



**FRESENIUS
KABI**

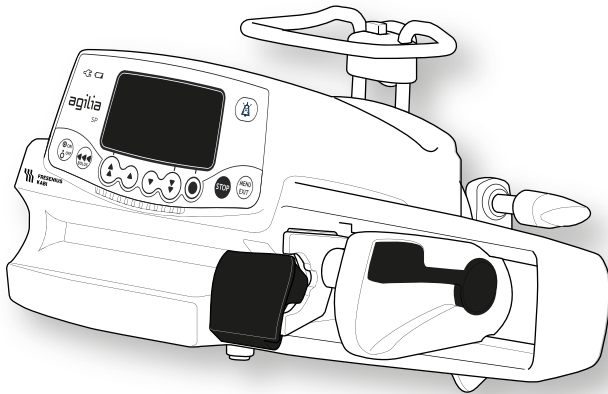
caring for life

Agilia SP

Syringe Infusion Pump

Applicable to software version 4.1

Instructions For Use
For Use in Healthcare Facilities



Symbol Descriptions

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)



Name and address of the manufacturer / Date of manufacture



Refer to the Instructions For Use



Name and address of the manufacturing facility



Product reference / part number



Protection against electric shock: class II



Product serial number



Non-ionizing electromagnetic radiation



Input terminal - connector



Fragile, handle with care



Output terminal - connector



This way up



Electrical fuses



Keep away from rain



Alternating Current (AC)



Temperature limitation



Direct Current (DC)



Humidity limitation

IP22

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



Atmospheric pressure limitation



Not for use in residential areas



General symbol for recyclable material



Part included in a recycling process



Eco packaging symbol



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



CE mark



Medical Device



Unique Device Identifier

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1 Introduction

1.1 Scope

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

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

Warning

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



- *The software version of the device is displayed on the start-up screen.*
- *The software version described in this IFU is displayed in the Release Notes, page 135.*

1.2 Principles of Operation

Agilia SP is a programmable electronic medical system dedicated to administering a pre-determined volume of a syringe at a programmed rate. This syringe pump ensures a fluid delivery, by pushing the syringe plunger and advancing the liquid to the patient through an extension set (applied part). Agilia SP is a transportable and reusable device that can be used everyday.

The size of a syringe can be between 5 mL and 60 mL. For a comprehensive list, refer to the System Components booklet. Agilia SP can be used for intermittent or continuous infusions. Agilia SP is intended for use on only one patient at a time. It can be reused indefinitely on multiple patients throughout its lifetime.

1.3 Intended Purpose

Infusion pump and accessories for IV administration of fluids.

1.4 Intended Use

1.4.1 Indications

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

| | Intended Products |
|-----------------------------|---|
| Parenteral Fluids | <ul style="list-style-type: none">▪ Standard solutions▪ Colloids▪ Parenteral nutrition |
| Medication | <ul style="list-style-type: none">▪ Diluted drugs▪ Antibiotics▪ Chemotherapy▪ Catecholamines▪ Short acting drugs▪ Anesthesia drugs |
| Blood and blood derivatives | <ul style="list-style-type: none">▪ Blood▪ Red blood cells▪ Platelets▪ Plasma▪ Albumin |

When using Agilia SP to infuse critical medications, ensure that backup pumps and syringes are available for immediate use. Only use Agilia SP for the infusion of fluids that are intended for infusion pumps.

Do not use the pump for epidural use.

Do not use the pump for enteral nutrition.

Administration Routes

The system allows infusion via the following access routes:

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



Warning

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



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

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

1.4.2 Contraindications

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

1.4.3 Intended users

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

Typical initial training duration: 1 hour.

It is recommended that users attend a refresher training session of about 20 minutes every year.

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

1.4.4 Intended patients

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

| | Patient Characteristics |
|-------------------|---|
| Sex | Male Female |
| Age | Neonates Pediatrics Adults Elderly |
| Weight | 0.25 kg to 350 kg |
| Body Surface Area | 0.05 m ² to 4.5 m ² |

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

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

1.4.5 Use Environment

Agilia SP is intended for use in healthcare facilities and in pre-hospital medical ground transportation, under the supervision of trained healthcare personnel.

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

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

Warning

Do not use the pump in the following environments:



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

Warning

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



Warning

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



Information

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



1.5 Clinical benefits

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

Clinical benefits of Agilia SP syringe pump are the following:

- Provide a controlled and accurate system for the infusion of small volumes of products, thus ensuring delivery of medications/fluids within their therapeutic window (volume delivery accuracy of the pump/syringe system is $\pm 3\%$ and flow rate is adjustable from 0.1 to 1200 mL/h, depending on syringe size).
- Provide users with infusion functions adapted to the needs of patients and healthcare professionals (continuous infusion and bolus infusion, several infusion modes, pause function, keep vein open function, view event log, infusion monitoring screen, adaptable flow rate, wide range of products compatible, compatible with syringes from 5 to 60 mL).
- Provide users with safety features and relevant alarms that improve infusion safety and prevent unexpected infusion discontinuation (Dynamic Pressure System, pressure monitoring, alarm system compliant with EN/IEC 60601-1-8).

1.6 Side-effects

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

1.7 Risks for patients

Failure to follow all instructions described in this document or loss or degradation of essential performance (Section 15.1, page 90.) may result in: overdose, underdose, delay of therapy, incorrect therapy, exsanguination, toxicity, infection, air embolism, trauma or electric shock.

2 Agilia Connect Infusion System

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

| Agilia range | | Description |
|--------------------|---|---|
| Software | Agilia Partner | Maintenance Software Software designed to maintain, configure, test and calibrate compatible Agilia infusion devices and accessories. |
| Accessories | Link Agilia Agilia Link Link+ Agilia | Stacking Rack Systems Rack systems designed to stack 4, 6 or 8 Agilia infusion pumps. Link Agilia / Agilia Link are designed to centralize the power supply. Link+ Agilia is designed to centralize the power supply and to centrally replicate infusion pump signalling. |
| | Agilia MRI Guard | MRI-Shielding System Agilia MRI Guard is intended to accommodate and power up to four Agilia infusion pumps so that these pumps can be operated in a Magnetic Resonance Imaging unit. |
| | Agilia Duo | Two-channel accessory The Agilia Duo is intended to centralize mains power for two attached Agilia pumps. |
| | Agilia Holder Ambulance | Accessory intended to be used in road ambulances equipped with AC power source and a horizontal rail in order to fix an infusion pump. |
| Disposables | Syringes | See section 13, page 84. |



Information

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

3 Description

3.1 Front View

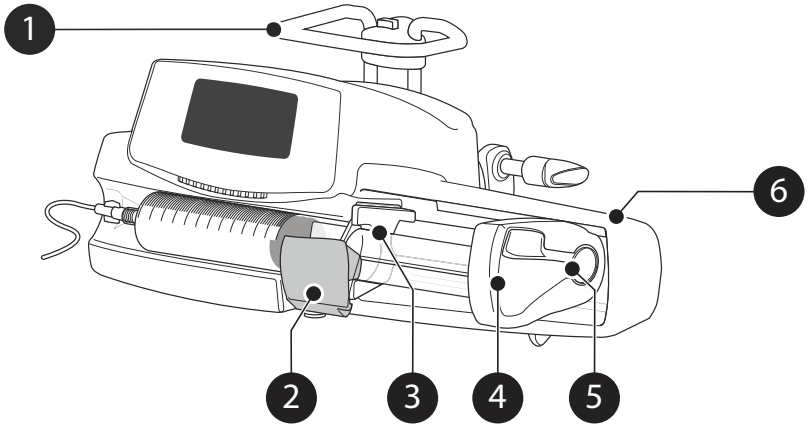
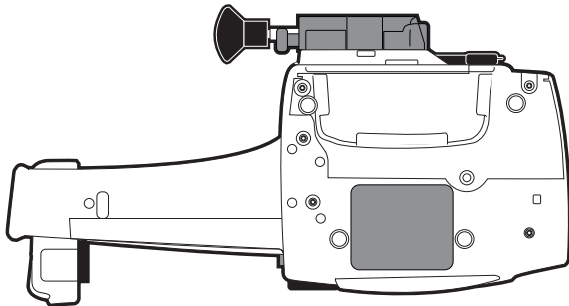


Figure 3.1: Front View

Legend

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

3.2 Bottom View (Device Identification Label)



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



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

For more information on device identification label symbols, see Symbol Descriptions, page 2.

3.3 Back View

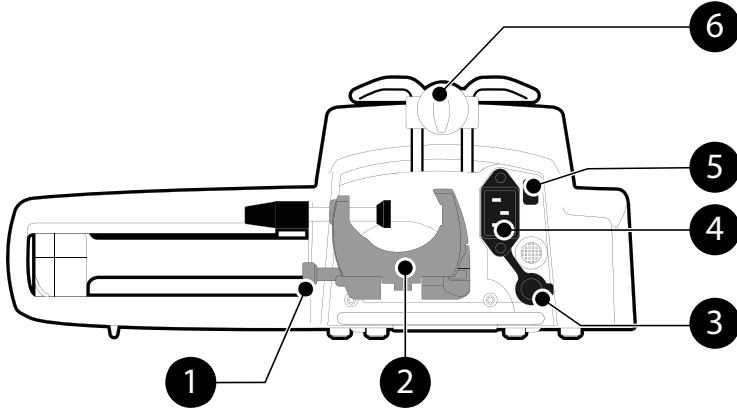





Figure 3.2: Back View

Legend

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

| Symbol | Location | Description |
|---|-------------------------------|---|
|   | Near Power Cord Inlet | Warning See section 18, page 101. |
|  | Near RS232 Communication Port | Warning See section 10, page 73. |

3.4 Keypad

3.4.1 Keypad Description

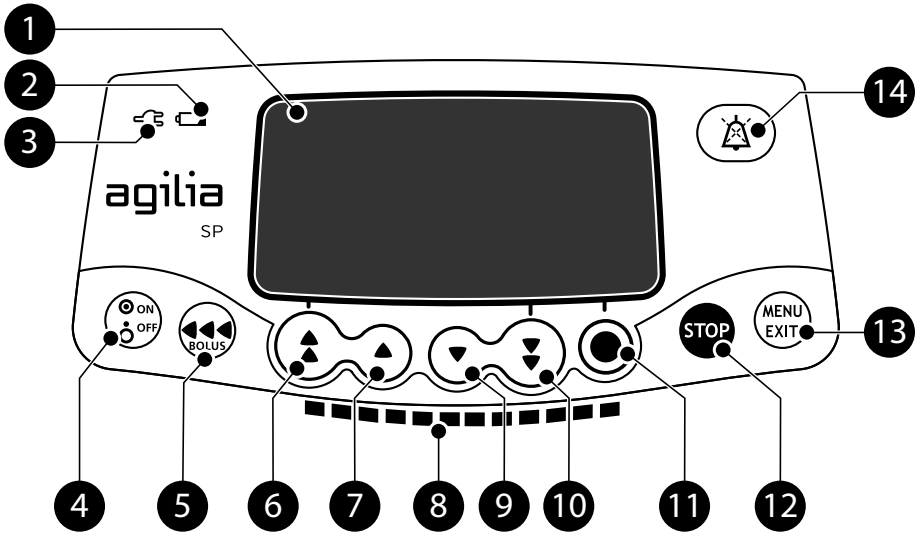








Figure 3.3: Keypad

Legend

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

3.4.2 Keypad Details





3.4.2.1 Selection Keys

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

Note:

- Pressing and holding any of the arrow keys results in faster increment or decrement.



3.4.2.2 Infusion Indicator Lights

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

Note:

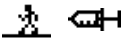

- Infusion indicator lights provide information about the infusion: in progress, or with a low, medium or high-priority alarm.
- Green indicator lights will continuously flash from right to left while the infusion is running.
- The frequency of flashing varies according to flow rate.

3.4.2.3 Status Indicators







| Indicator | Description |
|---|--|
|  | Power Supply Indicator When the device is attached to an active power supply, the indicator light is a constant green. If the pump is not connected to the AC power, it does not light up. |
|  | Battery Charge Status Indicator When the device is attached to an active power supply, the indicator light provides information about battery charge status: <ul style="list-style-type: none"> If the indicator is blinking, the battery is being charged. If the indicator is lit permanently, the battery is fully charged. If the pump is not connected to the AC power, it does not light up. |

3.5 Display and Symbols










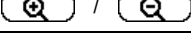

3.5.1 Infusion Status

| Symbol | Description |
|---|---|
|  | Infusion in Progress Symbols for infusion in progress. |
|  | Infusion Stopped STOP remains in the center of the screen until the user starts the infusion again. |





3.5.2 Screen Options

| Symbol | Description |
|---|---|
|  | Battery Logo <ul style="list-style-type: none">This symbol shows three different charge levels.<ul style="list-style-type: none"> < 30 % battery charge 30 % - 70 % battery charge > 70 % battery chargeIf the 'Battery logo' option is enabled, this symbol is displayed constantly.If the 'Battery logo' option is disabled, this symbol is only displayed when the pump is operating on battery. |
|  | Pressure Logo This symbol gives information about pump pressure settings and measured pressure levels. |
|  | Keypad locked symbol This symbol informs the user that the keypad is locked. |

3.5.3 Navigation Buttons

| Symbol | Description |
|---|---|
|  | Start |
|  | Confirm |
|  | Access Function |
|  | Access Function and Clear Settings |
|  | Exit Function |
|  | Change Selection |
|  | 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 75.

