



**FRESENIUS
KABI**

Agilia SP PCA WiFi

Syringe Infusion Pump

Applicable to software version 4.4

Instructions For Use

For Use in Healthcare Facilities



Symbols Description

Symbols used in this document



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



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



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



Information: recommendations to be followed.

Labelling symbols



Warning
(Refer to the Instructions For Use)



Refer to the Instructions For Use



Product reference / part number



Product serial number



Input terminal - connector



Output terminal - connector



Electrical fuses



Alternating Current (AC)



Direct Current (DC)

IP32

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

IP27

Ingress protection against water when immersed up to 1 m deep. Rating applies to patient handset but not to the handset connector.



Part included in a recycling process



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



Name and address of the manufacturer
/ Date of manufacture



Name and address of the manufacturing facility



Protection against electric shock: class II



Non-ionizing electromagnetic radiation



Fragile, handle with care



This way up



Keep away from rain



Temperature limitation



Humidity limitation



Atmospheric pressure limitation



General symbol for recyclable material



Eco packaging symbol



CE mark



Medical Device



Unique Device Identifier

CH

REP

Indicates the authorised representative in Switzerland

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1 Introduction

1.1 Scope

These Instructions For Use are applicable to the Agilia SP PCA WiFi pumps. These devices are referred to throughout this manual as the "Agilia SP PCA".

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



INFORMATION

Check that these Instructions For Use are applicable to the software version currently in your devices.

- The software version of the device is displayed on start-up screen.
- The software version described in these Instructions For Use is displayed on the cover page and in the *Release Notes* on page 179.

1.2 Principles of Operation

The Agilia SP PCA infusion pump 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).

The Agilia SP PCA infusion pump 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 and information provided in *Syringe List* on page 126.

The Agilia SP PCA infusion pump can be used for intermittent or continuous infusions.

The Agilia SP PCA infusion pump is used with the patient handset (applied part) for PCA/PCEA therapies.

The Agilia SP PCA infusion pump is intended for use on only one patient at a time. It can be reused indefinitely on multiple patients throughout its lifetime.

1.3 Intended Purpose

Infusion Pumps and Accessories for Administration of Fluids.

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

1.4 Intended Use

1.4.1 Indications

The Agilia SP PCA syringe pump is primarily intended for Patient Controlled Analgesia (PCA) and Patient Controlled Epidural Analgesia (PCEA) therapies, for the administration of analgesic drugs under the patient's or the clinician's control. The Agilia SP PCA syringe pump can also be used for general infusion.



INFORMATION

Clearly label Agilia SP PCA syringe pumps used to deliver epidural medications as "Epidural Only" according to policy/clinical practice of the healthcare facility.

Please ensure a sufficient quantity of Agilia SP PCA pumps is available to suit your needs.

The Agilia SP PCA syringe pump is indicated to administer products through clinically accepted routes. These products include:

	Intended Products	IV continuous and intermittent infusion	PCA	PCEA/CEI
Medication	■ Analgesic drugs	✓	✓	✓
	■ Antibiotics	✓	-	-
	■ Chemotherapy	✓	-	-
	■ Catecholamines	✓	-	-
	■ Short acting drugs	✓	-	-
	■ Anesthesia drugs	✓	-	✓
	■ Diluted drugs	✓	-	-
	■ Other diluted IV drugs	✓	-	-
	■ Epidural associated drugs	-	-	✓
Parenteral fluids	■ Standard solutions	✓	-	-
	■ Colloids	✓	-	-
	■ Parenteral nutrition	✓	-	-
Blood and blood derivatives	■ Blood	✓	-	-
	■ Red blood cells	✓	-	-
	■ Platelets	✓	-	-
	■ Plasma	✓	-	-
	■ Albumin	✓	-	-

When using Agilia SP PCA to infuse critical medications, ensure that backup pumps and syringes are available for immediate use.

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

Do not use the pump for enteral nutrition.



WARNING

- Administration of drugs indicated for epidural use in other routes than epidural could result in serious injury to the patient.
- Administration of drugs other than those indicated for epidural use through the epidural route could result in serious injury to the patient.

Administration Routes

The system allows infusion via the following access routes:

- Intravascular access with any device that administers a medical fluid and is equipped with a female Luer lock,
- Epidural access (use of NRFit® connector is recommended),
- Subcutaneous access.

1.4.2 Contraindications

The use of the Agilia SP PCA infusion pump for PCA/PCEA therapies requiring the patient handset is contraindicated for neonates, and for patients that have physical or mental disabilities to handle the handset.

1.4.3 Intended Users

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

In PCA and PCEA therapies, the bolus function with the handset can be used safely by patients, who must have the proper physical and mental abilities and have received appropriate training and instructions from the clinical staff.

The typical initial training duration for healthcare professionals is:

- 1 hour for the PCA interface.
- 1 hour for general infusion.

It is recommended that healthcare professionals attend a refresher training session of about 30 minutes every year.

For training, contact your Fresenius Kabi sales representative.

1.4.4 Intended Patients

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

	Patient Characteristics	
	PCA therapy	General infusion
Sex	Male / Female	
Age	Young pediatric patients / Adults / Elderly	Neonates / Young pediatric patients / 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

The Agilia SP PCA infusion pump 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 Agilia pumps in the following environments:

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



WARNING

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

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

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



INFORMATION

For more information on using the device in specific conditions, contact your Fresenius Kabi sales 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 benefit of Agilia SP PCA specifically related to PCA/PCEA therapies is the following:

- Allowing the patient to self-administer doses of analgesia using a lockable infusion pump programmed by the healthcare professional and equipped with appropriate functions and safety features (different PCA infusion modes: PCA bolus only mode, continuous mode, PCA bolus + continuous rate mode and PCA bolus + variable rate mode; clinician bolus function; patient handset; programming of lock-out time and cumulated limits; PCA history function to provide infusion data on PCA treatment received by the patient; compatibility with Dose Error Reduction Software [DERS]; protective cover and locking mechanisms; dedicated alarms compliant with EN/IEC 60601-1-8).

Other clinical benefits of Agilia SP PCA 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).
- Prevent infusion-related medication errors (with the use of up-to-date Dose Error Reduction Software [DERS] configured in line with policy/clinical practice of each healthcare facility).

1.6 Side-effects

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

1.7 Risks for patients

Failure to follow all instructions described in this document or loss or degradation of essential performance (*Essential Features* on page 130) may result in: over-delivery, under-delivery, delay of therapy, incorrect therapy, exsanguination, biological/chemical contamination, undetected air infused to patient, traumatic injuries or electrification.

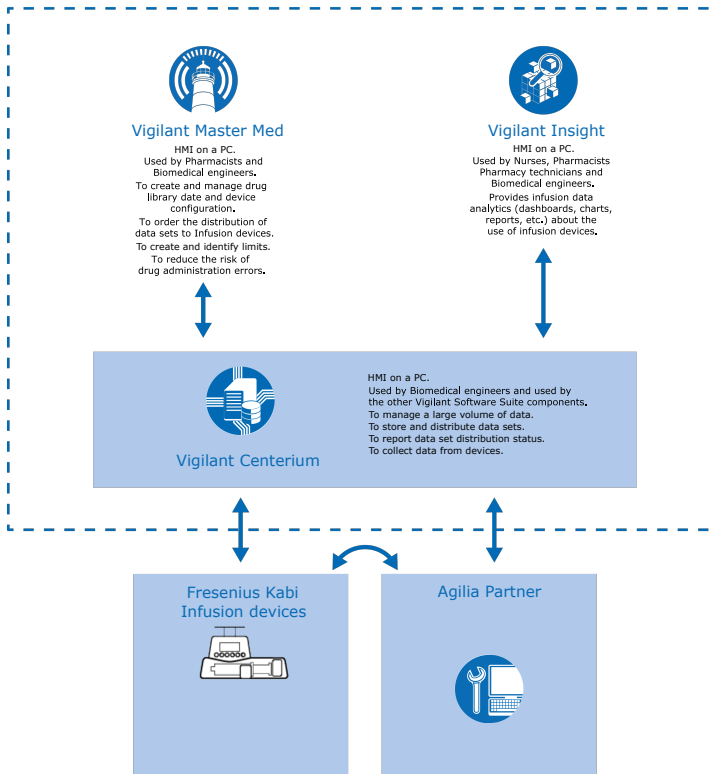
1.8 Cybersecurity Safety considerations

1.8.1 Agilia SP Infusion System

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



Vigilant Software Suite



1.8.2 Cybersecurity Recommendations

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

WARNING

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

- Your premises are secured.
- The device is installed within a secure network perimeter to prevent TCP/IP network access from unauthorized external system(s).
- When not in use, the Agilia SP PCA WiFi pump is securely stored.
- When not in use, the Agilia SP PCA WiFi Serial or USB Cables are disconnected and securely stored.
- Secure storage access is restricted to authorized personal only.
- The latest version of the device firmware is installed.
- The device passwords and access codes are changed from their default values. Refer to Technical Manual.
- The Agilia SP PCA WiFi pump shall enforce the usage of secure communications protocol for TCP/IP data flows exchanged with Vigilant Software Suite. Ensure WPA2



and HTTPS are configured on the Wifi module using Agilia Partner Maintenance Software.

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

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

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

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

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

2 Agilia Connect Infusion System

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

Agilia range		Description
Accessories	Link Agilia Agilia Link Link+ Agilia	Stacking Rack Systems Rack systems designed to stack 4, 6 or 8 Agilia infusion pumps. The Link Agilia / Agilia Link devices are designed to centralize the power supply. The Link+ Agilia device is designed to centralize the power supply and to centrally replicate infusion pump signalling.
	Agilia MRI Guard	MRI-Shielding System The Agilia MRI Guard accessory is intended to accommodate and power up to four Agilia infusion pumps so that these pumps can be operated in a Magnetic Resonance Imaging unit.
	Agilia Duo	Two-channel accessory The Agilia Duo accessory is intended to centralize mains power for two attached Agilia pumps.
Disposables	Syringes	See <i>Syringes</i> on page 126.



INFORMATION

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



INFORMATION

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

3 Description

3.1 Front View

This section shows the Agilia SP PCA pump with the cover closed and with the cover open.

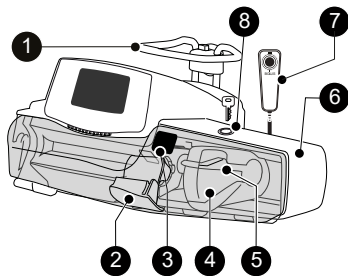


Figure 1: Front view with cover closed

Legend

- | | |
|------------------------|-----------------------|
| ① Handle | ⑤ Disengagement Lever |
| ② Syringe Barrel Clasp | ⑥ Syringe Guard |
| ③ Cover clasp | ⑦ Patient handset |
| ④ Plunger Driver | ⑧ Cover lock |
-

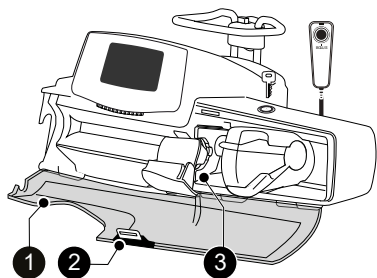


Figure 2: Front view with cover open

Legend

- | | |
|--------------------------|-------------------------|
| ① Clear protective cover | ③ Syringe flange cradle |
| ② Cover clasp | |
-

3.2 Back View

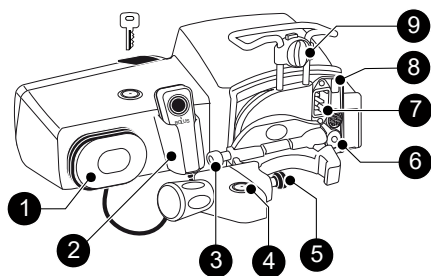


Figure 3: Back View

Legend	
1	Cord stowage
2	Patient handset and holder
3	Release button
4	Pole clamp lock
5	Rotating pole clamp
6	RS232 communication port
7	Power cord inlet
8	Infrared cell
9	Attachment lock knob

Symbol	Location	Description
 	Near Power Cord Inlet	Warning See <i>Technical Characteristics</i> on page 142.
	Near RS232 Communication Port	Warning See <i>Data Communication</i> on page 113.

3.3 Bottom View (Device Identification Label)

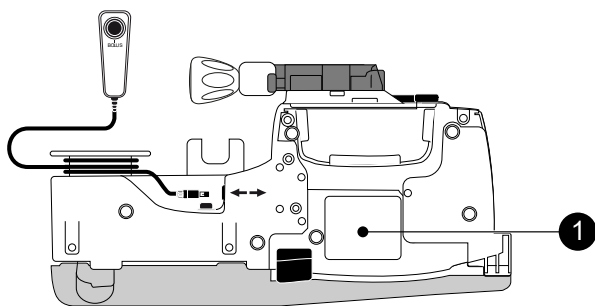


Figure 4: Bottom View

Legend

- ① Device Identification Label
-

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



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

For more information on device identification label symbols, see *Symbols Description* on page 2.

3.4 Patient Handset

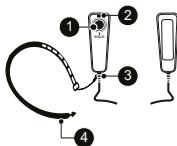


Figure 5: Patient handset and wrist strap

Legend

- | | |
|--|---------------|
| ① Bolus start button | ③ Cable gland |
| ② Blue LED on when patient handset is connected to pump (stays lit at all times to enable patient to locate handset) | ④ Wrist strap |
-

3.5 Keypad Description

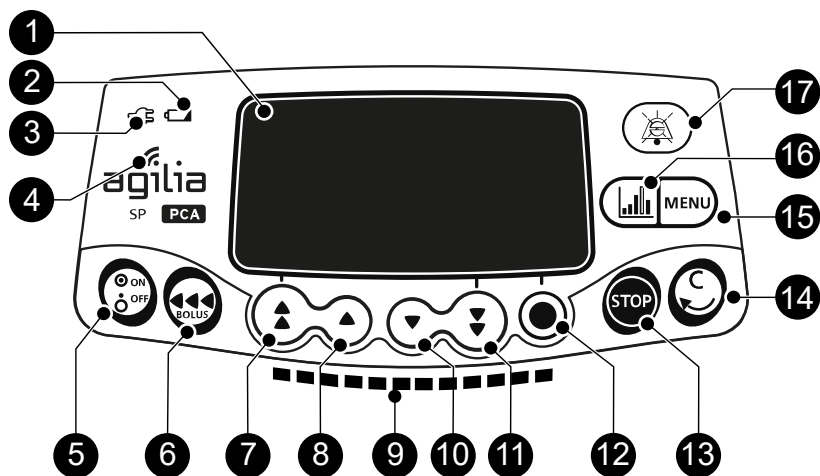


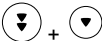
Figure 6: Keypad description

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

3.5.1 Keypad Details

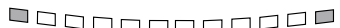
3.5.1.1 Selection Keys

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

Key	Description
	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.

3.5.1.2 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.
- Low and medium priority yellow lights can be combined with green flashing lights, which indicates infusion is still running.
- The frequency of flashing varies according to flow rate.

3.5.1.3 Status Indicators

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

3.6 Display and Symbols

3.6.1 Infusion Status

Symbol	Description
	Infusion in Progress (Basic Profile + Custom Profiles with a drug list) Symbols for infusion in progress.
	Infusion in progress (custom profiles with a drug library) Animated symbol displayed when the pump is infusing a drug from a drug library.

Symbol	Description
STOPPED	Infusion Stopped STOPPED remains in the center of the screen until the user starts the infusion again.

3.6.2 Screen Options

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

3.6.3 Navigation Buttons

Symbol	Description
	Start
	End
	Confirm
	Access function

Symbol	Description
	Access function and clear settings
	Exit function
	Change selection
	Program function
	Select / Deselect
	Review PCA settings
	Edit settings
	Move to the previous step/screen
	Move to the next step/screen
	Move to the previous screen
	See more information
	Zoom in / Zoom out
	Move the event marker to the left / right

3.6.4 Alarms and Safety Features

Symbol	Description
	Power disconnection
	Alarm silenced
	Pressure increase
	Drop in pressure

NOTE: For more information on alarms, see *Alarms and Safety Features* on page 116.

3.6.5 Infusion Features

Symbol	Description
	PCA therapy Displayed when programming PCA infusion or during PCA infusion.
	PCA bolus+continuous mode Displayed when PCA therapy includes PCA boluses and a continuous rate.
	Continuous only mode (in PCA therapy) Displayed when the PCA therapy includes a continuous rate only.
	PCA bolus only mode Displayed when the PCA therapy includes PCA boluses only.
	PCA bolus+variable rates mode Displayed when PCA therapy includes PCA boluses and variable infusion rates.
	Loading dose (PCA therapy) Displayed when programming or during infusion of a PCA loading dose.
	Programming mode (general infusion) Displayed when selecting the programming mode for a general infusion.
	Loading dose (general infusion) Displayed when programming a loading dose.
	Clinician bolus (PCA therapy) Displayed when programming or during infusion of a clinician bolus.

3.6.6 Data Communication

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

3.7 Packaging

Depending on your country, the packaging contents of the Agilia SP PCA infusion pump is different:

	Agilia SP PCA pump	Instructions For Use	System Components booklet	User information document (multilingual)	Power cord
Z0201XX	✓	✓	✓	-	✓
Z020101*	✓	-	-	✓	-

* Product codes ending by 01 are for the multi-country versions.

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

Packaging weight: Approximately 515 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 Definitions of Terms Used in PCA Therapy

PCA or Patient Controlled Analgesia

Refers to administration of an analgesic through the IV route (or SC route) by the patient using a special device.

PCEA or Patient Controlled Epidural Analgesia

Consists in the maintenance of an epidural analgesia by the patient himself, thanks to a pump equipped with a patient handset.

CEI or Continuous Epidural Infusion

Consists in a continuous infusion through the epidural route of administration.

Patient handset

The Agilia SP PCA pump is equipped with a patient handset connected to the pump, intended for the patient to use to trigger a PCA bolus.

Also called patient pendant, patient handset, bolus handle, dose request cord.

PCA bolus

Refers to a dose of analgesic prescribed and programmed by the clinician, that the patient can self-administer outside of the lockout time using the patient handset connected to the pump.

Also called patient bolus, demand bolus, bolus dose, PCA dose, incremental dose.

Lockout time

Time interval programmed by the clinician and activated by a bolus, during which the pump cannot administer a PCA bolus. The lockout time starts from the end of the bolus up until the beginning of the next authorized bolus.

Also called lockout interval, PCA lockout, PCA time interval.

Clinician bolus

Refers to a dose of drug administered by the pump, that can be allowed inside or outside the lockout time.

Loading dose

Refers to a bolus of analgesic administered before starting the PCA cycle to test the patient's reaction, sometimes also called "titration", "test dose" or "initial bolus". The loading dose can be repeated to obtain pain relief.

Continuous rate

Refers to the continuous infusion (flow rate or dose rate) of analgesic that can be programmed by the clinician, and administered to the patient during the PCA cycle.

Also called basal rate, continuous delivery rate, continuous infusion, background infusion.

Variable rates

Refers to continuous infusions of analgesic that can be programmed to start at different times of the day with a different rate for each one. The clinician can program up to three infusion rates (in volume or dose) to be administered daily to the patient.

Cumulated limits

Refer to the maximum amount of drug, programmed by the clinician, that can be administered to the patient over a rolling period of time. This maximum amount can be specified in terms of total dose or of number of boluses. The cumulated limits are calculated and updated by taking into account all doses administered: the PCA boluses, the continuous infusion, the clinician boluses, but not the loading dose.

DERS or Dose Error Reduction Software

Dose error reduction software is used to create drug definitions and pump configurations. By defining limits on parameters such as drug concentration, maximum dose, pressure limits or even disabling certain functions, the DERS reduces the potential for human error.

The Agilia SP PCA pump is designed to interface with a DERS to offer a selection of profiles and drug names. The clinician can select a drug and adjust the infusion parameters only within the limits defined by the DERS.

4.2 PCA Modes

A PCA infusion can be programmed with one of the following modes:

- PCA bolus, see *PCA Bolus Only Mode* on page 27
- Continuous rate, see *Continuous Rate Only Mode* on page 28
- PCA bolus + continuous rate, see *PCA Bolus + Continuous Mode* on page 28
- PCA bolus + variable rate, see *PCA Bolus + Variable Rates Mode* on page 29



INFORMATION

- In all PCA modes, it is possible to program cumulated safety limits on the maximum dose and the maximum number of boluses.
- In all PCA modes, the clinician can administer a bolus, including during lockout periods, as explained in *Administering a Clinician Bolus* on page 66.

4.2.1 PCA Bolus Only Mode

The clinician programs the allowed PCA bolus, and specifies the lockout time and the cumulated dose limits. The patient can self-administer a bolus outside of the lockout time as shown below. The clinician can administer a bolus at any time.

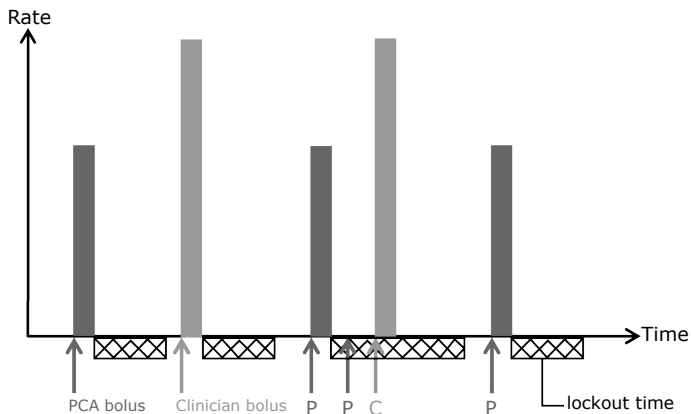


Figure 7: PCA bolus infusion mode

4.2.2 Continuous Rate Only Mode

The clinician programs a continuous only infusion rate and specifies the cumulated limits. In addition, the clinician can initiate a bolus at any time, but the patient cannot self-administer boluses, as shown below.

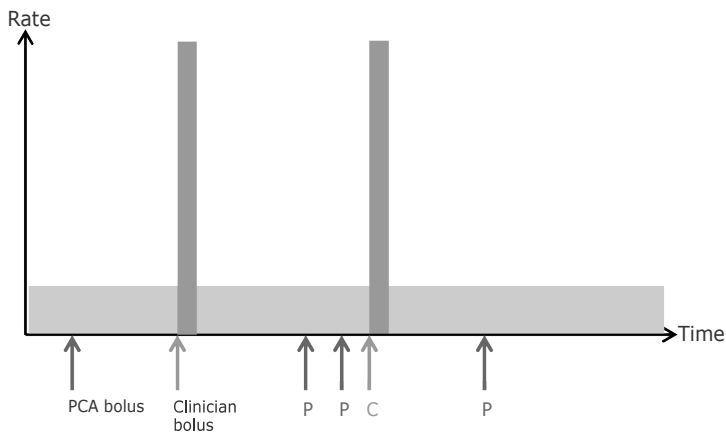


Figure 8: Continuous rate infusion mode

4.2.3 PCA Bolus + Continuous Mode

The clinician programs the allowed PCA bolus in volume or dose, a continuous infusion rate, and the cumulated limits.

The patient can self-administer a bolus outside of the lockout time, as shown below. The clinician can administer a bolus at any time.

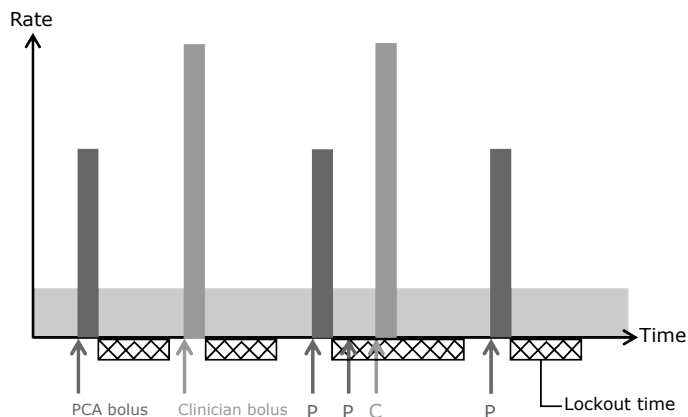


Figure 9: PCA bolus + continuous infusion mode

4.2.4 PCA Bolus + Variable Rates Mode

The clinician programs up to three different continuous flow rates or dose rates to start at specified times of the day over a 24 hour period. The clinician also programs the PCA bolus, and the lockout time.

The patient can self-administer a bolus outside of the lockout time as shown below. The clinician can administer a bolus at any time.

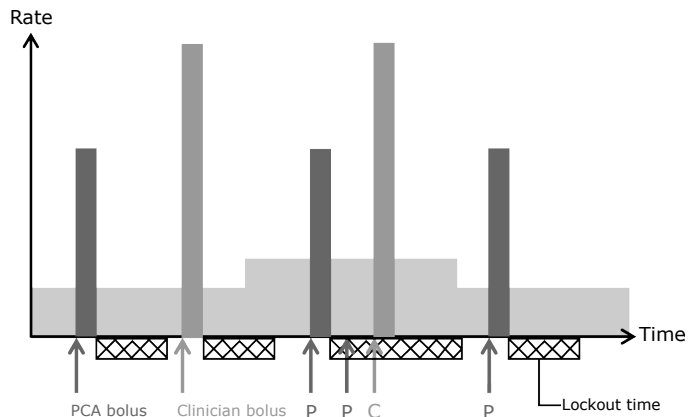


Figure 10: PCA bolus + variable rate mode

4.3 General Infusion Modes

A general infusion can be programmed with one of the following modes:

Infusion Mode	Description
Simple Rate	Infusion with a programmed flow rate (mL/h) or dose rate (for example, mg/h, microg/kg/min) of the full contents of the syringe.
Volume / Time Dose / Time	Infusion of a programmed volume (mL) or dose (for example mg, microg/kg) over a programmed period of time. The flow rate or dose rate is automatically computed.
Rate + Volume Limit	Infusion with a programmed flow rate (mL/h) or dose rate (for example, mg/h, microg/kg/min) with a limitation on the volume or dose to be infused.

