FRESENIUS KABI

caring for life

Agilia SP PCA WiFi

Syringe Infusion Pump

Applicable to software version 3.3

Instructions For Use

For Use in Healthcare Facilities

Symbols Description

Symbols used in this document

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

Recommendations to be followed.

Labelling symbols

	Warning (Refer to the Instructions for Use)		Name and address of the manufacturer / Date of manufacture
	Refer to the Instructions for Use		Name and address of the manufacturing facility
REF	Product reference / part number		Protection against electric shock: class II
SN	Product serial number		Non-ionizing electromagnetic radiation
	Input terminal - connector		Fragile, handle with care
	Output terminal - connector		This way up
	Electrical fuses		Keep away from rain
	Alternating Current (AC)		Temperature limitation
	Direct Current (DC)		Humidity limitation
IP22	Ingress protection against solid foreign objects (> 12.5 mm) and dripping liquids. Rating applies to pump.		Atmospheric pressure limitation
IP27	Ingress protection against water when immersed up to 1 m deep. Rating applies to patient handset but not to the handset connector.		General symbol for recyclable material
	Part included in a recycling process		Eco packaging symbol
	Protection against leakage current; defibrillation-proof type CF applied part	CE 0123	CE mark
MD	Medical Device	UDI	Unique Device Identifier

E367

RCM (Regulatory Compliance Mark) logo associated to the ERAC (Electrical Regulatory Authorities Council) registration number provided by Australian Radio Regulatory Authority.

Table of Contents

1 Introduction

1.1 Scope

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

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

WARNING

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

- The software version of the device is displayed on the start-up screen.
- The software version described in this IFU is displayed on the cover page and in the Release Notes, page 177.

1.2 Principles of Operation

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

Agilia SP PCA is a transportable and reusable device that can be used every day.

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 Section 15.1, page 126.

Agilia SP PCA can be used for bolus administration or continuous infusions.

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

Agilia SP PCA 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

Syringe Pumps and Accessories for IV Administration of Fluids.

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.

Agilia SP PCA 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.

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

Administration Routes

INFORMATION
The system allows infusion via the following access routes:

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

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

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

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

1.4.2 Contraindications

The use of the Agilia SP PCA for PCA/PCEA therapies requiring the patient handset is contra-indicated for neonates, and for patients that have physical or mental inabilities 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

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

	Patient Characteristics	
	PCA therapy	**General infusion**
Sex	Male / Female	
Age	Pediatrics / Adults / Elderly	Neonates / Pediatrics / Adults / Elderly
Weight	0.25 kg to 350 kg	
Body surface area	0.05 m² to 4.5 m²	

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

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

1.4.5 Use Environment

Agilia SP PCA is intended for use in healthcare facilities, under the supervision of trained healthcare personnel.

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

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

WARNING

Do not use the pump in the following environments:

- Explosive or flammable environments
- High humidity environments (shower, bath, etc.)
- Ultrasonic environments
- Ambulances
- Magnetic Resonance Imaging (MRI)
- Hyperbaric chambers

WARNING

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

WARNING

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

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 ±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 Agilia SP PCA.

1.7 Risks for patients

Failure to follow all instructions described in this document or loss or degradation of essential performance (Section 16.1, page 130) may result in: overdose, underdose, delay of therapy, incorrect therapy, exsanguination, toxicity, infection, air embolism, trauma or electric shock.

2 Agilia Connect Infusion System

Agilia range		Description
Pump	**Agilia VP range**	**Volumetric Infusion Pump** Pumps designed to deliver the contents of parenteral infusion container (bag or bottle) through a line connected to a patient.
	Agilia SP range	**Syringe Infusion Pump** Pumps designed to deliver the contents of a syringe through a line connected to a patient.
	Agilia SP PCA	**Patient-Controlled Analgesia (PCA) syringe infusion pump** Pumps intended for PCA therapy and epidural infusion under the patient's or the clinician's control.
	Agilia ProNeo	**Enteral Nutrition Syringe Pump for Neonates** Pumps designed to deliver enteral nutrition to neonates, preterm babies and children via clinically accepted routes of administration.
Vigilant Software Suite	**Vigilant Centerium**	**Server Software** Software intended to report status of compatible Fresenius Kabi infusion devices according to the identified installed base for fleet management, to store and distribute datasets to connected infusion devices and to report distribution status, besides supporting system maintenance operations.
	Vigilant Bridge	**EMR Auto-documentation** Software intended to establish connection between compatible Fresenius Kabi infusion pumps and the Electronic Medical Records (EMR) system. Infusion data is then automatically transmitted to the EMR.
	Vigilant Insight	**Infusion Data Reporting Software** Software intended to collect and report infusion information received from compatible Fresenius Kabi connected infusion devices to analyze and improve clinical settings included into a dataset.
	Vigilant Master Med	**Drug Library Software** Software intended to create, customize, and manage drug library data and device configurations to be uploaded to compatible Fresenius Kabi infusion devices.Vigilant Master Med is part of a Dose Error Reduction System (DERS).
	Vigilant Sentinel	**Infusion visualization system** Software designed to provide qualified healthcare personnel with a centrally aggregated view of infusion pumps' status within a hospital or hospital-type setting.
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. Link Agilia / Agilia Link are designed to centralize the power supply. Link+ Agilia is designed to centralize the power supply and to centrally replicate infusion pump signalling.
	Agilia MRI Guard	**MRI-Shielding System** Agilia MRI Guard is intended to accommodate and power up to four Agilia infusion pumps so that these pumps can be operated in a Magnetic Resonance Imaging unit.
	Agilia Duo	**Two-channel accessory** The Agilia Duo is intended to centralize mains power for two attached Agilia pumps.
Disposables	Syringes	See section 15, page 126.

INFORMATION

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

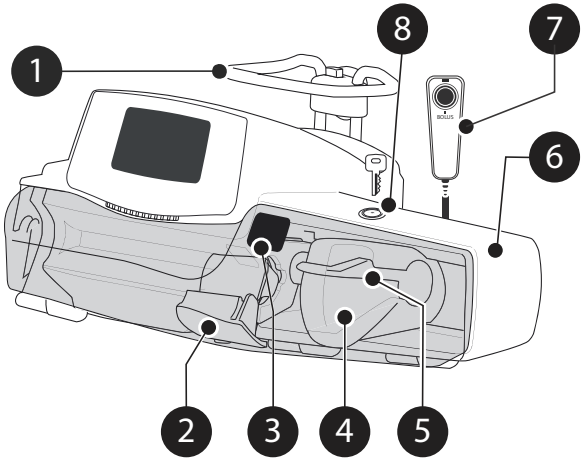
INFORMATION

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 Pump Front View

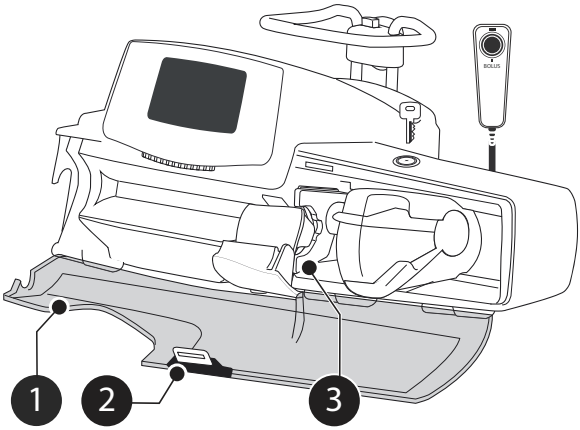
This section shows the Agilia SP PCA pump with the cover closed and with the cover open.