3.6 Packaging

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

| | Agilia SP pump | Instructions For Use | System Components booklet | User information document (multilingual) | Power cord |
|----------|----------------|----------------------|---------------------------|--|------------|
| Z018XXX | v | v | v | - | v |
| Z018X00* | v | - | - | v | - |

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

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

Packaging weight: Approximately 530 g.

Packaging consists of: Recycled cardboard.

Information



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

4 Fundamentals

4.1 Profiles

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

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



Information

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

4.1.1 Basic Profile

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

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

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

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

4.1.2 Custom Profiles

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

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



Information

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

4.2 Infusion Modes

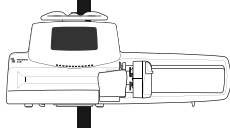
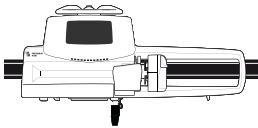
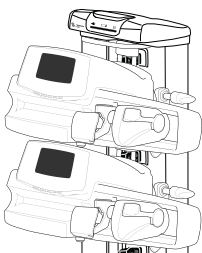
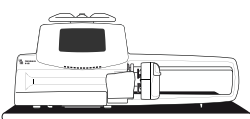
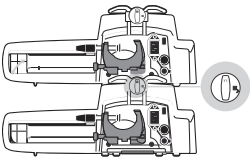
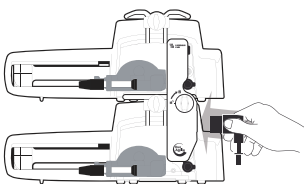
An infusion can be started according to the following modes:

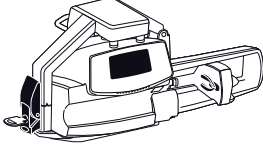
| Infusion Mode | Description |
|---------------|--|
| Simple Rate | Infusion with a programmed rate |
| Volume/Time | Infusion of a programmed volume over a programmed period of time |
| Volume Limit | Infusion with a limitation on the volume to be infused |

5 Installation

5.1 Types of Installations

A pump can be installed on any of the following:

| Location | Comments |
|---|--|
| On a Pole  | <p>☞ See section 5.3.1, page 27.</p> <p>Pole specifications:</p> <ul style="list-style-type: none"> ▪ Diameter: from 15 to 40 mm |
| On a Rail  | <p>☞ See section 5.3.2, page 28.</p> <p>Rail specifications:</p> <ul style="list-style-type: none"> ▪ Height: from 25 to 35 mm ▪ Depth: from 8 to 10 mm |
| On the Agilia Link or Link Agilia or Link+ Agilia Rack  | <p>☞ Refer to the relevant accompanying documents.</p> |
| On a Table  | <p>☞ See section 5.3.3, page 28.</p> <p>Only install a pump on a table if it is not possible to attach it to a pole, a rail or recommended Agilia accessory.</p> |
| On Another Pump  | <p>☞ See section 5.3.4, page 29.</p> |
| On an Agilia Duo  | <p>☞ Refer to the Agilia Duo accompanying documents.</p> |

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

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



Warning

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

5.2 Using the Rotating Pole Clamp

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

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

5.2.1 Rotating Pole Clamp Description

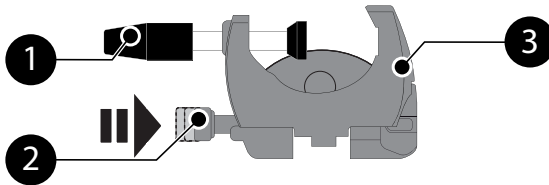


Figure 5.1: Rotating Pole Clamp System

Legend

- ① Screw Clamp
- ② Release Button
- ③ Rotating Pole Clamp

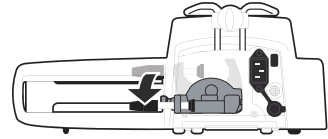
5.2.2 Using the Rotating Pole Clamp

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

5.2.2.1 *Folding the Clamp Down (outward)*

You can fold the clamp down as follows:

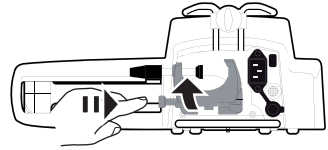
1. Push the release button.
2. Fold the clamp outward.



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

You can fold the clamp up as follows:

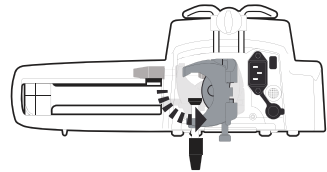
1. Push the release button.
2. Fold the pole clamp inward toward the pump.



5.2.2.3 *Rotating the Clamp*

You can rotate the clamp as follows:

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

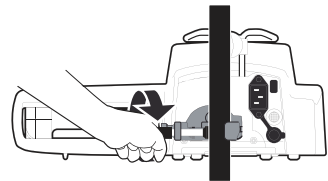


5.3 Attaching the pump(s)

5.3.1 Attaching to a Pole

1. Fold the pole clamp down to the horizontal position: see section 5.2.2.1, page 27.
2. Unscrew the clamp, attach to the pole, and screw the clamp until the pump is fully secured to the pole.
3. Make sure that the pump is securely attached.

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



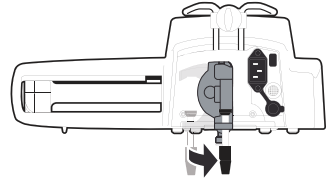
Information

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

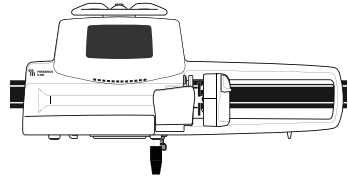
5.3.2 Attaching to a Rail

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

1. Rotate the pole clamp to the vertical position: see section 5.2.2.3, page 27.
2. Unscrew the clamp, attach to the rail, and screw the clamp until pump is fully secured to the rail.

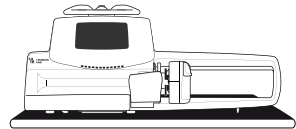


3. Make sure that the pump is securely attached.



5.3.3 Using on a Flat Table

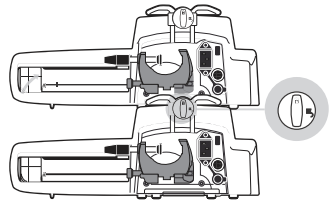
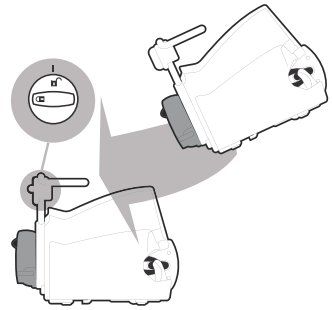
1. Fold the pole clamp up: see section 5.2.2.2, page 27.
2. Place the pump far enough from the table's edges to prevent it from accidentally being pushed off.





5.3.4 Attaching Two Pumps Together

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

1. Fold both pumps' pole clamps up: see section 5.2.2.2, page 27.
2. Slide the slot on the bottom of the upper pump onto the handle of the lower pump.
3. Turn the attachment lock knob on the lower pump handle clockwise until the locked symbol lines up with the marker.
4. Make sure the two pumps are securely attached together.
5. If needed, fold the two pole clamps down and secure them tightly to the pole.

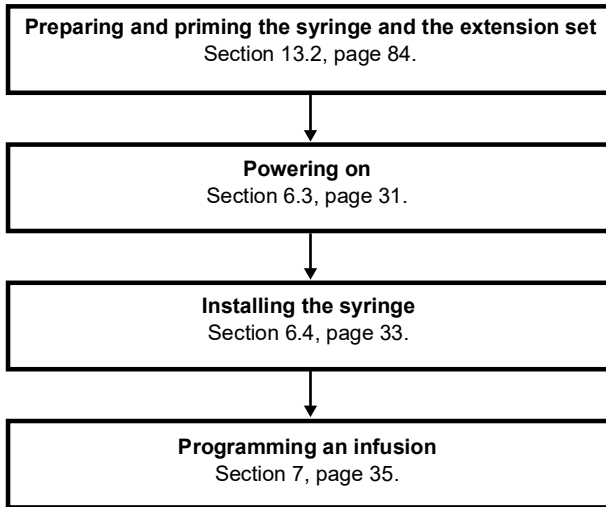


| Symbol | Location | Description |
|--|----------------------|-------------------|
|  | Attachment Lock Knob | Locked Position |
|  | Attachment Lock Knob | Unlocked Position |

6 Getting Started

6.1 Flowchart

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



Information

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

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




6.2 Using the Pump for the First Time


1. Make sure the pump is correctly installed at the bedside.
See section 5, page 25.
2. Plug the pump into the AC power supply.
See section 17.1, page 99.
3. Before starting the pump for the first time, you must charge the battery for approximately **6 hours**.
Wait until the pump is fully charged.
Do not use the pump during the first charge.
4. Power on the pump.
See section 6.3, page 31.
5. Install a syringe into the pump.
See section 6.4, page 33.


6.3 Powering on

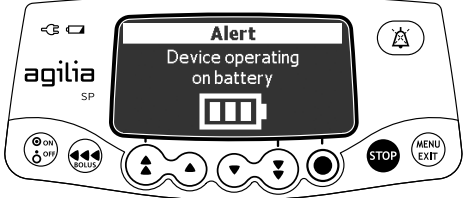



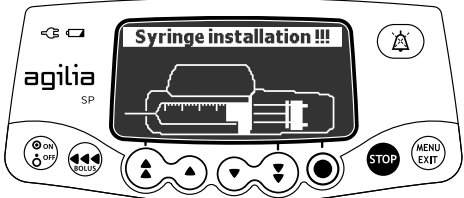

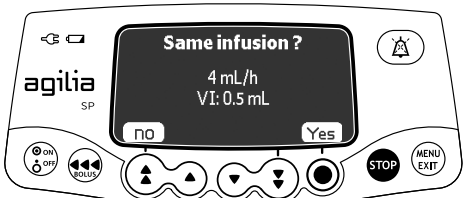


Information

- *The pump can operate using the battery; however, we recommend that the pump be connected to a power supply as often as possible during use in order to ensure that the battery remains charged.*
- *When the pump is connected to the power supply, check that the power supply indicator  lights up green, and that the power cord and the wall plug are accessible.*

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. If the language screen is displayed, select the language. Then, enter the date.
If the selection is incorrect, contact your biomedical department to reset the pump to its initial configuration.
4. Acknowledge the different screens listed in the table below.

| Screen After Powering on | Description |
|--|--|
|  | <p>Startup screen: the following information is displayed:</p> <ul style="list-style-type: none"> ▪ Product name / Ward name ▪ Date & time |

| Screen After Powering on | Description |
|---|---|
|  | <ul style="list-style-type: none"> ▪ The pump is operating on battery. The symbol shows three different charge levels: <ul style="list-style-type: none">  < 30 % battery charge  30 % - 70 % battery charge  > 70 % battery charge |
|  | <ul style="list-style-type: none"> ▪ No syringe is installed on the pump. ▪ Syringe installation !!! is displayed on top of the screen. ☞ Install a syringe. See section 6.4, page 33. |
|  | <ul style="list-style-type: none"> ▪ Maintenance reminder message (optional). |
|  | <ul style="list-style-type: none"> ▪ Same infusion screen (optional). Press Yes to keep previous infusion settings. |

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

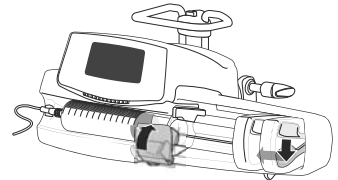
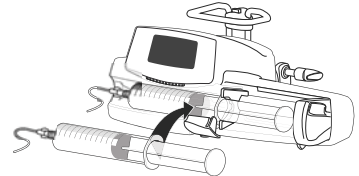
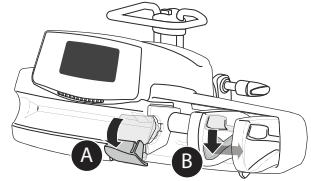
6.4 Installing a Syringe



Warning

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

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] and move the plunger driver gently to the left until it is in contact with the plunger head.
6. Check the general installation.