4.4 DERS Interface

This section explains the functions implemented in the pump so that it can interface with drug error reduction software (DERS).

4.4.1 Profiles

You can program the pump using the Basic Profile provided, or a custom profile.

Custom Profiles

Custom profiles can be created and uploaded to the pump using a compatible DERS. A custom profile contains the following:

- A specific device configuration that controls mechanical functions such as alarm volume, or pressure limits.
- A drug library (a set of drug entries with limits on infusion parameters) or drug list (a list of drugs without limits on infusion parameters).

INFORMATION



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

INFORMATION



When used for epidural analgesia, the Agilia SP PCA pump should be configured specifically for epidural analgesia only, with a dedicated custom profile.

Basic Profile

The pump is delivered with one default profile called Basic Profile. Basic Profile does not include a drug list or drug library.

Basic Profile has the following characteristics:

- All infusion settings are to be defined.
- DERS safeguards are unavailable:
 - The infusion is programmed without a drug name.
 - There are no limits on drug infusion parameters.

It is the caregiver's responsibility to adapt the pump configuration and infusion settings available in Basic Profile to the patient and to the protocol.

4.4.2 Drug Libraries

A drug library is a list of drug entries that include limits on drug infusion parameters. It can include drugs intended for PCA therapy and drugs intended for general infusion.



INFORMATION

- Each drug library can support a number of drug entries that are defined and validated by healthcare professionals in accordance with the protocols used at the healthcare facility and/or ward level.
- Drug settings may be adjusted on the pump within pre-defined programming limits, such as dose limits.
- Infusion modes defined in a custom drug entry are not adjustable on the pump.

4.4.3 Drug Lists

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

4.4.4 Drug Entries

Drug entries created in a DERS specify a number of parameters and values. Some parameters are mandatory. They are summarized in the table below.

Parameters	PCA	General infusion
Drug name	Value to be provided (no default value)	
Type of therapy	PCA infusion	General infusion
Drug concentration	Value to be provided for infusions programmed in dose rate	
Infusion mode	PCA bolus only Continuous only PCA bolus + continuous PCA bolus + variable	Simple rate Volume/Time Dose/Time Rate + Volume Limit
Prescription unit / Infusion rate	Volume or Dose	Flow rate or dose rate
Limits on dose selection or flow rate	Hard limits and soft limits (minimum and maximum values) on a range of values or on finite values	
PCA limits	Values to be provided for a single PCA bolus and cumulated limits	N/A

There is a special entry called Drug X that has no predefined parameters, see *Drug X* on page 32.

Hard Limits and Soft Limits

Programming limits can be set on flow rate or on drug concentration for each drug within a drug library. Two types of limits can be set:

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

The limits can define a range or finite values, as shown in the illustrations below.

Authorized Range



Authorized Finite Values



Legend

	Unauthorized range		Hard limits
	Programmable range		Soft limits
	Authorized range		Finite values
	Default value		

Limits for PCA therapy

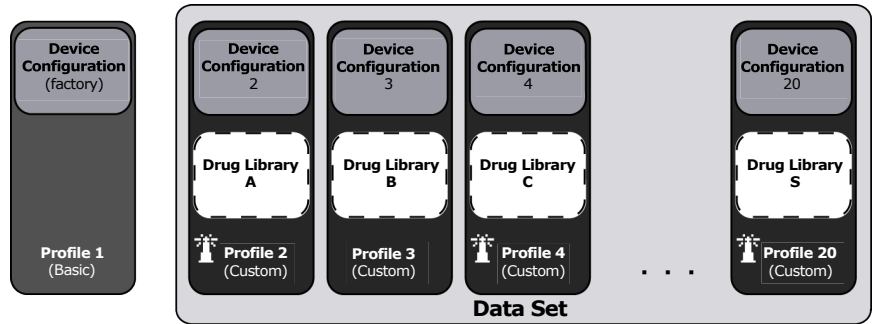
- In PCA therapy, in addition to the limits on flow rate and dose rate, it is possible to impose limits on PCA specific parameters:
- Limits on PCA bolus: hard and soft limits on volume or dose infused in a single bolus, minimum and maximum lockout time.
 - Cumulated limits: maximum number of boluses, and/or maximum dose assessed over a specified period of time.

4.4.5 Drug X

- Drug X entries with a flow rate or dose rate are open entries that can be selected if the intended drug is not found in the drug library. Their characteristics are:
- Fewer limits than the other drugs in the library.
 - No safeguards imposed by a DERS.
- It is strongly recommended to use Drug X entries in a limited number of clinical cases and under close patient monitoring by the clinical staff. In each custom profile, the healthcare facility can enable or disable Drug X entries.

4.4.6 Data Set

A data set is a combination of custom profiles that can be uploaded to the pump. A pump can manage up to 20 profiles: 1 Basic Profile and up to 19 custom profiles.

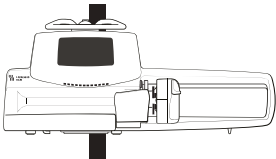
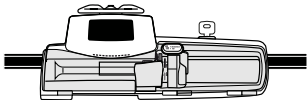
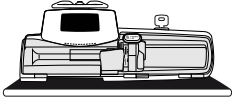
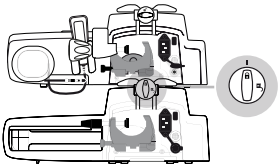
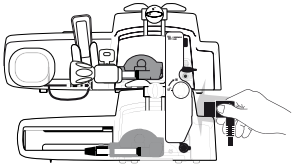


If there is no data set uploaded to the pump, the pump can be used with the Basic Profile.

5 Installation

5.1 Types of Installations

A pump can be installed on any of the following:

Location		Comments
On a Pole		■ See <i>Attaching to a Pole</i> on page 35. Pole specifications: ■ Diameter: from 0.6 to 1.6 in (15 to 40 mm)
On a Rail		■ See <i>Attaching to a Rail</i> on page 36. Rail specifications: ■ Height: from 1.0 to 1.4 in (25 to 35 mm) ■ Depth: from 0.3 to 0.4 in (8 to 10 mm)
On the Agilia Link Rack		■ Refer to the Agilia Link accompanying documents.
On a Table		■ See <i>Setting up on a Flat Surface</i> on page 36. Only install a pump on a table if it is not possible to attach it to a pole, a rail or recommended Agilia accessory.
On Another Pump		■ See <i>Attaching Several Pumps Together</i> on page 36.
On an Agilia Duo		■ Refer to the Agilia Duo accompanying documents.



WARNING

- The pump must be used in a horizontal and stable position to function properly.
- Use recommended Agilia accessories to ensure stability and prevent the pump from falling. Do not stack the pump with equipment other than those recommended.
- If Agilia devices or accessories appear damaged, stop using them and send them for maintenance instead.



INFORMATION

Connect the patient handset to the pump before stacking the pump on another pump or in an Agilia Link rack or Agilia Duo because the handset connector is placed under the pump.

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.

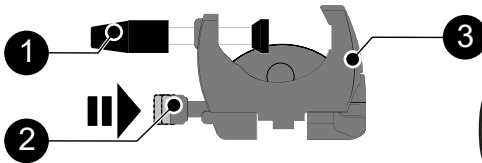


Figure 11: Rotating Pole Clamp System - Pole clamp folded up

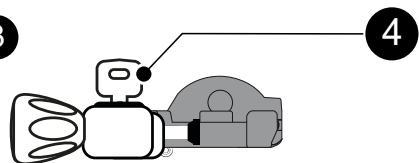


Figure 12: Rotating Pole Clamp System - Pole clamp folded out

Legend

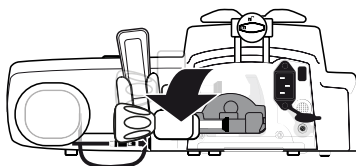
- | | |
|------------------|-----------------------|
| 1 Screw clamp | 3 Rotating pole clamp |
| 2 Release button | 4 Lock on screw clamp |

You can secure the rotating pole clamp vertically or horizontally by folding it outward until the release button clicks into the locked position as shown in *Folding the Clamp Down (outward)* on page 34, *Folding the Clamp Up (inward toward the pump)* on page 34 and *Rotating the Clamp* on page 35.

5.2.1 Folding the Clamp Down (outward)

You can fold the clamp down as follows:

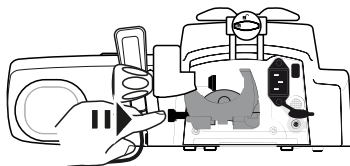
1. Push the release button.
2. Fold the clamp outward.



5.2.2 Folding the Clamp Up (inward toward the pump)

You can fold the clamp up as follows:

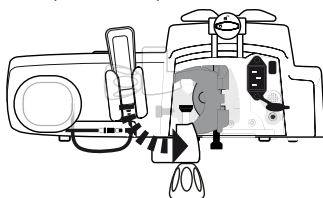
1. Push the release button.
2. Fold the pole clamp inward toward the pump.



5.2.3 Rotating the Clamp

You can rotate the clamp as follows:

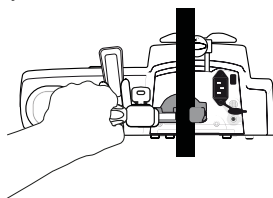
1. Fold the clamp up (see above).
2. Rotate the clamp to a vertical position.
3. If necessary, fold the clamp outward (see above).



5.3 Attaching the Pump

5.3.1 Attaching to a Pole

1. Fold the pole clamp down to the horizontal position: see *Folding the Clamp Down (outward)* on page 34.
2. Unscrew the clamp, attach to the pole, and screw the clamp until the pump is firmly secured to the pole.
3. Make sure that the pump is securely attached.



4. Lock the clamp and remove the key.



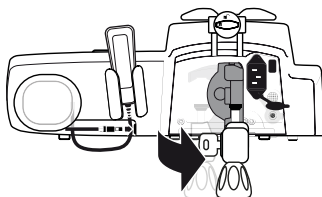
CAUTION

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

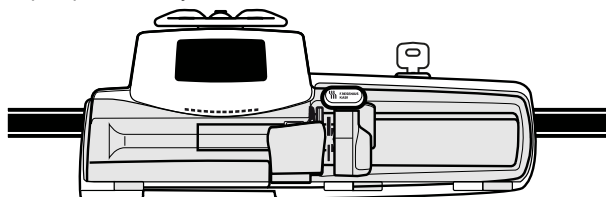
5.3.2 Attaching to a Rail

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

1. Rotate the pole clamp to the vertical position: see *Rotating the Clamp* on page 35.
2. Unscrew the clamp, attach to the rail, and screw the clamp until pump is fully secured to the rail.



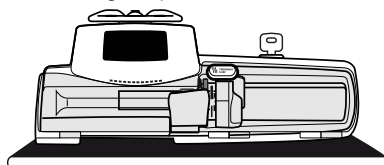
3. Make sure that the pump is securely attached.



4. Lock the clamp and remove the key.

5.3.3 Setting up on a Flat Surface

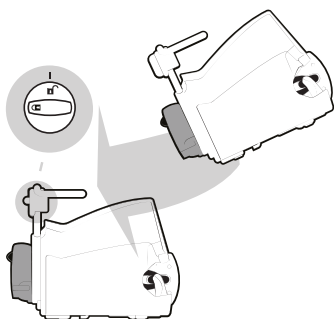
1. Fold the pole clamp up: see *Folding the Clamp Up (inward toward the pump)* on page 34.
2. Place the pump far enough from the edge to prevent it from accidentally being pushed off.



5.3.4 Attaching Several Pumps Together

You can attach up to three pumps together, for transport or to fix them to a pole.

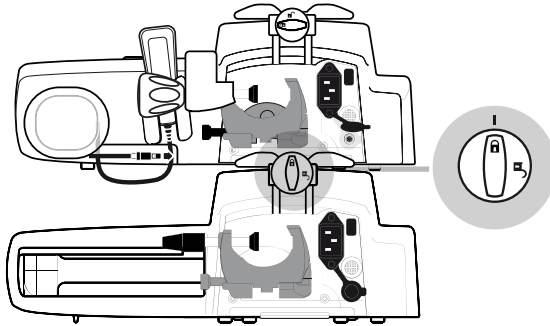
1. Fold both pumps' pole clamps up: see *Folding the Clamp Up (inward toward the pump)* on page 34.
2. Slide the slot on the bottom of the upper pump onto the handle of the lower pump.



3. Turn the attachment lock knob on the lower pump handle clockwise until the locked symbol lines up with the marker.

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

4. Make sure the pumps are securely attached together. Repeat steps 1 to 3 to attach a third pump to the other two.
5. If needed, fold the pole clamps down and secure them tightly to the pole.

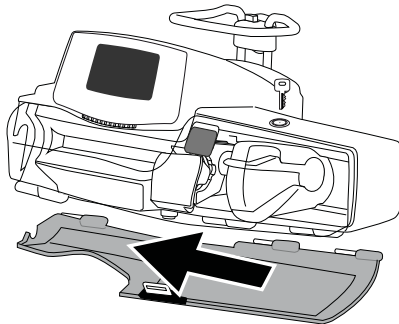


6. Lock the pole clamp on the Agilia SP PCA pump and remove the key.

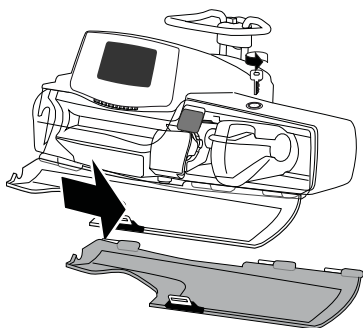
5.4 Installing and Removing the Protective Cover

The protective cover is recommended for PCA therapy but not mandatory.

1. Place the hinges of the protective cover opposite the holders on the pump casing.
2. Slide the cover to the left until it clicks into place.

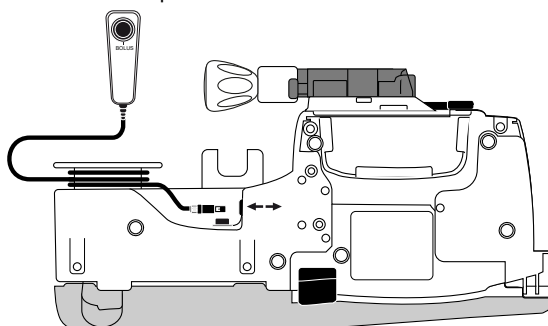


3. To remove the protective cover, unlock it to open it, then slide it to the right to unhinge it.



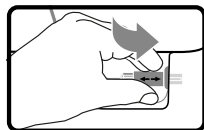
5.5 Connecting and Disconnecting the Patient Handset

1. Plug the handset into the connector placed under the handset holder.

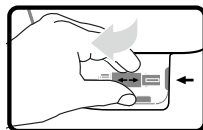
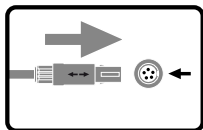


The connector is keyed. You will feel and hear it click into place when properly connected and a beep will be emitted. When the pump is on, a LED placed above the bolus button lights up.

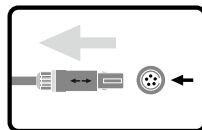
2. To disconnect the handset, hold the connector by the plastic ring.



Connection



Disconnection



Do not attempt to pull the cord, you will damage the connector.



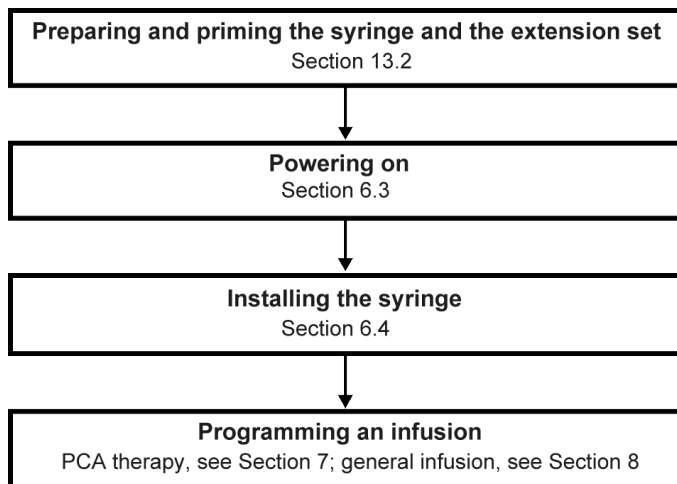
INFORMATION

- To ensure proper operation, use only the Fresenius Kabi patient handset provided with the pump.
- Do not connect or disconnect the patient handset after starting an infusion.

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 *Installation* on page 33.
2. Plug the pump into the AC power supply. See *AC Power Supply Precautions* on page 141.
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 *Powering on* on page 39.
5. Install a syringe into the pump. See *Installing a Syringe* on page 41.
6. Make sure the patient handset is connected and the protective cover is in place if you intend to use the pump for PCA therapy. See *Installing and Removing the Protective Cover* on page 37.

6.3 Powering on



CAUTION

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



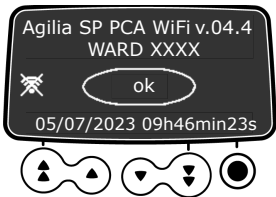
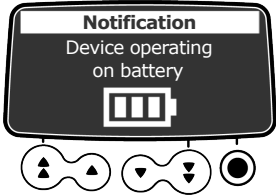
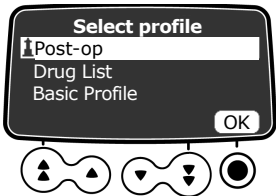
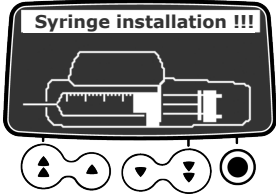
INFORMATION

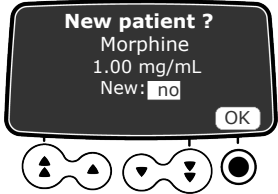
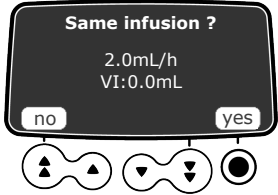
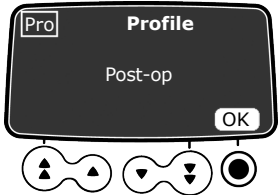
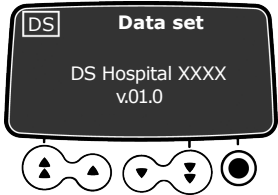
- When the pump is connected to the power supply, check that the power supply indicator  lights up green, and that the power cord and the wall plug are accessible.

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

Screen After Powering on	Description
	Startup screen: the following information is displayed: ■ Product name / Ward name ■ Date & time
	■ Displayed if the pump is operating on battery. ■ The symbol shows three different charge levels: –  < 30% battery charge –  30% - 70% battery charge –  > 70% battery charge
	■ Profile selection screen displayed if several profiles are available.
	■ No syringe is installed on the pump. ■ Syringe installation !!! is displayed on top of the screen.  Install a syringe. See <i>Installing a Syringe</i> on page 41.

Screen After Powering on	Description
	■ Maintenance reminder message (optional).
	■ New patient screen (in PCA therapy, optional). Select yes to clear the previous infusion settings, including the PCA history.
	■ Same infusion screen (in general infusion therapy, optional). Press  to select yes in order to keep the previous infusion settings.
	■ Profile confirmation screen (optional). Press  to select OK in order to confirm the profile. NOTE: This screen is associated with the "New patient" function above.
	■ Data Set information (optional)

5. Check that the device is parametrized as expected.

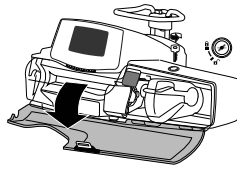
6.4 Installing a Syringe



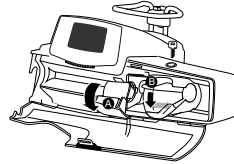
WARNING

Installing the syringe with the patient connected may induce a free flow or a bolus when installing the syringe.

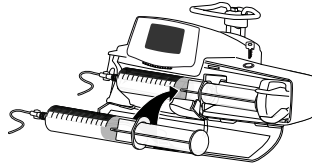
1. Unlock the pump cover to open the cover.



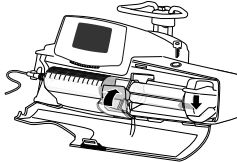
2. Open the syringe barrel clasp [A].
3. Push the disengagement lever [B] down and move the plunger driver to the right.



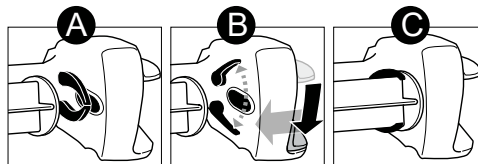
4. Place the syringe in its cradle, with the flanges correctly inserted in the provided slot.



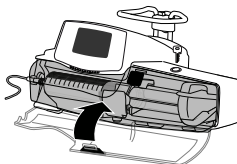
5. Secure the syringe with the syringe barrel clasp [A].



6. Push the disengagement lever [B] and move the plunger driver gently to the left until it is in contact with the plunger head.



7. Close the cover by pushing it until you feel and hear it click into place.
8. Remove the key and keep it in a safe place.
9. Check the general installation.





INFORMATION

- Do not use the syringe pump for PCA therapy if the cover is damaged. Using the pump without the protective cover or with a damaged cover would not allow security of medication syringe. The cover must be changed if it is damaged.
- The protective cover is recommended for PCA therapy but not mandatory. The pump's behavior in relation with the protective cover can be configured in the pump options.

6.5 Pump Height



WARNING

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



CAUTION

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

Precautions for pump position



CAUTION

- If multiple syringe pumps are used and it is not clinically feasible to position all of them at the same level as the distal tip of the catheter (or the fluid delivery site), prioritize placing high-risk or life-sustaining medications as close as possible to the distal tip of the catheter. When infusing several high-risk or life-sustaining medications, consider positioning the ones infusing at the lowest flow rates as close as possible to the level of the distal tip of the catheter.
- Minimize the height difference between the pump and the patient and avoid changes in the height of the pump (example: during transport of critically ill patients) to prevent unintended fluctuations in the flow rate.

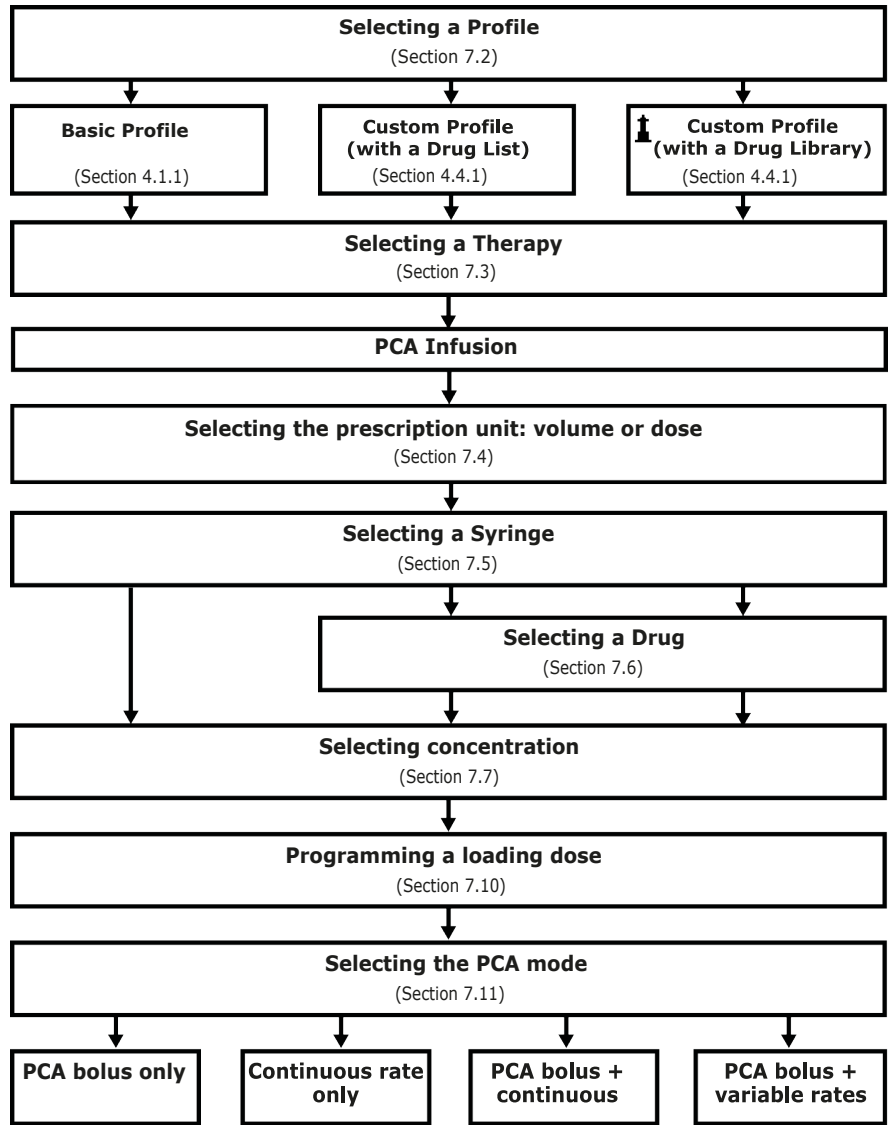
During the infusion, if the infusion pump is moved 1 m above the patient, a bolus (up to 0.35 mL) may occur. If the infusion pump is moved 1 m below the patient, an under-infusion (up to 0.05 mL) may occur.