Legend

1. Handle
2. Syringe barrel clasp
3. Cover clasp
4. Plunger driver
5. Disengagement lever
6. Syringe guard
7. Patient handset
8. Cover lock

Figure 3.1: Front view with cover closed

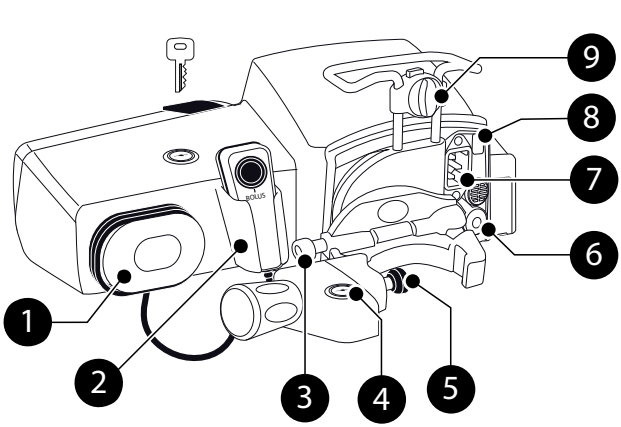


Legend

1. Clear protective cover
2. Cover clasp
3. Syringe flange cradle

Figure 3.2: Front view with cover open

3.2 Pump 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

Figure 3.3: Back View

Symbol	Location	Description
⚠ ⚠	Near power cord inlet	***Warning*** See Section 19, page 144
⚠	Near RS232 communication port	***Warning*** See Section 12, page 112

3.3 Pump Bottom View (Device Identification Label)

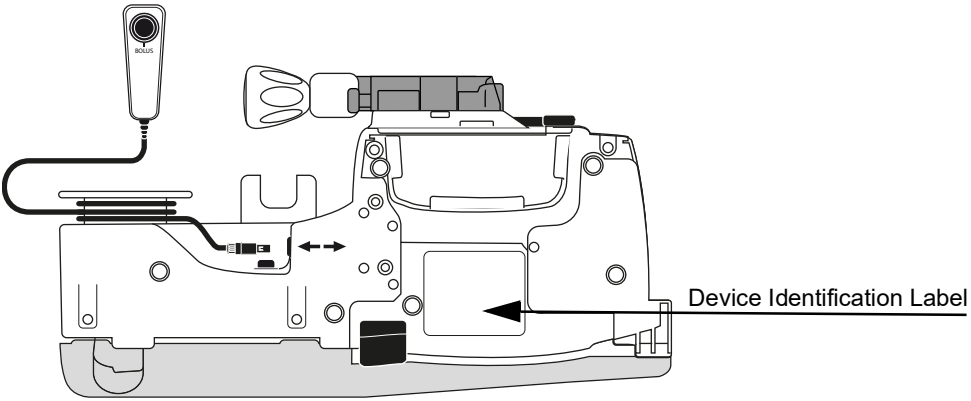


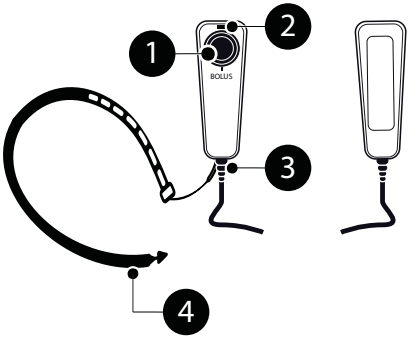
Figure 3.4: Bottom view

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

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

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

3.4 Patient Handset

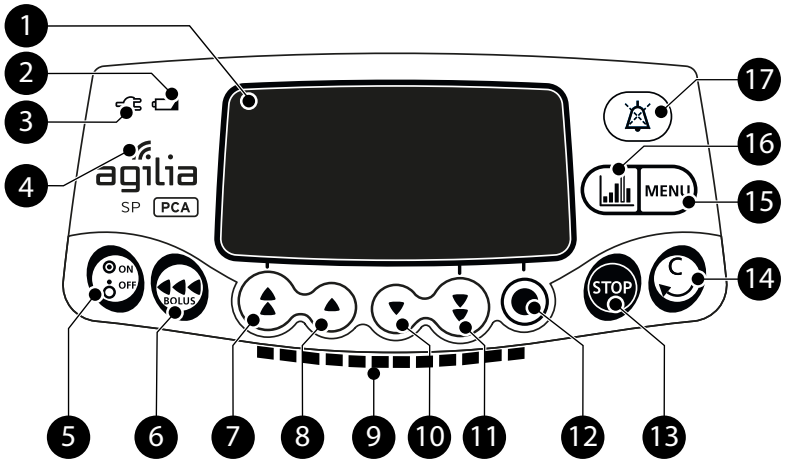


Legend

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

Figure 3.5: Patient handset and wrist strap

3.5 Keypad Description



Legend

1	Screen	7	Fast increment	13	Stop
2	Battery charge status indicator	8	Increment	14	Cancel value / Move back to previous field
3	Power supply indicator	9	Infusion indicator lights	15	Menu
4	Wi-Fi symbol	10	Decrement	16	PCA history
5	On / Off	11	Fast decrement	17	Alarm silence
6	Bolus / Prime	12	Confirm value / Move to next field		

Figure 3.6: Keypad description

3.5.1 Keypad Details

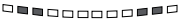
Table 3.7: Selection Keys

Key	Description
	Arrow keys Keys for setting volume, time, flow rate and other values.
+	Fast access to maximum value or top of a list
+	Fast access to minimum value or bottom of a list

Note:

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

Table 3.8: 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.*

Table 3.9: 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

Table 3.10: Infusion status

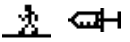
Symbol	Description
	**Infusion in progress (Basic Profile + custom profiles with a drug list)** Symbols for infusion in progress.
	**Infusion in progress (custom profiles with a drug library)** Animated symbol displayed when the pump is infusing a drug from a drug library.
STOP	**Infusion stopped** STOP remains in the center of the screen until the user starts the infusion again.

Table 3.11: 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.

Table 3.12: Navigation Buttons

Symbol	Description
start	Start
end	End
OK	Confirm
enter	Access function
New ?	Access function and clear settings
exit	Exit function

Symbol	Description
C	Change selection
prog	Program function
☑/☐	Select / Deselect
	Review PCA settings
	Edit PCA settings
prev.	Move to the previous step/screen
next	Move to the next step/screen
back	Move to the previous screen
i	See more information
	Zoom in / Zoom out
«-- --»	Move the event marker to the left / right

Table 3.13: Alarms and Safety Features

Symbol	Description
	Power disconnection
	Alarm silenced
	Pressure increase
	Drop in pressure

Note: For more information on alarms, see Section 14, page 116.

Table 3.14: Infusion Features

Symbol	Description
PCA	**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.

Symbol	Description
	**Loading dose (general infusion)** Displayed when programming a loading dose.
	**Clinician bolus (PCA therapy)** Displayed when programming or during infusion of a clinician bolus.

Table 3.15: Data Communication

Symbol	Description
	**Data set uploaded** A new data set has been uploaded to the pump.

3.7 Packaging

The Agilia SP PCA packaging contains the following:

- 1 Agilia SP PCA pump and its protective cover.
- 1 patient handset with a cable and connector, and a wrist strap.
- 1 Instructions For Use manual (this document).
- 1 System Components booklet.
- 1 power cord for the pump.

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 Figure 4.1, page 26
- Continuous rate, see Figure 4.2, page 27
- PCA bolus + continuous rate, see Figure 4.3, page 27
- PCA bolus + variable rate, see Figure 4.4, page 28

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 Section 7.21.2, page 68.

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.

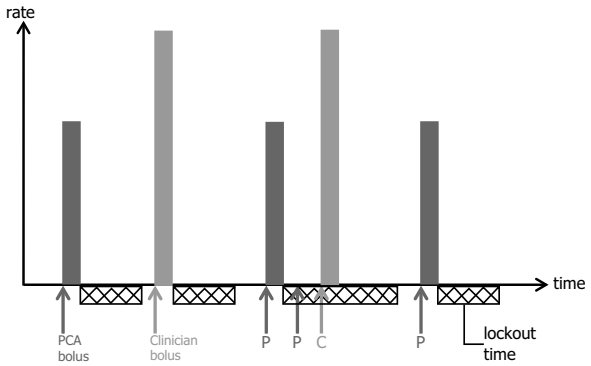


Figure 4.1: PCA bolus infusion mode

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.

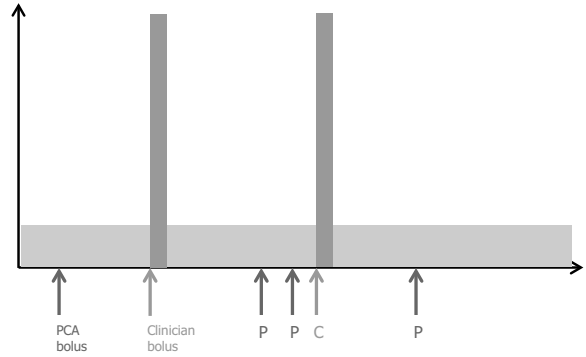


Figure 4.2: Continuous rate infusion mode

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.

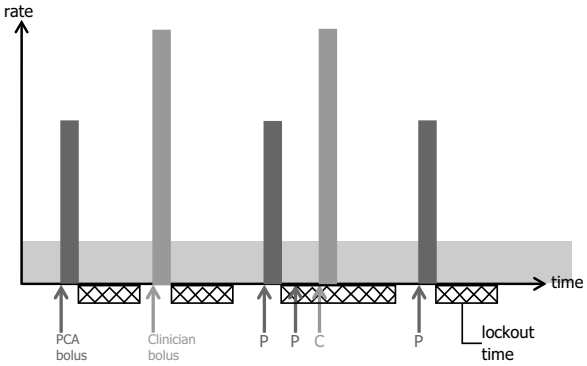


Figure 4.3: PCA bolus + continuous infusion mode

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.

