h; for a 60cc syringe: 1200 mL/h.*
- *Mean and standard deviations were established with 10 tested pumps.*
- *SR = Selectable Rate; LTR = Low Test Rate; MTR = Medium Test Rate.*
- *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.*
- TB: *analysis interval from the start of syringe use but after initial stabilization.*
- *Test conditions:*
  - *Flow rate: 0.1 to 1200 mL/h*
  - *Back-pressure: 0 mmHg*
  - *Viscosity: 50 % Dextrose solution*
  - *Ambient Temperature: 17°C to 23°C*
  - *Relative Humidity: 45 % to 80 %*
  - *Ambient Pressure: 1000 hPa*

  *Extension set tested: in PVC, length 150 cm, internal diameter 1.5 mm, external diameter 2.7 mm.*

### *15.8.1.4 Delivery Performance disclosure in Back-Pressure Conditions*

The pump is lifted above the patient 1.33m to get -100mmHg (back-pressure).

| Tested syringes reference | Mean Flow Error Initial (TB) % | | |
|---|---|---|---|
| | MinSR=LTR 0.1 mL/h | MTR 1 mL/h | MaxSR[1] 1200 mL/h or 250 mL/h |
| Covidien 60cc | 12.1 ± 3.2 | 2.5 ± 1.6 | 0.4 ± 0.2 |
| Covidien 6cc | 3.7 ± 1.7 | 1.1 ± 1.6 | -0.9 ± 0.5 |

| Tested syringes reference | Start-up Delay Time minutes | | |
|---|---|---|---|
| | MinSR=LTR 0.1 mL/h | MTR 1 mL/h | MaxSR[1] 1200 mL/h or 250 mL/h |
| Covidien 60cc | 44.1 ± 29.3 | 10 ± 4.8 | < 0.1 |
| Covidien 6cc | 33.5 ± 25.1 | 4.5 ± 2.4 | < 0.1 |

***Notes:***

- *(1) Flow rate at maximum selectable rate (MaxSR) depends of the syringe size: for a 6cc syringe: 250 mL/h; for a 60cc syringe: 1200 mL/h.*
- *Mean and standard deviations were established with 10 tested pumps.*
- *SR = Selectable Rate; LTR = Low Test Rate; MTR = Medium Test Rate.*
- *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.*
- TB: *analysis interval from the start of syringe use but after initial stabilization.*
- *Test conditions:*
  - *Flow rate: 0.1 to 1200 mL/h*
  - *Back-pressure: -100 mmHg*
  - *Viscosity: Distilled Water (grad 3)*
  - *Ambient Temperature: 17°C to 23°C*
  - *Relative Humidity: 45 % to 80 %*
  - *Ambient Pressure: 1000 hPa*
  - *Extension set tested: in PVC, length 150 cm, internal diameter 1.5 mm, external diameter 2.7 mm.*

## 15.8.2 Bolus Volume Accuracy

**WARNING**

Accuracy may be reduced when the infusion flow rate is below 1 mL/h.

| | Volume |
|---|---|
| **Direct Bolus*** | ± 10 % |

* Test condition: *Back pressure:* 0 mmHg

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

| Tested syringes reference | Bolus dose Volume mL | Bolus dose rate mL/h | Volumetric Accuracy % |
|---|---|---|---|
| Covidien 6cc | 0.1 | 180 | -0.3 ± 0.06 |
| | 0.3 (5% of syringe capacity) | 216 | 0.7 ± 0.04 |
| Covidien 60cc | 0.1 | 360 | -4.1 ± 8.8 |
| | 1 | 1200 | 0.2 ± 0.5 |
| | 5 | 1200 | 0.2 ± 0.4 |

***Notes:***

- ***Variations in atmospheric pressure and changes in altitude between new infusions does not impact flow rate accuracy.***
- *Mean and standard deviations were established with 10 tested pumps.*
- *Test conditions:*
  - *Basal Flow rate: None*
  - *Back-pressure: 0 mmHg*
  - *Viscosity: Distilled Water (grad 3)*
  - *Ambient Temperature: 17°C to 23°C*
  - *Relative Humidity: 45 % to 80 %*
  - *Ambient Pressure: 1000 hPa*
  - *Extension set tested: in PVC, length 150 cm, internal diameter 1.5 mm, external diameter 2.7 mm.*

### *15.8.2.2 Bolus Dose Volumetric Accuracy Disclosure in Back-pressure Conditions*

| Tested syringes reference | Bolus dose Volume mL | Bolus dose Rate mL/h | Volumetric Accuracy % |
|---|---|---|---|
| Covidien 60cc | 0.1 | 360 | -3.5 ± 14.7 |
| | 1 | 1200 | 0.3 ± 1.1 |

***Notes:***
- *Mean and standard deviations were established with 10 tested pumps.*
- *Test conditions:*
  - *Basal Flow rate: None*
  - *Back-pressure: -100 to +100 mmHg*
  - *Viscosity: Distilled Water (grad 3)*
  - *Ambient Temperature: 17°C to 23°C*
  - *Relative Humidity: 45 % to 80 %*
  - *Ambient Pressure: 1000 hPa*
  - *Extension set tested: in PVC, length 150 cm, internal diameter 1.5 mm, external diameter 2.7 mm.*

### *15.8.2.3 Bolus Dose Volumetric Accuracy Disclosure in Viscosity conditions*

| Tested syringes reference | Bolus dose Volume mL | Bolus dose Rate mL/h | Volumetric Accuracy % |
|---|---|---|---|
| Covidien 60cc | 0.1 | 360 | -2.4 ± 9.2 |
| | 1 | 1200 | 1.0 ± 0.6 |

***Notes:***
- *Mean and standard deviations were established with 10 tested pumps.*
- *Test conditions:*
  - *Basal Flow rate: None*
  - *Back-pressure: 0 mmHg*
  - *Viscosity: 20 % Dextrose solution*
  - *Ambient Temperature: 17°C to 23°C*
  - *Relative Humidity: 45 % to 80 %*
  - *Ambient Pressure: 1000 hPa*
  - *Extension set tested: in PVC, length 150 cm, internal diameter 1.5 mm, external diameter 2.7 mm.*