7 Programming a PCA Infusion

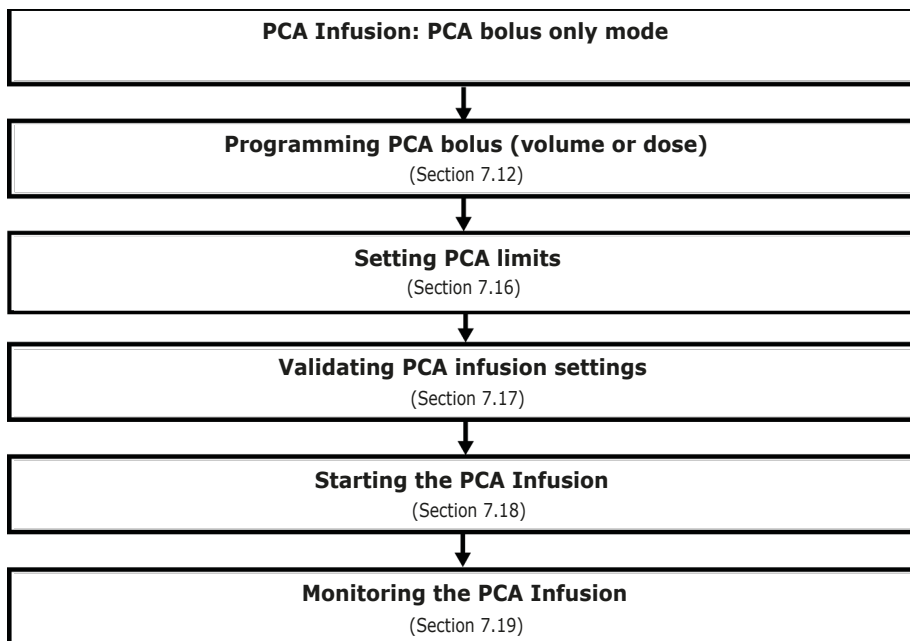
This section explains how to program a PCA infusion with the Agilia SP PCA infusion pump.

7.1 PCA Infusion Flowcharts

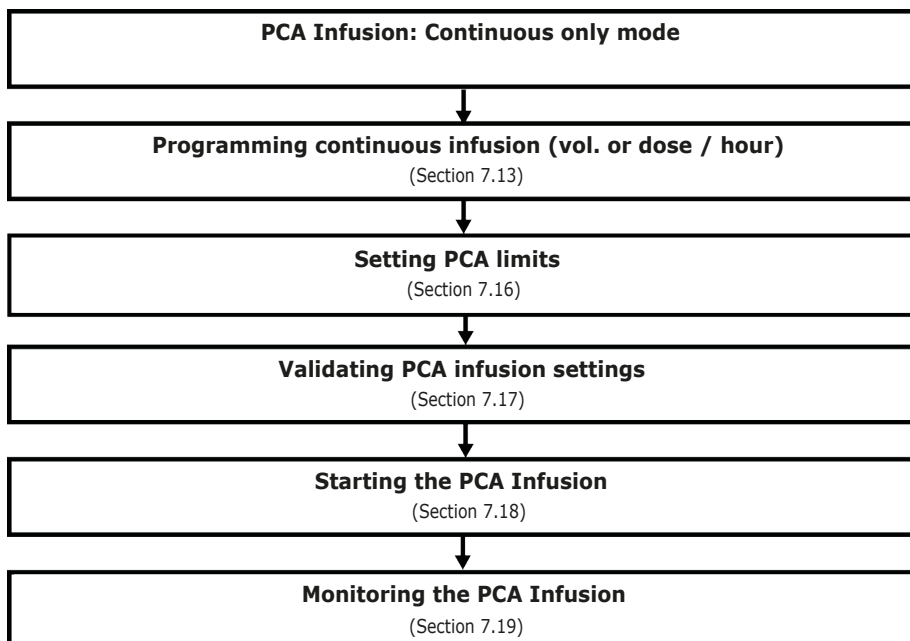
The following flowchart shows the steps to follow for all PCA modes.



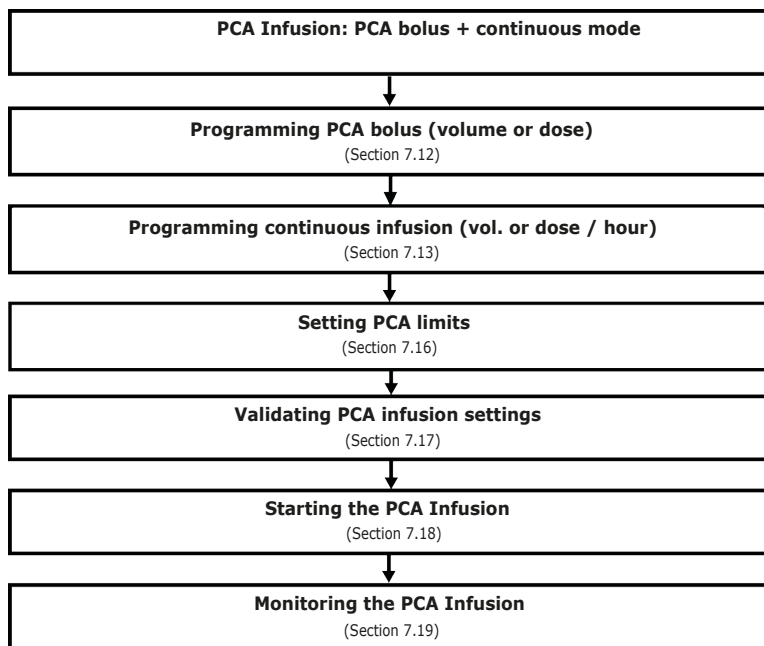
7.1.1 Programming PCA Infusion in PCA Bolus Only Mode



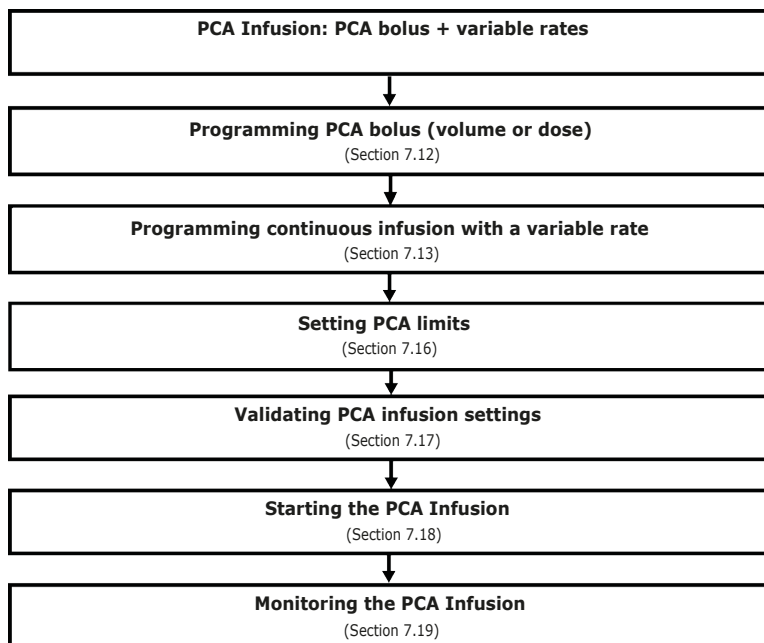
7.1.2 Programming PCA Infusion in Continuous Only Mode



7.1.3 Programming PCA Infusion in PCA Bolus + Continuous Mode



7.1.4 Programming PCA Infusion in PCA Bolus+Variable Rates Mode

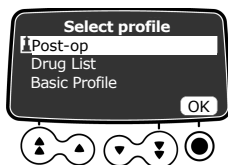


7.2 Selecting a Profile

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

You can switch to another a profile without turning off the pump. See *Profile* on page 90.

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



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



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

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

The selected profile information is displayed.



4. Press  to select **OK** in order to confirm the drug library version, or press the arrow key to select  to change the profile.

The drug library is loaded for the profile selected.

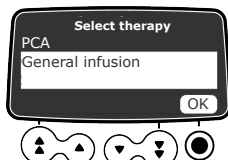
7.3 Selecting a Therapy

After selecting Basic Profile, the programming interface can take you to the **Select therapy** screen where you must choose between:

- PCA,
- General infusion.

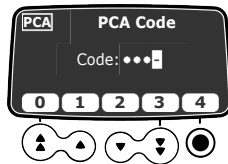
NOTE: By default, this choice is disabled in the pump configuration and this screen is not displayed. You must enter the PCA code as explained below to continue.

1. Press the arrow keys to select the therapy you want for the patient, and press  to select **OK**.



If you select **PCA**, you must enter a passcode in the following screen displayed.

2. Enter the 4-digit passcode using the keys below the numbers on the screen.



7.4 Selecting the Prescription Unit (Volume / Dose)

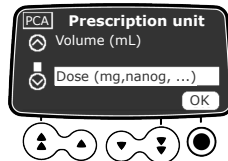
After selecting PCA therapy, the **Prescription unit** screen is displayed.

NOTE:

This screen is not displayed if you previously selected a custom profile, because the prescription unit is pre-defined.

- ➡ Use the arrow keys to select the prescription unit, and press the  key to select **OK** in order to confirm.

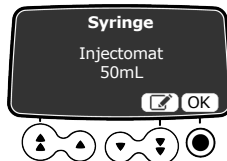
The example in this chapter shows how to program a PCA infusion in dose.



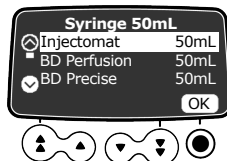
The syringe selection screen is displayed.

7.5 Selecting a Syringe

After selecting the prescription unit, the screen displays the syringe type installed in the pump. You must make sure the display is correct.



1. Press  to select **OK** to confirm the displayed syringe, or the arrow key to select  in order to change it.



2. If you have chosen to select another syringe, press the arrow keys to select a new syringe.
3. Press  to select **OK** in order to confirm the new syringe.
A clinical advisory message may appear, if one is configured for the selected syringe.
4. Press  to select **OK** to acknowledge the clinical advisory message, or the arrow key to select  in order to return to the syringe selection screen.

When you choose **OK**, the drug selection screen is displayed.



WARNING

When installing the syringe and programming the infusion, ensure that the syringe size and model displayed on Agilia pump matches the one loaded in the pump. If you can't find the appropriate syringe, contact your biomedical department or your Fresenius Kabi representative. Use of incompatible syringes can cause improper pump operation resulting in inaccurate fluid delivery, insufficient occlusion sensing, and other potential problems that can injure the patient.

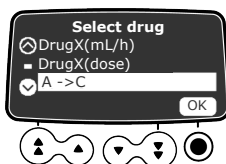
7.6 Selecting a Drug

After you confirm the syringe type, the screen displays a drug selection menu.

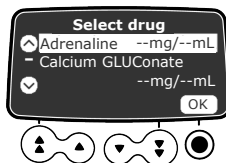
NOTE: This screen is not displayed if you previously selected the Basic Profile that does not offer a pre-defined drug list.

Drug names are sorted alphabetically with Drug X displayed at the top of the list:

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

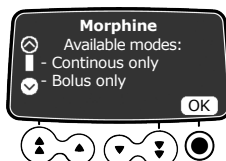


1. Use the arrow keys to scroll to the first letter of the drug name you want, and press **OK**.



A list of drugs is displayed.

2. Press the arrow keys to scroll to the drug's name, and press  to select **OK**.
A clinical advisory message may appear, if configured for the selected drug. See next step. If not, the **Concentration** screen is displayed.
3. Press  to select **OK** to acknowledge the clinical advisory message and continue programming, or press the  key to change the drug.
When you choose **OK**, the **Concentration** screen is displayed.



7.7 Selecting Drug Concentration

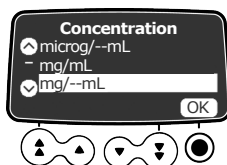
If the prescription unit you selected in *Selecting the Prescription Unit (Volume / Dose)* on page 48 is **Dose**, you must specify the drug concentration. Depending on the profile previously selected see:

- *Basic Profile and Custom Profile (with a Drug List)* on page 50
- *Custom Profiles with a Drug Library* on page 50

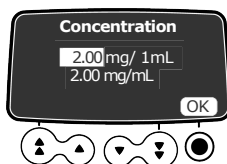
If you selected **Volume** in *Selecting the Prescription Unit (Volume / Dose)* on page 48, go to *Programming a PCA Loading Dose* on page 53.

7.7.1 Basic Profile and Custom Profile (with a Drug List)

After selecting the drug in a drug list, or directly after selecting the prescription unit if using the Basic Profile, the **Concentration** screen is displayed.



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



2. Press the arrow keys to select a mass value, and press  to select **OK**.
The concentration is automatically calculated and displayed in the unit selected above.
3. Press  to select **OK** in order to confirm.
If the **Loading dose PCA** screen is displayed, see *Priming the Syringe and the Extension Set* on page 52 to prime the syringe before infusing the drug.
If the **Dose rate** screen is displayed, select the appropriate dose rate unit as explained in *Selecting the Dose Rate* on page 74.

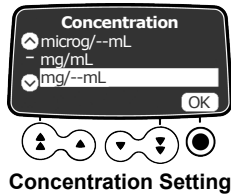
7.7.2 Custom Profiles with a Drug Library

After selecting a drug from a drug library, if you are allowed to adjust the drug concentration, the **Concentration** screen is displayed. The concentration can be adjusted:

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

For information on the limits that can be predefined in a custom profile, see *Drug Libraries* on page 31.

NOTE: This screen is not displayed if you are not allowed to adjust the concentration of the selected drug.



If a Concentration unit is selected:

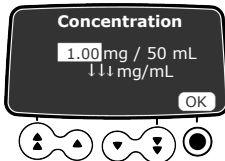
1. Press the arrow keys to select the Concentration.
2. Press  to select **OK** in order to confirm.

Dilution Setting

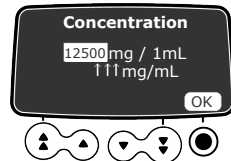
If a Dilution unit is selected:

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

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



Concentration below the Drug Library Software
hard limit



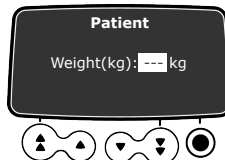
Concentration above the Drug Library Software
hard limit

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

7.8 Specifying the Patient's Characteristics

After selecting a drug and a drug concentration, the **Patient** screen can be displayed to allow you to specify the patient's body weight.

1. Press the arrow keys to enter the patient's weight.



2. Press  to confirm.

If the **Loading dose PCA** screen is displayed, see *Priming the Syringe and the Extension Set* on page 52 to prime the syringe before infusing the drug.

If the **Dose rate** screen is displayed, select the appropriate dose rate unit as explained in *Selecting the Dose Rate* on page 74.



INFORMATION

- The weight entry screen only appears if the selected drug uses weight for dose rate calculations.
- Custom profiles define a default body weight.

7.9 Priming the Syringe and the Extension Set

The pump includes a prime function that can be configured in Basic Profile (see the Technical manual) and in custom profiles. The following settings are available:

- **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.



DANGER

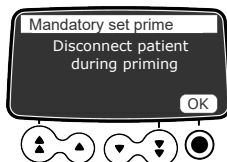
When priming, the patient must not be connected to the pump. Otherwise, air may be infused to the patient causing severe harm.



INFORMATION

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

If the mandatory or advisory message is not displayed, the right time to use the prime function is before infusing a loading dose, or before starting the infusion if you do not want to administer a loading dose.

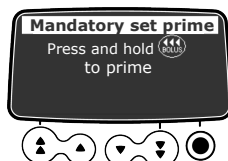


1. Press

The **Mandatory set prime** screen is displayed.

2. Make sure the extension set is not connected to the patient, as indicated on screen.

3. Press the



4. Press and hold the

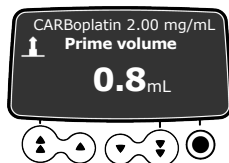
You can monitor priming in progress on the screen.

5. To end priming, release the

The prime volume is displayed.

6. Make sure there is no air in the extension set.

If necessary, press the bolus key again and repeat the procedure until there is no air left 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	■ Not triggered
Advised	■ Not triggered
Not displayed	■ 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.

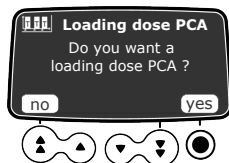
7.10 Programming a PCA Loading Dose

After selecting the drug concentration, and maybe the patient characteristics, the **Loading dose PCA** screen is displayed.



INFORMATION

You can request a PCA loading dose at any time during PCA infusion programming by pressing the bolus key .

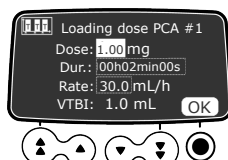


1. Press the  key to select **yes** to program a loading dose, or press the arrow key to select **no** if you do not need it.

If you select **no**, the PCA delivery mode screen is displayed. See *Selecting the PCA Mode* on page 55.

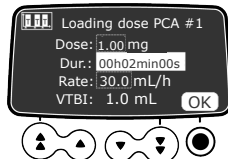
2. Use the arrow keys to enter a value for the dose, in this example in mg. The VTBI is automatically adjusted based on dose and duration settings.

3. Press the  key to select **OK** in order to confirm the dose.



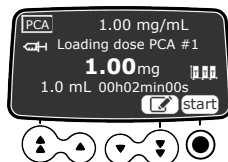
4. Use the arrow keys to enter the duration of the loading dose. The flow rate is automatically adjusted based on the duration setting.

5. Press the  key to select **OK** in order to confirm the duration.



6. Press the arrow keys to program the flow rate. The duration and the rate are interdependent.
7. Press the  key to select **OK** in order to confirm the loading dose settings.
8. See *Starting a PCA Infusion* on page 60 for precautions to take before starting the infusion.
9. Press the  key to select **start** in order to administer the loading dose.

If you need to adjust the settings, press the arrow key to select .



10. Monitor the progression of the loading dose on the screen.
11. At the end of the infusion of the loading dose, you can choose to administer another loading dose.

If you select **no**, the PCA delivery mode screen is displayed. See *Selecting the PCA Mode* on page 55.

7.11 Selecting the PCA Mode

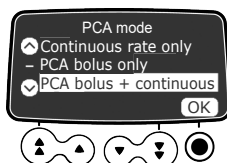
After dismissing the loading dose screen, the **PCA mode** screen is displayed. You can program a PCA infusion with the following infusion modes:

- Continuous rate only
- PCA bolus only
- PCA bolus + continuous
- PCA bolus + variable



INFORMATION

Check that the patient handset is connected before starting an infusion that authorizes PCA boluses.

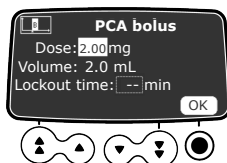


Press the arrow keys to scroll to the delivery mode that you want, and press the  key to select **OK**.

For Continuous rate only, see *Programming a Continuous Rate* on page 56. For all other modes, see *Programming a PCA Bolus* on page 55.

7.12 Programming a PCA Bolus

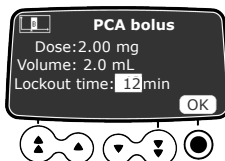
After selecting a PCA mode that includes bolus, the **PCA bolus** screen is displayed.



1. Press the arrow keys to enter a value for the dose, mL or mg, depending on the prescription unit previously selected.

When entering a value for a dose, the corresponding volume is automatically displayed.

2. Press the  key to select **OK** in order to confirm the dose.
3. Use the arrow keys to set the bolus lockout time.

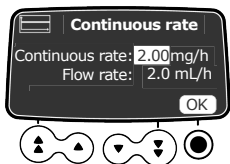


4. Press the  key to select **OK** in order to confirm the lockout time.

If the **Continuous rate** screen is displayed, see *Programming a Continuous Rate* on page 56. If the **Cumulated limit(s)** screen is displayed, see *Setting the Cumulated Limits* on page 58.

7.13 Programming a Continuous Rate

If you selected a PCA mode that includes a continuous rate, the **Continuous rate** screen is displayed.



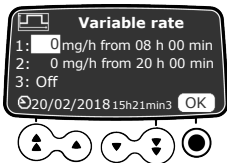
1. Use the arrow keys to enter a value for the rate, in mL/h or mg/h depending on the prescription unit previously selected.
2. Press the  key to select **OK** in order to confirm the continuous rate.
The **Cumulated limit(s)** screen is displayed. See *Setting the Cumulated Limits* on page 58.

7.14 Programming a PCA Infusion with Variable Rates

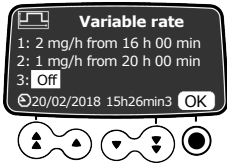
If you selected the PCA bolus + variable mode, after programming the PCA boluses, the **Current date/time** screen is displayed. It is important to check the current date and time are correct before you program the start time for varying infusion rates. While programming, the current date and time are shown at the bottom of the screen.



1. Press the  key to select **OK** in order to validate the current date and time, or press the arrow key to select  in order to correct the information displayed.
When you press **OK** to confirm the last element of the time display, the **Variable rate** screen is displayed.



2. Use the arrow keys to enter a value for the first dose, in mL/h or mg/h depending on the prescription unit previously selected.
3. Press the  key to select **OK** in order to confirm the dose rate.



4. Set the start time, and press the  key to select **OK**.
5. Set the value and start time of the second and third dose rate if required, and press the  key to select **OK** in order to confirm each value.
The **Cumulated limit(s)** screen is displayed. See *Setting the Cumulated Limits* on page 58.

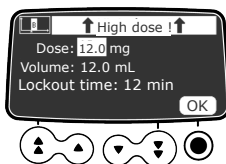
7.15 Programming an Infusion Beyond Soft Limits

A drug that is part of a drug library can have predefined limits on flow rate and dose settings. For information on the limits that can be defined, see *Drug Libraries* on page 31.

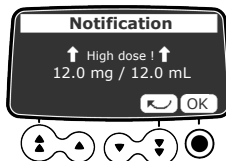
If you reach a limit when programming an infusion, the pump displays a message at the top of the screen. You can override soft limits but not hard limits, as shown in the examples below.

Overriding a soft limit

The procedure below shows an example of soft limit reached when programming a PCA bolus, and how to acknowledge it.



1. Use the arrow keys to reduce the dose, or press the  key to select **OK** in order to confirm it.
If you attempt to increase the dose, the hard limit alert is displayed.

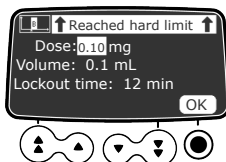


2. If you select **OK**, an alert message is displayed allowing you to cancel the dose, or to confirm it again.
The next programming screen is displayed and you can continue programming the infusion.

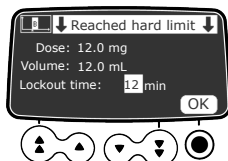
Acknowledging a hard limit

The figures below show an example of upper hard limit reached and of lower hard limit reached when programming a PCA bolus.

The figure below shows the screen displayed when you try to increment the value of **Dose**.



1. Press the  key to select **OK** in order to acknowledge the hard limit.
The high dose alert is displayed as shown above.



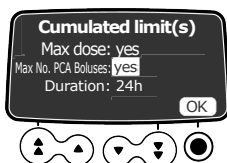
The figure above shows the screen displayed when you try to reduce the value of **Lockout time**.

2. Press the  key to select **OK** in order to acknowledge the hard limit.

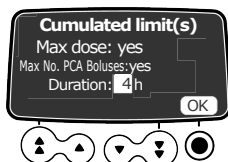
The next programming screen is displayed and you can continue programming the infusion.

7.16 Setting the Cumulated Limits

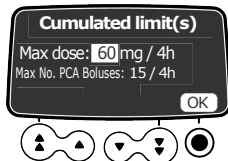
After setting the PCA mode and doses, the **Cumulated Limit(s)** screen is displayed to allow you to set safety limits. For a specified time period, you must set a limit on maximum dose, and you can set a limit on the maximum number of PCA boluses.



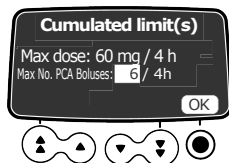
1. Use the arrow keys to select **yes** or **no**, for setting a limit on the maximum number of boluses that the patient can receive.
2. Press the  key to select **OK** in order to confirm your choice and move the cursor to the next field.



3. Use the arrow keys to set the time period for assessing the cumulated limits.
By default, the time period is 24 hours.
4. Press the  key to select **OK** in order to confirm the time period.



5. Use the arrow keys to set the maximum value for the dose in mL or in mg for the specified time period.
6. Press the  key to select **OK** in order to confirm the value and move the cursor to the next field.