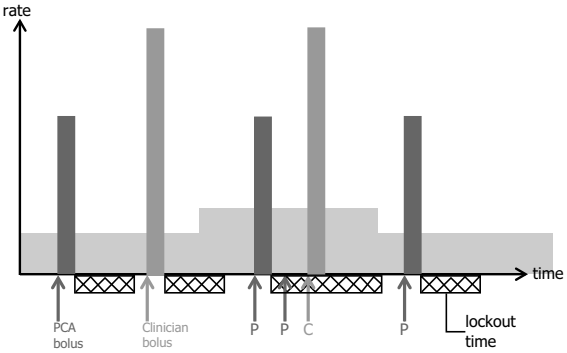


Figure 4.4: PCA bolus + variable rate mode

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 (mininmum 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

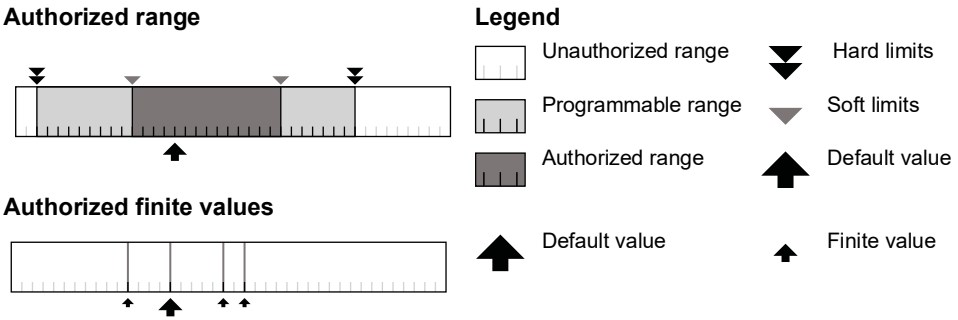
There is a special entry called Drug X that has no predefined parameters, see Section 4.4.5, page 31.

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 illlustrations below.



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

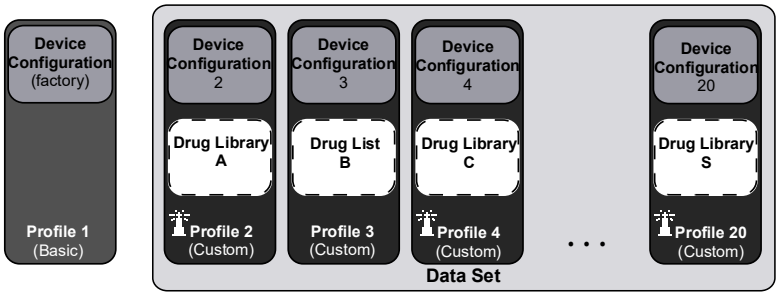
Drug X entries with a flow rate or dose rate are open entries that can be selected if the intended drug is not found in the drug library. Their characteristics are:

- 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.

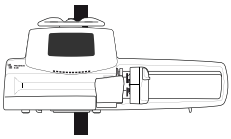
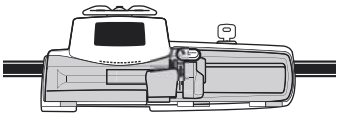
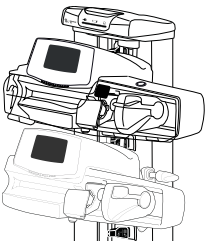
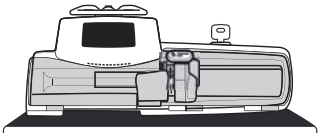
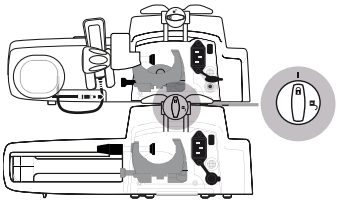
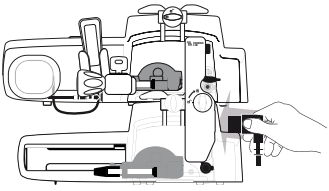


If there is no data set uploaded to the pump, the pump can be used with the Basic Profile.

5 Installation

5.1 Types of Installations

A pump can be installed on any of the following:

Location		Comments
On a pole		☞ See Section 5.3, page 34 **Pole specifications:** ▪ Diameter: from 0.6 to 1.6 in (15 to 40 mm)
On a rail		☞ See Section 5.3, page 34 **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 an Agilia Link rack		☞ Refer to the Agilia Link accompanying documents.
On a table		☞ See Section 5.3, page 34 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 Section 5.3, page 34
On an Agilia Duo		☞ Refer to the Agilia Duo accompanying documents.

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

WARNING

- The pump must be used in a horizontal and stable position to function properly.
- Use recommended Agilia accessories to ensure stability and prevent the pump from falling. Do not stack the pump with equipment other than those recommended.
- When the pump is installed onto an Agilia Link rack, make sure that it is correctly plugged in (hook clipped) so as to prevent the pump from falling.

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.

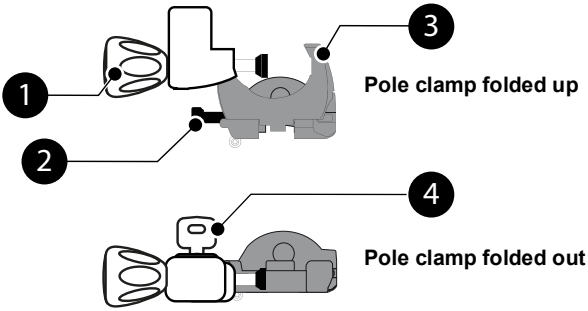
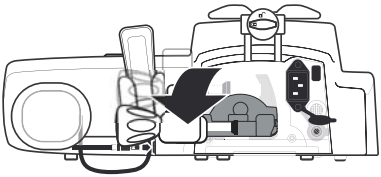


Figure 5.1: Rotating pole clamp system

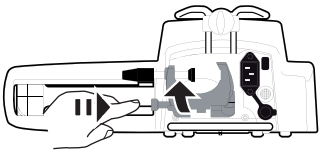
You can secure the rotating pole clamp vertically or horizontally by folding it outward until the release button clicks into the locked position as shown in Figure 5.2, Figure 5.3 and Figure 5.4.



You can fold the clamp down as follows:

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

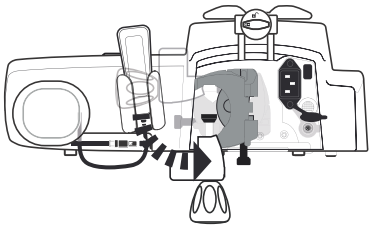
Figure 5.2: Folding the clamp down (outward)



You can fold the clamp up as follows:

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

Figure 5.3: Folding the clamp up (inward toward the pump)



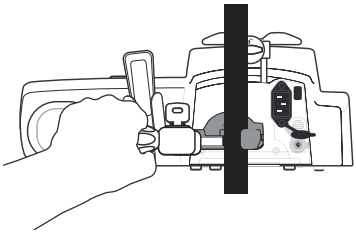
You can rotate the clamp as follows:

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

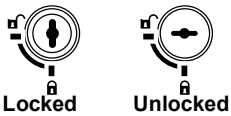
Figure 5.4: Rotating the clamp

5.3 Attaching the Pump

Attaching the Pump to a Pole



1. Fold the pole clamp down to the horizontal position, as shown in Section 5.2, page 33.
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.

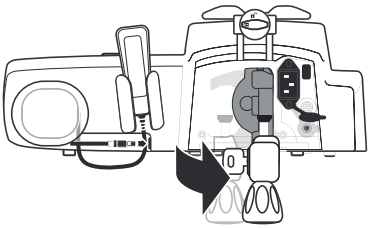


4. Lock the clamp and remove the key.

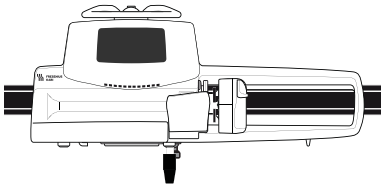
WARNING
When installed on a rolling stand, do not tip over the system more than 5°: it may fall.

Attaching the Pump to a Rail

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

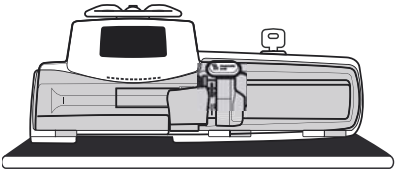


1. Rotate the pole clamp to the vertical position, as shown in Section 5.2, page 33.
2. Unscrew the clamp, attach to the rail, and screw the clamp until pump is fully secured to the rail.