6.5 Pump Height



Warning

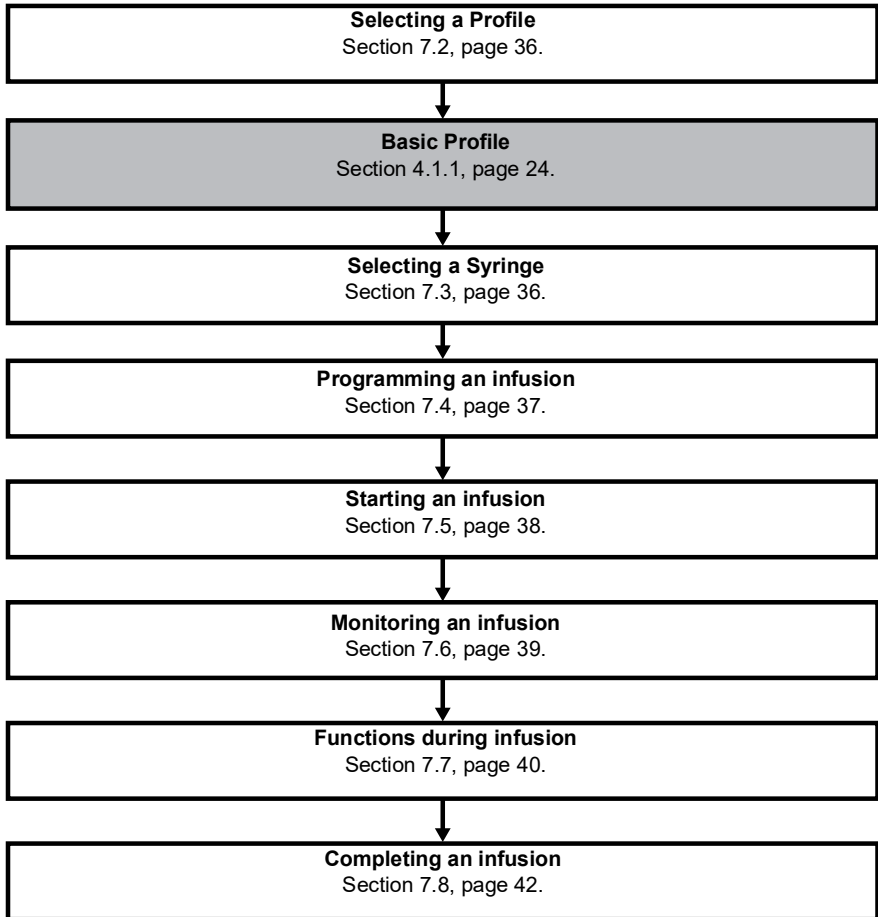
Ideally, the syringe pump should be level with the distal tip of the catheter (e.g., the site of fluid delivery; if accessing a central line the syringe pump should be at the level of the patient's heart). If the pump height is raised relative to the distal tip of the catheter (e.g., during patient transport), 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 transport of critically ill patients) to prevent unintended fluctuations in the flow rate.

7 Operation

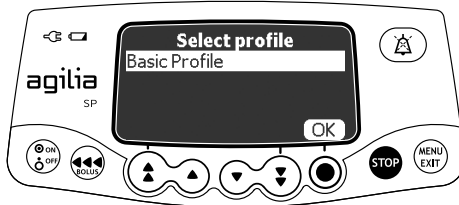
7.1 Flowchart



7.2 Selecting a Profile

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

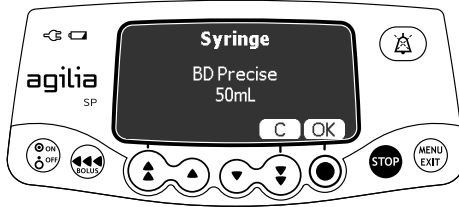
1. Press  to power on the pump.



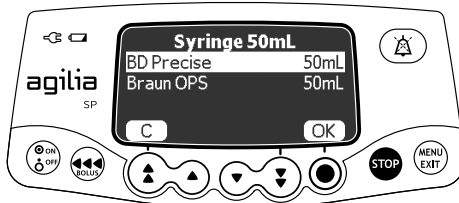
2. Press **OK** to select Basic Profile.

7.3 Selecting a Syringe

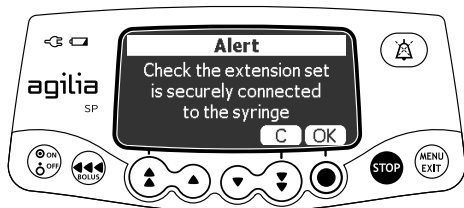
The pump automatically detects the size of the installed syringe.



1. Press **OK** to confirm the displayed syringe, or **C** 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 **C** to return to the syringe selection screen.

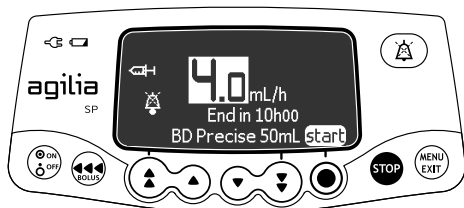


Warning

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.

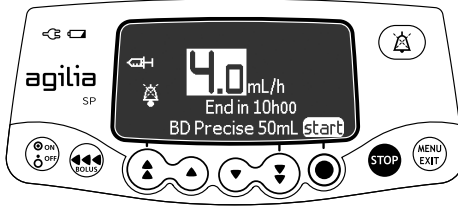
7.4 Programming an Infusion

- 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, see section 7.9.2, page 44.
 - Volume Limit, see section 7.9.3, page 45.



1. Press the arrow keys to program the flow rate.

7.5 Starting an Infusion



1. Check the delivery path integrity, (syringe and access device).
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.
6. Press **start** to start the infusion.

Warning



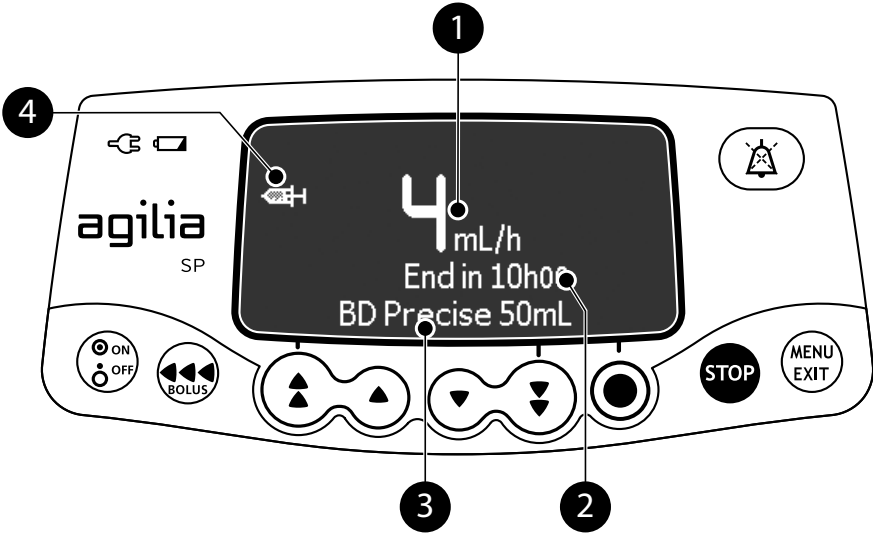
- *When connecting the syringe's extension set to the patient's access device, always use aseptic technique according to your healthcare facility policy.*
- *During programming and prior to starting an infusion, verify that the syringe size and model on the syringe pump's display screen matches the syringe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

7.6 Monitoring an Infusion

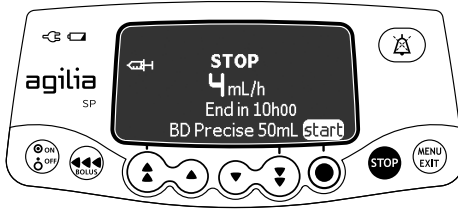


Legend

- 1** **Infusion Flow Rate (mL/h)**
To change the flow rate during an infusion, see section 7.7.2, page 40.
The flow rate is displayed with the largest font size.
 - 2** **Infusion Duration**
At the current rate, the remaining infusion time in hours and minutes.
 - 3** **Syringe Name / Ward Name** (configurable)
 - 4** **Infusion in progress symbol**
See section 3.5.1, page 21.
-

7.7 Functions During Infusion

7.7.1 Stop



To stop the infusion, press **STOP**.

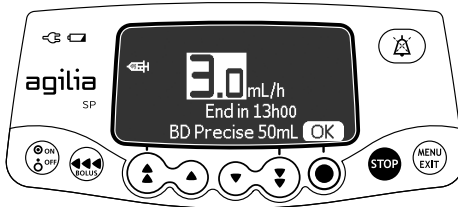
After 2 minutes, an alarm is generated as a reminder that the infusion is stopped.

To restart the infusion, first confirm or modify the programming settings, then start the infusion. See section 7.4, page 37.

7.7.2 Rate Titration

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

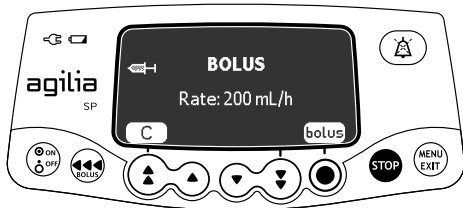
1. If required, stop the infusion, see section 7.7.1, page 40.
2. Press the arrow keys to modify the flow rate.
3. Press **OK** to confirm.




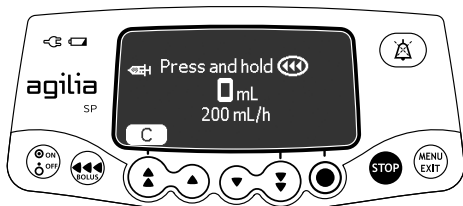
7.7.3 Administering a Direct Bolus



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

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




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



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

Information

- *The bolus volume is added to the Volume Infused (VI).*
- *The  key is not active when the menu screen is displayed.*
- *The occlusion pressure level is set to its maximum value: 900 mmHg / 120 kPa / 17.4 PSI.*



7.8 Completing an Infusion

7.8.1 Near End of Infusion Alert

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

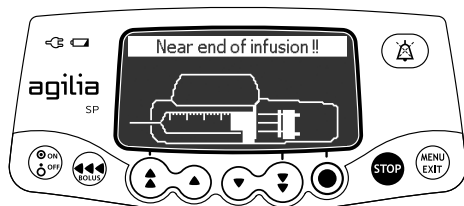
- An audible alarm is triggered.
- An alarm message appears on the pump screen.
- The infusion indicator lights flash yellow.


Near end of infusion alert is triggered when the 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 in the pump options. For more information, refer to the technical manual.

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 reaches the tip of the syringe. The syringe is not completely emptied (regular end of infusion).*
- *The infusion continues until the syringe is completely emptied. The flow rate decreases when the plunger reaches the tip of the syringe (empty syringe - only in Simple Rate mode).*

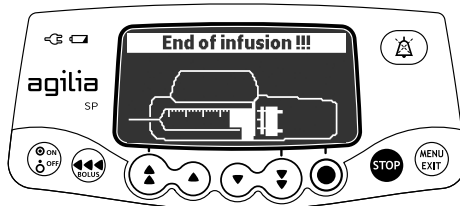
7.8.2 End of Infusion


When the infusion is complete, the following happens:

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

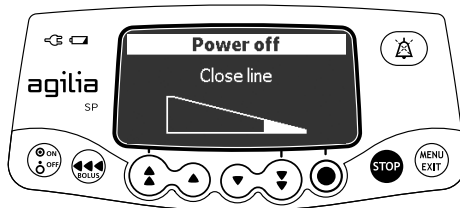
End of infusion settings are configurable in the pump options. For more information, refer to the technical manual.

Silencing the Alarm





1. Press  to silence the alarm.
2. Prepare a new syringe, and adjust the settings for a new infusion.

7.8.3 Powering off



You can power off the pump as follows:

1. Press  to stop the infusion.
2. Press and hold  until the pump powers off.

7.9 Infusion Modes

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

7.9.1 Simple Rate

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

For more information, see section 7.4, page 37.

7.9.2 Volume/Time

You can use this infusion mode to program a volume to be infused (VTBI) over a programmed period of time.

When the VTBI is reached, an alarm is triggered.

1. For information on how to access the **Volume/Time** menu, see section 8.9, page 62.



2. Press the arrow keys to set the volume to be infused (VTBI), 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 86.

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.

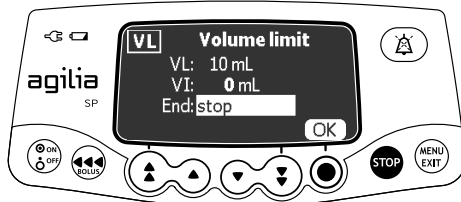


5. Press **start** to start the infusion.

7.9.3 Volume Limit

You can use this infusion mode to set a limit to the volume infused. When the limit is reached, an alarm is triggered.

1. Access the **Volume Limit** menu, see section 8.10, page 62.



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

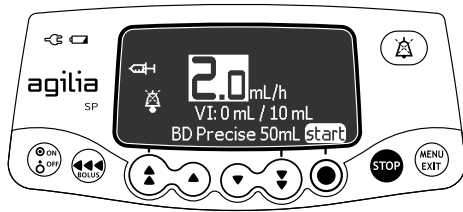
Information



- *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 86.*
- *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.