7. Use the arrow keys to set the maximum number of PCA boluses that the patient can self-administer during the specified time period.
8. Press the  key to select **OK** in order to confirm the number.
All the PCA settings you made are displayed for review and validation. See *Reviewing the PCA Infusion Settings* on page 59.

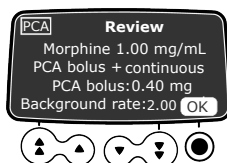


INFORMATION

The **Max No. PCA boluses** field is not displayed if the PCA mode is Continuous rate only.

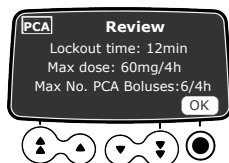
7.17 Reviewing the PCA Infusion Settings

After setting the parameters for PCA infusion, you must review and validate them.



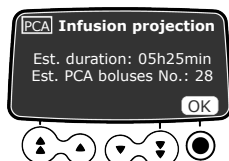
1. Press the  key to select **OK** in order to confirm the PCA mode, the bolus dose, and the background rate if applicable.

To change a setting, press the  cancel key and see *Modifying a Running PCA Infusion* on page 63.



2. Press the  key to select **OK** in order to confirm the lockout time and the maximum limits, if applicable.

To change a setting, press the  cancel key and see *Modifying a Running PCA Infusion* on page 63.



- Press the  key to select **OK** in order to confirm the information displayed on the screen, or press the  cancel key to change the settings.
If you select **OK**, the infusion start screen is displayed.



- Before you press **start**, see *Starting a PCA Infusion* on page 60 for precautions to take.
When you select **OK**, the infusion start screen is displayed.



INFORMATION

The estimated duration of the infusion is based on the assumption that the patient gets a PCA bolus after each lockout period.

7.18 Starting a PCA Infusion

After reviewing the PCA settings, check the following before starting the infusion.

- Check that there is no air in the syringe or in the extension set.
For information on priming the extension set, see *Priming the Syringe and the Extension Set* on page 52.
- Connect the extension set to the patient's access device.
- Check the integrity of the delivery path.
- If necessary, make sure the protective cover is closed and remove the key.
- Press **start** to start the infusion.
If the protective cover is open or missing, you will be prompted to confirm start. The keypad is automatically locked when you start the infusion.
- If PCA boluses are allowed, give the handset to the patient, and explain how to use the bolus button.
For information on using the patient handset, see *Administering a PCA Bolus* on page 65.



CAUTION

Before starting the infusion, you must close the protective cover and remove the key to avoid tampering or drug theft.

7.19 Supervising PCA Therapy

To supervise PCA therapy, you can:

- Monitor a running infusion directly on the screen (see below).
- Press the  key to view the total dose infused since the start of infusion.
- Display the history of PCA infusions for patient, see *Displaying PCA History* on page 62.

7.19.1 Monitoring the Running PCA Infusion

After starting a PCA infusion, you can monitor the infusion on the screen. Green lights indicate the infusion has started.

Infusion started in PCA bolus only mode

When an infusion is started in PCA bolus only mode, BOLUS ONLY is displayed on the screen. The green LED shows the infusion has started although the pump is not currently infusing.

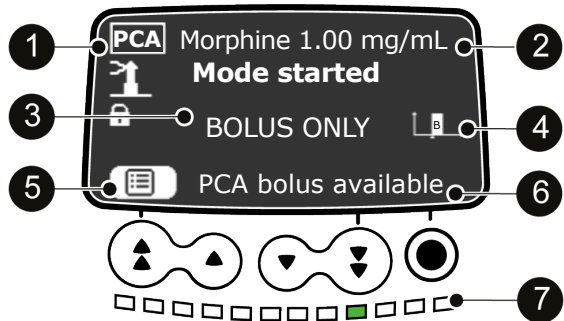


Figure 13: PCA infusion in bolus only mode (started but not currently infusing)

Legend

1 PCA therapy indicator	5 Summary of PCA setting
2 Drug name and/or concentration	6 Indication of PCA bolus available or lockout
3 Bolus only infusion mode	7 One green LED lit: infusion started but not currently infusing
4 PCA bolus indicator	

Infusion running in PCA bolus + continuous mode

When an infusion is started in PCA bolus + continuous mode, the green infusion indicator lights flash regularly to indicate the pump is infusing. The flashing speed reflects the flow rate.

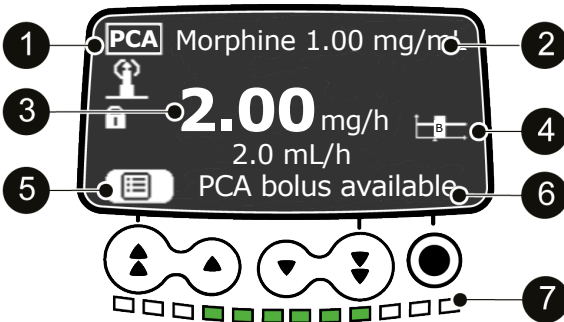


Figure 14: PCA infusion in progress in bolus + continuous mode - bolus available

Legend

1 PCA therapy indicator	5 Summary of PCA setting
-------------------------	--------------------------

- ② Drug name and/or concentration
- ③ Bolus only infusion mode
- ④ PCA bolus indicator
- ⑥ Indication of PCA bolus available or lockout
- ⑦ Green LEDs flashing regularly to indicate infusion in progress



INFORMATION

Display of infusion PCA bolus availability depends on the settings defined for this drug (custom profile) or on the pump configuration (Basic Profile).

PCA Bolus in progress

When the patient requests a PCA bolus, and it is delivered, the screen displays a progression bar, and a countdown of time and dose. The indicator lights flash fast.

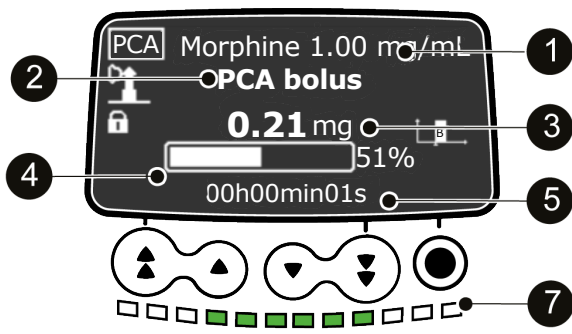


Figure 15: PCA bolus in progress

Legend	
① Drug name and/or concentration	④ Progress bar showing percentage of bolus infused
② PCA bolus in progress	⑤ Time countdown during bolus infusion
③ Dose countdown during bolus infusion	⑦ Green LEDs flashing fast to indicate bolus in progress

7.19.2 Displaying PCA History

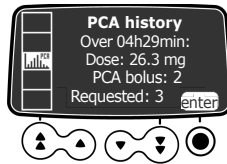
PCA infusion data is saved on the pump for 24 hours. During PCA infusion, or after it has ended, you can display information on the PCA treatment received by a patient.



INFORMATION

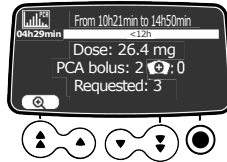
PCA infusion data is not saved when the pump is turned off.

1. Press the PCA history key  to display the PCA infusion data.
 The time shown corresponds to the duration programmed for the cumulated limits. You can see the total dose and number of PCA boluses administered over this time.

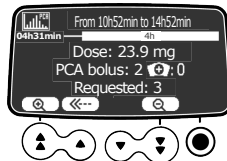


- Press to select **OK** in order to access the detailed PCA history.

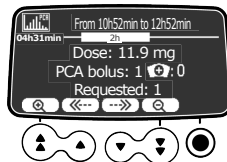
A time scale since the beginning of treatment is displayed above the PCA infusion data. The screen also shows the number of clinician boluses administered, if any, as well as the total number of boluses requested.



- Press the arrow key to select the magnifying glass in order to zoom in on a narrower time frame.
 The PCA infusion data corresponding to the new time frame is displayed.



- Use the back and forward double arrow buttons to navigate through the PCA data recorded since the beginning of treatment.
- Press the arrow key to select the magnifying glass in order to zoom out of the time frame observed.



- Press the cancel key or the menu key on the keypad twice to dismiss the PCA history.



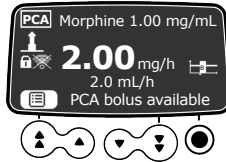
INFORMATION

Dose or Total dose in the PCA history represents the addition of the continuous rate, of clinician and PCA boluses, and of loading doses, if any, over the period displayed.

7.20 Modifying a Running PCA Infusion

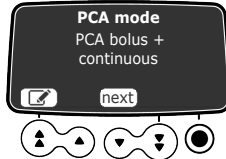
At any time during a PCA infusion, you can modify the infusion settings. You must enter the passcode for PCA therapy if prompted.

- Press **Stop** on the keypad to interrupt the PCA treatment.



2. Press the left fast increment key to select the summary of PCA settings (list icon) above it on the screen.

The current PCA delivery mode is displayed.



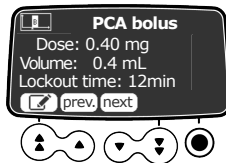
3. Do you want to change the PCA delivery mode?

- a. No: press the arrow key to select **next**.

The current PCA bolus settings are displayed. See next step.

- b. Yes: press the arrow key to select the edit icon .

See *Selecting the PCA Mode* on page 55.



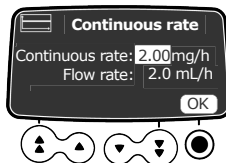
4. Do you want to change the bolus settings?

- a. No: press the arrow key to select **next**.

The current continuous rate settings are displayed. See next step.

- b. Yes: press the arrow key to select the edit icon .

See *Programming a PCA Bolus* on page 55.



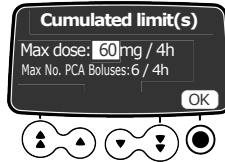
5. Do you want to change continuous rate settings?

- a. No: press the arrow key to select **next**.

The current cumulated limits settings are displayed. See next step.

- b. Yes: press the arrow key to select the edit icon .

See *Programming a Continuous Rate* on page 56.



6. Do you want to change the cumulated limits?

- a. No: press the  key to select **OK**.
The settings review screen is displayed. See next step.
- b. Yes: press the arrow key to select the edit icon .
See *Setting the Cumulated Limits* on page 58.



7. Review and validate the new settings, as explained in *Reviewing the PCA Infusion Settings* on page 59.

8. Press the  key to select **start** in order to resume the infusion with the new settings

The message below is displayed if you attempt to change PCA infusion settings without stopping the infusion in progress.

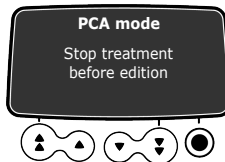


Figure 16: Alert message requiring to stop infusion

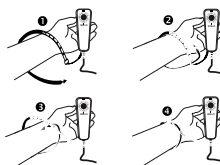
After 3 seconds, the message disappears.

7.21 Administering a Bolus

The patient and the clinician can administer a bolus.

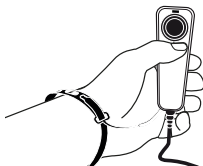
7.21.1 Administering a PCA Bolus

The patient can self-administer a PCA bolus if allowed by the PCA infusion programmed on the pump. The handset comes with a strap so that it can be attached to the patient's wrist, as shown.



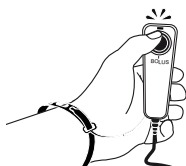
You must explain to the patient how to use the handset.

1. Hold the device in the palm of your hand, with the bolus button facing up.



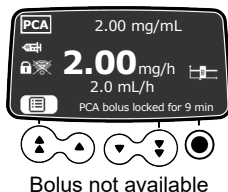
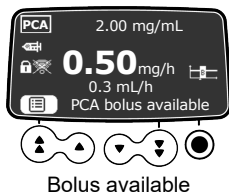
2. To trigger a bolus, press the bolus button on the handset.

The pump beeps and the blue LED above the bolus button flashes for a few seconds (default behavior).



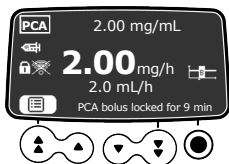
If a PCA bolus is not available due to the lockout period between two consecutive boluses, or because the maximum number of boluses allowed has been reached, on pressing the bolus button, the pump beeps and the LED on the patient handset flashes but the pump does not deliver the bolus.

By default, the pump display shows when a PCA bolus is available. This feature can be disabled in the pump configuration, as explained in *Pump Settings* on page 112.



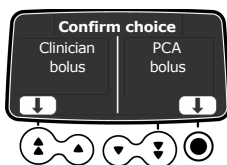
7.21.2 Administering a Clinician Bolus

As the clinician, you can administer a bolus during the PCA infusion in progress. In the example below, the patient cannot self-administer a bolus due to the lockout period, but you can administer a clinician bolus.

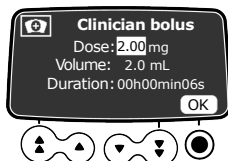


1. Press the Bolus key  on the keypad.

The screen displays the choice of a **Clinician bolus** or **PCA bolus**.



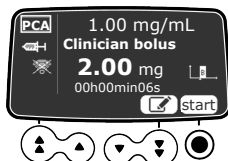
2. Select **Clinician bolus** using the confirmation key.
3. Enter the passcode for PCA therapy if prompted.



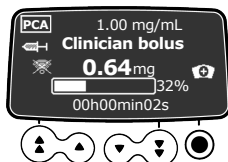
4. Set the value of the dose that you want to administer to the patient.
If you have already administered a PCA bolus, the previous dose is displayed.

5. Press **OK** to select **OK** in order to confirm the dose.

See *Administering a Clinician Bolus beyond Maximum Dose* on page 69 if the dose to be infused exceeds the maximum dose specified in the cumulated limits.



6. Press **start** to select **start** in order to administer the bolus, the arrow key to select  in order to modify the dose.



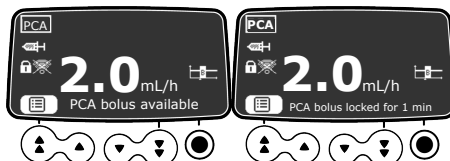
7. Monitor the progress of the bolus on the screen.

7.21.3 Viewing the Availability of a PCA Bolus

During the lockout period, and if the **Display PCA bolus** feature has been enabled in the pump options, you can see if a patient bolus is available or not.



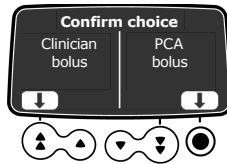
PCA bolus availability disabled



PCA bolus availability enabled

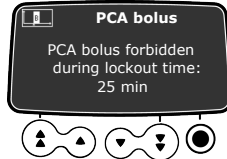
If a PCA bolus is not available, you can view the remaining time until it becomes available again.

1. Press the Bolus key  on the keypad.
The screen displays the choice of a **Clinician bolus** or **PCA bolus**.

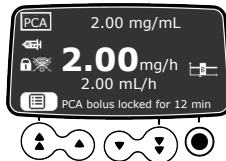


2. Select **PCA bolus** using the confirmation key.

A message is displayed with the remaining lockout time. After 10 seconds, the message disappears and the monitoring screen is shown again.



If the **Display lockout time** feature has also been enabled in the pump options, and a PCA bolus is not available, the actual lockout time is shown directly at the bottom of the monitoring screen.



7.22 Handling PCA Alarms and Alerts during Programming

This section shows the alerts and alarms that can be reported by the Agilia SP PCA infusion pump during infusion programming.

7.22.1 Low Remaining Volume

The messages below are displayed when you start the PCA infusion if the volume remaining in the syringe is less than 25% of the syringe capacity.

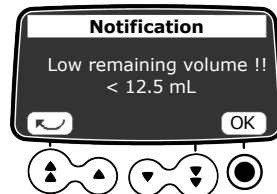
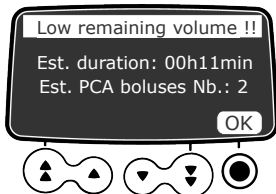


Figure 17: Remaining volume too low message

Press  to select **OK** in each screen in order to acknowledge the alert.

7.22.2 Low Remaining Bolus

The messages below are displayed when you start the PCA infusion if the volume remaining in the syringe represents less than 5 PCA boluses.



Figure 18: Remaining number of boluses too low message

Press  to select **OK** in each screen in order to acknowledge the alert.

7.22.3 Short Remaining Duration

The messages below are displayed when you start the PCA infusion if the volume remaining in the syringe represents less than 30 minutes of infusion time.

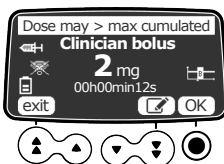


Figure 19: Remaining duration too low message

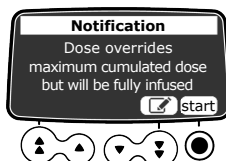
Press  to select **OK** in each screen in order to acknowledge the alert.

7.22.4 Administering a Clinician Bolus beyond Maximum Dose

When you program a clinician bolus, before you start the infusion, the pump adds the value of the bolus to the cumulated dose already infused. If the result exceeds the maximum dose authorized, the following alert message is displayed.



1. Press  to select **OK** in order to acknowledge the alert and continue without modifying the dose, or press the arrow key to select the edit icon  in order to modify the dose. When you select **OK**, the alert is displayed again.

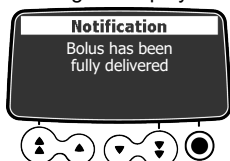


2. To administer the bolus although the maximum cumulated dose will be exceeded, press  to select **start**.

To modify the value of the dose, press the arrow key to select the edit icon .

3. Monitor the progression of the bolus on the screen.

At the end of the bolus, an information message is displayed.



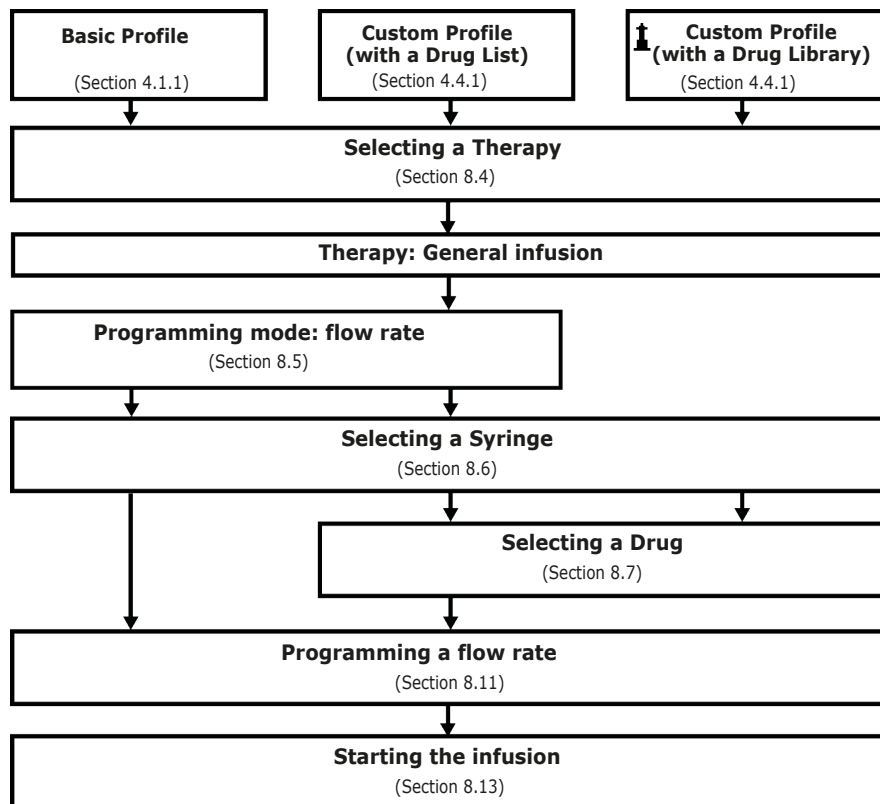
It is followed by a medium-priority maximum dose alarm, and the PCA infusion is stopped. See *Infusion Alarms* on page 120.



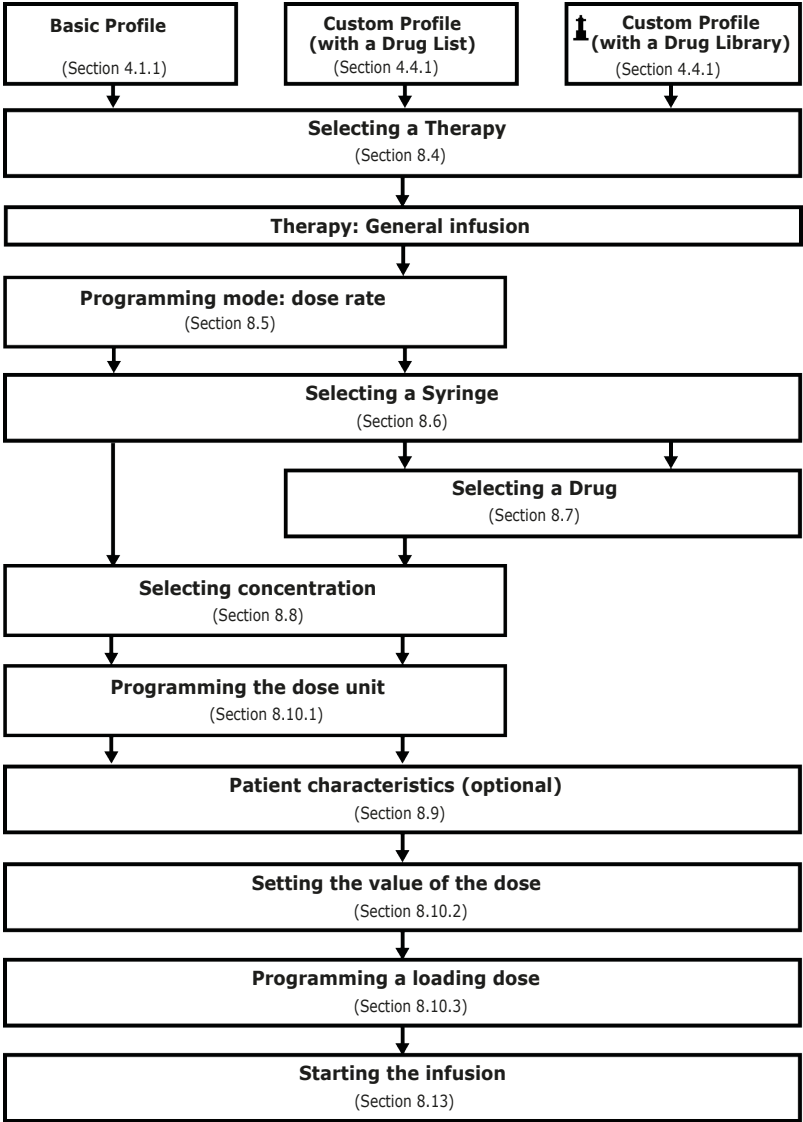
8 Programming a General Infusion

The Agilia SP PCA infusion pump can be used for general infusions as well as for PCA therapy. This section presents the general workflow for programming an infusion, and the procedures for general infusions with a flow rate or a dose rate.

8.1 Programming a General Infusion by Flow Rate



8.2 Programming a General Infusion by Dose Rate



8.3 Selecting a Profile

Profiles are available for selection if previously uploaded to the pump. See *Selecting a Profile* on page 47 for explanations on how to select a profile.

8.4 Selecting a Therapy

After selecting Basic Profile, the programming interface takes you to the **Select therapy** screen where you must choose **General infusion**. See *Selecting a Therapy* on page 47 for detailed explanations.

NOTE: By default, this choice is disabled in the pump configuration and this screen is not displayed.

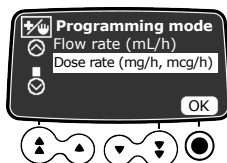
8.5 Selecting a Programming Mode (Flow Rate or Dose Rate)

After selecting General infusion therapy, you are prompted to select the **Programming mode** for the infusion, in volume (flow rate) or in mass (dose rate).

NOTE: This screen is not displayed if you previously selected a custom profile, because the programming mode is pre-defined.

➡ Use the arrow keys to select the programming mode and press  to select **OK** in order to confirm.

The syringe selection screen is displayed.



8.6 Selecting a Syringe

After selecting the programming mode, the screen displays the syringe type installed in the pump. You must make sure the display is correct, as explained in *Selecting a Syringe* on page 48.



WARNING

When installing the syringe and programming the infusion, ensure that the syringe size and model displayed on Agilia pump matches the one loaded in the pump. If you can't find the appropriate syringe, contact your biomedical department or your Fresenius Kabi representative. Use of incompatible syringes can cause improper pump operation resulting in inaccurate fluid delivery, insufficient occlusion sensing, and other potential problems that can injure the patient.

8.7 Selecting a Drug

After you confirm the syringe type, the screen displays a drug selection menu. See *Selecting a Drug* on page 49 for explanations on how to select a drug.

NOTE: This screen is not displayed if you previously selected the Basic Profile that does not offer a pre-defined drug list.

8.8 Selecting Drug Concentration

If the programming mode you selected in *Selecting a Programming Mode (Flow Rate or Dose Rate)* on page 73 is **Dose rate**, you must specify the drug concentration. See *Selecting Drug Concentration* on page 50 for detailed explanations.

If you selected **Flow rate** in *Selecting a Programming Mode (Flow Rate or Dose Rate)* on page 73, go to *Programming an Infusion by Flow Rate* on page 76.