3. Make sure that the pump is securely attached.
4. Lock the clamp and remove the key.

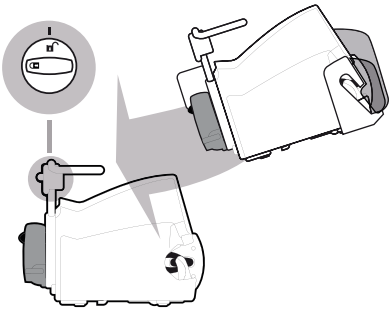
Setting up the Pump on a Flat Surface



1. Fold the pole clamp up, as shown in Section 5.2, page 33.
2. Place the pump far enough from the edge to prevent it from accidentally being pushed off.

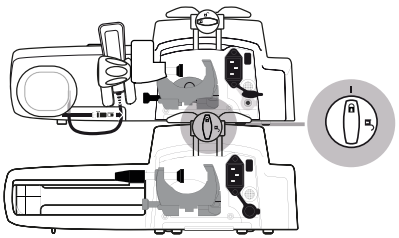
Attaching Several Pumps Together

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



1. Fold both pumps' pole clamps up, as shown in Section 5.2, page 33.
2. Slide the slot on the bottom of the upper pump onto the handle of the lower pump.

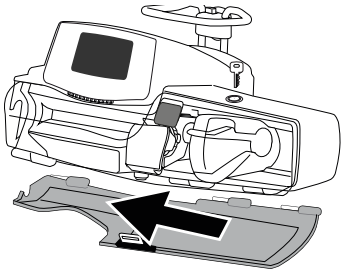
3. Turn the attachment lock knob on the lower pump handle clockwise until the locked symbol lines up with the marker.



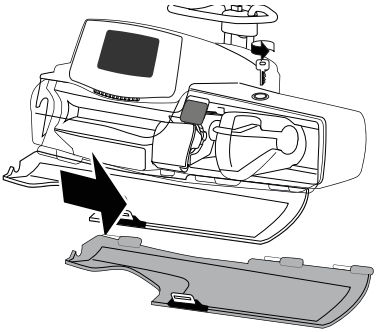
4. Make sure the pumps are securely attached together. Repeat steps 1 to 3 to attach a third pump to the other two.
5. If needed, fold the pole clamps down and secure them tightly to the pole.
6. Lock the pole clamp on the Agilia SP PCA pump and remove the key.

5.4 Installing and Removing the Protective Cover

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

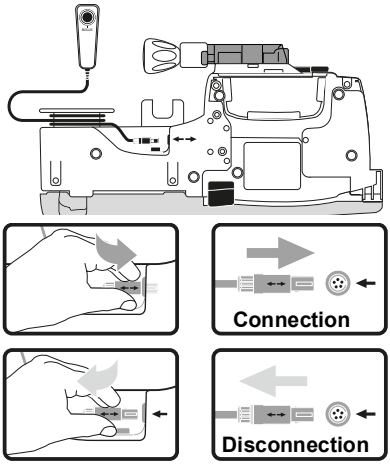


1. Place the hinges of the protective cover opposite the holders on the pump casing.
2. Slide the cover to the left until it clicks into place.



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

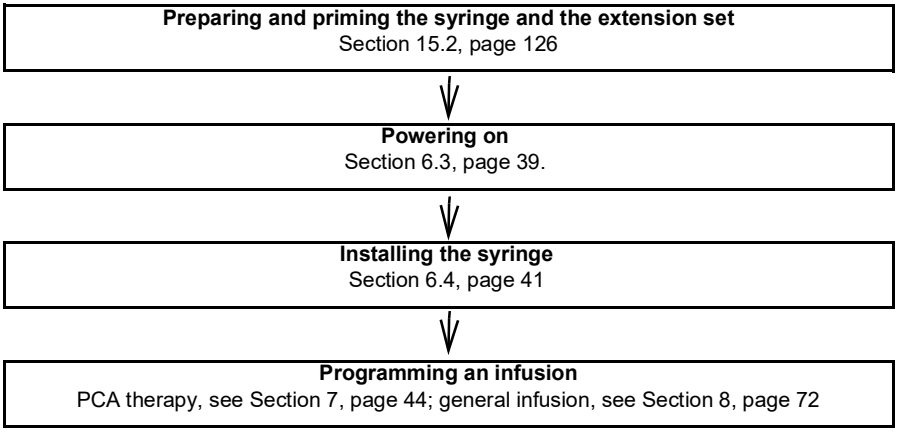
INFORMATION
To ensure proper operation, use only the **Fresenius Kabi** patient handset provided with the pump.

INFORMATION
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 setup.

6.2 Using the Pump for the First Time

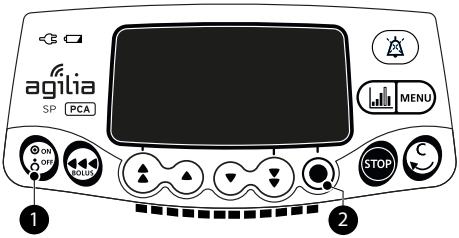
1. Make sure the pump is correctly installed at the bedside, as explained in Section 5, page 32.
2. Plug the pump into the AC power supply. See Section 18.1, page 142 for precautions. Do not power on the pump.
3. Before starting the pump for the first time, charge the battery for approximately **6 hours**. *Wait until the battery is fully charged. Do not use the pump during the first charge.*
4. Power on the pump following the instructions in Section 6.3, page 39.
5. Install a syringe in the pump, as explained in Section 6.4, 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 Section 5.4, page 36.

6.3 Powering on

INFORMATION

- The pump can operate on battery; however, it is recommended to connect it to an AC power supply as often as possible to ensure that the battery remains charged.
- When the pump is connected to the power supply, check that the power supply indicator lights up green, and that the power cord and the wall plug are accessible.

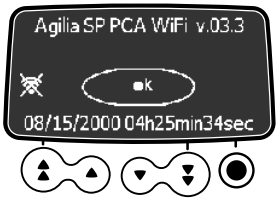
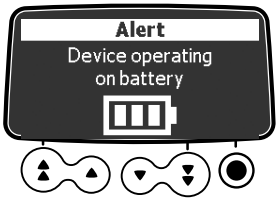
1. Press the Start/Stop button on the keypad.
   An auto-test checks the functionality of the pump.

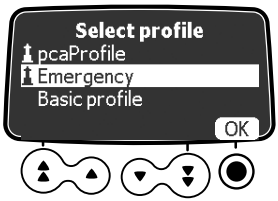
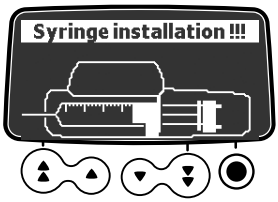
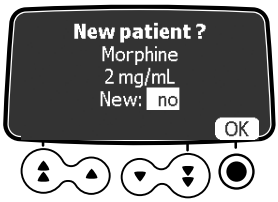
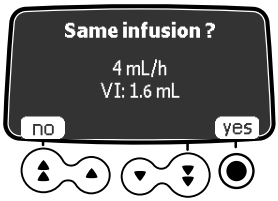
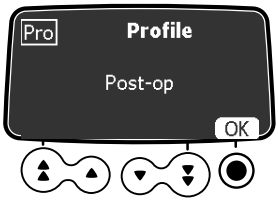
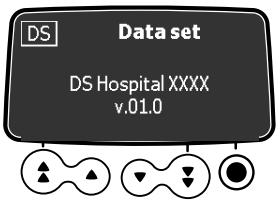


Legend

1. Start/Stop button
2. Confirm button

2. Make sure that all LED lights blink.
3. Successively acknowledge the screens listed in the table below by pressing the confirm button, if they are displayed.

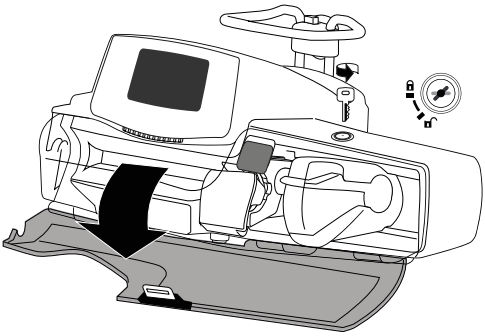
Screen after powering on	Description
	Startup screen: the following information is displayed: ▪ Product name and version number ▪ Ward name ▪ Wi-Fi module status ▪ Date and time
	▪ Maintenance reminder message (optional).
	▪ Displayed if the pump is operating on battery. ▪ The symbol shows three different charge levels: < 30 % battery charge 30 % - 70 % battery charge > 70 % battery charge

Screen after powering on	Description
	▪ 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 Section 6.4, page 41.
	▪ 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) Select **Yes** to keep the previous infusion settings.
	▪ Profile confirmation screen (optional). Press **Ok** to confirm the profile. *Note: This screen is associated with the "New patient" function above.*
	▪ Data set information (optional).