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

7.10 Other Functions

7.10.1 Priming the Syringe and the Extension Set

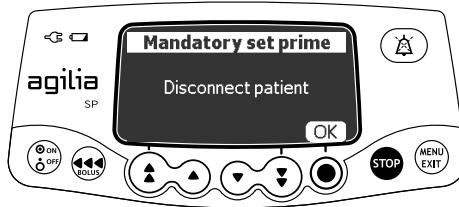
Note: The prime function can be configured in the pump options (Basic profile):

- **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.

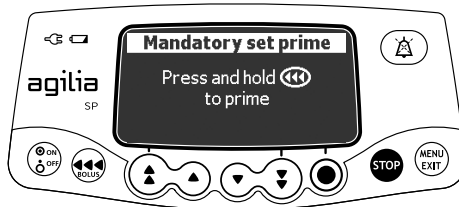
Information



We strongly recommend to always use the prime function, especially for life-sustaining drugs. Priming the syringe and the extension set removes all the mechanical gaps and ensures that the programmed flow rate is reached within the smallest delay once the start button is pressed.





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



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



Information

- Priming is only accessible prior to starting the infusion.
- The  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  key again to restart priming.

Quick-Start

Quick-start is designed to decrease the delay of therapy when the pump's prime function is not used.

When quick-start is triggered, the infusion starts at a high flow rate (120 mL/h) until the pump's plunger driver starts pushing the syringe plunger head. The flow rate then automatically switches to the programmed value.

At the beginning of an infusion, quick-start is triggered or not triggered in the following situations:

| Prime Function Configuration | Quick-start Trigger Rule |
|------------------------------|---|
| Mandatory | <ul style="list-style-type: none"> ▪ Not triggered |
| Advised | <ul style="list-style-type: none"> ▪ Not triggered |
| Not displayed | <ul style="list-style-type: none"> ▪ Triggered if flow rate is equal or inferior to 50 mL/h and the automatic priming is not done. ▪ Not triggered if the automatic priming is done by the user. |



Information

Priming the line automatically ensures better pump performances than using quick-start.

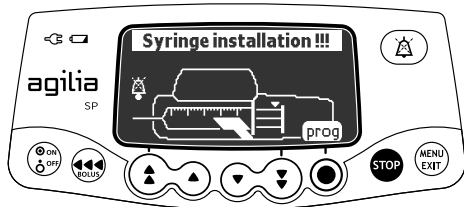


Warning


If the prime function is set as "Not displayed", and if the quick-start is triggered, an undesired bolus may occur in some cases. Always prefer the automatic prime function for life-sustaining drugs.

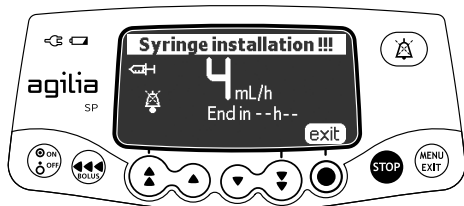
This function can be disabled according to the pump's configuration.

7.10.2 Pre-programming the Pump



You can program the pump before installing the syringe.

1. Press  to power on the pump.
Syringe installation !!! is displayed on top of the pump screen.
2. Make sure the syringe barrel clasp is folded up against the pump.
*The **prog** symbol is displayed.*
3. Press **prog**.
4. Program the infusion.
See section 7.4, page 37.










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 |  |
| Select |     |
| Confirm |  (corresponds to enter on the screen) |
| Select <input checked="" type="checkbox"/> / Deselect <input type="checkbox"/> |  |

8.1.2 Menu Description

| Menu | Symbol | Stop Infusion Required | Associated Procedure |
|------------------------|---|------------------------|---|
| Profile | Pro | NO | <ul style="list-style-type: none"> ▪ Displaying active profile information, page 51. |
| Pressure |  | NO | <ul style="list-style-type: none"> ▪ Modifying the pressure limit, page 52. |
| Keypad lock status |  | NO | <ul style="list-style-type: none"> ▪ Locking / Unlocking the keypad, page 55. |
| Battery life |  | NO | <ul style="list-style-type: none"> ▪ Viewing the battery life, page 57. |
| Volume Infused | mL? | NO | <ul style="list-style-type: none"> ▪ Viewing and clearing the volume infused, page 58. |
| Pause |  | YES | <ul style="list-style-type: none"> ▪ Programming a pause, page 59. |
| Day/Night mode |  | NO | <ul style="list-style-type: none"> ▪ Switching between day mode and night mode, page 60. |
| Volume/Time | V/T | YES | <ul style="list-style-type: none"> ▪ Programming a Volume/Time infusion, page 62. |
| Volume limit | VL | YES | <ul style="list-style-type: none"> ▪ Programming a Volume Limit infusion, page 62. |
| Alarm volume |  | NO | <ul style="list-style-type: none"> ▪ Adjusting the alarm volume, page 63. |
| Volume history |  | YES | <ul style="list-style-type: none"> ▪ Viewing the infusion history, page 64. |
| View flow rate history |  | NO | <ul style="list-style-type: none"> ▪ Viewing flow rate history, page 65. |
| View pressure history |  | NO | <ul style="list-style-type: none"> ▪ Viewing pressure history, page 66. |
| Syringe |  | NO | <ul style="list-style-type: none"> ▪ Displaying on-pump syringe information, page 67. |
| View event log |  | NO | <ul style="list-style-type: none"> ▪ Viewing the event log, page 68. |

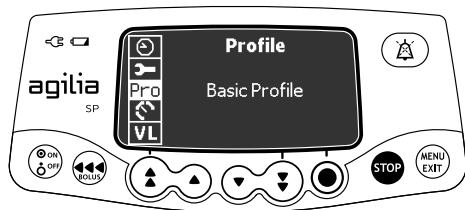
| Menu | Symbol | Stop Infusion Required | Associated Procedure |
|-------------|---|------------------------|--|
| Date / Time |  | NO | ▪ Setting the date and time, page 69. |
| Maintenance |  | NO | ▪ Displaying maintenance information, page 70. |

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


For more information on factory configuration, refer to Appendix: Factory Configuration, page 131.

8.2 Profile


| | |
|------------------|---------------------------------------|
| Symbol | Pro |
| Procedure | Displaying active profile information |







You can display the active profile name as follows:

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

8.3 Pressure

| | |
|-----------|---|
| Symbol |  |
| Procedure | Modifying the pressure limit |

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

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

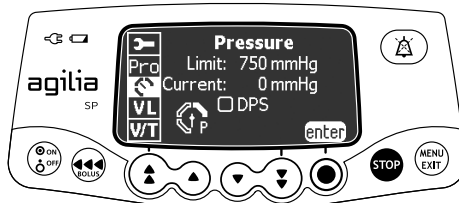
When the pressure limit is reached, an occlusion alarm is triggered. You must silence the alarm, resolve the occlusion and start the infusion again.

To consult the pressure settings, see section 15.5, page 92.



Warning

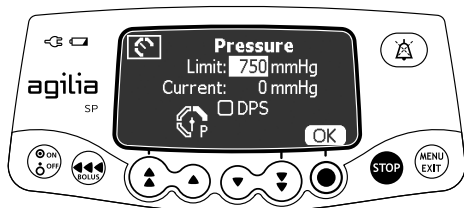
When addressing or clearing an occlusion:

- *Ensure the fluid flow to the patient is OFF to prevent administering an unintended bolus. An occlusion may pressurize the 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, or relieve the excess pressure through a stopcock, if present. The health care professional should weigh the relative risks of disconnection with the risks of an unintended bolus of drug.*
- *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.*

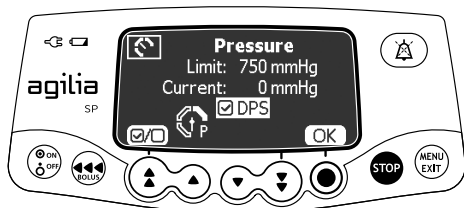


You can modify the pressure limit as follows:

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



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



6. Press to enable or disable the DPS function (optional).
7. Press **OK** to confirm.

Warning

To avoid the presence of air and to minimize the amount of time it takes the pump to recognize an occlusion and generate an alarm while infusing at low rates (e.g., less than 5 mL per hour, and especially flow rates less than 0.5 mL per hour):

- Consider occlusion pressure threshold setting and adjust it, as necessary. The lower the occlusion pressure threshold setting, the shorter the occlusion detection time. However, when infusing viscous or thick fluids (e.g., lipids), the occlusion pressure threshold setting may need to be adjusted to reduce false alarms.
- 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.
- Use extension set which have the smallest internal volume or deadspace (e.g., use microbore tubing when infusing at low rates, shorter length of tubing, etc.).






Information

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

8.4 Keypad Lock Status

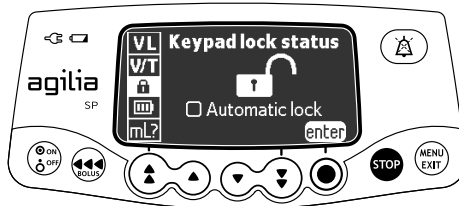
| | |
|-----------|---|
| Symbol |  |
| Procedure | Locking / Unlocking the keypad |

You can use this feature to avoid inadvertent key presses.



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

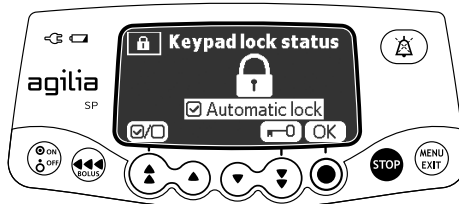
- *Automatic lock: The keypad will lock automatically at infusion start, or after a time-out.*
- *Unlock code: The user must enter a code to unlock the keypad.*




Locking the Keypad



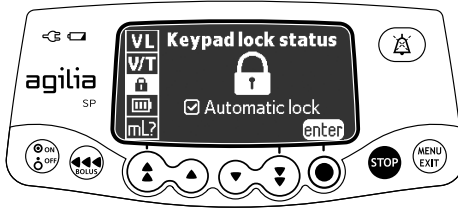
You can lock the keypad as follows:

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



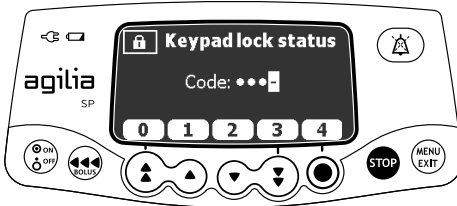
4. Lock the keypad as follows:
 - Press  to lock the keypad.
The keypad is locked and the screen displays .
 - Press  to activate the automatic lock.
The keypad will lock automatically at infusion start. If the keypad is unlocked during the infusion, it will lock again automatically after a time-out.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

Unlocking the Keypad

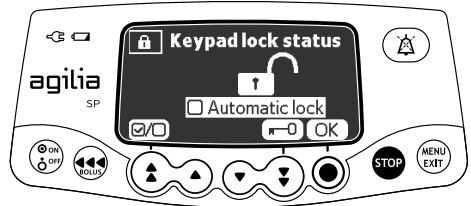


You can unlock the keypad as follows:


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






Unlock code enabled



Unlock code disabled


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

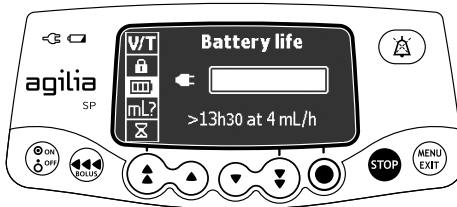
Information

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



8.5 Battery Life

| | |
|-----------|---|
| Symbol |  |
| Procedure | Viewing the battery life |





You can view the battery life as follows:

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

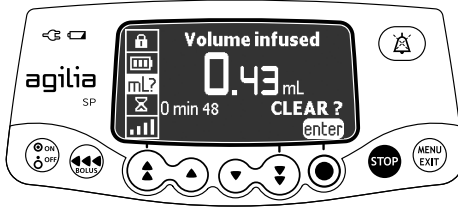
The bar graph shows a visual representation of battery life.