8.9 Specifying the Patient's Characteristics

After selecting a drug and a drug concentration, the **Patient** screen can be displayed to allow you to specify the patient's body weight or surface. See *Specifying the Patient's Characteristics* on page 51 for detailed explanations.



INFORMATION

- The weight entry screen is displayed only if the selected drug uses weight for dose rate calculations.
- The body surface area entry screen is displayed only if the selected drug uses body surface area for dose rate calculations.
- Custom profiles define a default weight or body surface area.

8.10 Programming an Infusion by Dose

When programming an infusion by dose, you will be prompted, as necessary, to:

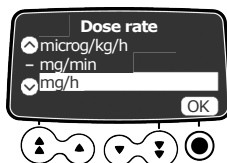
- Select the dose rate and the value of the dose
- Program a loading dose, if required

8.10.1 Selecting the Dose Rate

After selecting the drug concentration, the **Dose rate** screen is displayed.

NOTE: This screen is not displayed if you previously selected a custom profile from a drug library because the dose rate is pre-defined.

1. Press the arrow keys to select the dose rate units.



2. Press to select **OK** in order to confirm.

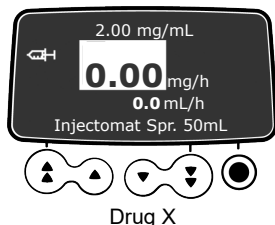
The next screen displayed allows you to set the dose to be infused. See *Selecting the Value of the Dose* on page 74.

8.10.2 Selecting the Value of the Dose

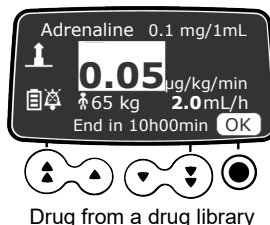
After selecting the dose rate, or after setting the patient characteristics, you must set the value of the dose to be infused.

NOTE:

At this stage in the workflow, instead of selecting the value of the dose as explained in this section, you can select a volume limit or a dose/time program as explained in *Advanced Infusion Programming Modes* on page 82.



Drug X



Drug from a drug library

1. Press the arrow keys to program the dose rate value.

2. Press to select **OK** in order to confirm.

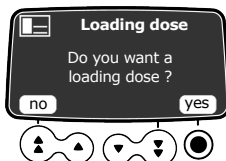
The **Loading dose** screen is displayed. See *Programming a Loading Dose* on page 75.

8.10.3 Programming a Loading Dose

After setting the value of the dose, you can program a loading dose.

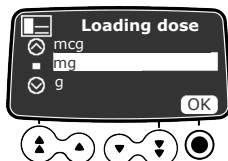
At this stage in the infusion programming sequence, before infusing the loading dose, you must prime the extension set. You can use the pump to prime the extension set as explained in *Priming the Syringe and the Extension Set* on page 52.

NOTE: In custom profiles, the loading dose feature can be deactivated. Therefore, the loading dose screen is not always displayed.

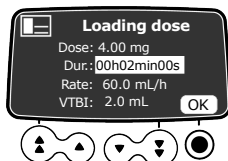


1. Press the  key to select **yes** in order to program a loading dose, or press the arrow key to select **no** if you do not need it.

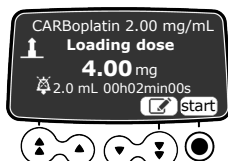
If you select **no**, you can start the infusion as explained in *Starting an Infusion* on page 77.



2. Select a mass unit for the loading dose, and press  key to select **OK** in order to confirm.

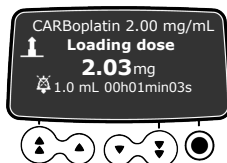


3. Press the arrow keys to enter a value for the dose, and press the  key to select **OK** in order to confirm.
4. Press the arrow keys to program the loading dose duration (__ h __ min __ s), and press the  key to select **OK** in order to confirm.
The VTBI is automatically calculated based on dose and duration settings.
5. Press the arrow keys to program the flow rate.
The duration and the rate are interdependent.
6. Press the  key to select **OK** in order to confirm the loading dose settings.



7. Before you press the  key to select **start** to initiate the loading dose, see *Starting an Infusion* on page 77 for precautions to take.

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



- Monitor the progression of the loading dose infusion on the screen.
Once the loading dose is finished, the pump automatically starts the programmed infusion.



INFORMATION

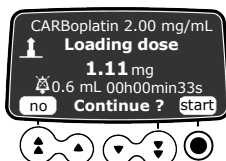
The loading dose is only available with the first start of an infusion. If no is pressed inadvertently, power the pump off and then on to access the loading dose again.



INFORMATION

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

Interrupting a Loading Dose



- To pause the loading dose, press .
The screen displays *Continue?*
- Choose one of the following options:
 - Press the arrow key to select **no** or  in order to stop the loading dose and proceed to the programmed infusion. Once you have stopped the loading dose, you cannot restart it.
 - Press  to select **start** in order to continue with the loading dose.

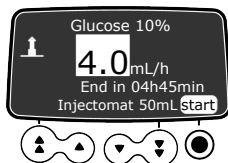
8.11 Programming an Infusion by Flow Rate

If the programming mode you selected in *Selecting a Programming Mode (Flow Rate or Dose Rate)* on page 73 is **Flow rate**, the Flow rate screen is displayed to allow you to set the value.



INFORMATION

At this stage in the workflow, instead of selecting the value of the flow rate as explained in this section, you can select a volume limit or a volume/time program as explained in *Advanced Infusion Programming Modes* on page 82.



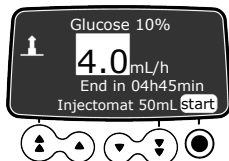
1. Use the arrow keys to set the value of the flow rate.
2. Before you press the key to select **start**, see *Starting an Infusion* on page 77 for precautions to take.

8.12 Programming an Infusion Beyond Soft Limits

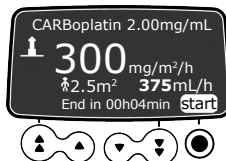
A drug that is part of a drug library can have predefined limits on flow rate and dose settings. For information on the limits that can be defined, see *Drug Libraries* on page 31.

If you reach a limit when programming an infusion, the pump displays a message at the top of the screen. You can override soft limits but not hard limits, as shown in *Programming an Infusion Beyond Soft Limits* on page 57.

8.13 Starting an Infusion



Flow rate



Dose



CAUTION

Check the complete infusion line from the syringe to the catheter prior to starting the infusion.

1. Check that there is no air in the syringe or in the extension set.
For information on priming the extension set, see *Priming the Syringe and the Extension Set* on page 52.
2. Connect the syringe's extension set to the patient's access device. Check the integrity of the delivery path.
3. Check the infusion settings prior to starting the infusion.
4. Press to select **start** in order to start the infusion.
The keypad is automatically locked.
- 5.



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.

8.14 Monitoring an Infusion

8.14.1 Monitoring an Infusion Programmed by Flow Rate

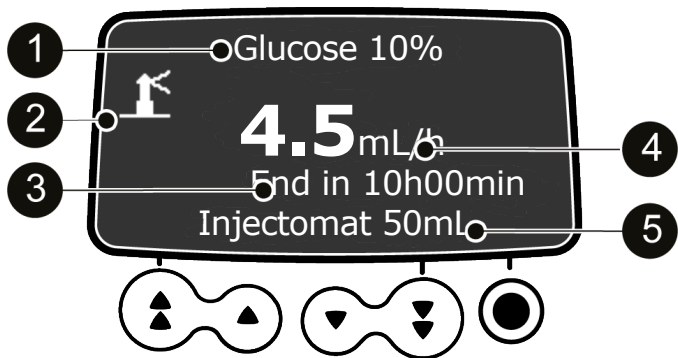


Figure 20: Infusion programmed by flow rate in progress

Legend	
1	Drug name and/or concentration if available
2	If present, lighthouse indicates drug selected from drug library
3	Remaining infusion time in hours and minutes, at the current rate
4	Flow rate (displayed with largest font size)
5	Syringe name / ward name (configurable)



INFORMATION

- To change the flow rate during infusion, see *Adjusting the Infusion Rate (Rate Titration)* on page 79.
- Display of infusion remaining time depends on the predefined settings for this drug.

8.14.2 Monitoring an Infusion Programmed by Dose

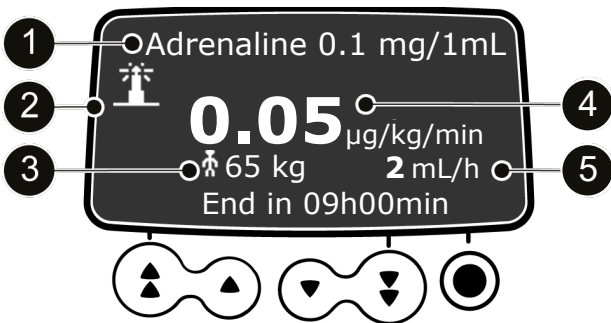


Figure 21: Infusion programmed by dose in progress

Legend

- | | |
|--|--|
| 1 Drug name and/or concentration | 4 Dose rate (displayed with largest font size) |
| 2 Lighthouse indicates drug selected from drug library | 5 Infusion flow rate |
| 3 Patient characteristics | |

INFORMATION

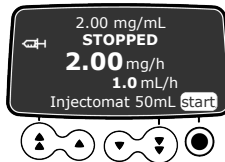


- To change the dose during infusion, see *Adjusting the Infusion Rate (Rate Titration)* on page 79.
- Display of patient body surface area or weight depends on the predefined settings for this drug.

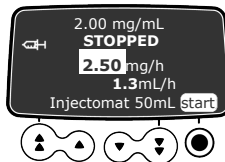
8.15 Adjusting the Infusion Rate (Rate Titration)

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

- If required, stop the infusion by pressing , as explained in *Stopping the Infusion in Progress* on page 86.



- Press the arrow keys to modify the flow rate or dose.



- Press the  key to select **start** in order to continue the infusion with the new infusion rate.

8.16 Administering a Bolus

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

- Direct bolus
- Programmed bolus

	Direct Bolus	Programmed Bolus
Access Key		 or 
Occlusion Pressure Level	Set to its maximum value: 900 mmHg / 120 kPa / 17.4 PSI	

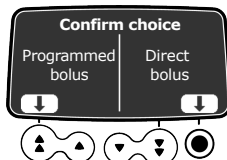


INFORMATION

- The bolus volume is added to the Volume Infused (VI).
- The  key is not active when the menu screen is displayed.

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

1. Press the Bolus key  on the keypad.



2. Select **Programmed bolus** using the arrow key or **Direct bolus** using the  key.
3. Then, see *Direct Bolus* on page 80 or see *Programmed Bolus* on page 80.

8.16.1 Direct Bolus

At any time during infusion, you can administer a bolus using the bolus  key.

NOTE: This feature can be deactivated in Basic Profile (see the Technical manual) and in custom profiles. Therefore, the Bolus screen is not displayed for all drugs.

1. During the infusion, press the bolus  key.
2. Press  to confirm access to bolus function.
3. To administer a direct bolus, press and hold the  key.
4. Monitor the volume infused on the main display until the desired bolus is reached.
5. To stop the bolus, release the  key.
The volume (or dose) infused is displayed for a few seconds on the screen. The infusion resumes its previous rate after the bolus is delivered.

8.16.2 Programmed Bolus

NOTE: This feature can be deactivated in Basic Profile (see the Technical manual) and in custom profiles. Therefore, the Programmed bolus screen is not displayed for all drugs.

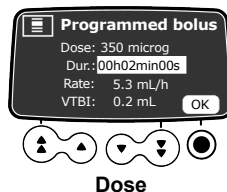
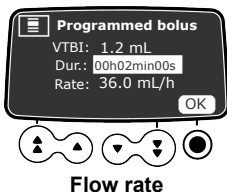
During the infusion, you can program a bolus in one of the following two ways:

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

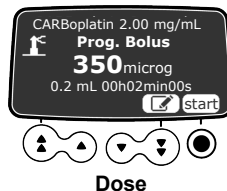
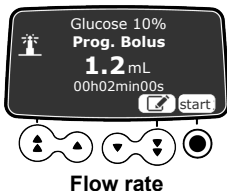
8.16.2.1 Programming a Bolus



1. Press the arrow keys to select the programmed bolus unit, and press  to select **OK**.
NOTE: This step is only applicable with Basic & TCI profile and custom profiles that contain a drug list. The infusion units for each drug of a drug library are pre-defined with Drug Library Software.
2. Press the arrow keys to program the bolus volume or dose, and press  to select **OK** in order to confirm.
3. Press the arrow keys to program the bolus duration (___ h ___ min ___ s), and press  to select **OK** in order to confirm.
 The flow rate is calculated automatically.
4. Press the arrow keys to program the flow rate.
 The duration and the rate are interdependant.



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

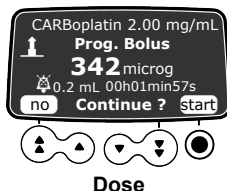
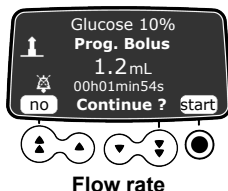


6. At this stage, you can:
 - Press the  key to select **start** in order to administer the bolus immediately.
 - Press the  key in order to save the settings without administering the bolus.
 - Press the arrow key to select  in order to change the bolus settings.
7. Monitor the progression of the bolus infusion on the screen.
 The infusion resumes its previous rate after the bolus has been delivered.

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

8.16.2.2 Interrupting a Programmed Bolus

1. Press  to interrupt the bolus.



2. Answer the question: *Continue?*

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

8.17 Advanced Infusion Programming Modes

The Agilia SP PCA infusion pump offers the following advanced programming modes:

- Volume/Time and Dose/Time
- Volume Limit

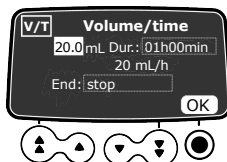
NOTE: The availability of these infusion modes depends on the pump configuration and the selected drug. They are not available for PCA therapy.

8.17.1 Volume/Time & Dose/Time

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

When the VTBI/DTBI is reached, an alarm is triggered.

1. Access the Volume/Time or Dose/Time, see *Volume/Time & Dose/Time* on page 100.



2. Press the arrow keys to set the volume or dose to be infused (VTBI / DTBI), and press  to select **OK**.

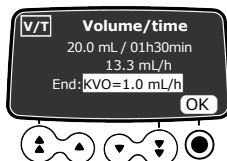
The infusion rate is automatically calculated.



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 *Changing a Syringe* on page 127.

3. Press the arrow keys to set the infusion time, and press  to select **OK**.
The infusion rate is automatically readjusted.



4. Press the arrow keys to configure the end of infusion settings and press  to select **OK** in order 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.



WARNING

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

- **Continuous:** After the VTBI is completed, the infusion continues at the programmed flow rate.



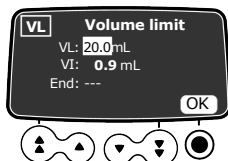
5. Press  to select **start** in order to start the infusion.

If the loading dose screen is displayed, see *Programming a Loading Dose* on page 75. The loading dose is included in the volume or the dose that you programmed. When the infusion starts the remaining VTBI and remaining time are displayed on the screen and updated every minute.

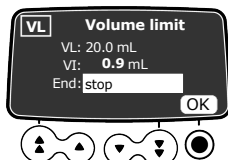
8.17.2 Volume Limit

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 *Volume Limit* on page 101.



2. Press the arrow keys to set the volume limit, and press  to select **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 *Changing a Syringe* on page 127.
- 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  to select **OK** in order to confirm.

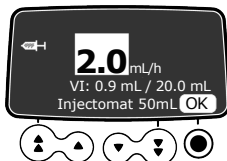
- **Stop:** The infusion stops when the volume limit is reached.
- **Keep Vein Open (KVO):** After the volume limit is reached, the infusion continues at a preset flow rate to keep the access device open.



WARNING

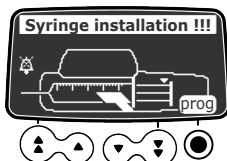
The KVO (Keep Vein Open) function shall not be used with critical or life-sustaining drugs, as it may lead to critical harm for the patient.

- **Continuous:** After the volume limit is reached, the infusion continues at the programmed flow rate.



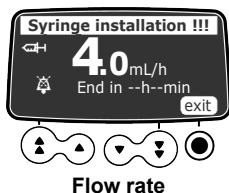
- Press the arrow keys to set the value of the flow rate or dose rate, and press  to select **OK**.
- Press  to select **start** in order to start the infusion.
If the loading dose screen is displayed, see *Programming a Loading Dose* on page 75. The loading dose is included in the volume or the dose that you programmed. When the infusion starts the remaining VTBI is displayed on the screen.

8.18 Pre-programming the Pump



You can program the pump before installing the syringe.

- Press  to power on the pump.
Syringe installation !!! is displayed on top of the pump screen.
- Make sure the syringe barrel clasp is folded up against the pump.
The **prog** symbol is displayed.
- Press the  key to select **prog**.
- Program the infusion.
See *Selecting a Programming Mode (Flow Rate or Dose Rate)* on page 73.



- Press the  key to select **exit** in order to confirm.

6. When ready, install the syringe.
7. Press the  key to select **start** in order to start the infusion.

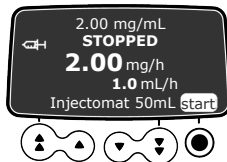
9 Ending an Infusion

This section explains how to stop an infusion in progress, how to complete an infusion that runs until the end of the syringe, and how to power off the pump.

9.1 Stopping the Infusion in Progress

You can stop the infusion in progress at any time, for example to move the patient, or to modify the infusion settings.

1. To interrupt the PCA treatment, press .
After 2 minutes, an alarm is generated as a reminder that the infusion is stopped.



2. Perform the task that requires the infusion to be stopped.
3. Press  to select **start** in order to resume the PCA treatment.

9.2 Completing an Infusion

Two alarms are generated as the running infusion gets close to the end:

- A near end of infusion alarm.
- An end of infusion alarm.

9.2.1 Near End of Infusion

Before 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.

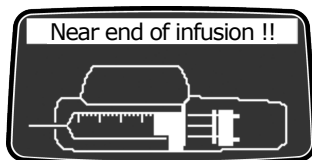
The near end of infusion alert is triggered when the two criteria below are reached simultaneously:

- Time before end of infusion < specified threshold (value between 1 mn and 30 mn, by default, 5 mn), AND
- Remaining volume of fluid in syringe < 10% of syringe capacity

Near end of infusion alert settings are configurable in Basic Profile (see the Technical manual) and in custom profiles.

Silencing the Near End of Infusion Alert

1. Press  to silence the alarm.
2. If required, press  to select **OK** in order to confirm the empty syringe mode.



Empty syringe mode

Depending on the pump configuration, after the plunger reaches the tip of the syringe, the following happens:

- Regular end of infusion: the infusion stops, the syringe is not completely emptied.
- Empty syringe mode: the flow rate decreases when the plunger reaches the tip of the syringe and the infusion continues until the syringe is completely emptied.

The empty syringe mode is available only for infusions in Simple Rate mode.

9.2.2 End of Infusion

NOTE:

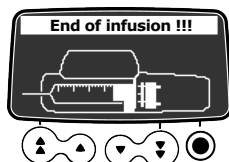
When the infusion is complete, the following happens:

- 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 Basic Profile (see the Technical Manual) and in custom profiles.

9.2.2.1 Silencing the Alarm

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

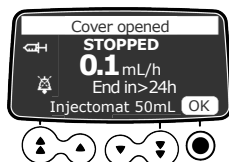


9.3 Unlocking the Pump Keypad

There are two possible methods for unlocking the keypad of the Agilia SP PCA infusion pump.

- By using the keypad lock status menu, as explained in *Keypad Lock Status* on page 93.
- By opening the protective cover (if it is in use and if the auto-unlock on opening cover has been enabled in the pump options), as explained below.

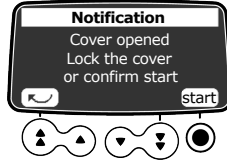
1. To interrupt the infusion in progress, press .
2. Use the key to open the protective cover.



3. If necessary, press the  key to silence the cover open alarm.
4. Perform the task that requires the keypad to be unlocked (example: press the arrow keys to change the flow rate).



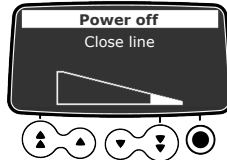
5. When you have finished, close the cover, remove the key, and press **start**.



9.4 Powering off the Pump

If the keypad is locked, you must first unlock it, as explained in *Keypad Lock Status* on page 93. To power off the pump, you must first unlock the keypad.

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



10 Menus

10.1 Overview

10.1.1 Using the Keypad

Operation	Key
Access menu or exit menu	
Direct access to PCA history	
Select option, increment or decrement value	   
Confirm choice displayed above key	    
Select ☒ / Deselect ☐ (toggle)	

10.1.2 Menu Description

The displayed menu may change depending on the pump configuration. For more information on factory configuration, refer to *Appendix: Factory Configuration* on page 172.

Menu	Symbol	Stop Infusion Required	Associated Procedure
Profile	Pro	NO	■ <i>Profile</i> on page 90.
Pressure		NO	■ <i>Pressure</i> on page 91.
Keypad lock status		NO	■ <i>Keypad Lock Status</i> on page 93.
Keypad automatic lock		NO	■ <i>Keypad Automatic Lock</i> on page 94.
Battery life		NO	■ <i>Battery Life</i> on page 95.
Volume Infused	mL?	NO	■ <i>Volume Infused / Dose Infused</i> on page 96.
Dose Infused			
Pause		YES	■ <i>Pause</i> on page 96.
Programmed bolus		NO	■ <i>Programmed Bolus</i> on page 97.
Clinician bolus		YES	■ <i>Clinical Information</i> on page 109.
PCA history		NO	■ <i>View PCA History</i> on page 104.
PCA treatment		NO	■ <i>View PCA Treatment Information</i> on page 104.

Menu	Symbol	Stop Infusion Required	Associated Procedure
PCA event log		NO	■ <i>View PCA Event Log on page 105.</i>
Patient		NO	■ <i>Patient on page 99.</i>
Day/Night mode		NO	■ <i>Day/Night Mode on page 99.</i>
Volume/Time	V / T	YES	■ <i>Volume/Time & Dose/Time on page 100.</i>
Dose/Time	D / T	YES	
Volume limit	VL	YES	■ <i>Volume Limit on page 101.</i>
Alarm volume		NO	■ <i>Alarm Volume on page 101.</i>
Volume-Dose history		YES	■ <i>Volume-Dose History on page 102.</i>
View flow rate history		NO	■ <i>View Flow Rate History on page 102.</i>
View pressure history		NO	■ <i>View Pressure History on page 103.</i>
Syringe		NO	■ <i>Syringe on page 107.</i>
View event log		NO	■ <i>View Event Log on page 106.</i>
Date / Time		NO	■ <i>Date / Time on page 107.</i>
Maintenance		NO	■ <i>Maintenance on page 107.</i>
Library information		NO	■ <i>Library Information on page 108.</i>
Clinical information		NO	■ <i>Clinical Information on page 109.</i>
Data Set	DS	NO	■ <i>Data Set on page 109.</i>

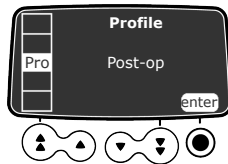
10.2 Profile

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



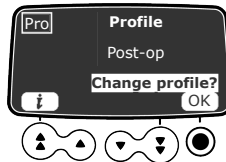
INFORMATION

The Profile function is not available in PCA therapy.

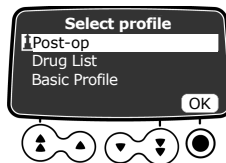


You can display the active profile name as follows:

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



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



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

10.3 Pressure

Symbol	
Procedure	Modifying the pressure limit

Agilia pumps control the pressure inside the infusion line. If the infusion line is partially or totally blocked (called an "occlusion") for any reason, the pressure level inside the line increases. This triggers the occlusion alarms. The pressure limit that triggers these alarms can be configured as shown below. The pump pressure limit is pre-defined in the pump options in one of the following modes:

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

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

- Variable  P

The pressure limit is adjustable within a pre-defined range.

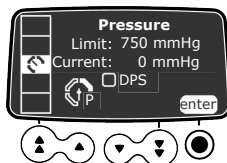
When the pressure limit is reached, an occlusion alarm is triggered. You must silence the alarm, resolve the occlusion and start the infusion again.

To consult the pressure settings, see *Pressure Management* on page 134.



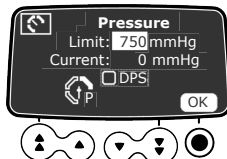
WARNING

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 healthcare professional should weigh the relative risks of disconnection with the risks of an unintended bolus of drug.



You can modify the pressure limit as follows:

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



4. Press the arrow keys to increase or decrease the pressure limit.
5. Press  to select **OK** to validate.
6. Press the arrow keys to select  to enable or disable the DPS function (optional).
7. Press  to select **OK** in order to confirm.



WARNING

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

- Consider adjusting the pressure thresholds according to the route of administration and to the infused medication to minimize the occlusion detection time and the time to trigger the related alarms, especially at flow rates below 1 mL/h. The lower the occlusion pressure threshold is, the shorter the occlusion detection time will be.
- Use the smallest compatible syringe size to deliver the intended medication, especially when infusing life-sustaining drugs. This minimizes the amount of friction and compliance of the syringe plunger head, optimizes pump accuracy and reduces post-occlusion bolus volumes.
- 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.