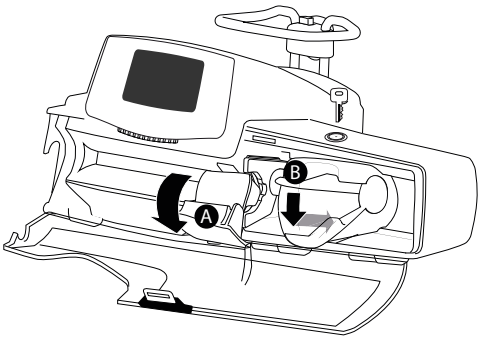
6.4 Installing a Syringe

WARNING

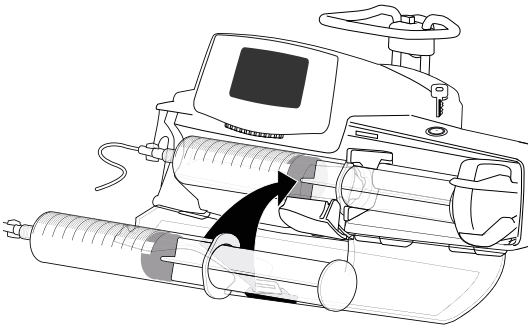
Installing a syringe must only be done when the patient is not connected.



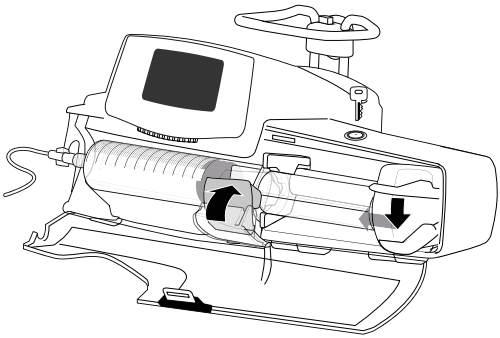
1. Unlock the pump cover to open the cover.



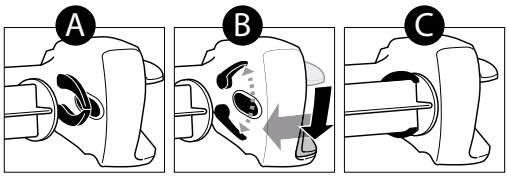
2. Open the syringe barrel clasp [A].
3. Push the disengagement lever [B] down and move the plunger driver to the right.



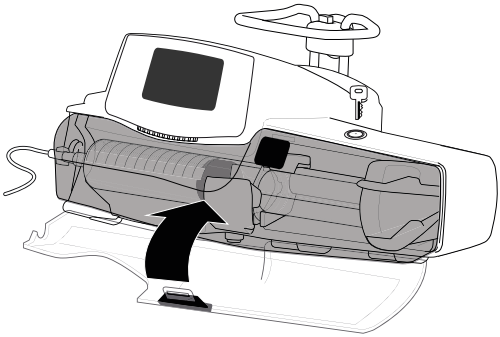
4. Place the syringe in its cradle, with the flanges correctly inserted in the slot.



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



6. Press the disengagement lever 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 with the protective cover if the cover is damaged. The cover must be changed if it is damaged.

INFORMATION

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

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

Precautions for pump position

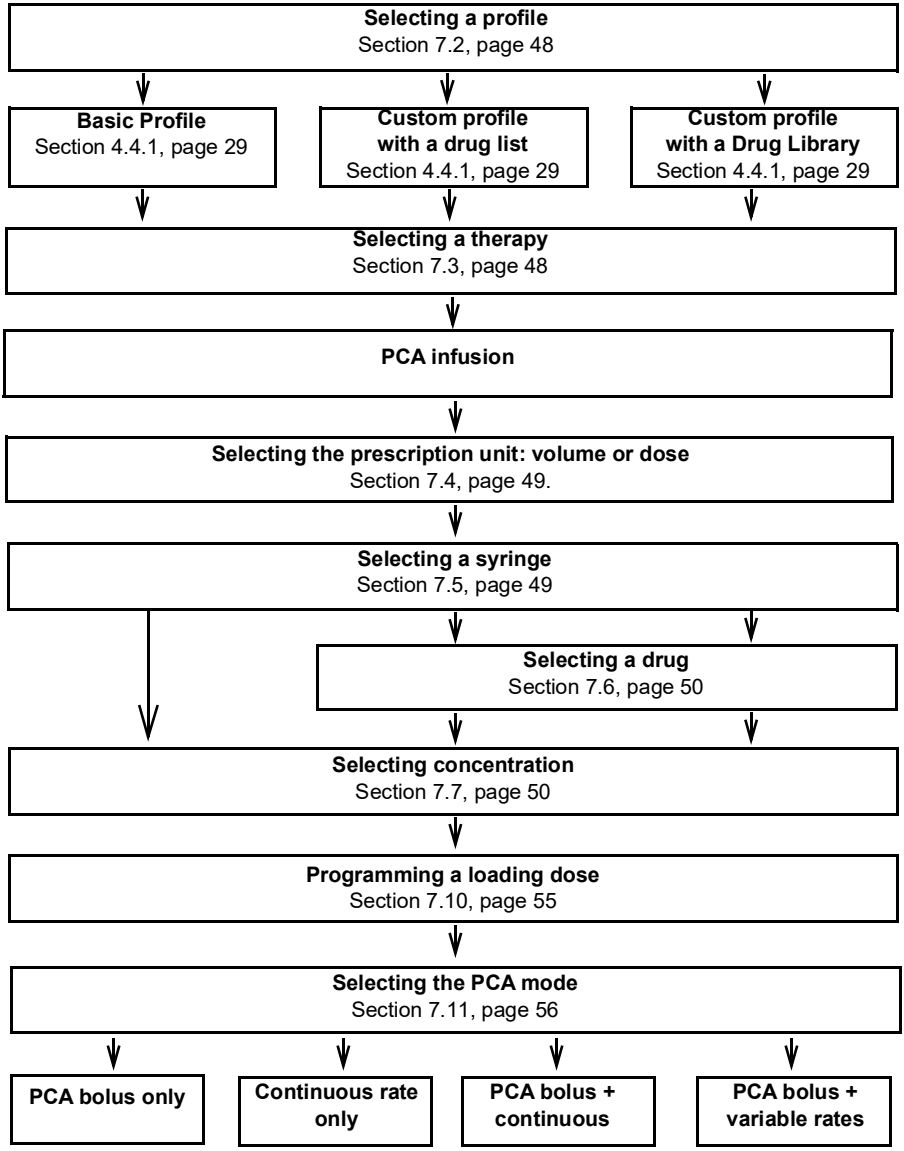
- If using multiple syringe pumps and it is not clinically feasible to have all pumps level with the distal tip of the catheter (or the site of fluid delivery), place the high risk or life-sustaining medications as close to level with the distal tip of the catheter as possible. When infusing multiple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

7 Programming a PCA Infusion

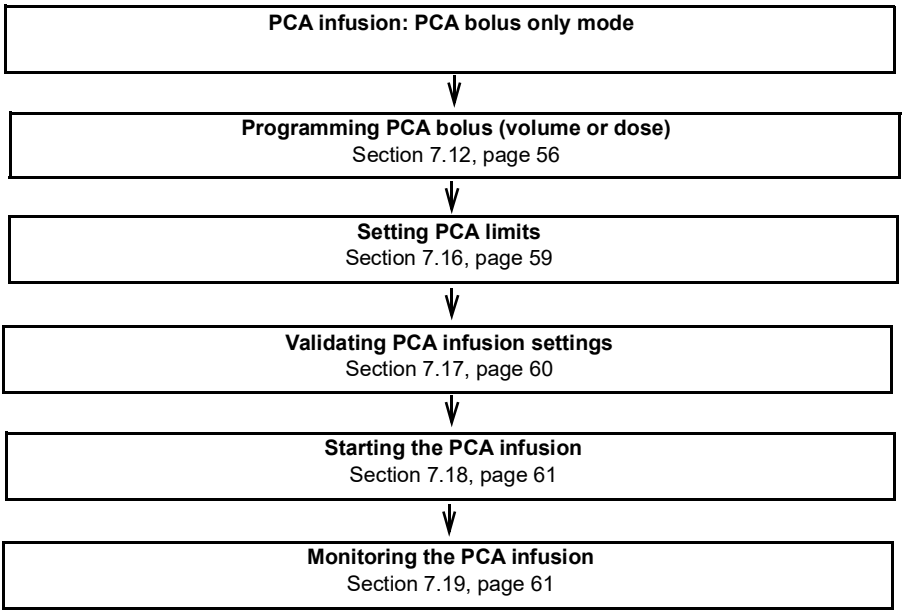
This section explains how to program a PCA infusion with the Agilia SP PCA pump.