The symbol displayed shows the following:


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

8.6 Volume Infused

| | |
|-----------|---|
| Symbol | mL? |
| Procedure | Viewing and clearing the volume infused |



You can view and clear the volume infused as follows:


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

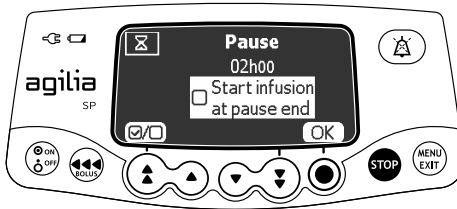


Information



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

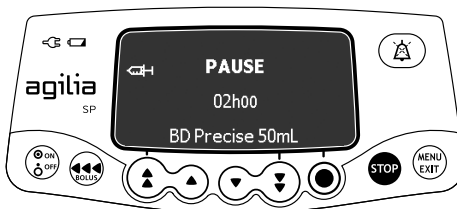
8.7 Pause

| | |
|-----------|---|
| Symbol |  |
| Procedure | Programming a pause |



You can program a pause as follows:

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






Information



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

8.8 Day/Night Mode

| | |
|-----------|---|
| Symbol |  |
| Procedure | Switching between day mode and night mode |

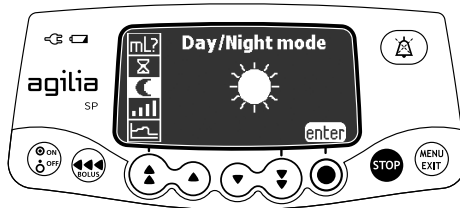
This function switches between day mode  and night mode .

The default night mode settings are as follows:



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

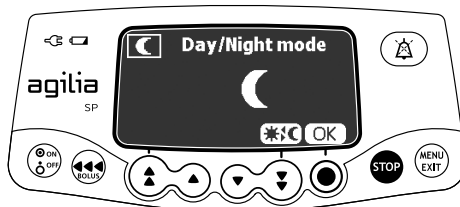
Depending on your pump configuration, the switch between day and night mode may be managed either through this menu (manual mode), or according to pre-defined settings (auto mode). For more information, refer to the technical manual.




Switching from Day Mode to Night Mode



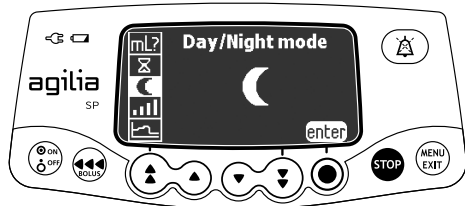
You can switch to night mode as follows:

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





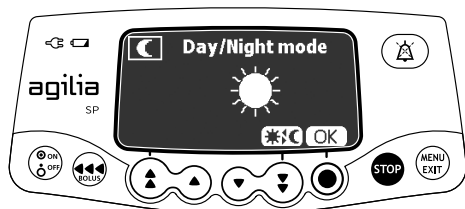
4. Press   to activate night mode.
The screen displays .
5. Press **OK** to confirm.



Switching from Night Mode to Day Mode



You can switch to day mode as follows:

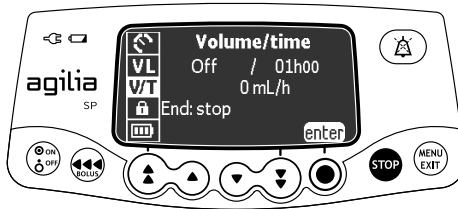
1. Press .
2. Press the arrow keys to select .
3. Press **enter**.




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

8.9 Volume/Time

| | |
|------------------|------------------------------------|
| Symbols | V/T |
| Procedure | Programming a Volume/Time infusion |

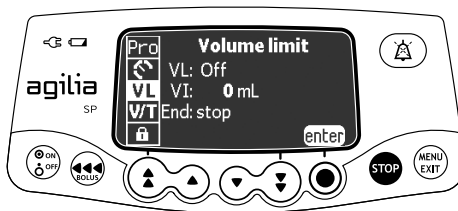



1. Press .
2. Press the arrow keys to select V/T .
3. Press **enter**.

For more information on how to program a Volume/Time infusion, see section 7.9.2, page 44.

8.10 Volume Limit


| | |
|------------------|-------------------------------------|
| Symbol | VL |
| Procedure | Programming a Volume Limit infusion |

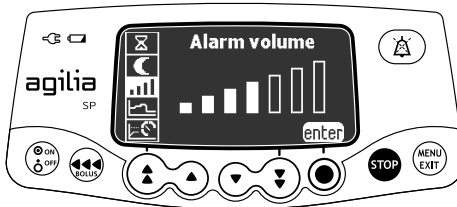


1. Press .
2. Press the arrow keys to select VL .
3. Press **enter**.



For more information on how to program a Volume Limit infusion, see section 7.9.3, page 45.

8.11 Alarm Volume


| | |
|-----------|---|
| Symbol |  |
| Procedure | Adjusting the alarm volume |



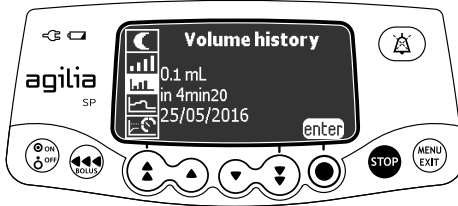
You can adjust the alarm volume as follows:

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



8.12 Volume History

| | |
|-----------|---|
| Symbol |  |
| Procedure | Viewing the infusion history |

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




You can view the infusion history as follows:

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

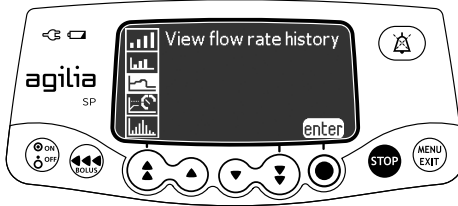


4. Press the arrow keys to select the desired infusion.
The selected infusion's details are displayed:
 - Volume infused
 - Infusion total duration
 - Infusion date & time
5. Press **exit** to return to the menu.



8.13 View Flow Rate History

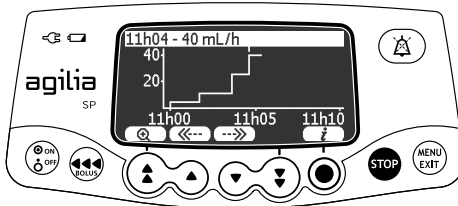
| | |
|-----------|---|
| Symbol |  |
| Procedure | Viewing flow rate history |




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



You can view flow rate history as follows:

1. Press .
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  to view information about the selected event.

Information

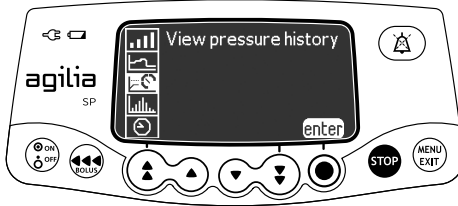


- *The history is not refreshed while the history screen is displayed. To refresh the history data, exit and select the history again.*
- *Flow rate history is not stored after powering off.*



8.14 View Pressure History

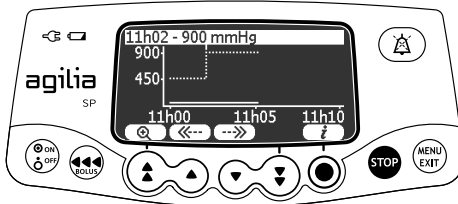
| | |
|-----------|---|
| Symbol |  |
| Procedure | Viewing pressure history |




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



You can view pressure history as follows:

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




4. Press the  and  buttons to browse the events.
5. Press  to view information about the selected event.

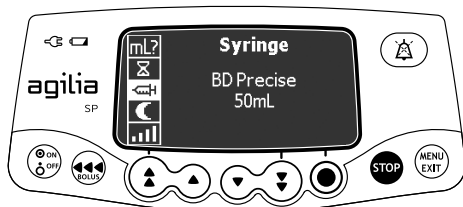
Information





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

8.15 Syringe

| | |
|-----------|---|
| Symbol |  |
| Procedure | Displaying on-pump syringe information |



You can display on-pump syringe information as follows:

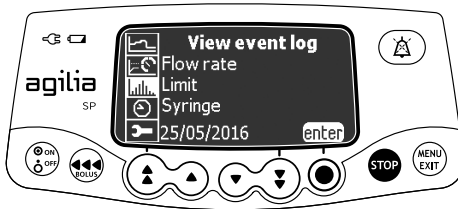
1. Press .
2. Use the arrow keys to select .
3. Press **enter**.
The following information is displayed:
 - Syringe capacity
 - Syringe brand / name

8.16 View Event Log



| | |
|-----------|---|
| Symbol |  |
| Procedure | Viewing the event log |

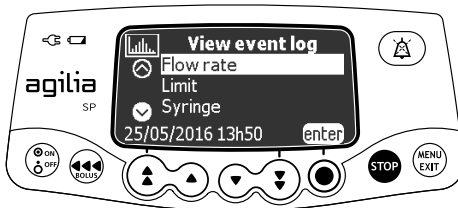
The event log displays details of the last events that occurred on the pump. Events are stored in the log even after the pump is powered off and on again. The log can store up to 1500 events. Older events are overwritten.

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

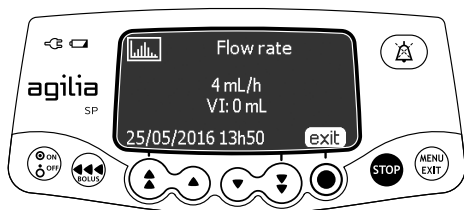


You can view the event log as follows:

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



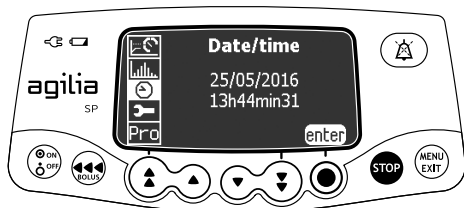
4. Press the arrow keys to select the desired event.
5. Press **enter**.
The details of the event are displayed.



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

8.17 Date / Time


| | |
|-----------|---------------------------|
| Symbol | |
| Procedure | Setting the date and time |

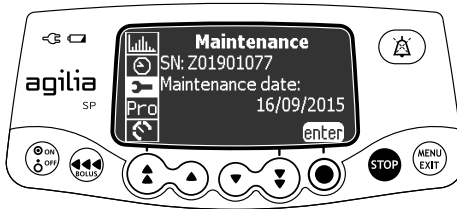


You can set the date and time as follows:



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

8.18 Maintenance

| | |
|-----------|---|
| Symbol |  |
| Procedure | Displaying maintenance information |



You can display maintenance information as follows:









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

The following information is displayed:

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

9 Options

9.1 Commands

| Operation | Key |
|--|---|
| Options access |  +  |
| Option selection |     |
| Confirm |  (corresponds to enter on the screen) |
| Select <input checked="" type="checkbox"/> / Deselect <input type="checkbox"/> |  |

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

9.2 Option Descriptions

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

| Option | Access Code? | Description Location |
|-----------------------------|--------------|-----------------------|
| Pump Settings | No | Section 9.3, page 72. |
| Basic Profile Configuration | Yes | Technical Manual |
| Profile | Yes | Technical Manual |
| Maintenance | Yes | Technical Manual |



Information

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

9.3 Pump Settings

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

| Function | Choice | Default Pump Setting |
|--|---|---|
| [User 2]: Menu items | ▪ Maintenance: display or hide maintenance | Disabled |
| | ▪ Date / Time: display or hide date/time menu | Disabled |
| [User 3]: Contrast | ▪ Adjustment of screen contrast using the fast increment and decrement keys | Medium level |
| [User 7]: Date/Time | ▪ Date selection: dd/mm/yyyy | Production plant date and time |
| | ▪ Time selection: __ h __ | |
| [User 8]: Language | ▪ A scrolling list with all available languages | Official language of the target country |
| [Par 5]: Syringe selection | ▪ Enable/Disable selected syringe confirmation screen | Disabled |
| [Par 6]: Syringes | ▪ Checkbox list with the names of available syringes, and other syringes sizes | Section 13.1, page 84. |
| [Par 13]: AC power disconnection alert | ▪ Enable/Disable "AC power disconnection" message and "Device operating on battery" message at power on | Enabled |
| [Par 28]: Automatic power on with disengagement | ▪ Enable/Disable automatic device powering on at disengagement lever push | 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 37]: Alarm system | ▪ Enable/Disable preventive silence for alarm system | Enabled |
| [Par 38]: Keypad unlock code | ▪ Set or disable keypad unlock code (4-digit). Disable value: 0000 | 0000 (Disabled) |

10 Data Communication

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

10.1 Data Communication Cables

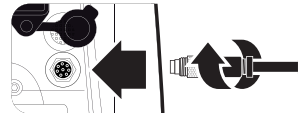
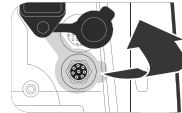
Information



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

10.2 Using the Communication Port

1. Remove the protective cap from the pump's RS232 communication port.
2. Connect the cable to the RS232 communication port by turning the cable wheel.



Information



Do not disconnect communication cables while data is being transferred.