10.4 Keypad Lock Status

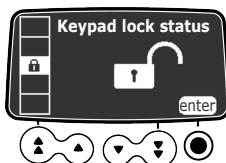
Symbol	
Procedure	Locking / Unlocking the keypad

You can use this feature to avoid inadvertent key presses.

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

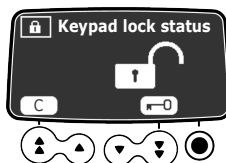
- Unlock code: The user must enter a code to unlock the keypad.

Locking the Keypad



You can lock the keypad as follows:

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

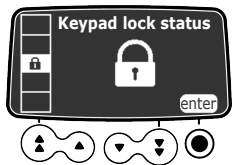


4. Press to lock the keypad.

The keypad is locked and the screen displays .

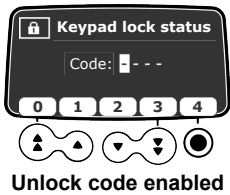
5. Press to select **OK** in order to confirm.

Unlocking the Keypad

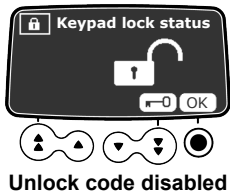


You can unlock the keypad as follows:

- 1. Press .
- 2. Press  to select **enter**.



Unlock code enabled



Unlock code disabled

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

The keypad is unlocked and the screen displays .

INFORMATION



- The  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.

10.5 Keypad Automatic Lock

Symbol	
Procedure	Activating / Deactivating the keypad automatic lock

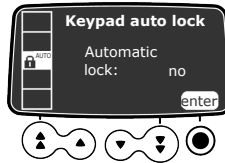
You can use this feature to avoid inadvertent key presses. Depending on the device configuration, the keypad automatic lock feature may or may not be available.

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

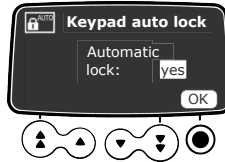
Activating the Keypad Automatic Lock

You can activate the keypad automatic lock as follows:

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



3. Press  to select **enter**.



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

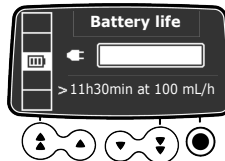
Deactivating the Keypad Automatic Lock

To deactivate the keypad automatic lock:

1. Unlock the keypad: see *Unlocking the Keypad* on page 94.
2. Press .
3. Press the arrow keys to select .
4. Press  to select **enter**.
5. Press the arrow keys to set the Automatic lock to *no*.

10.6 Battery Life

Symbol	
Procedure	Viewing the battery life



You can view the battery life as follows:

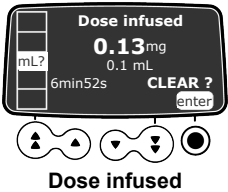
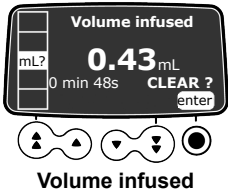
1. Press .
 2. Press the arrow keys to select .
- The time remaining under current flow rate conditions is displayed.

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

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

10.7 Volume Infused / Dose Infused

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



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

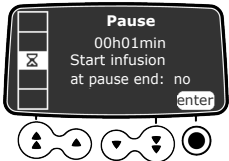
1. Press .
2. Press the arrow keys to select **mL ?**.
The total volume, or total dose, infused includes the programmed infusion, loading doses and boluses. The length of time over which they were infused is also displayed.
3. To clear the volume or dose infused, press  to select **enter**.
4. Press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



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

10.8 Pause

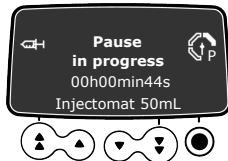
Symbol	
Procedure	Programming a pause (available for General infusions, not available for PCA infusions)



You can program a pause as follows:

1. Press  to stop the infusion.
2. Press .

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



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



INFORMATION

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

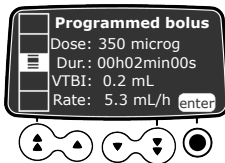
10.9 Programmed Bolus

Symbol	
Procedure	Programming a bolus



INFORMATION

The programmed bolus function is not available in PCA therapy.

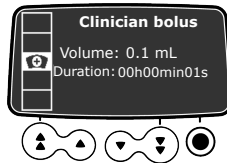


To program a bolus, see *Programmed Bolus* on page 80.

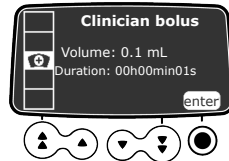
10.10 Clinician Bolus

Symbol	
Procedure	Programming a clinician bolus

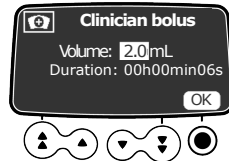
You can program and start a clinician bolus as follows.



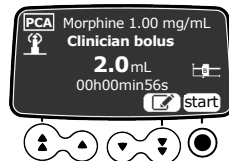
1. Press **MENU**, then press the arrow keys to select . The screen displays the default settings for a clinician bolus, or the values programmed in the last clinician bolus administered.
2. To modify the settings, unlock the keypad, as explained in *Keypad Lock Status* on page 93. The keypad will lock automatically again within 15 seconds.
3. Display the **Clinician bolus** screen again. The **enter** button is now available.



4. Press  to select **enter**.
5. Set the value of the dose. The volume is automatically adjusted.



6. Press  to select **OK** to confirm the settings. The clinician bolus start screen is displayed.



7. Choose one of the options:
 - Press the  key to select **start** in order to start infusion of the clinician bolus
 - Press the  key in order to save the settings without administering the bolus
 - Press the arrow key to select  in order to modify the settings

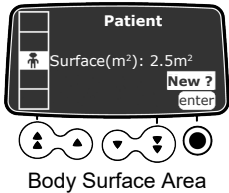
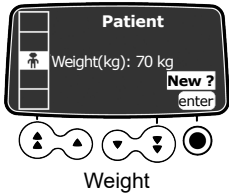
10.11 Patient

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



INFORMATION

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



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

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

10.12 Day/Night Mode

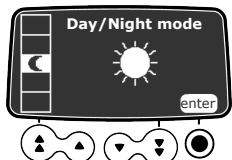
Symbol	
Procedure	Switching between day mode and night mode

This function switches between day mode  and night mode . The default night mode settings are as follows:

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

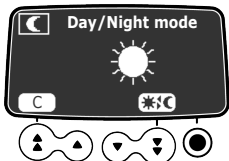
Depending on your pump configuration, the switch between day and night mode may be managed either through this menu (manual mode), or according to pre- defined settings (auto mode). For more information, refer to the technical manual.

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



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

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



4. Press  to activate night mode (the screen displays ) or day mode (the screen displays )
5. Press  to select **OK** in order to confirm.

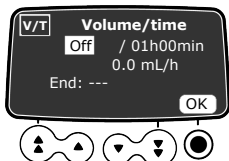
10.13 Volume/Time & Dose/Time

Symbol	V/T D/T
Procedure	Programming a Volume/Time or Dose/Time infusion

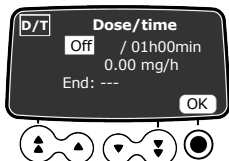


INFORMATION

The V/T and D/T functions are not available in PCA therapy.



Volume/Time



Dose/Time

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

For more information on how to program a Volume/Time or Dose/Time infusion, see *Volume/Time & Dose/Time* on page 82.

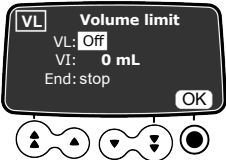
10.14 Volume Limit

Symbol	VL
Procedure	Programming a Volume Limit infusion

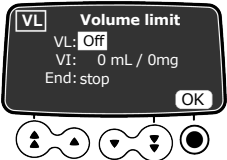


INFORMATION

The VL function is not available in PCA therapy.



Volume/Time

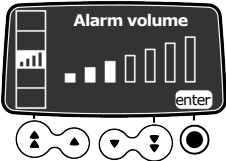


Dose/Time

1. Press .
2. Press the arrow keys to select VL.
3. Press  to select **enter**.
For more information on how to program a Volume Limit infusion, see *Volume Limit* on page 83.

10.15 Alarm Volume

Symbol	
Procedure	Adjusting the alarm volume



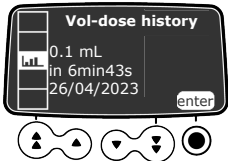
You can adjust the alarm volume as follows:

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

10.16 Volume-Dose History

Symbol	
Procedure	Viewing the infusion history

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



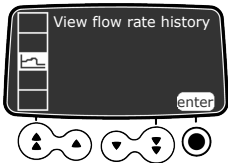
You can view the infusion history as follows:

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

10.17 View Flow Rate History

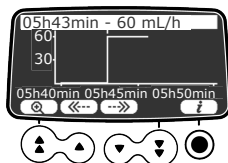
Symbol	
Procedure	Viewing flow rate history

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  to select **enter**.
The following information is displayed: an event marker (cursor), the event details (time and flow rate), the measured flow rate (solid line).



4. Press the arrow keys to select and in order to browse the events.
5. Press to select in order to view information about the selected event.



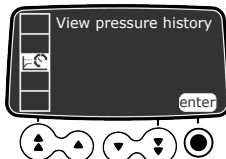
INFORMATION

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

10.18 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 to select **enter**.
The following information is displayed: an event marker (cursor), the event details (time and pressure limit), the pressure limit (dotted line), the measured pressure (solid line).



4. Press the arrow keys to select and in order to browse the events.
5. Press to select in order to view information about the selected event.



INFORMATION

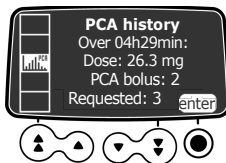
- The history is not refreshed while the history screen is displayed. To refresh the history data, exit and select the history again.
- Pressure history is not stored after powering off.

10.19 View PCA History

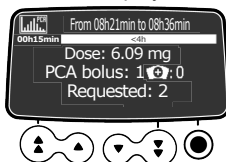
Symbol	
Procedure	Viewing PCA history

You can view the PCA infusion history as follows:

1. Press .
2. Press the arrow keys to select .
The data for the time period specified in the cumulated limits is displayed.



3. Press to select **enter** for details on treatment in progress.
The time scale since beginning of treatment is displayed above the PCA infusion data.



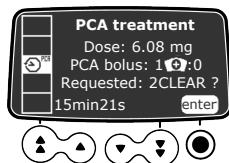
4. Use the arrow buttons or the zoom in and zoom out buttons to display previous time periods, or a different length of time, as explained in *Displaying PCA History* on page 62.

10.20 View PCA Treatment Information

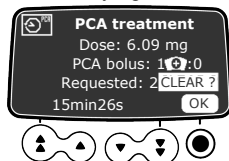
Symbol	
Procedure	Viewing PCA treatment information

You can view information on the PCA treatment in progress as follows:

1. Press .
2. Press the arrow keys to select .
Summary information on the PCA treatment administered is displayed: total dose infused, number of PCA boluses and clinician boluses, time since the beginning of treatment.



- If you want to reset the count to zero on these indicators, press the confirm key  once to highlight the **CLEAR ?** option, then press the confirm key again to validate.



INFORMATION

The PCA history and PCA event log keep the information that is erased from the PCA treatment screen. The PCA treatment reset is an event that is shown in the event log.

10.21 View PCA Event Log

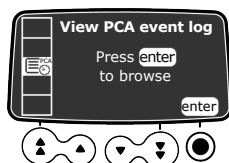
Symbol	
Procedure	Viewing PCA event log

The PCA event log shows all the actions related to the PCA therapy in progress. It is a subset of the pump event log. It can store up to 1500 events. When it is full, older events are overwritten. Events are stored in the log even after the pump is powered off and on again.

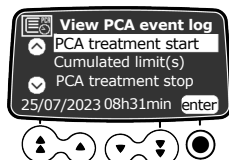
NOTE: When the AC power is disconnected for a period of time, or when the batteries are not operating, the log file is kept in a non-volatile memory for approximately 10 years.

You can view the PCA event log as follows:

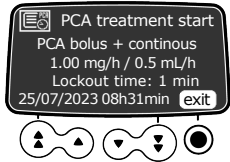
- Press .
- Press the arrow keys to select . A list of events is displayed.



- Press  to select **enter**. The first event in the list is highlighted.



- Press the arrow keys to scroll through the list and to select an event.
- Press  to select **enter**.
Details of the selected event are displayed.



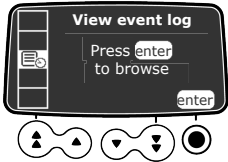
- Press  to select **exit** in order to return to the event list. Press  or  twice to return to the infusion screen.

10.22 View Event Log

Symbol	
Procedure	Viewing the event log

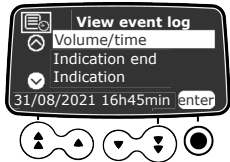
The event log displays details of the last events that occurred on the pump. Events are stored in the log even after the pump is powered off and on again. The log can store up to 1500 events. Older events are overwritten.

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



You can view the event log as follows:

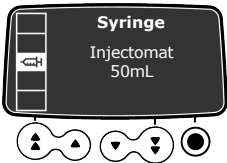
- Press .
- Press the arrow keys to select .
- Press  to select **enter** in order to browse the events.



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

10.23 Syringe

Symbol	
Procedure	Displaying on-pump syringe information



You can display on-pump syringe information as follows:

1. Press .
2. Press the arrow keys to select .
The following information is displayed: syringe capacity, syringe brand / name.

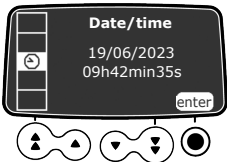
10.24 Date / Time

Symbol	
Procedure	Setting the date and time



INFORMATION

In PCA therapy, the **Date/Time** function is disabled during infusion to avoid affecting time based safety limits.



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

You can set the pump date and time as follows:

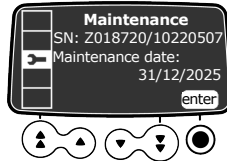
1. Press .
2. Scroll to  by using the arrow keys. Then, press  to select **enter** to display the Date/time settings.
3. Use the arrow keys to set the Day, Month, Year, Hours and Minutes.
4. Press  to select **OK** to save your changes.

10.25 Maintenance

Symbol	
--------	---

Procedure

Displaying maintenance information



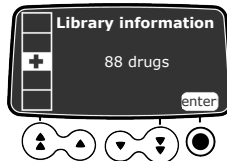
You can display maintenance information as follows:

1. Press .
2. Press the arrow keys to select .
3. Press  to select **enter**.
4. Press the arrow keys to scroll through the maintenance information.
The following information is displayed: pump serial number, next maintenance date (dd/mm/yyyy), pump model, software version, total operating time since last maintenance.

10.26 Library Information

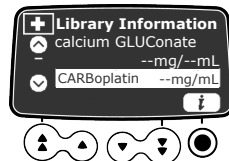
Symbol**Procedure**

Displaying drug library information



You can display drug library information as follows:

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

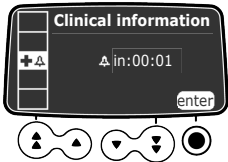


4. Press the arrow keys to select a drug.
5. Press  to select  to view information on the selected drug.

10.27 Clinical Information

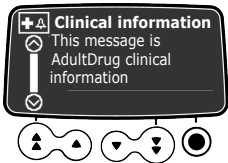
Symbol	
Procedure	Viewing remaining time before clinical information display

For drugs selected from a custom profile, clinical information messages can be displayed.



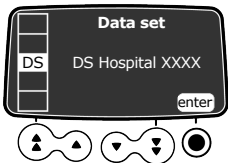
You can view the remaining time before clinical information display as follows:

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



10.28 Data Set

Symbol	DS
Procedure	Displaying active data set information



You can display active data set information as follows:

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



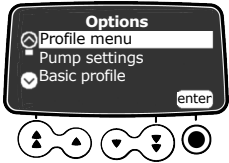
11 Advanced Pump Configuration

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

11.1 Accessing the Pump Configuration Options

Display the pump configuration options as follows:

-  Pump off, simultaneously press  + .
- The **Options** screen is displayed. See *Pump Settings* on page 112 for details on the **Pump settings** options. For information on other options, refer to the Technical manual.



Using the Keypad

Operation	Key
Option selection	   
Confirm	 (corresponds to enter on the screen)
Select ☒ / Deselect ☐	

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

11.2 Option Groups

Four different option groups are available on the pump. These Instructions For Use only describe the "Pump Settings" options.

Option	Access Code?	Description Location
Pump settings	Yes Default code: 0100	<i>Pump Settings</i> on page 112.
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.
The Default access code may be modified using Agilia Partner Maintenance Software.

11.3 Pump Settings

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

Function	Choice	Default Pump Setting
[User 1]: Screen option	■ V/T D/T programming in view list	Enabled
	■ Enable/Disable framing of editable values	Enabled
[User 2]: Menu items	■ Maintenance: display or hide maintenance menu	Disabled
	■ Date / Time: display or hide date/time menu	Disabled
[User 3]: Contrast	■ Adjustment of screen contrast using the fast increment and decrement keys	Medium level
[User 7]: Date/Time	■ Date selection: dd/mm/yyyy	Production plant date and time
	■ Time selection: __ h __ min	
[User 8]: Language	■ A scrolling list with all available languages	Official language of the target country
[User 14]: Wi-Fi module	■ Enable/Disable the Wi-Fi module	Enabled
[Par 5]: Syringe selection	■ Enable/Disable selected syringe confirmation screen	Enabled
[Par 6]: Syringes	■ Checkbox list with the syringes sizes and the names of available syringes	Specific to product code
[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 (Disabled) / Remove trailing 0 during programming (Disabled)
[Par 37]: Alarm system	■ Enable/Disable preventive silence for alarm system	Enabled

12 Data Communication

12.1 Overview

Important cybersecurity recommendations

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

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

Cable Communication	Wi-Fi Communication
Connection of 1 pump to a PC for the following purposes: ■ Data set upload (via Drug Library Software) ■ Maintenance (via Agilia Partner)	Communication between a hospital information system server and a number of identified pumps for the following purposes: ■ Data set upload ■ Pump history retrieval



INFORMATION

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

To prevent unauthorized connections to the Agilia SP PCA Syringe Infusion Pump (cybersecurity threats), do as follows:

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

12.2 Communication via Agilia Cables

12.2.1 Data Communication Cables

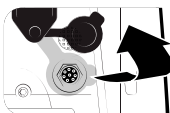


INFORMATION

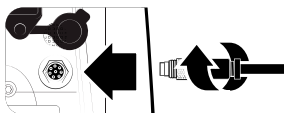
- Only use recommended Agilia cables.
- All connections and disconnections must be performed by qualified and appropriately trained staff.
- All IT devices (including computers, hubs and switches) inside the patient area (< 1.5 m) must comply with IEC/EN 60601-1 (leakage current).
- IT devices connected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

12.2.2 Using the Communication Port

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



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



INFORMATION

Do not disconnect communication cables while data is being transferred.

12.3 Communication via Wi-Fi

The Wi-Fi option allows the pump to connect to a hospital information system without cables.

To activate or deactivate the Wi-Fi module, see *Pump Settings* on page 112. For more information on the Wi-Fi module, refer to the technical manual.

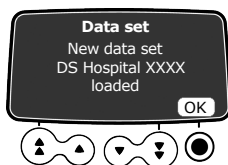
Wi-Fi pumps can be configured with Wi-Fi module enabled or disabled.

12.4 Data Set Upload

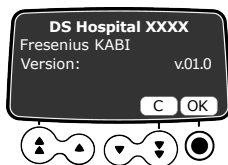
A new data set may be uploaded to the pump while it is infusing. The new data set will be installed at the next pump start-up.

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

1. Power on the pump.



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



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



INFORMATION

It is the hospital's responsibility to define a data set and upload it to the device.

13 User Test

The following protocol provides a quick integrity check guide to ensure that the pump and patient handset are functional. Perform this user test before each use of the pump and patient handset.

1. Check the external appearance of the pump including the protective cover for the absence of cracks or other visible damage.
2. Check the patient handset including the cable gland and cable connector for the absence of cracks or other visible damage.
3. Check that the locks on the protective cover and on the rotating pole clamp are functional.
4. Check for the absence of visible damage on the power cord inlet and the power cord.
5. When used on a pole or a rail, check that the pump is securely attached.
6. Connect the pump to the AC power supply, and check that the power indicator lights up and a beep is emitted.
7. Power on the pump, and wait for the auto-test to complete. Check the display and light indicators.
8. Press any key and listen for a key beep (if key beep is activated).
9. Connect the patient handset and check that the LED above the bolus button lights up.
10. Before programming an infusion, press the bolus button on the patient handset and listen for a beep.



INFORMATION

If any one of the above tests is not satisfactory, do not use the pump or handset.

14 Alarms and Safety Features

14.1 Introduction

Agilia SP PCA has a continuous monitoring system that begins when the pump is started. When an alarm is triggered, a message is displayed on the pump screen. We recommend that the user stand in front of the pump to read the message before acknowledgment.



CAUTION

- Audible alarm signals from medical devices may be masked by environmental noise. Make sure to set the alarm volume high enough so that you can hear the alarm signal above environmental noise.
- For pumps used in a dedicated ward (ICU, surgery rooms, etc.), it is recommended that you disable the ability to select the profile, thereby locking the pumps to the selected profile. This ensures that all alarms that may be triggered by the pumps behave the same way in a given ward.

14.2 Alarm Descriptions

There are several different levels of alarm priorities:

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

Alarm Priority	Required Operator Response	Description
High (!!!)	Immediate response	■ The infusion stops. ■ The infusion indicator lights flash red. ■ The pump emits audible alarm signals. ■ An alarm description is displayed on the pump screen. ■ Depending on the alarm, the  key silences the alarm for no time limit or for a defined duration. For detailed description of each alarm, see <i>List of Alarms</i> on page 117.
Medium (!!)	Prompt response	■ The infusion continues. ■ The infusion indicator lights flash yellow. ■ The pump emits audible alarm signals. ■ Depending on the alarm, the  key silences the alarm. For detailed description of each alarm, see <i>List of Alarms</i> on page 117.

Alarm Priority	Required Operator Response	Description
Low (!)	Awareness	- The infusion continues. - The infusion indicator lights (LEDs) yellow are ON. - The pump emits audible alarm signals. - Depending on the alarm, the  key silences the alarm. For detailed description of each alarm, see <i>List of Alarms</i> on page 117.
Information Signals	Awareness	- The infusion continues. - An information message is displayed on the pump screen. - For detailed description of each alarm, see <i>List of Alarms</i> on page 117.

14.3 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.

14.4 List of Alarms

14.4.1 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.

Message	Priority	Stops Infusion?	Problem / Resolution
Disengagement mechanism !!!	High (!!!)	Yes	Disengaged mechanism. NOTE:  Check the syringe installation. NOTE: the  key silences the alarm for 2 minutes.
Remove completely syringe !	Low (!)	No	Preventive auto-test on potential failure of plunger head.  Remove and reinstall the syringe. NOTE: the  key silences the alarm for 2 minutes.

14.4.2 Protective Cover Alarms

Message	Priority	Stops Infusion?	Problem / Resolution
Cover missing !!!	High (!!!)	Yes	In PCA therapy only, if the protective cover is mandatory, message displayed if it is not installed.  Install the cover or confirm start of infusion without the cover. NOTE: the  key silences the alarm for 2 minutes.
Cover opened !!!	High (!!!)	Yes	If the protective cover is mandatory, message displayed if it is left open.  Close the cover or confirm start of infusion without the cover. NOTE: the  key silences the alarm for 2 minutes.
Cover installed !!	Medium (!!)	No	Cover is installed on the pump while an infusion is in progress or stopped.  Remove the cover from the pump, or close it. NOTE: the  key silences the alarm for no time limit.
Cover opened !!	Medium (!!)	No	In general infusion, the protective cover is opened during infusion.  Silence the alarm and close the cover. NOTE: the  key silences the alarm for no time limit.

Message	Priority	Stops Infusion?	Problem / Resolution
Cover opened	Information signal	No	If the protective cover is not mandatory, message displayed if it is left open.  Remove cover or press OK to acknowledge cover is open.
Cover opened Lock the cover or confirm start	Information signal	No	If the protective cover is not mandatory, message displayed if it is left open, and acknowledged.  Close the cover or confirm start of infusion without the cover.
Cover installed Close or remove the cover	Information signal	No	If the protective cover is not mandatory, message displayed if it is installed during infusion.  Close the cover.

14.4.3 Patient Handset Alarms

Message	Priority	Stops Infusion?	Problem / Resolution
Patient handset not plugged in the pump !!	Medium (!!)	No	The patient handset is missing or not connected although the handset is mandatory.  Connect the patient handset to the pump. NOTE: the  key acknowledges the alarm.

14.4.4 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.
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 time duration from 1 minute to 12 hours.

14.4.5 Volume/Time Alarms

Message	Priority	Stops Infusion?	Problem / Resolution
End of volume/time !!!	High (!!!)	Yes	The VTBI/DTBI is completed. NOTE: the  key acknowledges the alarm.
End of dose/time !!!			
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/DTBI has dropped to less than 10% of the syringe capacity. NOTE: the  key silences the alarm for no time limit.
Near end of dose/time !!			
End of volume/time !	Low (!)	No	The VTBI/DTBI is completed and the end of infusion setting is set as "KVO" or "continuous". NOTE: the  key silences the alarm for a time duration from 1 minute to 12 hours.
End of dose/time !			