7.1 PCA Infusion Flowcharts

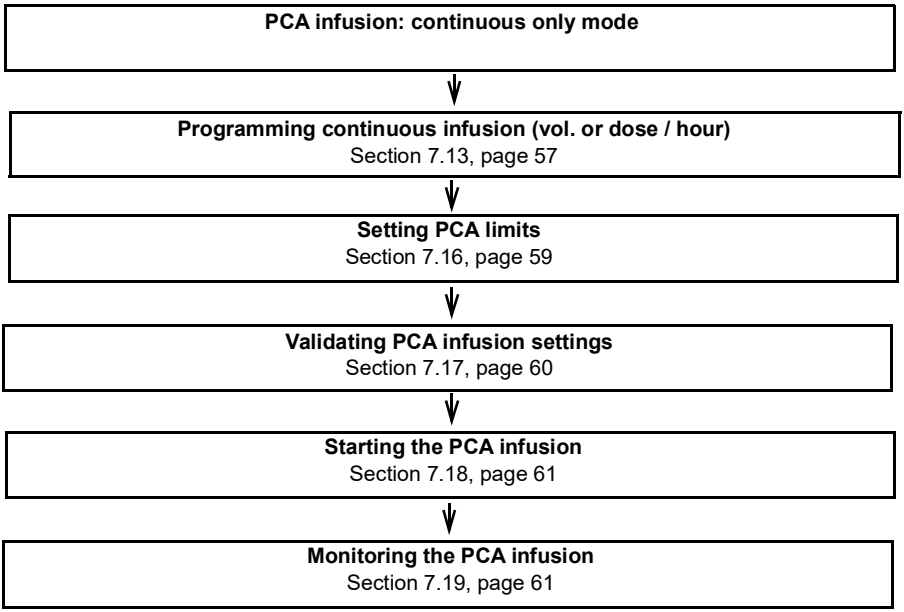
The following flowchart shows the steps to follow for all PCA modes.



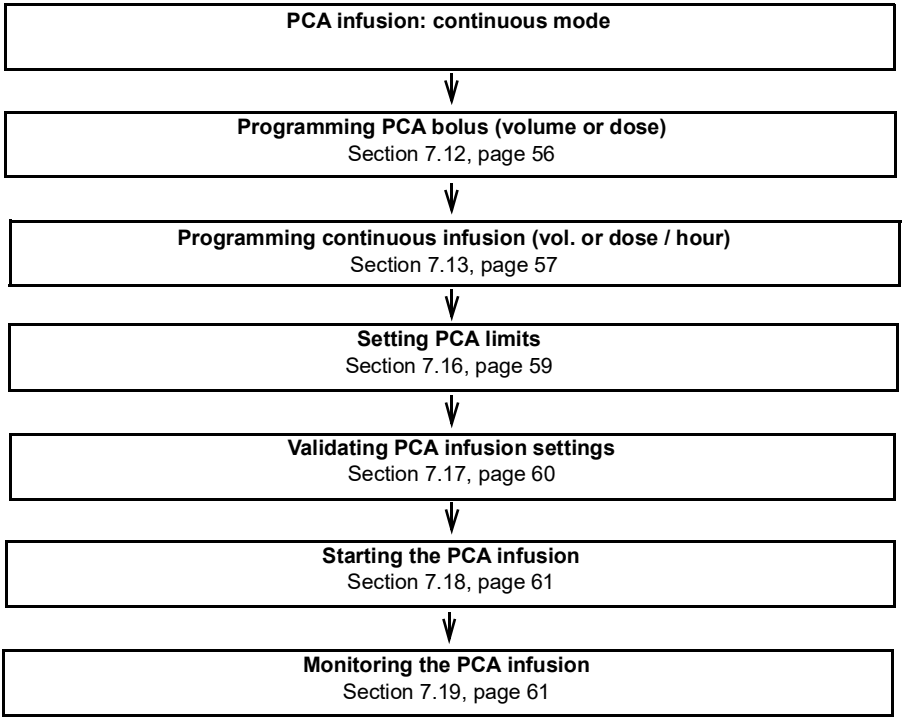
7.1.1 Programming PCA Infusion in PCA Bolus Only Mode



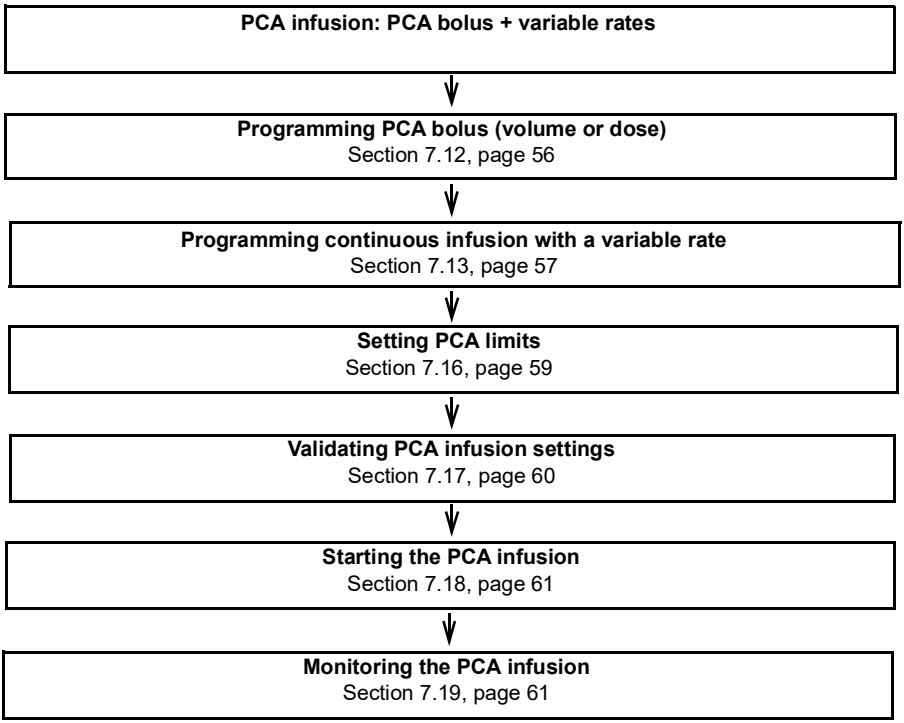
7.1.2 Programming PCA Infusion in Continuous Only Mode



7.1.3 Programming PCA Infusion in PCA Bolus + Continuous Mode

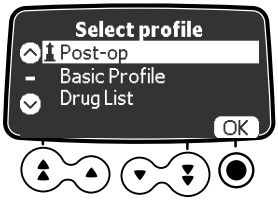


7.1.4 Programming PCA Infusion in PCA Bolus+Variable Rates Mode



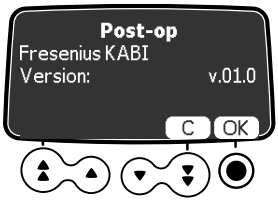
7.2 Selecting a Profile

Profiles are available for selection if previously uploaded to the pump.



1. Press the On/Off button 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 the target group of patients.

   The lighthouse symbol indicates a drug from a drug library.



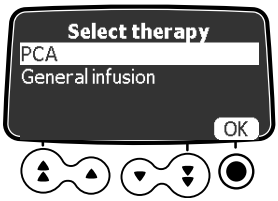
3. Press **OK** to confirm.
   The selected profile information is displayed.
4. Press **OK** to confirm the drug library version, or **C** to change the profile.
   The drug library is loaded for the selected profile.

7.3 Selecting a Therapy

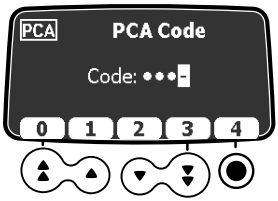
After selecting Basic Profile, the programming interface can take you to the **Select therapy** screen where you must choose between:

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

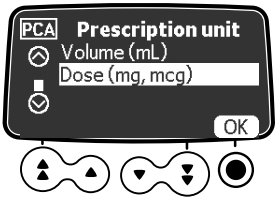


2. Enter the 4-digit passcode using the keys below the numbers on the screen.

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.*

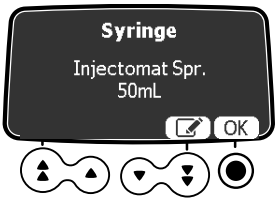


1. Use the arrow keys to select the prescription unit, and press **OK** to confirm
   The example in this chapter shows how to program a PCA infusion in dose.
   The syringe selection screen is displayed.

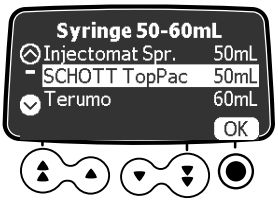
7.5 Selecting a Syringe

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

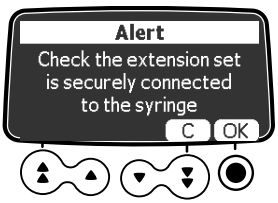
WARNING
During programming and prior to starting an infusion, verify that the syringe size and model on the syringe pump's display screen match the syringe size and model loaded in the syringe pump.