11 User Test

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

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

12 Alarms and Safety Features

12.1 Introduction

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

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





Warning


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

12.2 Alarm Descriptions

There are several different levels of alarm priorities:

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

| Alarm Priority | Required Operator Response | Description |
|----------------|----------------------------|---|
| High (!!!) | Immediate response | <ul style="list-style-type: none">▪ The infusion stops.▪ The infusion indicator lights flash red.▪ The pump emits audible alarm signals.▪ An alarm description is displayed on the pump screen.▪ The  key silences the alarm for two minutes. End of infusion is acknowledged. For detailed description of each alarm, please refer to List of Alarms, page 77. |
| Medium (!!) | Prompt response | <ul style="list-style-type: none">▪ The infusion continues.▪ The infusion indicator lights flash yellow.▪ The pump emits audible alarm signals.▪ Depending on the alarm, the  key silences the alarm for no time limit or for a defined duration. For detailed description of each alarm, please refer to List of Alarms, page 77. |





| Alarm Priority | Required Operator Response | Description |
|---------------------|----------------------------|--|
| Low (!) | Awareness | <ul style="list-style-type: none"> ▪ The infusion continues. ▪ The infusion indicator lights (LEDs) yellow are ON. ▪ The pump emits audible alarm signals. ▪ Depending on the alarm, the  key silences the alarm for no time limit or for a defined duration. For detailed description of each alarm, please refer to List of Alarms, page 77. |
| Information Signals | Awareness | <ul style="list-style-type: none"> ▪ The infusion continues. ▪ An information message is displayed on the pump screen. |

12.3 General Remarks



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


12.4 List of Alarms

12.4.1 Syringe Alarms




| Message | Priority | Stops Infusion? | Problem / Resolution |
|-----------------------------|------------|-----------------|---|
| Syringe installation !!! | High (!!!) | Yes | The syringe is not installed correctly (plunger driver, syringe barrel clasp or flange detection). ☞ Check the syringe installation. Note: The  key silences the alarm for 2 minutes. |
| Plunger head alarm !!! | High (!!!) | Yes | The plunger head is missing or incorrectly inserted. ☞ Check the syringe installation. Note: The  key silences the alarm for 2 minutes. |
| Disengagement mechanism !!! | High (!!!) | Yes | Disengaged mechanism. ☞ Check the syringe installation. Note: The  key silences the alarm for 2 minutes. |
| Remove completely syringe ! | Low (!) | No | This message displays when the pump is switched ON and OFF more than 5 times after the syringe type and brand have been confirmed. ☞ Remove and reinstall the syringe. Note: The  key silences the alarm for 2 minutes. |

12.4.2 Volume Limit Alarms



| Message | Priority | Stops Infusion? | Problem / Resolution |
|-----------------------------|-------------|-----------------|--|
| End of volume limit !!! | High (!!!) | Yes | The volume limit is reached. Note: The  key acknowledges the alarm. |
| Near end of volume limit !! | Medium (!!) | No | The time remaining is less than the defined time duration (adjustable between 1 and 30 minutes), and the remaining VTBI is less than 10% of the syringe capacity. Note: The  key silences the alarm for no time limit. |




| Message | Priority | Stops Infusion? | Problem / Resolution |
|-----------------------|----------|-----------------|--|
| End of volume limit ! | Low (!) | No | The volume limit is reached and the end of infusion setting is set as "KVO" or "continuous". Note: The  key silences the alarm for a duration from 1 minute to 12 hours. |

12.4.3 Volume/Time Alarms


| Message | Priority | Stops Infusion? | Problem / Resolution |
|----------------------------|-------------|-----------------|---|
| End of volume/time !!! | High (!!!) | Yes | The VTBI is completed. Note: The  key silences the alarm for no time limit. |
| Near end of volume/time !! | Medium (!!) | 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. Note: The  key silences the alarm for no time limit. |
| End of volume/time ! | Low (!) | No | The VTBI is completed and the end of infusion setting is set as "KVO" or "continuous". Note: The  key silences the alarm for a duration from 1 minute to 12 hours. |




12.4.4 Infusion Alarms

| Message | Priority | Stops Infusion? | Problem / Resolution |
|-------------------------|-------------|-----------------|---|
| End of infusion !!! | High (!!!) | Yes | The infusion is completed (simple rate). Note: The  key silences the alarm for 2 minutes. |
| Near end of infusion !! | Medium (!!) | 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. Note: The  key silences the alarm for 2 minutes. |



| Message | Priority | Stops Infusion? | Problem / Resolution |
|---------------------|--------------------|-----------------|---|
| Check settings !! | Medium (!!) | No | An infusion value has been modified using the keys, but has not been confirmed. ☞ Check this value and press OK to confirm. Note: The  key silences the alarm for 2 minutes. |
| Waiting settings !! | Medium (!!) | No | A value must be entered. ☞ Enter a value and press OK to confirm. Note: The  key silences the alarm for 2 minutes. |
| Waiting start !! | Medium (!!) | No | The infusion settings have been entered, but the infusion has not been started with start key. ☞ Check the infusion settings. ☞ Press start to start the infusion. Note: The  key silences the alarm for 2 minutes. |
| Reached hard limit | Information signal | No | The upper or lower hard limit is reached. |



12.4.5 Pressure Alarms

| Message | Priority | Stops Infusion? | Problem / Resolution |
|---------------------|------------|-----------------|--|
| Occlusion alarm !!! | High (!!!) | Yes | The pressure in the infusion line has reached the threshold level. ☞ Check whether the infusion line is occluded. If necessary, readjust the pressure threshold. See section 8.3, page 52. Note: The  key silences the alarm for 2 minutes. |



| Message | Priority | Stops Infusion? | Problem / Resolution |
|------------------------|-------------|-----------------|---|
| Occlusion pre alarm !! | Medium (!!) | No | <p>In-line pressure has reached the following value:</p> <ul style="list-style-type: none"> ▪ 25 mmHg / 2.5 kPa / 0.5 PSI below the programmed threshold (from 50 to 250 mmHg). ▪ 50 mmHg / 5 kPa / 1 PSI below the programmed threshold (over 250 mmHg). <p>☞ Check the infusion line.</p> <p>☞ Set the correct pressure threshold.</p> <p>Note: The  key silences the alarm for no time limit.</p> |
| Pressure increase ! | Low (!) | No | <p>The pressure is increasing in the infusion line.</p> <p>☞ Check for occlusions in the infusion line.</p> <p>Note: The  key acknowledges the alarm.</p> |
| Drop in pressure ! | Low (!) | No | <p>The pressure is decreasing in the infusion line.</p> <p>☞ Check the downstream Luer lock connection and the integrity of the entire line.</p> <p>Note: The  key silences the alarm for no time limit.</p> |

12.4.6 Battery Alarms

| Message | Priority | Stops Infusion? | Problem / Resolution |
|--|------------|-----------------|---|
| Alert !!! Very low battery Connect to power and wait | High (!!!) | Yes | <p>The battery is discharged. The pump will power OFF automatically within 5 minutes.</p> <p>☞ Connect the pump to a power supply immediately. The pump displays "Battery alarm solved" message.</p> <p>Note: The  key silences the alarm for 2 minutes.</p> |
| Alert !!! Very low battery Too low to use Wait for charge | High (!!!) | Yes | <p>Very low battery.</p> <p>☞ Allow time to charge.</p> <p>Note: The  key silences the alarm for 2 minutes.</p> |

| Message | Priority | Stops Infusion? | Problem / Resolution |
|---|-------------|-----------------|--|
| Alert !! Low battery Connect to power | Medium (!!) | No | Low battery. ☞ Connect the pump to a power supply. Note: The  key silences the alarm for no time limit. |
|  | Low (!) | No | If the pump is not used during an extended period, connect to a power supply and wait until the battery is charged. |




12.4.7 Power Alarms

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


12.4.8 Keypad Alarms

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

12.4.9 Technical Error Alarms

| Message | Priority | Stops Infusion? | Problem / Resolution |
|---|------------|-----------------|---|
| Erxx(yyy) !!! | High (!!!) | Yes | <p>Technical alarm.</p> <p>☞ Contact your qualified technician or your Fresenius Kabi sales representative.</p> <p>Note: The  key silences the alarm for 30 seconds</p> |
| High internal temperature ! | Low (!) | No | <p>Temperature increase.</p> <p>☞ Check device environment.</p> <p>Note: The  key silences the alarm for 2 minutes.</p> |
| Alarm reporting not available on the Link ! | Low (!) | No | <p>The pump is mounted on a Link+ Agilia rack that has not been upgraded.</p> <p>☞ Contact your qualified technician or your Fresenius Kabi sales representative.</p> <p>Note: The  key acknowledges the alarm.</p> |

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

1. Record the error message `Erxx(yyy) !!!`.
2. Disconnect the pump from the power supply.
3. Switch the pump off by pressing the  key.



Warning

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

12.4.10 Audio-only Information Signals

| Type | Comment | Stops Infusion? | Activation |
|------------------------------------|----------------------------|-----------------|---|
| Switch mode | Beep until key is released | No | Beep starts when action is not allowed |
| Start infusion at the end of pause | 3 beeps | N/A | At the end of a pause, when the infusion automatically starts |
| AC power connection | 1 beep | No | When power is connected |
| Forbidden key | 1 beep | No | Repeated until key is released |
| Key beep | 1 beep | No | For each key pressed |
| Other non validation beep | 1 beep | No | For each key pressed |
| Direct bolus | 1 beep | No | Repeated for each mL infused |
| Syringe prime | 1 beep | N/A | Repeated every 5 seconds |
| End of pause | 4 beeps | N/A | At the end of pause - repeated |

13 Syringes

13.1 Syringe List



Information

- *The Agilia SP pump offers a maximum 100 syringes of different types, brands and sizes. For a list of compatible syringes, and for ordering information, refer to the System Components booklet.*
- *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.*

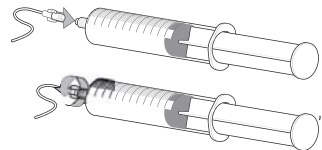


Warning

- ***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, refer to the System Components booklet. 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.*

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 local practices.
5. If necessary, fill the syringe and check that it is watertight.
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: +18 °/+30 °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.*
- *Some extension sets may have components such as a filter that require special instructions (e.g., air filter).*
- *Certain drugs may require specific extension sets.*
- *Connect the infusion line in accordance with procedures in your healthcare facility using good medical practices. 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 connecting to the pump.*

Precautions for the use of extension sets



- Use extension sets which have the smallest internal volume or “dead-space” to minimize residual volumes between the syringe and the patient when administering medications or fluids at low infusion rates (e.g., less than 5mL per hour, and especially flow rates less than 0.5 mL per hour). This reduces the amount of time it takes for fluid to reach the patient, maintains delivery accuracy, and reduces occlusion detection times.

For example:

- 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 (dead-space) of in-line filters should be minimized
 - Connection sites: The number of connection sites such as stopcocks and Y-sites should be limited, and high risk or life-sustaining solutions should be connected as close to the intravenous access site as possible.
- Avoid use of 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).

13.3 Operations for Syringes

13.3.1 Removing a Syringe

1. Press  to stop the infusion.
2. Disconnect the patient.
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. Disconnect the extension set from the access device in accordance with healthcare facility protocol.

13.3.2 Changing a Syringe

1. Remove the syringe,
See section 13.3.1, page 86.
2. Prepare a new syringe and follow the steps described in the flowchart.
See section 6.1, page 30.
3. After the new syringe is installed, acknowledge the "same therapy" screen (optional screen).



Warning

Electronically prime the syringe pump system after replacing a near-empty syringe with a replacement syringe.



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.

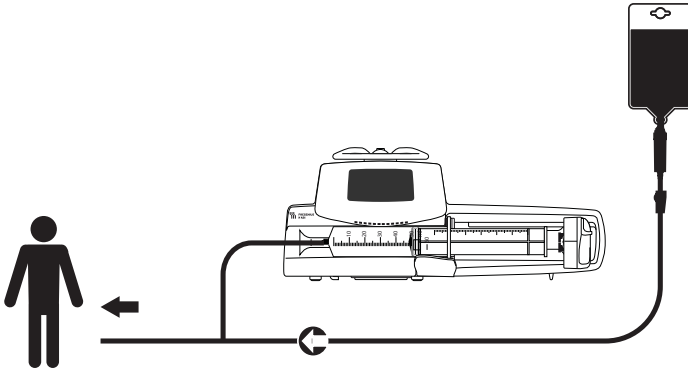


Figure 13.1: Gravity Infusion (in parallel with a pump)

Information

- **Fresenius Kabi** recommends the use of a back check valve or positive pressure infusion devices when an infusion on the pump is connected to a gravity line. This will prevent the back-up of IV fluid or medication into the gravity line.
- If there is no back check valve on a gravity infusion line during a multi-line infusion, it 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 incompatibilities during a multi-line infusion. **Fresenius Kabi** recommends infusing the critical drugs first.



14 Device Storage

14.1 Precautions for Storage

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



Warning

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

14.2 Storage and Transport Conditions

Observe the following conditions for storage and transport:

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

14.3 Preparing the Device for Storage

Prepare the device for storage as follows:

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

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

14.4 Using the Device After Storage

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

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

We recommend charging the battery for at least 6 hours.

We recommend that the "User test" is performed when the device is installed after storage, and before being used on a patient, see section 11, page 74.