14.4.6 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.
Max cumulated dose !!	Medium (!!)	Yes	In PCA therapy, the maximum dose specified in the cumulated limits is reached.  Wait until the time you can restart the infusion.  Or, modify the infusion settings to increase the cumulated dose limit, and restart the infusion. NOTE: the  key silences the alarm for 60 minutes, after which a brief reminder beep will sound.
Maximum PCA boluses !!	Medium (!!)	No	In PCA therapy, the maximum number of PCA boluses specified has been infused.  Wait until the time a PCA bolus becomes available again.  Or, modify the infusion settings to increase the cumulated limit on the number of boluses, and restart the infusion. NOTE: the  key silences the alarm for no time limit.

Message	Priority	Stops Infusion?	Problem / Resolution
Maximum cumulated dose nearly reached !	Low (!)	No	In PCA therapy, the maximum dose specified in the cumulated limits is nearly reached. ☞ Wait until the time a PCA bolus becomes available again. ☞ Or, modify the infusion settings to increase the cumulated dose limit to allow more PCA boluses, and restart the infusion. NOTE: the  key silences the alarm for no time limit.
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 no time limit.
Check settings !!	Medium (!!)	No	The flow rate (or dose) has been modified using the keys but has not been confirmed. ☞ Check the flow rate (or dose) and press OK to confirm. NOTE: the  key silences the alarm for 2 minutes.
Waiting settings !!	Medium (!!)	No	A value must be entered. ☞ Enter a value and press OK to confirm. NOTE: the  key silences the alarm for 2 minutes.
Waiting start !!	Medium (!!)	No	The infusion settings have been entered, but the infusion has not been started with start key. ☞ Check the infusion settings, ☞ Press start to start the infusion. NOTE: the  key silences the alarm for 2 minutes.
End of clinician bolus !	Low (!)	No	Displayed after administration of a clinician bolus in excess of the maximum dose specified in the cumulated limits. Alternates with the maximum dose high priority alarm.
Upper soft max	Information signal	No	The upper soft limit is exceeded, according to the drug settings defined in the drug library.
Lower soft min	Information signal	No	The lower soft limit is exceeded, according to the drug settings defined in the drug library.

Message	Priority	Stops Infusion?	Problem / Resolution
Reached hard limit	Information signal	No	The upper or lower hard limit is reached.

14.4.7 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 in relation to the flow rate. See <i>Pressure</i> on page 91. NOTE: the  key silences the alarm for 2 minutes.
Occlusion pre alarm !!	Medium (!!)	No	In-line pressure has reached the following value: ■ 25 mmHg / 2.5 kPa / 0.5 PSI below the programmed threshold (from 50 to 75 mmHg) or ■ 50 mmHg / 5 kPa / 1 PSI below the programmed threshold (over 100 mmHg) ☞ Check the infusion line. ☞ Set the correct pressure threshold. NOTE: the  key silences the alarm for no time limit.
Pressure increase !	Low (!)	No	The pressure is increasing in the infusion line. ☞ Check for occlusions in the infusion line. NOTE: the  key acknowledges the alarm.
Drop in pressure !	Low (!)	No	The pressure is decreasing in the infusion line. ☞ Check the downstream Luer lock connection and the integrity of the entire line. NOTE: the  key acknowledges the alarm.

14.4.8 Battery Alarms

Message	Priority	Stops Infusion?	Problem / Resolution
Alert !!! Very low battery Connect to power and wait	High (!!!)	Yes	The battery is discharged. The pump will power OFF automatically within 5 minutes.  Connect the pump to a power supply immediately. The pump displays "Battery alarm solved" message. NOTE: the  key silences the alarm for 2 minutes.
Alert !!! Very low battery Too low to use Wait for charge	High (!!!)	Yes	Very low battery.  Allow time to charge. NOTE: the  key silences the alarm for 2 minutes.
Alert !! Low battery Connect to power	Medium (!!)	No	Low battery.  Connect the pump to a power supply. NOTE: the  key silences the alarm for no time limit.
	Low (!)	No	If the pump is not used during an extended period, connect to a power supply and wait until the battery is charged.

14.4.9 Power Alarms

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

14.4.10 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			

14.4.11 Technical Error Alarms

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

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

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



CAUTION

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

14.5 Audio Only Information Signals

Type	Comment	Stops Infusion?	Activation
Switch off	Beep until key is released	No	Beep starts when action is not allowed
End of loading dose	3 beeps	No	At the end of the loading dose
End of programmed bolus	3 beeps	No	At the end of a programmed bolus
Start infusion at the end of pause	3 beeps	N/A	At the end of a pause, when the infusion automatically starts
End of pause	4 beeps	N/A	At the end of pause - repeated
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	Beep until key is depressed	N/A	When purge reached end after 5ml
Patient handset button continuously pressed	1 beep	No	Repeated until key is released
PCA bolus accepted	1 specific beep	No	Patient handset button is pressed and PCA bolus is available
PCA bolus refused	1 specific beep	No	Patient handset button is pressed and PCA bolus is not available

15 Syringes

15.1 Syringe List



CAUTION

Pay attention to syringes specifications (expiration date, storage, sterility, change interval, disposal). To obtain this information, refer to the syringe manufacturer's instructions. Using an expired syringe may impact the infusion pump performances.



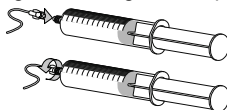
INFORMATION

- The Agilia SP PCA 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.

Fresenius Kabi cannot accept responsibility for any flow rate errors that are due to changes to syringe specifications introduced by the manufacturer.

15.2 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.



WARNING

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



INFORMATION

- 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.
- 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.



INFORMATION

When used for epidural analgesia, it is recommended using yellow color-coded consumables and extension sets with ISO-compliant NRFit® neuraxial connector.

Precautions for the use of extension sets



WARNING

When used for epidural analgesia, it is recommended using consumables and extension sets without injection port.



WARNING

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



CAUTION

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

15.3 Operations for Syringes

15.3.1 Removing a Syringe

1. Press  to stop the infusion.
2. Disconnect the extension set from the patient's access device in accordance with the healthcare facility's protocol.
3. Open the syringe barrel clasp.
4. Push the disengagement lever down and remove the syringe from its cradle.
5. Disconnect the syringe from its extension set.

15.3.2 Changing a Syringe

1. Remove the syringe. See *Removing a Syringe* on page 127.
2. Prepare a new syringe and follow the steps described in the flowchart. See *Flowchart* on page 39.
3. After the new syringe is installed, acknowledge the "same therapy" screen (optional screen).



INFORMATION

Properly dispose of used syringes.

15.3.3 Syringe Replacement Interval

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

15.3.4 Gravity Infusion in Parallel with a Pump

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

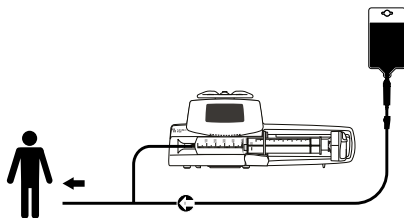


Figure 22: Gravity Infusion (in parallel with a pump)



WARNING

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



CAUTION

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



INFORMATION

If there is no back check valve on a gravity infusion line during a multi-line infusion, it will be impossible to detect patient-side occlusions. Such an occlusion could cause the pumped drug to back up into the gravity line, and later be infused in an uncontrolled manner when the occlusion is released.

16 Device Storage

16.1 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.

16.2 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 above sea-level

16.3 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.

16.4 Using the Device After Storage

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

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

We recommend charging the battery for at least 6 hours.

We recommend that the "User test" is performed when the device is installed after storage, and before being used on a patient, see *User Test* on page 115.

17 Specifications

This chapter describes all of the parameters that you can use to program an infusion with the Agilia SP PCA infusion pump as well as the essential features that classify it as a medical device.



INFORMATION

The range of settings and default values described in this section correspond to the factory configuration.

The range of settings and default values can be adjusted in Basic Profile (see the Technical manual) and in custom profiles. Increment rules can be modified in custom profiles.

17.1 Essential Features

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

Feature	Refer to
Flow Rate Accuracy	<i>Flow Rate Accuracy</i> on page 130. <i>Trumpet and Start-up Curves</i> on page 145.
Time to Detect Occlusion	<i>Occlusion Alarm Accuracy and Bolus Volume at Occlusion Release</i> on page 131.
Bolus Volume After Occlusion Release	<i>Occlusion Alarm Accuracy and Bolus Volume at Occlusion Release</i> on page 131.
Management of High-priority Alarms	<i>Alarms and Safety Features</i> on page 116.

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

NOTE: All tests below are in accordance with the IEC 60601-2-24 standard. Values are representative of syringes used during internal tests and are provided as indicators only.

17.2.1 Flow Rate Accuracy

	Accuracy
Flow Rate	± 3%

* Test condition: Flow rate: 5 mL/h

17.2.2 Effects of Pressure Variations on Accuracy

Changes in the position of the pump in relation to the patient's access device can affect the accuracy of the pump as shown below.

Back pressure	Accuracy (from mean values)
+ 39.9 kPa	~ - 3%
+ 13.33 kPa	~ - 1.5%
- 13.33 kPa	~ + 1.5%

17.2.3 Occlusion Alarm Accuracy and Bolus Volume at Occlusion Release

The time to detect an occlusion varies depending on syringe size, flow rate and pressure, as shown in the table below. Note that this time is always better with a smaller syringe and lower pressure.

	Accuracy			
Occlusion Alarm Response Time*	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 conditions: Temperature: 20 °C, Extension set length: 150 cm

** Syringe: BD Precise

	Accuracy			
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 50 mL

NOTE:

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

17.2.4 Bolus Volume Accuracy

	Accuracy
Direct Bolus*	$\leq 10 \text{ mL}: \pm 0.2 \text{ mL}$
Programmed Bolus*	$> 10 \text{ mL}: \pm 3\%$

* Test condition: 25 measurements, Back pressure: 0 mmHg, Temperature: 20 °C, Extension set length: 60 in (150 cm), Syringe: BD Precise.

17.2.5 Pressure Accuracy

	Accuracy
Pressure	$\leq 500 \text{ mmHg}: \pm 75 \text{ mmHg}$ $> 500 \text{ mmHg}: \pm 15\%$

17.3 Flow Rate Settings

	Unit	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* PCA bolus**	mL/h	50 → 1200	50 → 600	50 → 600	50 → 350	50 → 250	50	
		200	120	120	60	60	Default values	
Programmed bolus Clinician bolus Loading dose PCA loading dose	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)
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.

** PCA bolus default value: 200 mL/h.

*** KVO default value = 1 mL/h.

17.4 Volume To Be Infused (VTBI) Settings

	Unit	Range of Settings	Default Value	Minimum Increment
Volume Limit	mL	0.1 → 999	N/A	0.1 1 (0.1 → 99.9) (100 → 999)
Volume/Time	mL	0.1* → 99.9*	0*	0.1 (0.1 → 99.9)
PCA patient bolus PCA clinician bolus Loading dose	mL	0.1* → 99.9*	0.1*	0.1
Direct Bolus	mL	0.1 → 60**	N/A	N/A
Programmed Bolus Loading dose	mL	0.1* → 99.9*	0.1*	0.1

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

** 60 mL with drug, 10 mL without drug

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

17.5 Dose To Be Infused (DTBI) Settings

	Unit	Range of Settings	Default Value	Minimum Increment
Dose	All	0.01* → 9999*	0*	0.01 (0.01 → 9.99) 0.1 (10.0 → 99.9) 1 (100 → 9999)
Programmed bolus PCA bolus Clinician bolus PCA loading dose Loading Dose	All	0.01* → 9999*	0.01*	0.01 (0.01 → 9.99) 0.1 (10.0 → 99.9) 1 (100 → 9999)

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

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

17.6 Infusion Time

	Format	Range of Settings	Default Value	Minimum Increment
Infusion Time	__ h __ min	00h01min → 96h00min	N/A	00h01min
Programmed Bolus PCA bolus Clinician bolus PCA loading dose	__ h __ min __ s	00h00min01sec → 24h00min00sec	N/A	00h00min01sec → 00h59min59sec 00h01min00sec → 24h00min00sec
Loading Dose	__ h __ min __ s	00h00min01sec → 24h00min00sec	N/A	00h00min01sec → 00h59min59sec 00h01min00sec → 24h00min00sec
KVO Silence Alarm Duration	__ h __ min	00h01min → 12h00min	01h00min*	N/A
Pause	__ h __ min	00h01min → 24h00min	N/A	00h01min
Lockout time	__ min	01min → 360min	N/A	01min

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

Infusion time can only be set for Volume/Time or Dose/Time infusions.

17.7 Concentration

The settings available for concentration shown below apply for PCA therapy and general infusion.

	Unit	Range of Settings	Default Value	Minimum Increment
Concentration	Dose unit	0.01 → 70000	N/A	0.01 (0.01 → 9.99) 0.1 (10.0 → 99.9) 1 (100 → 70000)
Volume of Diluent	mL	1 → 60	N/A	1

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

17.8 Patient Data

The patient body surface area is not a parameter available in PCA therapy.

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

17.9 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

		Range of Settings (*)	Default Value (*)	Minimum Increment (*)
3 Levels	Low	50 → 300	100	50
	Medium	150 → 700	250	50
	High	250 → 900	500	50

		Range of Settings (*)	Default Value (*)	Minimum Increment (*)
Variable	Full Range	50 → 900	750	25 (50 → 250) 50 (250 → 900)
	Maximum Limit	500 → 900	900	50
DPS	Raise Threshold	50 → 400	100	50
	Drop Threshold	100 → 400	100	50

* These values are in mmHg

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

17.10 Units and Conversion Rules

17.10.1 Prescription Units

In PCA therapy, you can select the prescription units listed in the table below to program an infusion. You cannot select the prescription unit for a general infusion.

	Volume	Dose
Default units for PCA mode in Basic Profile	-	microg, mg
Available by configuration	mL	nanog, microg, mg, g, microg/kg, mg/kg, mmol, mUnit, Unit cal, kcal, mEq

17.10.2 Concentration Units

	Units	Suffix
Default units for PCA mode in Basic Profile	mg, microg	/mL
Concentration Units	nanog, microg, mg, g	/mL, /--mL
	mmol	
	mUnit, Unit	
	cal, kcal	
	mEq	

17.10.3 Dose Units

	Units
Default units for PCA mode in Basic Profile	microg/h mg/h

	Units
Dose Units	nanog/h, nanog/kg/min, nanog/kg/h
	microg/min, microg/h, microg/kg/min, microg/kg/h
	mg/min, mg/h, mg/24h, mg/kg/min, mg/kg/h, mg/kg/24h, mg/m ² /h, mg/m ² /24h
	g/h, g/kg/min, g/kg/h, g/kg/24h
	mmol/h, mmol/kg/h, mmol/kg/24h
	mUnit/min, mUnit/kg/min, mUnit/kg/h
	Unit/min, Unit/h, Unit/kg/min, Unit/kg/h
	kcal/h, kcal/24h, kcal/kg/h
	mEq/min, mEq/h, mEq/kg/min, mEq/kg/h
	mL/kg/min, mL/kg/h, mL/kg/24h

17.10.4 Conversion of Units

The pump uses the following conversions of units:

- 1 micro unit = 1000 nano unit
- 1 m unit = 1000 micro unit
- 1 k unit = 1000 unit
- 1 unit/h = 24 unit/24 h
- 1 unit/min = 60 unit/h

17.10.5 Conversion of Concentrations and Dose Rates

When you start an infusion, the pump converts the parameters you programmed into a volume and a flow rate using the equations below.

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

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

18 Cleaning and Disinfecting

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



INFORMATION

Lock the keypad before performing a cleaning to avoid any unintended modification of the infusion parameters.

18.1 Recommended and Prohibited Agents



CAUTION

Recommended agents

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



CAUTION

The following cleaning and disinfecting agents are prohibited:

- Trichloroethylene
- Abrasive detergents
- Agents with high alcohol concentration (> 30%)

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

18.2 Quick Cleaning Procedures

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

18.2.1 Quick Cleaning for the Pump



INFORMATION

A quick cleaning of the pump during infusion does not replace the need for a complete cleaning procedure.

1. Make sure 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, as explained in *Cleaning Instructions*.

18.2.2 Quick Cleaning for the Patient Handset



INFORMATION

A quick cleaning of the patient handset during infusion does not replace the need for a complete cleaning procedure as described in *Instructions for Cleaning and Disinfecting* on page 139.

1. Press the **stop** key  on the pump in order to avoid an unintended bolus while cleaning the patient handset.

2. Use ready-to-use wipes to wipe down all exposed surfaces of the patient handset, cable gland, and cable.
3. Restart the infusion.
4. At the end of the infusion, perform the complete cleaning protocol, as explained in *Cleaning Instructions*.

18.3 When to Clean and Disinfect the Pump and the Patient Handset

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.

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

Only trained staff can clean and disinfect the pump.



CAUTION

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

- The pump and the handset are not intended to be sterilized. Do not put them in an autoclave or immerse them in any liquid.
- Do not spray liquids directly on connectors: preferentially use cleaning wipes.

18.4.1 Cleaning Instructions

Prerequisites

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

Protocol for the pump

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, protective cover and keylock, 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 handset holder and cable stowage, 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.

Protocol for the patient handset

1. Place the patient handset 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, button area, strap, cable gland, cable, and connector).

Do not allow liquids to run, leak, or drip into the housing or the connector.

4. Make sure the patient handset remains damp for at least 1 minute to dissolve all organic matter.
5. Allow the pump to dry completely at room temperature.

18.4.2 Disinfection Instructions

Prerequisites

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

Protocol for the pump

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 handset holder and cable stowage, 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.

Protocol for the patient handset

1. Place the previously cleaned patient handset on a clean surface or disposable underlay.
2. Use a ready-to-use wipe to wipe down all exposed surfaces making sure to cover all hard-to-reach areas.

Do not allow liquids to run, leak, or drip into the housing or the connector.
3. Using a fresh ready-to-use wipe, repeat step 2.
4. Leave the disinfection agent on the patient handset for at least 3 minutes.
5. Allow the device to dry completely at room temperature.

19 Power Management

19.1 AC Power Supply Precautions

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



WARNING

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



CAUTION

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

19.2 Battery Precautions

The device uses a Lithium-ion rechargeable battery.

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

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



CAUTION

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

19.3 Battery Operating Mode

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

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



INFORMATION

During operation, leave the device connected to the power supply in order to maintain the battery's charge and maximum capacity, and to maximize battery lifetime and performance. The essential performance and behaviour of the device are not affected during charging.

20 Technical Characteristics

20.1 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		100 V - 240 V ~ / 50 / 60 Hz with functional earth
	Power supply	
	Maximum consumption	10-15 VA
	Protective fuse	1 X T1.6AH 250V accessible in the battery compartment

20.2 Battery

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

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

The device is equipped with one of these batteries:

- 7.2 V 2.2 Ah
- 7.34 V 2.75 Ah

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

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

Characteristics	7.34 V 2.75 Ah - Li-ion Smart battery		
Weight	Approximately 100 g		
Battery Life	Flow Rate	Wi-Fi	Battery Life
	5 mL/h	✓	> 8 h
	5 mL/h	x	> 17 h
Battery Recharge	Pump OFF: < 7 h / Pump ON: < 21 h		

✓ = Wi-Fi enabled

x = Wi-Fi disabled or not used

20.3 Power Consumption

The pump typically consumes about 3.5 W in standard operating conditions.

20.4 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.

20.5 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

20.6 Sound Levels

20.6.1 Operating Pump Sound Levels (without alarms)

Flow Rate (mL/h)	Sound Level (dB(A))
0	21
1	23
20	27
100	30
400	49
1200	32

NOTE: These values are provided for information purposes only.

20.6.2 Alarms Sound Levels

Alarm Priority	Range for sound alarm volume adjusted at minimum (see <i>Alarm Volume</i> on page 101)			Range for sound alarm volume adjusted at maximum (see <i>Alarm Volume</i> on page 101)		
	Range values		Measured values	Range values		Measured values
High	55	70	63.2	70	80	75.1

Alarm Priority	Range for sound alarm volume adjusted at minimum (see <i>Alarm Volume</i> on page 101)			Range for sound alarm volume adjusted at maximum (see <i>Alarm Volume</i> on page 101)		
	Range values		Measured values	Range values		Measured values
Medium	54	64	58.5	64	75	70
Low	52	62	56.8	59	70	64.2

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

20.7 Compliance

Electro-medical equipment safety	Compliant with the following standards: ■ EN/IEC 60601-1 ■ EN/IEC 60601-1-8	IP32 (pump) IP27 (handset except connector)   	Index of protection against ingress of water or particulate matter
EMC (Electromagnetic compatibility)	Compliant with the following standard: ■ EN/IEC 60601-1-2		Protection against leakage current: Defibrillation-proof type CF applied part*
Particular standards	■ EN/IEC 60601-2-24		Protection against electric shocks: class II Functional earth**

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

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

20.8 Dimensions and Weight

Pump dimensions and weight without protective cover

H / W / D	150 x 350 x 195 mm
Weight	Approximately 2.5 kg
Screen Size	70 x 35 mm

Pump dimensions and weight with protective cover

H / W / D	150 x 350 x 210 mm
Weight	Approximately 2.7 kg

Patient handset dimensions and weight

H / W / D	20 x 35 x 115 mm (without cable) or 20 x 35 x 1960 mm (with cable)
Weight	Approximately 65 g

20.9 Trumpet and Start-up Curves



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

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

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

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

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

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.

20.9.1 Flow Rate: 1 mL/h

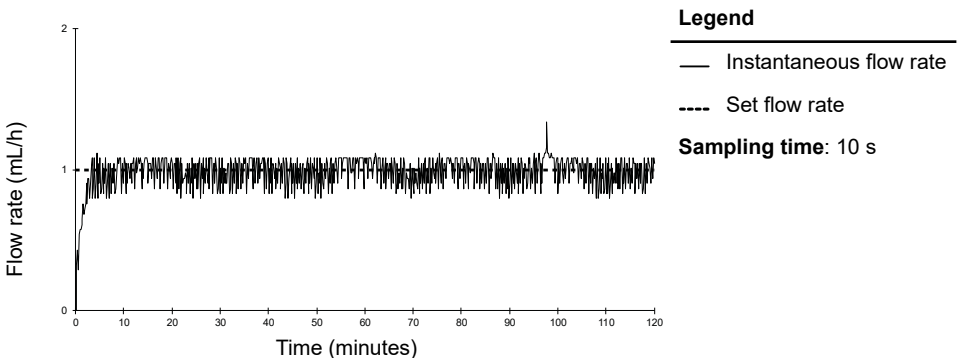


Figure 23: Start-up and instantaneous flow rate (1 mL/h over 2 hours)

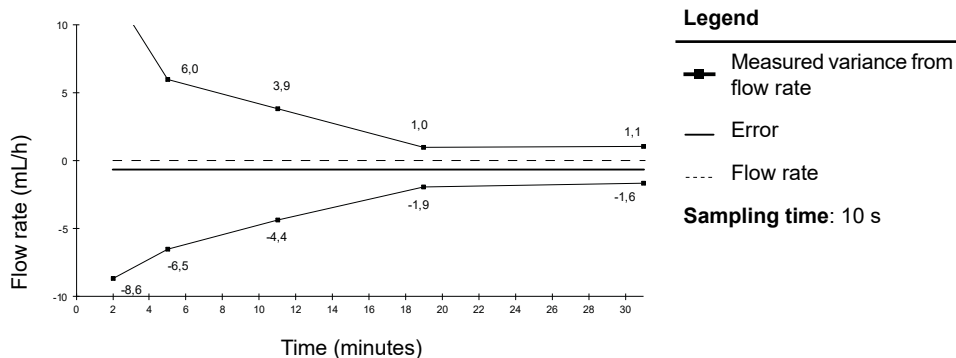


Figure 24: Trumpet curves for 2, 5, 11, 19, 31 minutes observation windows (1 mL/h over 2 hours)

20.9.2 Flow Rate: 5 mL/h

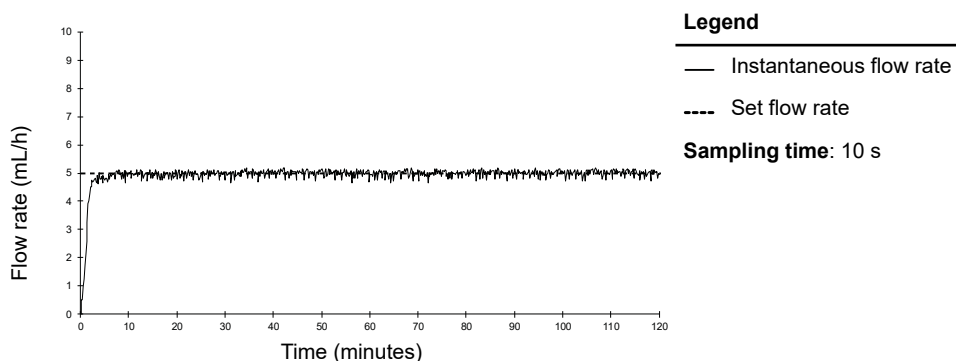


Figure 25: Start-up and instantaneous flow rate (5 mL/h over 2 hours)

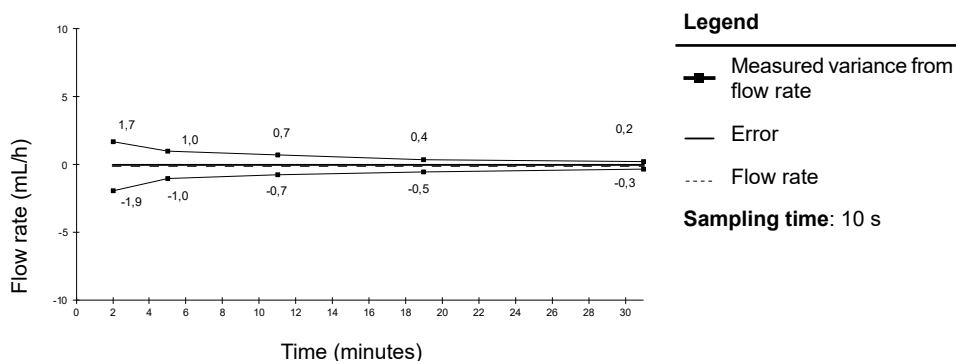


Figure 26: Trumpet curves for 2, 5, 11, 19, 31 minutes observation windows (5 mL/h over 2 hours)

21 Wi-Fi

21.1 General Information

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

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

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

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

Agilia infusion pumps contain transmitter with the following IDs:

- FCC ID: Z64-CC3235MOD
- IC ID: 4511-CC3235MOD

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

Agilia infusion pumps support a hidden network.