## 15.8.3 Pressure Accuracy for Downstream Occlusion Detection

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

## 15.8.4 Effects of Pumping on Fluid Temperature

| | Impact on Fluid Temperature | |
|---|---|---|
| | **Ambient Temperature** | **Temperature increase** |
| **Effects of Ambient Temperature on Infusion** | 22 °C ± 2 °C | < 2 °C |
| **Test at maximum operating temperature** | 40 °C | < 1 °C |

***Note**: the maximum duration of accuracy tests was 96 hours.*

## 15.8.5 Loading Dose Volumetric Accuracy Disclosure

| Tested syringe reference | Loading dose Volume mL | Loading dose Rate mL/h | Loading Dose Volumetric Accuracy % | |
|---|---|---|---|---|
| | | | With Startup Delay Reduction | Without Startup Delay reduction |
| **Covidien 60cc** | 0.1 | 360 | -15 ± 7.4 | -78 ± 25 |
| | 1 | 1200 | 1.6 ± 1.0 | 9.6 ± 10.9 |

***Notes**:*

- *Mean and standard deviations were established with 10 tested pumps.*
- *Test conditions:*
  - *Back-pressure: 0 mmHg;*
  - *InletPressure: 50cm*
  - *Viscosity: Distilled Water (grad 3)*
  - *Ambient Temperature: 17°C to 23°C*
  - *Relative Humidity: 45 % to 80 %*
  - *Ambient Pressure: 1010 hPa*
  - *Extension set tested: in PVC, length 150 cm, internal diameter 1.5 mm, external diameter 2.7 mm.*

## 15.9 Infusion of blood and blood derivatives

### 15.9.1 Test results

Testing was performed using both 5 mL and 60 mL syringes under three different test conditions:

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

to determine if the Agilia SP 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 SP MC WiFi pumps.

| Condition | Syringe size (in mL) | 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** | 60 | 1200 | Close to 900 | Close to 42 | 37.4°F | 21 | 0.049% |
| **Nominal Infusion** | 60 | 600 | ~ 100 - 200 | Random | 71.6 °F | 21 | 0.041% |
| **Worst-case Long Infusion** | 60 | 15 | Close to 900 | Close to 42 | 71.6 °F | 21 | 0.138% |
| **Worst-case Rapid Infusion** | 5 | 250 | Close to 900 | Close to 42 | 37.4°F | 21 | 0.124% |
| **Nominal Infusion** | 5 | 125 | ~ 100 - 200 | Random | 71.6 °F | 21 | 0.042% |
| **Worst-case Long Infusion** | 5 | 1.25 | Close to 900 | Close to 42 | 71.6 °F | 21 | 0.090% |

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

5 mL syringe tests consisted of the infusion of 5 mL of aged human blood within four hours (1.25 mL/h) or as rapidly as possible (250 mL/h).

60 mL syringe tests consisted of the infusion of 60 mL of aged human blood within four hours (15 mL/h) or as rapidly as possible (1200 mL/h).

Syringes used for testing: BD Plastipak 5 mL and BD Syringe 50 mL.

## 15.10 Units and Conversion Rules

### 15.10.1 Concentration Units

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

### 15.10.2 Dose Rate Units

| | Units |
|---|---|
| **Dose Rate Units** | nanog/h,<br>nanog/kg/min, nanog/kg/h |
| | mcg/min, mcg/h,<br>mcg/kg/min, mcg/kg/h |
| | mg/min, mg/h, mg/24h,<br>mg/kg/min, mg/kg/h, mg/kg/24h,<br>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 |

## 15.10.3 Conversion Rules

| | | |
|---|---|---|
| **Conversion Rules** | $\text{mL/h} = \frac{\textit{unit/kg/h (dose rate)} \times \textit{kg (weight)}}{\textit{unit/mL (concentration)}}$ | Conversion of a dose rate including the unit/kg into volume flow rate (mL/h) |
| | $\text{mL/h} = \frac{\textit{unit/m}^2\textit{/h (dose rate)} \times \textit{m}^2\textit{ (body surface area)}}{\textit{unit/mL (concentration)}}$ | Conversion of a dose rate including the unit/$m^2$ into volume flow rate (mL/h) |
| | $\text{mL/h} = \frac{\textit{unit/h (dose rate)}}{\textit{unit/mL (concentration)}}$ | Expression of a volumetric flow rate |
| | $\text{mL} = \frac{\textit{unit/kg (dose)} \times \textit{kg (weight)}}{\textit{unit/mL (concentration)}}$ | Conversion of a dose including the unit/kg into volume (mL) |
| | $\text{mL} = \frac{\textit{unit/m}^2\textit{ (dose)} \times \textit{m}^2\textit{ (body surface area)}}{\textit{unit/mL (concentration)}}$ | Conversion of a dose including the unit/$m^2$ into volume (mL) |
| | $\text{mL} = \frac{\textit{unit (dose)}}{\textit{unit/mL (concentration)}}$ | 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 163.

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 162.

## 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, syringe barrel area, syringe guard, plunger driver, disengagement lever, syringe barrel clasp, 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 163.