15 Specifications



Information

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

15.1 Essential Features

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

| Feature | Refer to |
|--------------------------------------|---|
| Flow Rate Accuracy | Section 15.6.1, page 93. Section 18.9, page 104. |
| Time to Detect Occlusion | Section 15.6.3, page 93. |
| Bolus Volume After Occlusion Release | Section 15.6.4, page 94. |
| Management of High-priority Alarms | Section 12, page 75. |

15.2 Flow Rate

| | 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 0.1 1 | (0.10 → 9.99) (10.0 → 99.9) (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 | |
| KVO** | mL/h | 0.1 → 5 | 0.1 → 5 | 0.1 → 5 | 0.1 → 5 | 0.1 → 5 | 0.1 | |

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

** KVO default value = 1 mL/h.

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 1 (0.1 → 99.9) (100 → 999) |
| Volume/Time | mL | 0.1 → 99.9 | 0.1 | 0.1 |
| Direct Bolus | mL | 0.1 → 60 | N/A | 0.1 |

Applicable for all syringe sizes (50/60 mL, 30 mL, 20 mL, 10 mL, 5 mL)

15.4 Infusion Time

| | Format | Range of Settings | Default Value | Minimum Increment |
|-----------------------------------|-------------------|-------------------------------|---------------|-------------------|
| Infusion Rate | __ h __ min __ | 00h00min01 → 96h00min00 | N/A | 00h00min01 |
| KVO Silence Alarm Duration | __ h __ | 00h01 → 12h00 | 01h00* | 00h01 |
| Pause | __ h __ | 00h01 → 24h00 | N/A | 00h01 |

Applicable for all syringe sizes (50/60 mL, 30 mL, 20 mL, 10 mL, 5 mL)

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

15.5 Pressure Management

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

| | | Format | Range of Settings | Default Value | Minimum Increment |
|-----------------|------------------------|--------|-------------------|---------------|------------------------------------|
| 3 Levels | Low | mmHg | 50 → 300 | 100 | 50 |
| | Medium | mmHg | 150 → 700 | 250 | 50 |
| | High | mmHg | 250 → 900 | 500 | 50 |
| Variable | Full Range | mmHg | 50 → 900 | 500 | 25 50 (50 → 250) (250 → 900) |
| | Maximum Limit | mmHg | 500 → 900 | 900 | 50 |
| DPS | Raise Threshold | mmHg | 50 → 400 | 100 | 50 |
| | Drop Threshold | mmHg | 100 → 400 | 100 | 50 |

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

15.6 Accuracy



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

Values are representative of syringes used during internal tests and are provided as indicators only.

15.6.1 Flow Rate Accuracy

| | Accuracy |
|-----------|----------|
| Flow Rate | ± 3% |

15.6.2 Effects of Pressure Variations on Accuracy

| Back Pressure | Accuracy (From Mean Values) |
|---------------|--------------------------------|
| + 39.9 kPa | ~ - 3% |
| + 13.33 kPa | ~ - 1.5% |
| - 13.33 kPa | ~ + 1.5% |

15.6.3 Occlusion Alarm Accuracy

| Occlusion Alarm Response Time* | Accuracy | | | |
|--------------------------------|-----------|----------|---------------------------|--------------|
| | Syringe** | Rate | Occlusion Alarm Threshold | |
| | | | 50 mmHg | 900 mmHg |
| | 50 mL | 0.1 mL/h | < 5 hours | < 28 hours |
| | | 1 mL/h | < 30 minutes | < 3 hours |
| | | 5 mL/h | < 7 minutes | < 30 minutes |
| | 20 mL | 0.1 mL/h | < 4 hours | < 14 hours |
| | | 1 mL/h | < 20 minutes | < 75 minutes |
| | | 5 mL/h | < 5 minutes | < 15 minutes |

* Test condition: Temperature: 20 °C, Extension set length: 150 cm

** Syringe: BD Precise

15.6.4 Volume Accuracy



Warning

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

| | Accuracy | | | |
|------------------------------------|--|--------|-------------------------------------|-------------------------------------|
| Direct Bolus* | $\leq 10 \text{ mL}: \pm 0.2 \text{ mL}$ $> 10 \text{ mL}: \pm 3\%$ | | | |
| Bolus Volume at Occlusion Release* | Syringe** | Rate | Bolus Volume at Occlusion Release | |
| | | | 50 mmHg | 900 mmHg |
| | 50 mL | 5 mL/h | $-0.05 \leq X \leq 0.35 \text{ mL}$ | $-0.05 \leq X \leq 0.35 \text{ mL}$ |

* Test condition: Back pressure: 0 mmHg

** Syringe: BD Precise

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

15.6.5 Pressure Accuracy

| | Accuracy |
|----------|--|
| Pressure | $< 500 \text{ mmHg}: \pm 75 \text{ mmHg}$ $> 500 \text{ mmHg}: \pm 15 \%$ |

16 Cleaning and Disinfecting

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

Warning



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

Quick Cleaning Only

Note: This quick cleaning does not replace the need for a complete cleaning.

1. Check that the keypad is locked in order to avoid unintended modification of the infusion parameters. Do not move the pump.
2. Use ready-to-use wipes to wipe down all exposed surfaces of the pump.
3. At the end of the infusion, perform the complete cleaning protocol, see section 16.3.1, page 96.

16.1 When to Clean and Disinfect the Pump

Thoroughly clean and disinfect the pump in the following cases:

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

16.2 Recommended and Prohibited Agents

We recommend the following cleaning and disinfecting agents:

16.2.1 Recommended Agents

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

16.2.2 Prohibited Agents

The following cleaning and disinfecting agents are prohibited:

- Trichloroethylene
- Abrasive detergents
- Undiluted alcohol

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

16.3 Instructions for Cleaning and Disinfecting

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

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

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



Warning

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

16.3.1 Cleaning Instructions

Prerequisites

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

Protocol

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

16.3.2 Disinfecting Instructions

Prerequisites

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

Protocol

1. Place the previously cleaned pump on a clean surface or disposable underlay.
2. Use a ready-to-use wipe to wipe down all exposed surfaces of the pump, making sure to cover all cracks, crevices, and hard-to-reach areas. You can use the silver handle to lift and move the pump.
 - *When wiping down the sides, avoid wetting the connector sockets.*
 - *Do not allow liquids to run, leak, or drip into the pump housing.*

- 3.** Set down the pump, and wipe down the silver handle, the attachment lock knob, the screw clamp and the release button.
- 4.** Use a fresh ready-to-use wipe to gently wipe down the back side of the syringe barrel clasp and all exposed surfaces in the syringe barrel area.
- 5.** Using a fresh ready-to-use wipe, repeat steps 2 to 4.
- 6.** Leave the disinfecting agent on the pump for at least 3 minutes.
- 7.** Wipe down the power cord and any pump accessories.
- 8.** Allow the pump to dry completely at room temperature.

17 Power Management

17.1 AC Power Supply Precautions

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

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

Warning



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

17.2 Battery Precautions

The device uses a Lithium-ion rechargeable battery.

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

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

Information

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



17.3 Battery Operating Mode

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

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

Information

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




18 Technical Characteristics

18.1 Power Supply

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

The power cord conductor must have a cross section of at least 0.75 mm².

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

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

18.2 Battery

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

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



| | | |
|-------------------------|-------------------------------------|-------------------------------|
| Characteristics | 7.2 V 2.2 Ah - Li-ion Smart battery | |
| Weight | Approximately 100 g | |
| Battery Life | Flow Rate 5 mL/h | Battery Life > 11 h |
| Battery Recharge | Pump OFF: < 6 h / Pump ON: < 20 h | |

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.

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

18.5 Infrared Communication

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

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

18.6 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 (dBA) | |
|-----------------|-------------------|-----|
| | min | Max |
| High-priority | 55 | 63 |
| Medium-priority | 50 | 57 |
| Low-priority | 45 | 52 |

18.7 Compliance

| | | |
|--|--|--|
| ElectroMedical Equipment Safety | Compliant with the following standards: <ul style="list-style-type: none"> IEC 60601-1 IEC 60601-1-8 | IP22 Index of protection against ingress of water or particulate matter |
| EMC (ElectroMagnetic Compatibility) | Compliant with the following standard: <ul style="list-style-type: none"> IEC 60601-1-2 |  Protection against leakage current: Defibrillation-proof type CF applied part* |
| Particular Standards | <ul style="list-style-type: none"> IEC 60601-2-24 |  Protection against electric shocks: class II  Functional earth** |

* After a defibrillation, the pump recovery time is around 2 seconds.

** The functional earth is directly connected to the power supply cord. It reduces residual current that may disturb ECG or EEG devices.

18.8 Dimensions and Weight

| | |
|--------------------|----------------------|
| H / W / D | 135 x 345 x 170 mm |
| Weight | Approximately 2.1 kg |
| Screen Size | 70 x 35 mm |

18.9 Trumpet and Start-up Curves

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

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

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

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

Syringe used: BD Precise 50 mL

Fluid used: distilled water

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

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

18.9.1 Flow rate: 1 mL/h

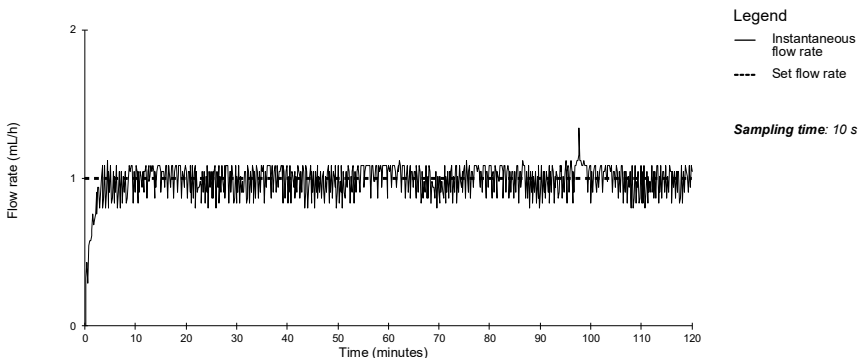


Figure 18.1: Start-up and instantaneous flow rate (1 mL/h over first 2 hours on 96 hours)

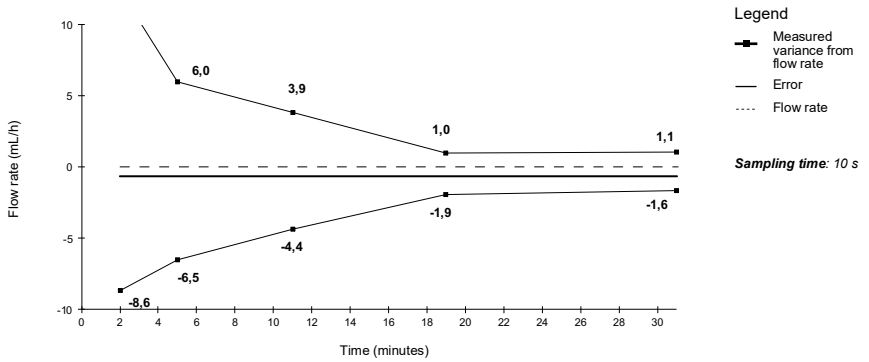


Figure 18.2: Trumpet curves for 2, 5, 11, 19, 31 minutes observation windows (1 mL/h over first 2 hours on 96 hours)

18.9.2 Flow rate: 5 mL/h

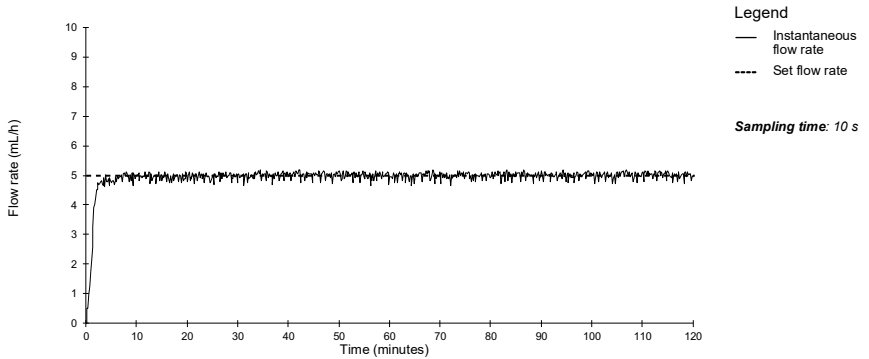


Figure 18.3: Start-up and instantaneous flow rate (5 mL/h over first 2 hours on 96 hours)