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



INFORMATION

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

21.2 Technical Specifications

	Description
Technology	IEEE 802.11 a/b/g/n
Frequency Band	■ 2.412 → 2.472 GHz (2.4 GHz is ISM band) ■ 5.180 → 5.825 GHz (High Band)
Modulation	DSSS, CKK, OFDM, MCS7
Wireless Security	WEP64, WEP128, WEP64 shared, WEP128 shared, WPA, WPA-Enterprise, WPA-Enterprise TLS, WPA-Enterprise TTLS, WPA2, WPA2-Enterprise, WPA2-Enterprise TLS, WPA2-Enterprise TTLS
Network Protocols	IPv4 TCP/IP, DHCP, HTTP/HTTPS
Typical Transmit Power (± 2 dBm)	■ 16 dBm for 802.11b DSSS ■ 16.3 dBm for 802.11b CCK ■ 15.3 dBm for 802.11g/n OFDM ■ 15.1 dBm in 802.11a mode

21.3 Electromagnetic Compatibility

For information on electromagnetic compatibility, see *Guidance and Manufacturer's Declaration on EMC* on page 153.

USA - FCC Notice



INFORMATION

Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

Europe - Radio Equipment Directive

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

21.4 Protocols and Standards

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

- IEEE 802.11a/b/g/n standard
- WEP64, WEP128, WEP64 shared, WEP128 shared, WPA, WPA-Enterprise, WPA-Enterprise TLS, WPA-Enterprise TTLS, WPA2, WPA2-Enterprise, WPA2-Enterprise TLS, WPA2-Enterprise TTLS (Wi-Fi protected access) is a long-term security solution for wireless networks. For more information, refer to the IEEE 802.11.
- TCP (Transmission Control Protocol / Internet Protocol), IPv4 (Internet Protocol Version 4), DHCP (Dynamic Host Configuration Protocol), HTTP (Hypertext Transfer Protocol) and HTTPS (Hypertext Transfer Protocol Secure) are standard data transport protocols used for the internet and other similar networks.

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

22 Troubleshooting

Issue	Recommended Actions
The pump is unstable when mounted.	■ Check that the rotating pole clamp is fastened.
The pump is damaged, or you notice something abnormal (unusual noise, abnormal heat or smoke).	■ Remove the power cord. ■ Contact your biomedical department or your Fresenius Kabi sales representative immediately.
The pump has been dropped or was subjected to a force that may have produced internal damage.	■ Do not use the pump. ■ Contact your biomedical department or your Fresenius Kabi sales representative.
The power supply indicator does not light up when the pump is racked into the Agilia Link device.	■ Check that the Agilia Link device is connected to the mains. ■ Check the pump is correctly slotted in the Agilia Link device. You should hear a beep. ■ If the problem persists, check that the AC power supply indicator lights up when the pump is connected directly to the mains. ■ Contact your biomedical department or your Fresenius Kabi sales representative.
The lock on the pump for the protective cover is jammed.	■ Contact your biomedical department or your Fresenius Kabi sales representative.
The pump cannot be removed from the pole.	■ Make sure the lock on the pole clamp is unlocked. ■ Contact your biomedical department or your Fresenius Kabi sales representative.
The pump does not start after pressing  .	■ Connect the pump to the AC power supply to see if the battery is fully discharged. ■ Contact your biomedical department or your Fresenius Kabi sales representative.
Data communication cables cannot be connected or removed from the pump.	■ Check the cable connector. ■ Check the pump connector. ■ Contact your biomedical department or your Fresenius Kabi sales representative.
Flow rate variance is higher than flow rate accuracy.	■ Check the infusion line configuration. ■ Check the fluid viscosity. ■ Check that the fluid temperature is within the recommended range. ■ Contact your biomedical department or your Fresenius Kabi sales representative.
Keypad problem (keys, LEDs).	■ Check the general condition of the keypad. ■ Check the contrast. ■ Contact your biomedical department or your Fresenius Kabi sales representative.

Issue	Recommended Actions
The pump powers off on its own.	■ Connect the pump to the AC power supply. ■ Contact your biomedical department or your Fresenius Kabi sales representative.
The battery alarm is ON even though the pump has been correctly charged.	■ Check the AC power voltage. ■ Contact your biomedical department or your Fresenius Kabi sales representative.
The pump powers off when it is disconnected from the AC power supply.	■ The battery is completely discharged: charge the battery. ■ Contact your biomedical department or your Fresenius Kabi sales representative.
The LED on the patient handset does not light up.	■ Check that the handset is connected to the pump and that the pump is On. ■ Check that the handset connector is correctly plugged in and that the cable is not damaged. ■ Connect the handset connector to another Agilia SP PCA infusion pump to see if the problem persists. ■ Contact your biomedical department or your Fresenius Kabi sales representative.
No beep when pressing the bolus button on the patient handset.	■ Check that the handset is connected to the pump and that the pump is On. ■ Check that the bolus button beep is enabled in the pump configuration. ■ Contact your biomedical department or your Fresenius Kabi sales representative.
Wi-Fi communication error.	■ Contact your IT or biomedical department, or your Fresenius Kabi sales representative.
At start-up, the pump displays: "Software is upgrading...".	■ Connect the pump to the AC power supply. Then, wait few minutes without touching the keypad until the message disappears and the pump starts as usual. ■ Contact your biomedical department or your Fresenius Kabi sales representative.

23 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.

24 Warranty

24.1 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.

24.2 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.

24.3 Warranty Conditions for Accessories

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

25 Guidance and Manufacturer's Declaration on EMC

25.1 Electromagnetic Compatibility



DANGER

Do not use Agilia SP PCA WiFi in an MRI environment.



WARNING

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

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

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

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

25.2 Electrostatic Discharge (ESD)



CAUTION

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

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

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

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

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

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

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

25.3 EMC and essential performances

In standard operating conditions (see *Use Environment* on page 11), the essential performance of the Agilia pump is defined in *Essential Features* on page 130.

In the event of electromagnetic disturbances above the limits defined in the applicable EMC standards, if the essential performance is lost or degraded, the consequences for the patient are: over-delivery, under-delivery, delay of therapy, electrification.

It is the responsibility of the customer or user to check the equipment before use as described in *User Test* on page 115, and to consider the EMC guidance of *Electromagnetic Compatibility and Interference Guidance* on page 154.

25.4 Electromagnetic Compatibility and Interference Guidance

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

The Agilia pump is classified as a Class B device according to CISPR 11 emitted radiation.

WARNING

- 
- Use of the Agilia pump adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.
 - Maintain a minimum distance of 30 cm between Agilia pumps and any portable radiofrequency (such as smartphones, antennas...). For RTLS tags use, see *Real Time Location System Tag* on page 166. Electromagnetic perturbations may damage the Agilia devices and alter their performance if this distance is not maintained.
 - Maintain a minimum distance of 30 cm between Agilia pumps and:
 - Electro-surgical equipment,
 - Electro-encephalography (EEG) devices,
 - Electro-cardiography (ECG) devices.Electromagnetic perturbations may damage the Agilia devices and alter their performance if this distance is not maintained.
 - Do not expose the Agilia pumps directly to ultrasonic devices. Mechanical perturbations may damage the devices and alter their performance if the distance is not maintained.
 - Use of accessories, transducers and cables other than those specified or provided by the manufacturer of the Agilia pump could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.
 - Prolonged exposure to X-ray environments can damage the electronic components of the device and influence the flow rate accuracy. For a safe usage, we recommend to:
 - always put the device at the maximum distance from the patient and the source,
 - limit the presence of the device in such environments.

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

- Reorient or relocate the Agilia pump, the patient or disruptive equipment.
- Change the routing of cables.
- Connect the Agilia pump power plug to a protected / backed-up / filtered supply or directly to the UPS circuit (uninterruptible power supply).

- Increase the separation between the Agilia pump and disruptive equipment.
- Plug the Agilia pump into an outlet on a different circuit from the one to which the patient or disruptive equipment is connected.
- In any case, whatever the context, the user should conduct interoperability testing in a real situation to find the correct setup and location.

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

For further information on EMC compliance, please refer to the Agilia pump Technical Manual.

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

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

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

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

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

Immunity Test	IEC 60601-1-2 Ed3 ----- IEC 60601-2-24 Test Level	Compliance Level Obtained by the Device	Electromagnetic Environment - Guidance
Electrostatic Discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air ----- ± 8 kV contact ± 15 kV air	± 8 kV contact ± 15 kV air	Floor coverings made from wood, tiles and concrete, with relative humidity level at least 30%, make it possible to guarantee the necessary level of conformity. If it is not possible to guarantee this environment, additional precautions must be taken, such as: use of anti-static equipment, preliminary user discharge and the wearing of antistatic clothing.
Electrical fast Transient / burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input output lines	± 2 kV for power supply lines ± 1 kV for input output lines	AC power quality should be that of a typical commercial or healthcare facility environment.
Surge IEC 61000-4-5	± 1 kV differential mode ± 2 kV common mode	± 1 kV differential mode ± 2 kV common mode	AC power quality should be that of a typical commercial or healthcare facility environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	< 5% U_t (> 95% dip in U_t) for 0.5 cycles	< 5% U_t (> 95% dip in U_t) for 0.5 cycles	AC power quality should be that of a typical commercial or healthcare facility environment. For short and long interruptions (< than battery life) of AC power, the internal battery provides continuity of service.
	40% U_t (60% dip in U_t) for 5 cycles	40% U_t (60% dip in U_t) for 5 cycles	
	70% U_t (30% dip in U_t) for 25 cycles	70% U_t (30% dip in U_t) for 25 cycles	
	< 5% U_t (> 95% dip in U_t) for 5 s	< 5% U_t (> 95% dip in U_t) for 5 s	

Immunity Test	IEC 60601-1-2 Ed3 ----- IEC 60601-2-24 Test Level	Compliance Level Obtained by the Device	Electromagnetic Environment - Guidance
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	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.

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



WARNING

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

Immunity Test	IEC 60601-1-2 Ed3 ----- IEC 60601-2-24 Test Level	Compliance Level Obtained by the Device	Electromagnetic Environment - Guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz ----- Not applicable	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

Immunity Test	IEC 60601-1-2 Ed3 ----- IEC 60601-2-24 Test Level	Compliance Level Obtained by the Device	Electromagnetic Environment - Guidance
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz ----- 10 V/m 80 MHz to 2.5 GHz	10 V/m	$D = 0.35 \sqrt{P}$, for a frequency of 80 MHz to 800 MHz $D = 0.7 \sqrt{P}$, for a frequency of 800 MHz to 2.5 GHz P is the maximum output power rating of the transmitter in Watts (W) according to the transmitter manufacturer, and D is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey (a), should be less than compliance level (b). Interference may occur in the vicinity of equipment marked with the following symbol: 

NOTE:

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

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



INFORMATION

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

Rated Maximum Output Power of Transmitter (W)	Separation Distance According to Transmitter Frequency in Meters (m) IEC 60601-1-2 Ed3		
	150 kHz to 80 MHz $D = 0.35 \sqrt{P}$	80 MHz to 800 MHz $D = 0.35 \sqrt{P}$	800 MHz to 2.5 GHz $D = 0.7 \sqrt{P}$
0.01	0.04	0.04	0.07
0.1	0.11	0.11	0.22
1	0.3	0.3	0.7
10	1.1	1.1	2.2
100	3.5	3.5	7

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



INFORMATION

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

25.4.5 EMC test deviations and supplementary tests

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

Immunity test	IEC 60601-1-2 IEC 60601-2-24 Test level	Compliance level obtained by the device	Electromagnetic environment – guidance
Discharge (ESD) IEC 61000-4-2	± 8 kV contact ± 15 kV air	± 8 kV contact ± 15 kV air	Wooden, tiled or concrete flooring, with a relative humidity level at least 30%, makes it possible to guarantee the level of necessary conformity. If it is not possible to guarantee this environment, the additional precautions must be taken, such as: use of anti-static material, preliminary user discharge and wearing anti-static clothing.

Immunity test	IEC 60601-1-2 IEC 60601-2-24 Test level	Compliance level obtained by the device	Electromagnetic environment – guidance
Radiated RF - IEC 61000-4-3	10 V/m, 80 MHz to 2.7 GHz For radio conformity according to IEC 301489-1 and IEC 30189-17: 3 V/m, 2.7 GHz to 6 GHz	10 V/m, 80 MHz to 2.7 GHz 3 V/m, 2.7 GHz to 6 GHz	Portable and mobile RF communications equipment should be used no closer to any part of the Agilia pump, including cables, than the recommended separation distance calculated from the equation applicable to the frequency and power of transmitter. For standard communication services and equipment, the specific frequencies were tested for a minimum approach distance of 30 cm.
Near field radiated RF IEC 61000-4-3 test method	385 MHz, PM 18Hz, 27 V/m 450 Mhz, 1 KHz, 28 V/m 710 MHz, PM 217 Hz, 9 V/m 745 MHz, PM 217 Hz, 9 V/m 780 MHz, PM 217 Hz, 9 V/m 810 MHz, PM 18 Hz, 28 V/m 870 MHz, PM 18 Hz, 28 V/m 930 MHz, PM217 18 Hz, 28V/m 1720 MHz, PM 217 Hz, 28 V/m 1845 MHz, PM 217 Hz, 28 V/m 1970 MHz, PM 217 Hz, 28 V/m 2450 MHz, PM 217 Hz, 28 V/m 5240 MHz, PM 217 Hz, 9 V/m 5500 MHz, PM 217 Hz, 9 V/m 5785 MHz, PM 217 Hz, 9 V/m	385 MHz, PM 18Hz, 27 V/m 450 Mhz, 1 KHz, 28 V/m 710 MHz, PM 217 Hz, 9 V/m 745 MHz, PM 217 Hz, 9 V/m 780 MHz, PM 217 Hz, 9 V/m 810 MHz, PM 18 Hz, 28 V/m 870 MHz, PM 18 Hz, 28 V/m 930 MHz, PM217 18 Hz, 28V/m 1720 MHz, PM 217 Hz, 28 V/m 1845 MHz, PM 217 Hz, 28 V/m 1970 MHz, PM 217 Hz, 28 V/m 2450 MHz, PM 217 Hz, 28 V/m 5240 MHz, PM 217 Hz, 9 V/m 5500 MHz, PM 217 Hz, 9 V/m 5785 MHz, PM 217 Hz, 9 V/m	For minimal distance approach 30 cm (12 inches) Portable and mobile RF communications equipment should be used no closer to any part of the Agilia pump, including cables, than the recommended minimal separation distance (30 cm) for these frequencies
Electrical Fastransient / 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

Immunity test	IEC 60601-1-2 IEC 60601-2-24 Test level	Compliance level obtained by the device	Electromagnetic environment – guidance
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 bands	3 Vrms 150 KHz to 80 MHz And 6 Vrms in the ISM bands	Portable and mobile RF communications equipment should be used no closer to any part of the Agilia pump including cables, than the recommended separation distance calculated from the equation applicable to the frequency and power of transmitter (see table 6)

Immunity test	IEC 60601-1-2 IEC 60601-2-24 Test level	Compliance level obtained by the device	Electromagnetic environment – guidance
Power frequency (50 / 60 Hz) magnetic field IEC 61000-4-8	30 A / m	400 A / m	If necessary, the power magnetic field should be measured in the intended installation location to make sure it is lower than the compliance level. If the measured field in the location where the Agilia pump is used exceeds the applicable magnetic field compliance level above, the Agilia pump should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Agilia pump, or installing magnetic shielding.

Immunity test	IEC 60601-1-2 IEC 60601-2-24 Test level	Compliance level obtained by the device	Electromagnetic environment – guidance
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0% Ut (100% dip in Ut) for 0,5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0% Ut (100% dip in Ut) for 1 cycle 70% Ut (30% dip in Ut) for 25 cycles at 50 Hz for 30 cycles at 60 Hz at 0°	0% Ut (100% dip in Ut) for 0,5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0% Ut (100% dip in Ut) for 1 cycle 70% Ut (30% dip in Ut) for 25 cycles at 50 Hz for 30 cycles at 60 Hz at 0°	Electricity power quality should be that of a typical domestic, commercial or hospital environment. For short and long interruptions (< than battery autonomy) of electricity power supply, the internal battery provides the continuity of service. For very long (> than battery autonomy) interruptions of electricity power supply, the Agilia pump must be powered from an external Uninterruptible Power Supply (UPS). Note: Ut is the a/c mains voltage prior to application of the test level.
Proximity magnetic field IEC 61000-4-39 Test method	134.2 KHz Pulse modulation 2.1 KHz 13.56 MHz Pulse modulation 50 KHz	65 A/m 7.5 A/m	The RFID Immunity phenomena should be in the frequency range 9 KHz to 13.56 MHz.

26 Servicing

26.1 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.

26.2 Maintenance Requirements



WARNING

Perform preventive maintenance at least once every 6 years. Failure to comply with these maintenance procedures could damage the device and result in altered performances.



WARNING

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



CAUTION

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

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

- Preventive maintenance should be performed by trained and qualified technical personnel in compliance with the technical manual and procedures. Only authorized service personnel should attempt to repair the device.
- Internal inspection of the device requires compliance with special procedures to avoid damage to the device.
- When replacing components, only use spare parts from Fresenius Kabi.

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



INFORMATION

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

26.3 Quality Control

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



INFORMATION

These control checks must be performed by trained technical personnel, and are not covered by any contract or agreement provided by Fresenius Kabi.

26.4 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:

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

27 Real Time Location System Tag

27.1 Tag Installation



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



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

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

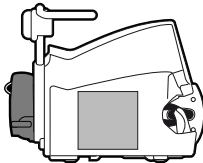


Figure 27: Agilia SP range of pumps (left panel)



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

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

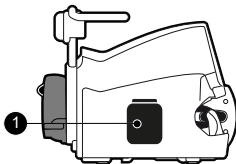


Figure 28: Location for Agilia SP range of pumps

27.2 Use environment

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

27.3 Tag Compliance



CAUTION

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

Radio, EMC (Electromagnetic compatibility)	FCC Part 15 Subpart C class B subpart B EN/IEC 300-328, EN/IEC 301-489 Radio Equipment Directive 2014/53/EU (RED) Radio Equipment S.I.2017/2016 (RED) RoHS 2 Directive 2011/65/EU, RoHS 2 Directive S.I.2012/3032 Safety: CE, UKCA
Safety	EN62368/UL62368/IEC62368, Japan 201-200209

A Glossary of Terms

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

Term	Description
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
HTTPS	HyperText Transfer Protocol over TLS
Hz	Hertz
IC	Industry Canada
IEC	International Electrotechnical Commission
IEEE	Institute of Electrical and Electronics Engineers
in	Inches
IT	Information Technology
IV	Intravascular
kg	Kilograms
KVO	Keep Vein Open
lb(s)	Pound(s)
LED	Light Emitting Diode
mA	Milliamperes
mEq	Milliequivalents
mL/h	Milliliters per hour
mmHg	Millimeters of Mercury

Term	Description
mmol	Millimole
MOS	Metal Oxyde Semiconductor
MRI	Magnetic Resonance Imaging
mW/sr	Milliwatts per steradian
N/A	Not Applicable
NFS	Network File System
NMR	Nuclear Magnetic Resonance
OCS	Occlusivity Check System
OFDM	Orthogonal Frequency Division Multiplexing
OLE	Object Linking and Embedding
OPC	Open Platform Communications
OR	Operating Room
OTS	Off-The-Shelf
PC	Personal Computer
PCA	Patient Controlled Analgesia
PSI	Pounds per Square Inch
PSK	Phase Shift Keying
QAM	Quadrature Amplitude Modulation
QPSK	Quadrature Phase Shift Keying
REF	Product reference / part number
RF	Radio Frequency
RFID	Radio Frequency IDentification
RPC	Remote Procedure Call
RS232	Serial interface connector
SN	Serial Number
SELV	Safety Extra Low Voltage
SIR	Asynchronous Serial Infrared
SQL	Structured Query Language
TLS	Transport Layer Security
UDI	Unique Device Identifier
USB	Universal Serial Bus

Term	Description
Ut	Test specification level
V	Volts
V/m	Volts per meter
VA	Volt-Amperes
VDC	Volts Direct Current
VI	Volume Infused
VLAN	Virtual Local Area Network
VPN	Virtual Private Network
Vrms	Root Mean Square Voltage
VTBI	Volume to Be Infused
W	Watts
WPA	Wi-Fi Protected Access
XSS	Cross-Site Scripting

B Appendix: Factory Configuration

Menus

Feature	Default setting	Feature	Default setting
Profile	Disabled	Volume-Dose history	Enabled
Pressure	Enabled	View flow rate history	Disabled
Keypad lock status	Enabled	View pressure history	Disabled
Battery life	Enabled	Syringe	Enabled
Volume infused / Dose infused	Enabled	View event log	Disabled
Pause	Enabled	View PCA event log	Enabled
Programmed bolus	Enabled	PCA treatment	Enabled
Clinician bolus	Enabled	Date / Time	Enabled
Patient	Disabled	Maintenance	Disabled
Day/Night mode	Enabled	Library information	Disabled
Volume/Time - Dose/Time	Enabled	Clinical information	Disabled
Volume Limit	Enabled	Data Set	Disabled
Alarm volume	Enabled		

PCA modes

Feature	Default setting	Feature	Default setting
Continuous only	Enabled	PCA bolus + variable	Disabled
PCA bolus only	Enabled	Clinician bolus	Enabled
PCA bolus + continuous	Enabled	PCA loading dose	Disabled

General infusion modes

Feature	Default setting	Feature	Default setting
Simple Rate	Disabled	Volume Limit	Disabled
Volume/Time - Dose/Time	Disabled		

General infusion features

Feature	Default setting	Feature	Default setting
Loading Dose	Disabled	Prime Set	Disabled
Programmed Bolus	Enabled	Empty syringe	Disabled
Direct Bolus	Enabled	Dynamic Pressure System (DPS)	Enabled
KVO	Enabled	Near end of max dose	Enabled

Cover

Feature	Default setting	Feature	Default setting
Install mandatory	Enabled	Auto-lock keyboard at cover close	Enabled
Lock mandatory	Enabled	Auto-unlock keyboard at cover open	Enabled

Patient handset

Feature	Default setting	Feature	Default setting
Auto-unlock keyboard at cover open	Enabled	Sound for PCA bolus request	Enabled

Flow rate

Feature	Default setting	Feature	Default setting
Continuous rate	N/A	Direct bolus / Programmed bolus	200 mL/h
PCA bolus / PCA loading dose	200 mL/h	KVO	1 mL/h

Features not enabled in the factory configuration can be enabled in the pump options or in custom profiles. Otherwise, they can be enabled on request.

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Release Notes

Date	Software version	Description
October 2023	4.2	Creation
July 2024	4.3	Cover: Removed "Caring for life" from Fresenius Kabi logo § 1.8.2: Updated Cybersecurity recommendations § 7.22.4 and 14.4.6: Updated Maximum cumulated dose alarm § 20.6.2: Updated Alarms sound levels § 21: Updated WiFi specifications
September 2025	4.4	§ 18.1: Modified list of prohibited agents for cleaning and disinfecting § 21.2.1: Modified description for wireless security

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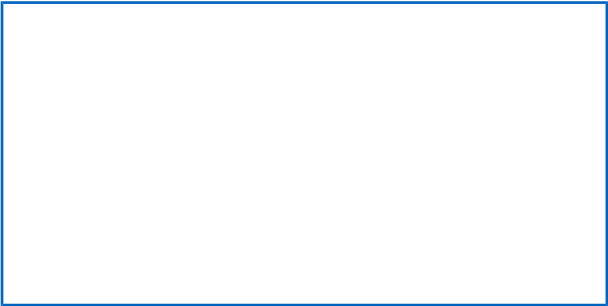
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First CE Mark: 2018

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