## 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.

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 the pump, 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:<br>- Add one ounce (1 pump action) of ENZOL Enzymatic Detergent liquid concentrate per gallon of water.<br>- 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, syringe location, keyboard, push guard, plunger driver, disengagement lever, syringe barrel clasp…) of the pump, from top to bottom. You can use the metal handle to lift and move the pump.<br>- When wiping down the sides, avoid wetting the connector sockets.<br>- 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 syringe barrel clasp and move the plunger driver to the right. |
| **9.** Using a fresh piece of gauze or soft cloth dampened with cleaning agent, thoroughly wipe down the back side of the syringe barrel clasp and all exposed surfaces in the syringe barrel area. |
| **10.** Wipe down thoroughly again all exposed surfaces of the device. |
| **11.** Make sure the pump remains damp for at least 1 minute to dissolve all organic matter. |
| **12.** 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, and the narrow or hard-to-reach areas. |
| **13.** Complete the cleaning by wiping down the power cord and any pump accessories. |
| **14.** Dampen a fresh piece of gauze with tap water, and rinse all exposed surfaces of the pump. |
| **15.** Allow the pump to dry completely at room temperature. |
| **16.** 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. |

### 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 164
- 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 163.

| 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).<br>You can use the metal handle to lift and move the pump.<br>- When wiping down the sides, avoid wetting the connector sockets.<br>- 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 of the pump. |
| **5.** Open the syringe barrel clasp, move the plunger driver to the right and gently wipe down the exposed surfaces (back side of the syringe barrel clasp and all exposed surfaces in the syringe barrel area). |
| **6.** Using a fresh ready-to-use wipe, repeat steps 3 to 5. |
| **7.** Leave the disinfecting agent 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 dry at room temperature. |

# 17 Power Management

## 17.1 AC Power Supply Precautions

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

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

**WARNING**

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

## 17.2 Battery Precautions

The device uses a Lithium-ion rechargeable battery.

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

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

See section 18.2, page 168. for more information about battery specifications.

**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** | **Wi-Fi** | **Battery Life** |
| | 5 mL/h | ✓ | > 6 h |
| | 5 mL/h | ✗ | > 11 h |
| **Battery Recharge** | Pump OFF: < 6 h / Pump ON: < 20 h | | |

*✓ = Wi-Fi enabled*
*✗ = Wi-Fi disabled or not used*

## 18.3 Power Consumption

The pump typically consumes about 3.5 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 to connect the device to a computer.

This cable is composed of a binder connector, to plug into the pump, and a USB plug to computer:

Pump side (proprietary serial RS232 male connector)

Computer side (proprietary 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 SP 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. 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 | 23 |
| 20 | 27 |
| 100 | 30 |
| 400 | 49 |
| 1200 | 32 |

*Note: These values are provided for information purposes only.*

### 18.6.2 Alarms Sound Levels

| Alarm Priority | Sound Level (dB) | |
|---|---|---|
| | min | Max |
| High-priority | 54 ±6 | 66 ±6 |
| Medium-priority | 50 ±6 | 62 ±6 |
| Low-priority | 48 ±6 | 55 ±6 |

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

## 18.7 Compliance

| | | | |
|---|---|---|---|
| **ElectroMedical Equipment Safety** | Compliant with the following standards:<br>▪ IEC 60601-1<br>▪ IEC 60601-1-8 | **IP22** | Index of protection against ingress of water or particulate matter |
| **EMC (ElectroMagnetic Compatibility)** | Compliant with the following standard:<br>▪ 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 13.6 x 6.7 in (135 x 345 x 170 mm) |
| **Weight** | Approximately 4.6 lbs (2.1 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 SP Infusion System is intended for adult and pediatric care for the intermittent or continuous delivery of parenteral fluids, medication, 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 SP Infusion System is also intended for neonatal care for the intermittent or continuous delivery of parenteral fluids for hydration and nutrition, medication, blood, and blood derivatives through clinically accepted parenteral routes of administration and critical drugs under specific conditions. 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**

Accuracy may be reduced when the infusion flow rate is below 1 mL/h.

**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 15.8, **"Accuracy"** on page 149 and section 18.9, **"Trumpet, Start-up Curves and AAMI TIR101: 2020 Delivery Performance"** on page 171). In order to ensure patient safety in high risk populations (e.g. neonates), close monitoring is recommended in low flow rate infusions.

It is recommended to use the smallest syringe possible to reduce the delay before the pump reaches the expected accuracy or stabilizes at the programmed flowrate.

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.

Tests were performed using Covidien/Monoject 60 mL syringe and distilled water.

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

- Limit the range of available flow rates in accordance with the maximum flow rate to be used.
- Lower the pressure threshold in order to gain in time to detect occlusion.