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



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



4. If necessary, press **OK** to acknowledge the clinical advisory message, or **C** to return to the syringe selection screen.
   *When you choose **OK**, the drug selection screen is displayed.*

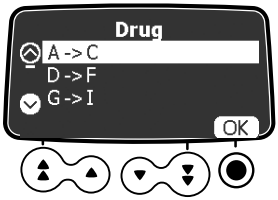
7.6 Selecting a Drug

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

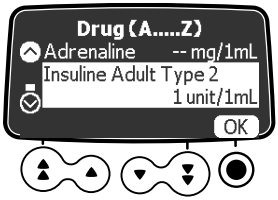
Note: *This screen is not displayed if you previously selected the Basic Profile that does not offer a pre-defined drug list.*

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

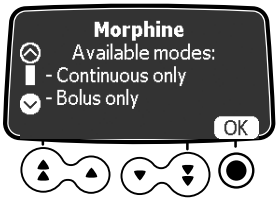
- *Drug X*
- *A -> C*
- *D -> F*
- *G -> I*
- *J -> L*
- *M -> O*
- *P -> R*
- *S -> U*
- *V -> Z*



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. Use the arrow keys to scroll to the drug you want, and press **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 **OK** to acknowledge the clinical advisory message and continue programming, or the cancel key to change the drug.
   *When you choose **OK**, the **Concentration** screen is displayed.*

7.7 Selecting Drug Concentration

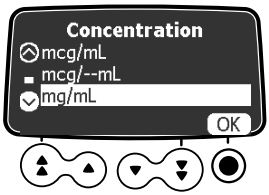
If the prescription unit you selected in step 7.4 is **Dose**, you must specify the drug concentration. Depending on the profile previously selected see:

- Basic Profile and Custom Profiles with a Drug List, page 51
- Custom Profiles with a Drug Library, page 51

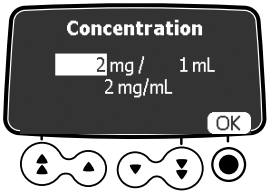
If you selected **Volume** in step 7.4, go to Section 7.10, page 55.

7.7.1 Basic Profile and Custom Profiles 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. Use the arrow keys to select the concentration unit, and press **OK**.



2. Use the arrow keys to specify the values required for mass and/or volume and press **OK** to confirm each value.
   The concentration is automatically calculated and displayed in the unit previously selected.
3. Press **OK** to confirm the concentration.
   If the PCA loading dose screen is displayed, see Section 7.9 to prime the syringe before infusing the drug.
   If the Dose rate screen is displayed, select the appropriate dose rate unit as explained in Section 8.10.1, page 75.

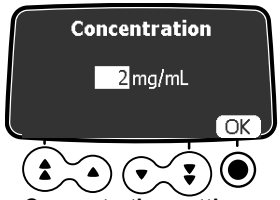
7.7.2 Custom Profiles with a Drug Library

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 ajusted:

- 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 Section 4.4.2, page 30.

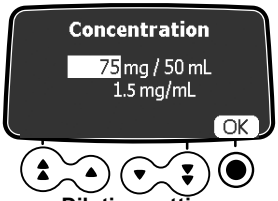
Note: *This screen is not displayed if you are not allowed to adjust the concentration of the selected drug.*



Concentration setting

If a Concentration unit is selected:

1. Press the arrow keys to select the Concentration.
2. Press **OK** to confirm.
   If the Patient characteristics screen is displayed, see below; if the PCA loading dose screen is displayed, see Section 7.10, page 55.



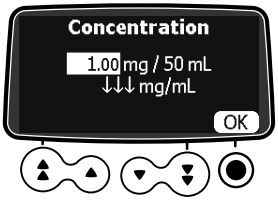
Dilution setting

If a Dilution unit is selected:

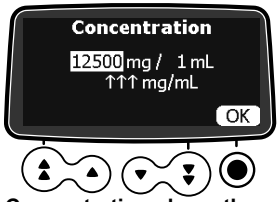
1. Press the arrow keys to select the Dose then press **OK** to confirm.
2. Press the arrow keys to select the Volume then press **OK** to confirm.
   If the Patient characteristics screen is displayed, see below; if the PCA loading dose screen is displayed, see Section 7.10, page 55

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

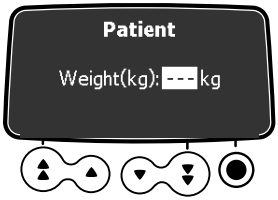


Concentration above the Drug Library Software hard limit

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. Use the arrow keys to enter the patient's weight.
2. Press **OK** to confirm.
   If the PCA loading dose screen is displayed, see Section 7.9 to prime the syringe before infusing the drug.
   If the Dose rate screen is displayed, select the appropriate dose rate unit as explained in Section 8.10.1, page 75.

INFORMATION

- The weight entry screen is displayed only 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.*

INFORMATION

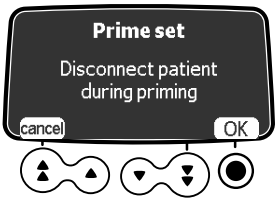
We strongly recommend to always use the prime function, especially for life-sustaining drugs. Priming the syringe and the extension set removes all the mechanical gaps and ensures that the programmed flow rate is reached within the smallest delay once the start button is pressed.

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.

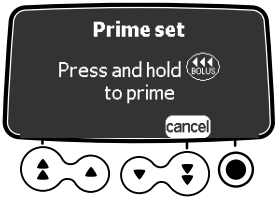
WARNING

Priming the syringe must only be done when the patient is not connected.

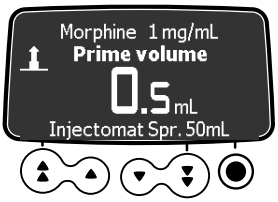
1. Press the bolus key .
   The Prime set screen is displayed.



2. Make sure the extension set is not connected to the patient, as indicated on the screen, and press **OK** to proceed.



3. Press and hold the key to prime.
   You can monitor priming in progress on the screen.
4. To end priming, release the key.
   The prime volume is displayed.



5. 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 BOLUS key is not active when the menu screen is displayed.
- During priming, the occlusion pressure level is set to its maximum value 900 mmHg / 120 kPa / 17.4 PSI.
- Priming is limited to 5 mL maximum. Above 5 mL, you must release and press the BOLUS key again to 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	▪ Triggered if flow rate is equal or inferior to 50 mL/h **and** automatic priming has not been done. ▪ Not triggered if automatic priming has been done by the user.
Not displayed	

INFORMATION

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

WARNING

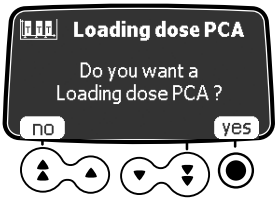
If priming has not been performed, a quick start could result in an undesired bolus in some cases. Always prefer the automatic prime function for life-sustaining drugs.

7.10 Programming a PCA Loading Dose

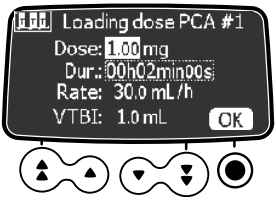
After selecting the drug concentration, and maybe the patient characteristics, the **Loading dose PCA** screen is displayed.

INFORMATION

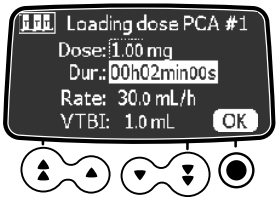
- You can request a PCA loading dose at any time during PCA infusion programming by pressing the bolus key .



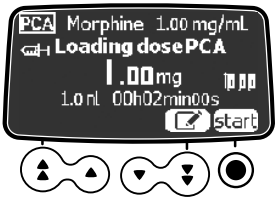
1. Select **yes** to program a loading dose, or **no** if you do not need it.
   *If you select **no**, the PCA delivery mode screen is displayed. See Section 7.11, page 56.*



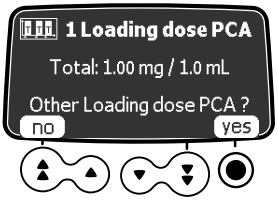
2. Use the arrow keys to enter a value for the dose, in this example in mg. *The VTBI is automatically adjusted based on dose and duration settings.*
3. Press **OK** to confirm the dose.



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 **OK** to confirm the duration.
6. Press the arrow keys to program the flow rate.
   The duration and the rate are interdependant.
7. Press **OK** to confirm the loading dose settings.
8. See Section 7.18, page 61 for precautions to take before starting the infusion.
9. Select **start** to administer the loading dose.
   If you need to adjust the settings, press .