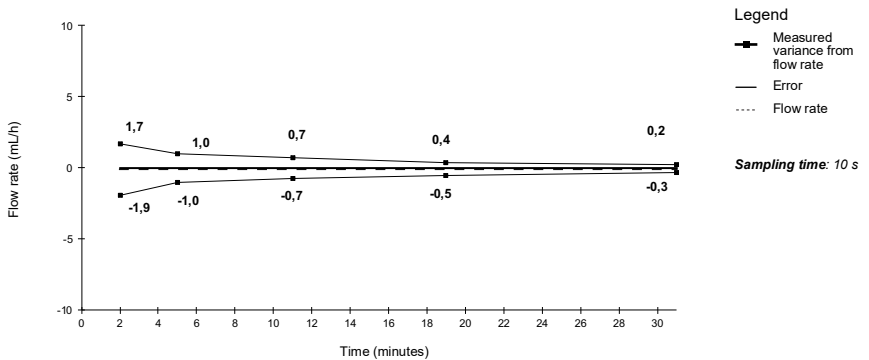



Figure 18.4: Trumpet curves for 2, 5, 11, 19, 31 minutes observation windows (5 mL/h over first 2 hours on 96 hours)

19 Troubleshooting

| Issue | Recommended Actions |
|--|---|
| The pump is unstable when mounted. | <ul style="list-style-type: none"> ▪ Check that the rotating pole clamp is fastened. |
| The pump is damaged, or you notice something abnormal (unusual noise, abnormal heat or smoke). | <ul style="list-style-type: none"> ▪ Remove the power cord. ▪ Contact your biomedical department or your Fresenius Kabi sales representative immediately. |
| The pump has been dropped or was subjected to a force that may have produced internal damage. | <ul style="list-style-type: none"> ▪ Do not use the pump. ▪ Contact your biomedical department or your Fresenius Kabi sales representative. |
| The pump cannot be installed or removed from the Link Agilia or Agilia Link or Link+ Agilia. | <ul style="list-style-type: none"> ▪ Check the rotating pole clamp position. ▪ Contact your biomedical department or your Fresenius Kabi sales representative. |
| The pump does not start after pressing  . | <ul style="list-style-type: none"> ▪ Connect the pump to the AC power supply to see if the battery is fully discharged. ▪ Contact your biomedical department or your Fresenius Kabi sales representative. |
| Data communication cables cannot be connected or removed from the pump. | <ul style="list-style-type: none"> ▪ Check the cable connector. ▪ Check the pump connector. ▪ Contact your biomedical department or your Fresenius Kabi sales representative. |
| Flow rate variance is higher than flow rate accuracy. | <ul style="list-style-type: none"> ▪ Check the infusion line configuration. ▪ Check the fluid viscosity. ▪ Check that the fluid temperature is within the recommended range. ▪ Contact your biomedical department or your Fresenius Kabi sales representative. |
| Keypad problem (keys, LEDs). | <ul style="list-style-type: none"> ▪ Check the general condition of the keypad. ▪ Check the contrast. ▪ Contact your biomedical department or your Fresenius Kabi sales representative. |
| The power supply indicator does not light up. | <ul style="list-style-type: none"> ▪ Connect the pump to the AC power supply. ▪ Contact your biomedical department or your Fresenius Kabi sales representative. |
| The pump powers off on its own. | <ul style="list-style-type: none"> ▪ Connect the pump to the AC power supply. ▪ Contact your biomedical department or your Fresenius Kabi sales representative. |
| The battery alarm is ON even though the pump has been correctly charged. | <ul style="list-style-type: none"> ▪ Check the AC power voltage. ▪ Contact your biomedical department or your Fresenius Kabi sales representative. |
| The pump powers off when it is disconnected from the AC power supply. | <ul style="list-style-type: none"> ▪ The battery is completely discharged: charge the battery. ▪ Contact your biomedical department or your Fresenius Kabi sales representative. |

| Issue | Recommended Actions |
|---|---|
| <p>At start-up, the pump displays: "Software is upgrading..."</p> | <ul style="list-style-type: none"> ▪ Connect the pump to the AC power supply. Then, wait few minutes without touching the keypad until the message disappears and the pump starts as usual. ▪ Contact your biomedical department, or your Fresenius Kabi sales representative. |

20 Recycling

Batteries, accessories and devices with this label must not be disposed of with general waste.



They must be collected separately and disposed of according to local regulations.

Before disposal, make sure that a qualified technician removes the battery from the device according to the procedure described in the Technical Manual.



Information

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

21 Warranty

21.1 General Warranty Conditions

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

21.2 Limited Warranty

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

- The device must have been used according to the instructions described in this document and in other accompanying documents.
- The device must not have been damaged while being stored or repaired, and must not show signs of improper handling.
- The device must not have been altered or repaired by unqualified personnel.
- The internal battery of the device must not have been replaced by a battery other than that specified by the manufacturer.
- The serial number (SN) must not have been altered, changed or erased.

Information



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

21.3 Warranty Conditions for Accessories

Batteries and accessories may have specific warranty conditions.

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

22 Guidance and Manufacturer's Declaration on EMC

22.1 Electromagnetic Compatibility



Warning

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

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

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

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

22.2 Electrostatic Discharge (ESD)



Information

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

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

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

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

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

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

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

22.3 Electromagnetic Compatibility and Interference Guidance

The Agilia pump has been tested in accordance with the electromagnetic compatibility standards applicable to medical devices. Its immunity is designed to ensure correct operation. Limitation of the emitted radiation avoids undesirable interference with other equipment.

The Agilia pump is classified as a Class B device according to CISPR 11 emitted radiation. The user might be required to take mitigation measures, such as relocating or reorienting the equipment.

Warning



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

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

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

- Reorient or relocate the Agilia pump, the patient or disruptive equipment.
- Change the routing of cables.
- Connect the Agilia pump power plug to a protected / backed-up / filtered supply or directly to the UPS circuit (uninterruptible power supply).
- Increase the separation between the Agilia pump and disruptive equipment.
- Plug the Agilia pump into an outlet on a different circuit from the one to which the patient or disruptive equipment is connected.
- In any case, whatever the context, the user should conduct interoperability testing in a real situation to find the correct setup and location.

22.4 EMC and essential performances

In the case of electromagnetic disturbances, if the essential performance, Section 15.1, page 90, is lost or degraded, the consequences for the patient are as follows: overdose, underdose, delay of therapy, air embolism, trauma, exsanguination.

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



Warning

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

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

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



Warning

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

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


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

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



Warning

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

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

Notes:

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

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

Information



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

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

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

Information



- *At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.*
- *These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.*

22.4.5 EMC test deviations and supplementary tests

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

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

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

23 Servicing

23.1 Information on Device Servicing

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

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

Information



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

23.2 Maintenance Requirements



Warning

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



Warning

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



Warning

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

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

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

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



Information

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

23.3 Quality Control

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

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



Information

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

23.4 Notification of serious incident

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

Information and contact information:

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

24 Cybersecurity

24.1 Cybersecurity and IT-Network environment

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

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

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

Warning



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

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

Policy recommendations

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

IT-Network recommendations

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

Software used to maintain or operate medical devices may be deployed on different host computers: desktop, laptop, servers, ...

However, such software deployment shall comply with the same use conditions as those for healthcare facility network deployment. Ideally, the host computer will belong to the healthcare facility network, and therefore will be protected in the same manner as the network.

Information



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

24.2 Inherent design



Warning

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

Agilia system pumps design includes security mechanisms. Communication with software application are secured, Wi-Fi and availability of data is verified, user interface can be locked on demand, Agilia pumps only communicate at their initiative on a configurable manner.

Fresenius Kabi strongly recommends to read and implement good practices included in Section 24.3, page 122.

24.3 Information regarding cybersecurity

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



Warning

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

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

**Warning**

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

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

**Warning**

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

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

**Information**

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

Network configuration

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

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

**Warning**

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

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

Login and passwords

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

Hardening

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

Warning



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

24.4 Firewall configuration

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

24.5 Potential vulnerabilities

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

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

| Vulnerability | Typical Threat Events |
|---|---|
| Lack of integrity checking | Adversaries could manipulate communications undetected. |
| Inadequate authentication between wireless clients and access points | Strong mutual authentication between wireless clients and access points is needed to ensure that clients do not connect to a rogue access point deployed by an adversary. |
| Inadequate data protection between wireless clients and access points | Sensitive data between wireless clients and access point should be protected using strong encryption to ensure that adversaries cannot gain unauthorized access to the unencrypted data. Ensure protection from fraudulent Wi-Fi access points (Evil Twin) that appear to be legitimate but are set up to eavesdrop on wireless communications. |
| Poor remote access controls | Remote access capabilities must be adequately controlled to prevent unauthorised individuals from gaining access to the system. |
| Inadequate firewall and router logs | Without proper and accurate logs, it might be impossible to determine what cause a security incident to occur. |
| Unprotected ports or services | Unused ports (such as Forgedoor) and services must be closed or turned off. |
| Physical Access | |
| Unauthorised personnel have physical access to devices | <ul style="list-style-type: none"> ▪ Physical theft or damage of data ▪ Unauthorised personnel add, remove or change resources of devices ▪ Install unauthorised utilities (undetected interception of data) |
| Unsecured physical ports | <ul style="list-style-type: none"> ▪ Flash/thumb drivers ▪ Keystroke logger ▪ Other unauthorised utilities to exploit unsecure physical ports |
| Network Configuration and Communication | |
| A flat network with no zones (no segregation between corporate and device networks) | <ul style="list-style-type: none"> ▪ Unauthorised access to medical devices through facility's IT-network ▪ Distribute malware across facility's IT-networks ▪ Intercept or manipulate unencrypted messages (plain text) |
| Improperly selected and configured firewall (weak firewall rules) | <ul style="list-style-type: none"> ▪ Phishing attack (spear phishing, mobile phishing) ▪ Identity spoofing ▪ Firewall bypassed ▪ Man-in-the-middle attacks |
| Malware protection not installed or not up-to-date | <ul style="list-style-type: none"> ▪ Disseminate virus, ransomware among networks ▪ Plant spyware (for monitoring and eavesdropping) ▪ Audit log manipulation or destruction |

| Vulnerability | Typical Threat Events |
|---------------|-----------------------|
|---------------|-----------------------|

Software vulnerabilities

| | |
|-------------------------------------|---|
| Inadequately assess security of OTS | A wide variety of security implications and vulnerabilities have been identified with various OTS operating systems or control protocols such as OLE, DCOM, RPC, OPC, etc. |
| Database vulnerabilities | Databases with web interfaces may be vulnerable to typical web attacks like XSS, SQL injection. The information contained in database makes them high-value targets for any attacker. |

Security Policies and Procedures

| | |
|--|--|
| Lack of or inadequate authentication, authorisation, access control policies and incident detection and response plan or procedure | <ul style="list-style-type: none"> ▪ Vulnerabilities regarding authentication, authorisation, access control policies, incident detection and response plan or procedure could lead to multiple threat events (attacks) or more likely. ▪ For example incident detection (such as unusual CPU usage due to Cryptojacking) and response plans, procedures and methods are necessary for rapidly detecting incident, minimizing loss and destruction, preserving evidence for later forensic examination, mitigating the weakness that were exploited, and restoring system services. ▪ Having an inadequately shared network between Medical Device Network and Corporate Network (for example, it does not have dedicated VLAN for medical devices) could make it possible for virus and worm to spread to medical devices. |
|--|--|

25 Glossary of Terms

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

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

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

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

Appendix: Factory Configuration

| | Feature | Availability |
|--------------|------------------------|--------------|
| Menus | Profile | ✘ |
| | Pressure | ✓ |
| | Keypad lock status | ✓ |
| | Battery life | ✓ |
| | Volume infused | ✓ |
| | Pause | ✓ |
| | Patient | ✘ |
| | Day/Night mode | ✓ |
| | Volume/Time | ✘ |
| | Volume Limit | ✓ |
| | Alarm volume | ✓ |
| | Volume history | ✘ |
| | View flow rate history | ✘ |
| | View pressure history | ✘ |
| | Syringe | ✘ |
| | View event log | ✘ |
| | Date / Time | ✘ |
| Maintenance | ✘ | |

| | Feature | Availability |
|--------------------------|-------------------------------|--------------|
| Infusion Modes | Simple Rate | ✓ |
| | Volume/Time | ✘ |
| | Volume Limit | ✓ |
| Infusion Features | Direct Bolus | ✓ |
| | KVO | ✓ |
| | Prime Set | ✘ |
| | Dynamic Pressure System (DPS) | ✓ |

✓ = Activated with factory configuration (Basic Profile).

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

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Release Notes

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

This document may contain inaccuracies or typographical errors.

Modifications may thus be made, and included in later editions.

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

The screenshots 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.

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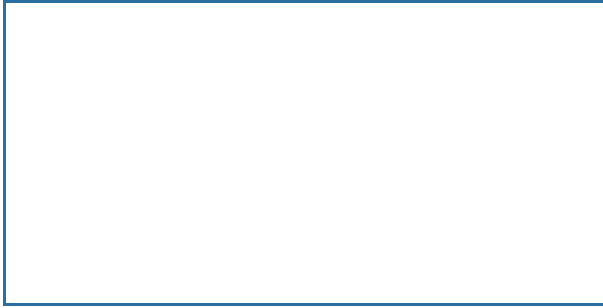
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