## 18.9.1 Flow rate: 0.1 mL/h

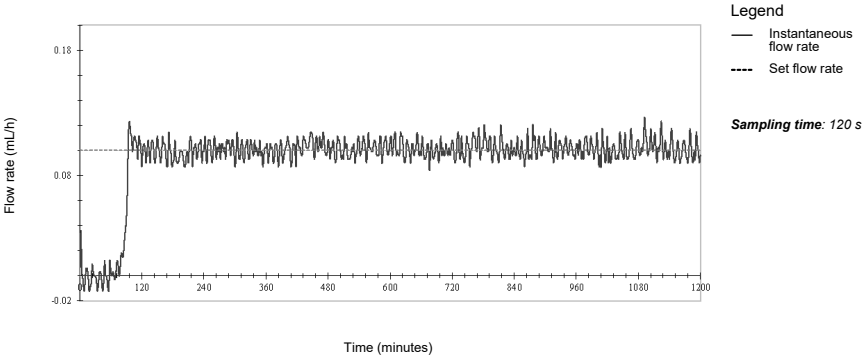



**Figure 18.1:** Start-up and instantaneous flow rate (0.1 mL/h over 20 hours)

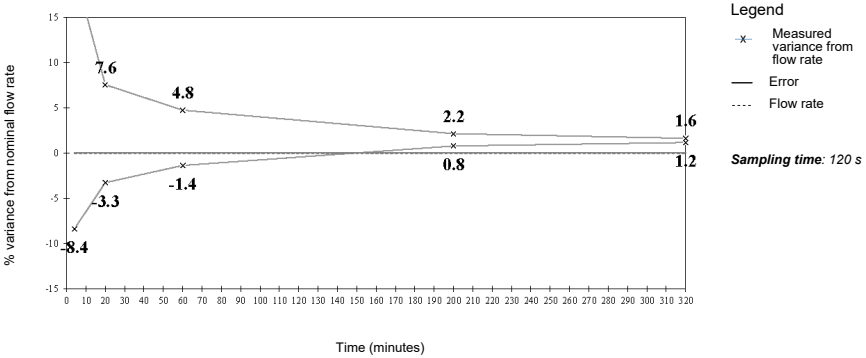



**Figure 18.2:** Trumpet curves for 4, 20, 60, 200, 320 minutes observation windows (0.1 mL/h over 20 hours)

## 18.9.2 Flow rate: 1 mL/h

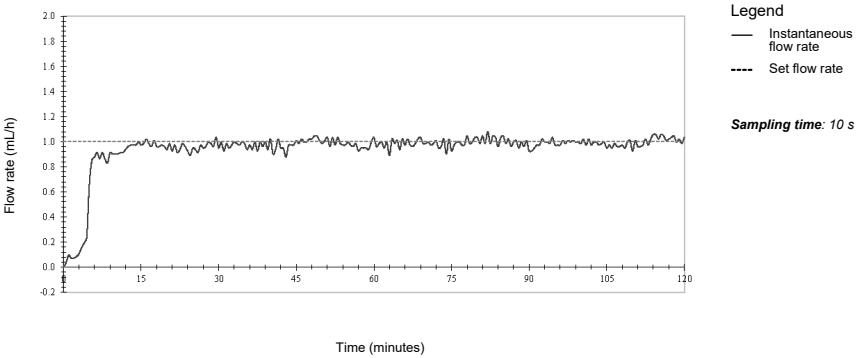



**Figure 18.3:** Start-up and instantaneous flow rate (1 mL/h over 2 hours)

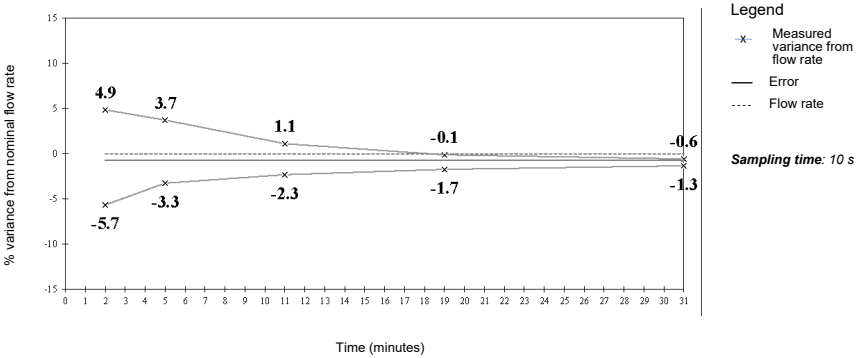



**Figure 18.4:** Trumpet curves for 2, 5, 11, 19, 31 minutes observation windows (1 mL/h over 2 hours)

## 18.9.3 Flow rate: 5 mL/h

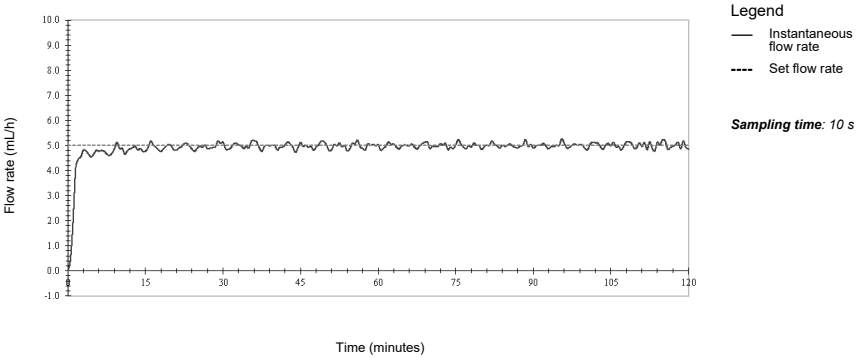



**Figure 18.5:** Start-up and instantaneous flow rate (5 mL/h over 2 hours)

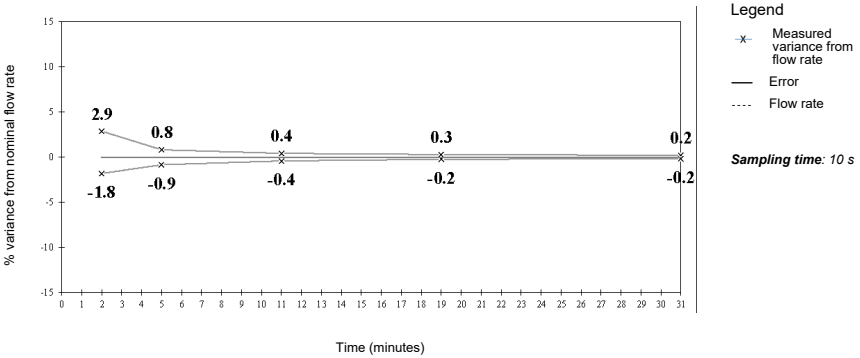
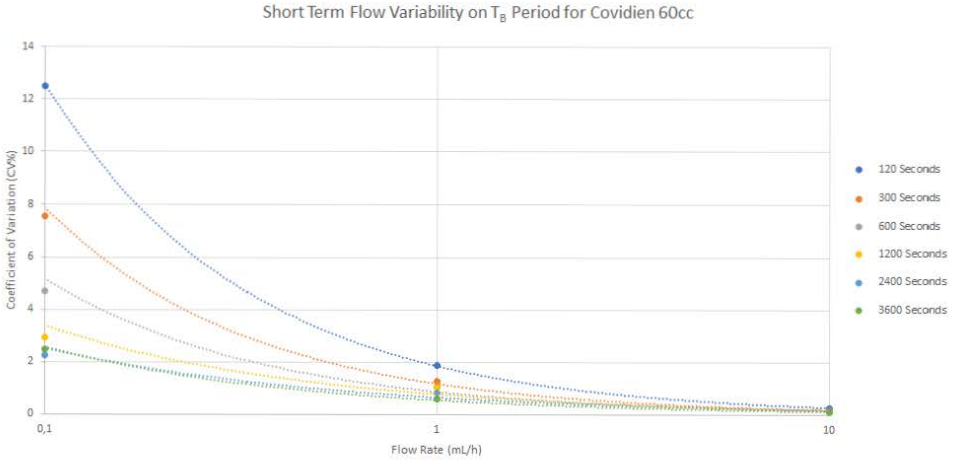
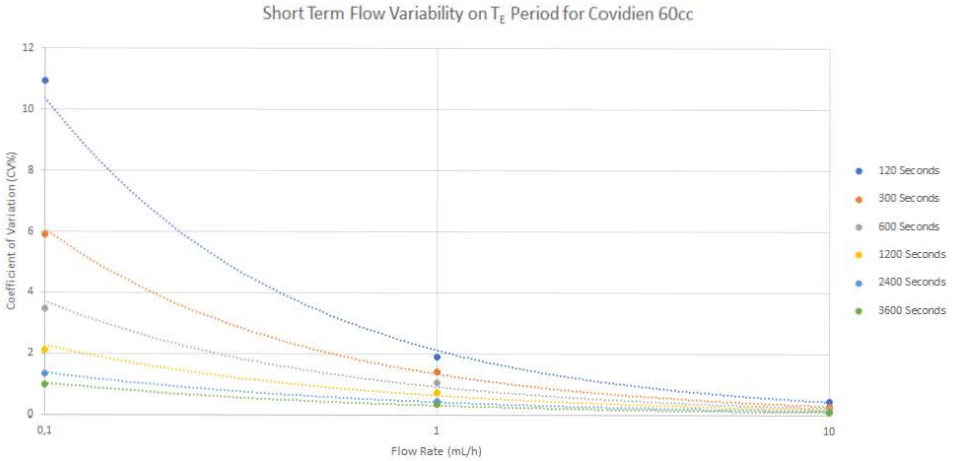
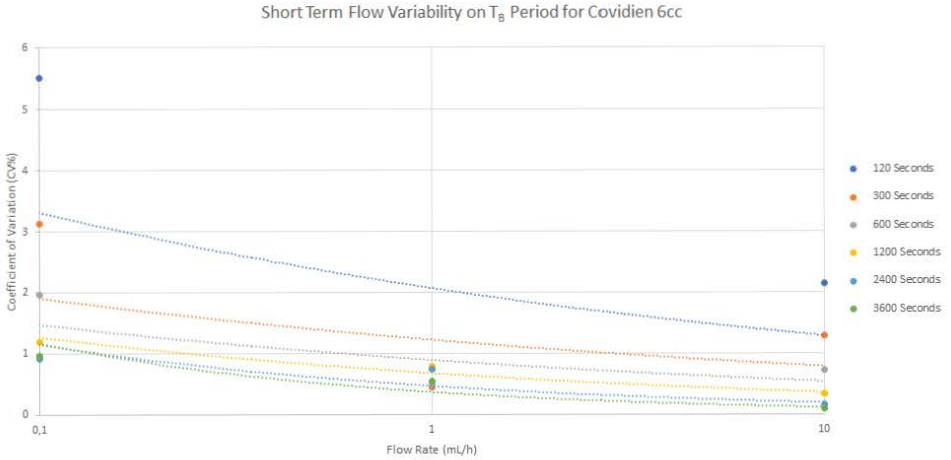


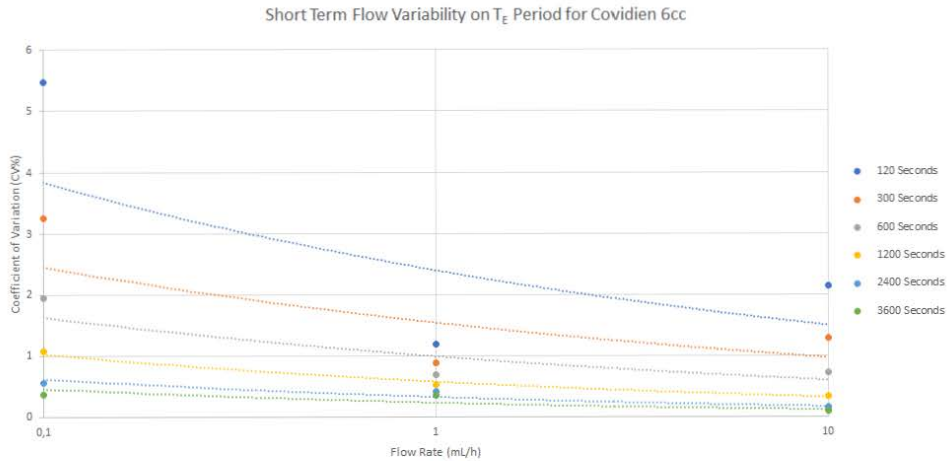

**Figure 18.6:** Trumpet curves for 2, 5, 11, 19, 31 minutes observation windows (5 mL/h over 2 hours)

## 18.9.4 AAMI TIR101:2020 Coefficient of Variability (CV%)



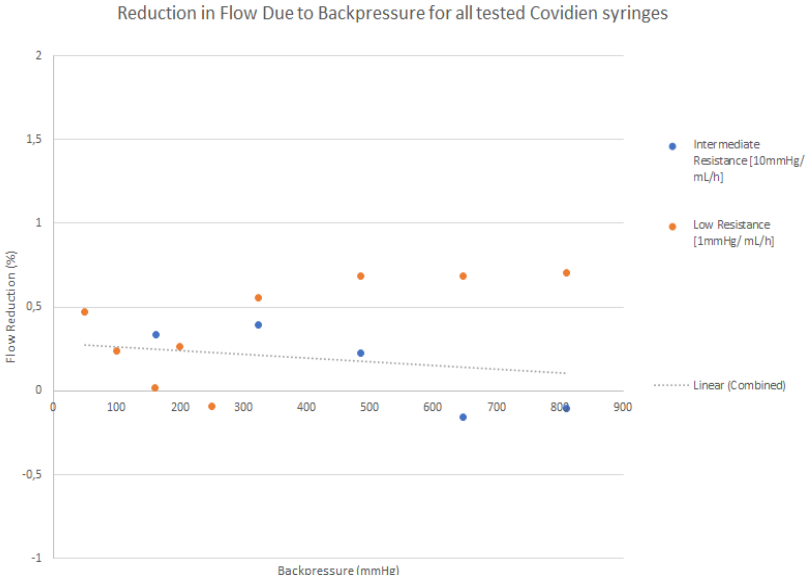




Short Term Flow Variability on $T_B$ Period for Covidien 6cc
Coefficient of Variation (CV%)
0
1
2
3
4
5
6
0,1
1
10
Flow Rate (mL/h)
120 Seconds
300 Seconds
600 Seconds
1200 Seconds
2400 Seconds
3600 Seconds


Short Term Flow Variability on $T_E$ Period for Covidien 6cc
Coefficient of Variation (CV%)
0
1
2
3
4
5
6
0,1
1
10
Flow Rate (mL/h)
120 Seconds
300 Seconds
600 Seconds
1200 Seconds
2400 Seconds
3600 Seconds

## 18.9.5 AAMI TIR101:2020
### Reduction in Flow Due to Back Pressure

Flow rate reduction due to backpressure caused by inline resistance tested according to the conditions described in TIR101:2021.



## 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.*

**For 6cc syringes:**

| Target Infusion Flow Rate | Recommended Pressure Threshold | Expected Time to Detect Downstream Occlusion | Post-occlusion unintended bolus (average per minute over 5 minutes) |
|---|---|---|---|
| 0.1 mL/h | 50 mmHg | 21.4 ± 7.2 minutes | 0.00389 ± 0.00152 mL/min |
| 0.5 mL/h | 50 mmHg | 5.6 ± 1.9 minutes | 0.00595 ± 0.00238 mL/min |
| 1 mL/h | 50 mmHg | 1.3 ± 0.5 minutes | 0.00257 ± 0.00101 mL/min |
| 1.5 mL/h | 100 mmHg | 1.6 ± 0.6 minutes | 0.00463 ± 0.00188 mL/min |
| 2 mL/h | 150 mmHg | 1.4 ± 0.5 minutes | 0.00568 ± 0.00200 mL/min |
| 5 mL/h | 200 mmHg | 1 ± 0.5 minute | 0.00645 ± 0.00406 mL/min |
| 10 mL/h | 200 mmHg | 0.6 ± 0.1 minutes | 0.00318 ± 0.00215 mL/min |
| 10.1 to 250 mL/h | 200 to 900 mmHg | Less than 3 minutes | < +10% of the intended volume over one minute |
| 250 mL/h | 900 mmHg | 19.9 ± 1.9 seconds | 0.02350 ± 0.00218 mL/min |

*Note: When using Agilia SP with 6cc syringes to infuse critical drugs, prefer programmed flow rates equal to or greater than 1 mL/hr.*

**For 60cc syringes:**

| Target Infusion Flow Rate | Recommended Pressure Threshold | Expected Time to Detect Downstream Occlusion | Post-occlusion unintended bolus (average per minute over 5 minutes) |
|---|---|---|---|
| 0.1 mL/h | 50 mmHg | 2.3 ± 0.8 hours | 0.01077 ± 0.00536 mL/min |
| 1 mL/h | 100 mmHg | 19.6 ± 5.9 minutes | 0.01871 ± 0.00582 mL/min |
| 2 mL/h | 200 mmHg | 14 ± 2 minutes | 0.01752 ± 0.00145 mL/min |
| 5 mL/h | 100 mmHg | 3.7 ± 0.6 minutes | 0.01287 ± 0.00259 mL/min |
| 10 mL/h | 200 mmHg | 2.7 ± 0.6 minutes | 0.01493 ± 0.00322 mL/min |
| 10.1 to 25 mL/h | 200 mmHg | Less than 5 minutes | < +10% of the intended volume over one minute |
| 25 to 1200 mL/h | 200 to 900 mmHg | Less than 5 minutes | < +10% of the intended volume over one minute |
| 1200 mL/h | 900 mmHg | 35.7 ± 5.1 seconds | 0.04393 ± 0.01409 mL/min |

*Note: When using Agilia SP with 60cc syringes to infuse critical drugs, prefer programmed flow rates equal to or greater than 5 mL/hr.*

**WARNING**

When addressing or clearing an occlusion:

- Ensure the fluid flow to the patient is clamped to prevent administering an unintended bolus. An occlusion may pressurize the infusion tubing and syringe, 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.
- Be aware that using larger size syringes on a high plunger force setting may produce a larger post occlusion bolus due to excessive syringe plunger head compliance.

To resolve an occlusion, see section 12.4.5, page 131.

# 19 Wi-Fi

## 19.1 General Information

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

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

Agilia infusion pumps contain transmitter with the following IDs:

- 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 Wi-Fi functionalities

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

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

**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)<br>▪ 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<br>▪ WPA2 Enterprise TLS<br>▪ WPA2 Enterprise TTLS<br>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<br>▪ 17 dBm for 802.11b CCK<br>▪ 15 dBm for 802.11g/n OFDM<br>▪ 12 dBm in 802.11a mode |

Please note:
For Wireless security, WPA2-Entreprise is the minimum recommended level of security to secure Wi-Fi network.

### 19.2.2 Electromagnetic Compatibility

For information on electromagnetic compatibility, see section 22, page 187.

#### *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 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 Wi-Fi Quality of Service

The wireless functionality does not require a specific level of Wi-Fi 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 intented. For more information, contact your **Fresenius Kabi** representative.

### 19.2.5 Wi-Fi Data Integrity

Data integrity is inherent in the design:

- Data that is transported through Wi-Fi, or Data that is pending to be transported through Wi-Fi, 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 Wi-Fi 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 Wi-Fi settings in Agilia Partner Maintenance software. |
| Wi-Fi icon is displayed as follow:  . | Wi-Fi is disabled: biomedical department shall turn on the Wi-Fi in pump dedicated menu and/or in Agilia Partner Maintenance software. |
| Wi-Fi icon is displayed as follow:  . | No Wi-Fi signal is received by the pump: biomedical department shall check the Wi-Fi access points localization. |
| Battery is low, and Wi-Fi is automatically turned off. | Connect the pump to the AC power supply. |
| Pump internal temperature is too high, and Wi-Fi is automatically turned off. | Wait until temperature decreases, and Wi-Fi 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.<br>▪ Remove the power cord.<br>▪ 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.<br>▪ 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.<br>▪ Contact your biomedical department or your **Fresenius Kabi** representative. |
| The pump does not start after pressing (ON/OFF). | ▪ Connect the pump to the AC power supply to see if the battery is fully discharged.<br>▪ Contact your biomedical department or your **Fresenius Kabi** representative. |
| Data communication cables cannot be connected or removed from the pump. | ▪ Check the cable connector.<br>▪ Check the pump connector.<br>▪ Contact your biomedical department or your **Fresenius Kabi** representative. |
| Flow rate variance is higher than flow rate accuracy. | ▪ Check the infusion line configuration.<br>▪ Check the fluid viscosity.<br>▪ Check that the fluid temperature is within the recommended range.<br>▪ Contact your biomedical department or your **Fresenius Kabi** representative. |
| Keypad problem (keys, LEDs). | ▪ Check the general condition of the keypad.<br>▪ Check the contrast.<br>▪ 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.<br>▪ Contact your biomedical department or your **Fresenius Kabi** representative. |
| The pump powers off on its own. | ▪ Connect the pump to the AC power supply.<br>▪ 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.<br>▪ 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.<br>▪ Contact your biomedical department or your **Fresenius Kabi** representative. |
| Wi-Fi communication error. | ▪ Contact your IT or biomedical department, or your **Fresenius Kabi** representative. |
| At start-up, the pump displays: "Software is upgrading...". | ▪ Connect the pump to the AC power supply. Then, wait few minutes without touching the keypad until the message disappears and the pump starts as usual.<br>▪ 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 SP MC WiFi 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 SP MC WiFi pump should ensure that it is used in such environments.
- The Agilia SP MC WiFi pump must not be used in the presence of intense electromagnetic fields, such as those generated by certain electrically powered medical devices. Agilia SP 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 1.8, page 22), the essential performance of the Agilia pump is defined in section 15.1, page 145.

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 123, 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 SP 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<br>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<br>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<br>IEC 61000-3-2 | Complies<br>Class A | |
| Voltage fluctuations<br>Flicker emissions<br>IEC 61000-3-3 | Complies | |

### Electromagnetic immunity

| Immunity test | IEC 60601-1-2 Test level | Compliance level obtained by the device | Electromagnetic environment – guidance |
|---|---|---|---|
| Electrostatic Discharge (ESD)<br>IEC 61000-4-2 | ± 8 kV contact<br>± 15 kV air | ± 8 kV contact<br>± 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<br>IEC 61000-4-3 | 3 V/m,<br>80 MHz to 6 GHz | 3 V/m,<br>80 MHz 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<br>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 18Hz, 27 V/m<br>450 MHz, PM 18Hz, 28 V/m<br>710 MHz, PM 217 Hz, 9 V/m<br>745 MHz, PM 217 Hz, 9 V/m<br>780 MHz, PM 217 Hz, 9 V/m<br>810 MHz, PM 18 Hz, 28 V/m<br>870 MHz, PM 18 Hz, 28 V/m<br>930 MHz, PM 18 Hz, 28V/m<br>1720 MHz, PM 217 Hz, 28 V/m<br>1845 MHz, PM 217 Hz, 28 V/m<br>1970 MHz, PM 217 Hz, 28 V/m<br>2450 MHz, PM 217 Hz, 28 V/m<br>5240 MHz, PM 217 Hz, 9 V/m<br>5500 MHz, PM 217 Hz, 9 V/m<br>5785 MHz, PM 217 Hz, 9 V/m | 385 MHz, PM 18Hz, 27 V/m<br>450 MHz, PM 18Hz, 28 V/m<br>710 MHz, PM 217 Hz, 9 V/m<br>745 MHz, PM 217 Hz, 9 V/m<br>780 MHz, PM 217 Hz, 9 V/m<br>810 MHz, PM 18 Hz, 28 V/m<br>870 MHz, PM 18 Hz, 28 V/m<br>930 MHz, PM 18 Hz, 28V/m<br>1720 MHz, PM 217 Hz, 28 V/m<br>1845 MHz, PM 217 Hz, 28 V/m<br>1970 MHz, PM 217 Hz, 28 V/m<br>2450 MHz, PM 217 Hz, 28 V/m<br>5240 MHz, PM 217 Hz, 9 V/m<br>5500 MHz, PM 217 Hz, 9 V/m<br>5785 MHz, PM 217 Hz, 9 V/m | For minimal distance approach 30 cm (12 inches)<br><br>Portable and mobile RF communications equipment should be used no closer to any part of the Agilia pump, including cables, than the recommended minimal separation distance (30 cm) for these frequencies |
| Electrical Fast transient / Burst IEC 61000-4-4 | ± 2 kV<br>for power supply lines<br><br>± 1 kV<br>for input output lines<br><br>100 kHz repetition | ± 2 kV<br>for power supply lines<br><br>± 1 kV<br>for input output lines<br><br>100 kHz repetition | Electricity power quality should be that of a typical domestic, commercial or hospital environment. |
| Surge IEC 61000-4-5 | ± 1 kV<br>differential mode<br><br>± 2 kV<br>common mode | ± 1 kV<br>differential mode<br><br>± 2 kV<br>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<br><br>150 kHz to 80 MHz<br><br>and 6 Vrms in the ISM | 3 Vrms<br><br>150 kHz to 80 MHz<br><br>and 6 Vrms in the ISM | 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. |

| Immunity test | IEC 60601-1-2 Test level | Compliance level obtained by the device | Electromagnetic environment – guidance |
|---|---|---|---|
| Power frequency (50 / 60 Hz) magnetic field IEC 61000-4-8 | 30 A / m<br>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.<br><br>If the measured field in the location where the Agilia pump is used exceeds the applicable magnetic field compliance level above, the Agilia pump should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Agilia pump, or installing magnetic shielding. |
| Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11 | 0 % Ut<br>(100% dip in Ut)<br>for 0,5 cycle<br>at 0°, 45°, 90°,<br>135°,180°, 225°, 270°<br>and 315°<br><br>0% Ut<br>(100% dip in Ut)<br>for 1 cycle<br><br>70% Ut<br>(30% dip in Ut)<br>for 25 cycles at 50 Hz<br>for 30 cycles at 60 Hz<br>at 0°<br><br>0% Ut<br>(100% dip in Ut)<br>for 250 cycles at 50 Hz<br>for 300 cycles at 60 Hz | 0 % Ut<br>(100% dip in Ut)<br>for 0,5 cycle<br>at 0°, 45°, 90°,<br>135°,180°, 225°, 270°<br>and 315°<br><br>0% Ut<br>(100% dip in Ut)<br>for 1 cycle<br><br>70% Ut<br>(30% dip in Ut)<br>for 25 cycles at 50 Hz<br>for 30 cycles at 60 Hz<br>at 0°<br><br>0% Ut<br>(100% dip in Ut)<br>for 250 cycles at 50 Hz<br>for 300 cycles at 60 Hz | Electricity power quality should be that of a typical domestic, commercial or hospital environment.<br><br>For short and long interruptions (< than battery autonomy) of electricity power supply, the internal battery provides the continuity of service.<br><br>For very long (> than battery autonomy) interruptions of electricity power supply, the Agilia pump must be powered from an external Uninterruptible Power Supply (UPS).<br><br>**Note**: Ut is the a/c mains voltage prior to application of the test level. |

## Additional immunity test and specific test 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<br>710 MHz, PM 217 Hz, 28 V/m<br>787 MHz, PM 217 Hz, 28 V/m<br>810 MHz, PM 217 Hz, 44 V/m<br>830 MHz, PM 217 Hz, 44 V/m<br>870 MHz, PM 217 Hz, 44 V/m<br>1750 MHz, PM 217 Hz, 28 V/m<br>1875 MHz, PM 217 Hz, 28 V/m<br>1970 MHz, PM 217 Hz, 28 V/m<br>2560 MHz, PM 217 Hz, 28 V/m<br>2655 MHz, PM 217 Hz, 28 V/m | 28 V/m<br>28 V/m<br>28 V/m<br>44 V/m<br>44 V/m<br>44 V/m<br>28 V/m<br>28 V/m<br>28 V/m<br>28 V/m<br>28 V/m | For minimal distance approach 10 cm (4 inches).<br><br>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 | (*) | Same as 5 A/m ISO 15693 test. |
| | 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 | 54 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.

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 8.21, page 113.

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 Data Management Cables

| | | |
|---|---|---|
| Agilia USB Cable | Communication cable for USB connection | Z073550 |

## 24.2 Associated Software

| | | |
|---|---|---|
| Agilia Partner | Maintenance Software (CD)<br>Maintenance Software (eDownload) | Z067048<br>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.

## 24.3 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 |

## 24.4 Syringes

For flow rate accuracy information refer to section 15.8.1, page 150.

| Syringe | Reference | Rate (mL/h) | |
|---|---|---|---|
| | | min | Max |
| Monoject™ 6 mL Syringe, Luer-Lock Tip | 1180600777 | 0.1 | 250 |
| Monoject™ 60 mL Syringe, Luer-Lock Tip | 1186000777T | 0.1 | 1200 |

**INFORMATION**

We recommended extension sets with the following properties: length: 150 cm; internal diameter: 1.5 mm; external diameter: 2.7 mm; and, ideally, should be made of PVC.

# 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 |
| **CDC** | Centers for Disease Control |
| **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 |
| **DHCP** | Dynamic Host Configuration Protocol |
| **DPS** | Dynamic Pressure System |
| **DSSS** | Direct Sequence Spread Spectrum |
| **DTBI** | Dose to Be Infused |

## 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

| | |
|---|---|
| **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 |

## N

| | |
|---|---|
| **N/A** | Not Applicable |

## O

| | |
|---|---|
| **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

**WPA** Wi-Fi Protected Access

# Appendix: Factory Configuration

| | Feature | Availability |
|---|---|---|
| **Menus** | Profile | ✗ |
| | Pressure | ✓ |
| | Keypad lock status | ✓ |
| | Battery life | ✓ |
| | Volume infused | ✓ |
| | Pause | ✓ |
| | Programmed bolus | ✗ |
| | Patient | ✗ |
| | Day/Night mode | ✓ |
| | Volume Limit | ✓ |
| | Alarm volume | ✓ |
| | Volume-Dose history | ✗ |
| | View flow rate history | ✗ |
| | View pressure history | ✗ |
| | Syringe | ✓ |
| | View event log | ✓ |
| | Date/Time | ✓ |
| | Maintenance | ✗ |
| | Library information | ✗ |
| | Clinical information | ✗ |
| | Data Set | ✗ |

| | Feature | Availability |
|---|---|---|
| **Infusion Modes** | Simple Rate | ✓ |
| | Volume/Time | ✗ (1) |
| | Volume Limit | ✓ |
| | Direct Bolus | ✗ (1) |
| **Infusion Features** | Programmed Bolus | ✓ |
| | Loading Dose | ✗ |
| | KVO | ✗ |
| | Prime | ✓ |
| | Advised Prime | ✗ |
| | 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.*

# Index

## 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



Rx only

FRESENIUS KABI

caring for life

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

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