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 choose **no**, the PCA delivery mode screen is displayed. See Section 7.11, page 56.*

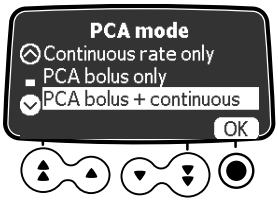


7.11 Selecting the PCA Mode

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

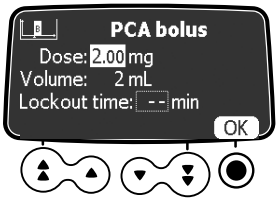
INFORMATION
Check that the patient handset is connected before starting an infusion that authorizes PCA boluses.



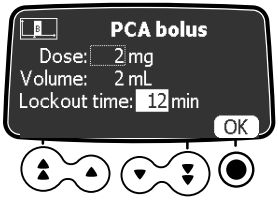
1. Press the arrow keys to scroll to the delivery mode that you want, and press **OK**.
   *For **Continuous rate only**, see Section 7.13, page 57.*
   ***For all other modes,** see Section 7.12, page 56..*

7.12 Programming a PCA Bolus

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



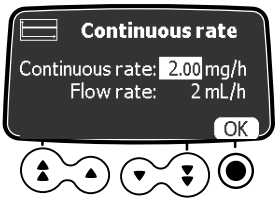
1. Press the arrow keys to enter a value for the dose, mL or mg, depending on the prescription unit previously selected.
   When entering a value for a dose, the corresponding volume is automatically displayed.
2. Press **OK** to confirm the dose.



3. Use the arrow keys to set the bolus lockout time.
4. Press **OK** to confirm the lockout time.
   *If the **Continuous rate** screen is displayed, see Section 7.13. If the **Cumulated limits** screen is displayed, see Section 7.16, page 59.*

7.13 Programming a Continuous Rate

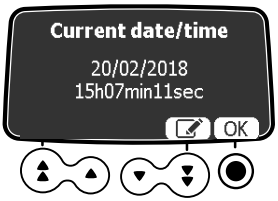
If you selected a PCA mode that includes a continuous rate, the **Continuous rate** screen is displayed.



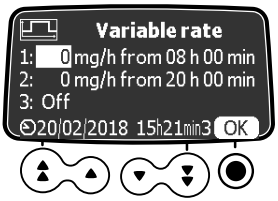
1. Use the arrow keys to enter a value for the rate, in mL/h or mg/h depending on the prescription unit previously selected.
2. Press **OK** to confirm the continuous rate.
   *The **Cumulated limits** screen is displayed. See Section 7.16, page 59.*

7.14 Programming a PCA Infusion with Variable Rates

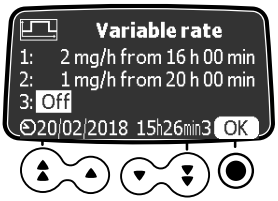
If you selected the PCA bolus + variable mode, after programming the PCA boluses, the **date/time** screen is displayed. It is important to check the current date and time are correct before you program the start time for varying infusion rates. While programming, the current date and time are shown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



1. Press **OK** to validate the current date and time, or press to correct the information displayed.
   When you press OK to confirm the last element of the time display, the variable rates 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 **OK** to confirm the dose rate.
4. Set the start time, and press **OK**.



5. Set the value and start time of the second and third dose rate if required, and press **OK** to confirm each value.
   *The **Cumulated limits** screen is displayed. See Section 7.16.*

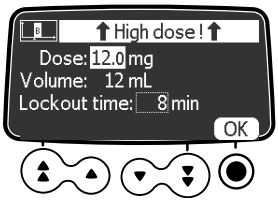
7.15 Programming an Infusion Beyond Soft Limits

A drug that is part of a drug library in a custom profile can have predefined limits on flow rate and dose settings. For information on the limits that can be defined, see Section 4.4.2, page 30.

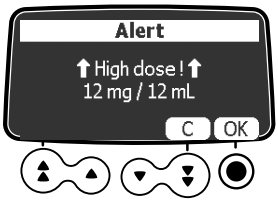
If you reach a limit when programming an infusion, the pump displays a message at the top of the screen. You can override soft limits but not hard limits, as shown in the examples below.

Overriding a soft limit

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



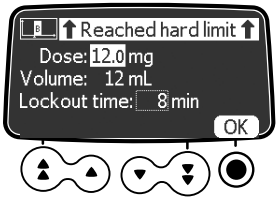
1. Use the arrow keys to reduce the dose, or press **OK** to confirm it.
   If you attempt to increase the dose, the hard limit alert is displayed.



2. If you press **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.

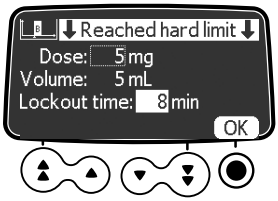
Acknowledging a hard limit

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



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

Press **OK** to acknowledge the hard limit.
The high dose alert is displayed as shown above.

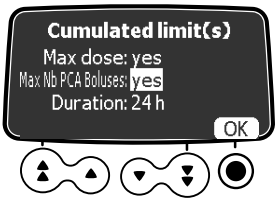


The figure opposite shows the screen displayed when you try to reduce the value of **Lockout time**.

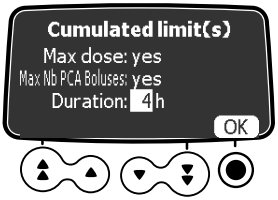
Press **OK** to acknowledge the hard limit.
The next programming screen is displayed and you can continue programing the infusion.

7.16 Setting the Cumulated Limits

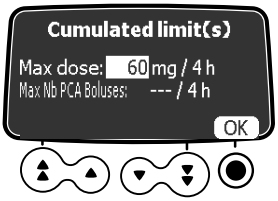
After setting the PCA mode and doses, the **Cumulated Limit(s)** screen is displayed to allow you to set safety limits. For a specified time period, you **must** set a limit on maximum dose, and you **can** set a limit on the maximum number of PCA boluses.



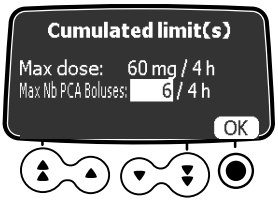
1. Use the arrow keys to select **yes** or **no**, for setting a limit on the maximum number of boluses that the patient can receive.
2. Press **OK** to confirm your choice and move the cursor to the next field.



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 **OK** 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 **OK** to confirm the value and move the cursor to the next field.



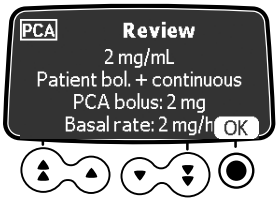
7. Use the arrow keys to set the maximum number of PCA boluses that the patient can self-administer during the specified time period.
8. Press **OK** to confirm the number.
   All the PCA settings you made are displayed for review and validation. See Section 7.17.

INFORMATION

The Max Nb PCA boluses field is not displayed if the PCA mode is Continuous only.

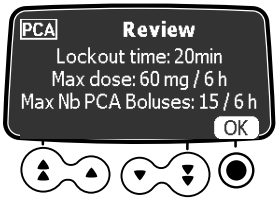
7.17 Reviewing the PCA Infusion Settings

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



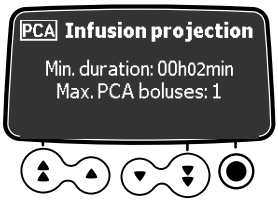
1. Press **OK** to confirm the PCA mode, the bolus dose, and the background rate if applicable.

   To change a setting, press the cancel key and see Section 7.20, page 65.

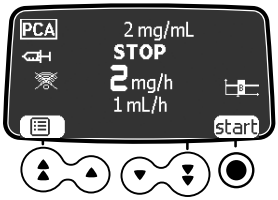


2. Press **OK** to confirm the lockout time and the maximum limits, if applicable.

   To change a setting, press the cancel key and see Section 7.20, page 65.



3. Press **OK** to confirm the information displayed on the screen, or press the cancel key to change the settings.
   When you press OK, the infusion start screen is displayed .



4. Before you press **start**, see Section 7.18, page 61 for precautions to take.
   When you start the infusion, the keypad is automatically locked (see Section 9.3 to unlock the keypad).

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.

1. Check that there is no air in the syringe or in the extension set.
   For information on priming the extension set, see Section 7.9, page 53.
2. Connect the extension set to the patient's access device.
3. Check the integrity of the delivery path.
4. If necessary, make sure the protective cover is closed and remove the key.
5. 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.
6. 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 Section 7.21.1, page 66.

WARNING
When connecting the extension set to the patient's access device, always use an aseptic technique in accordance with your healthcare facility's policy.

WARNING
Before actually 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:

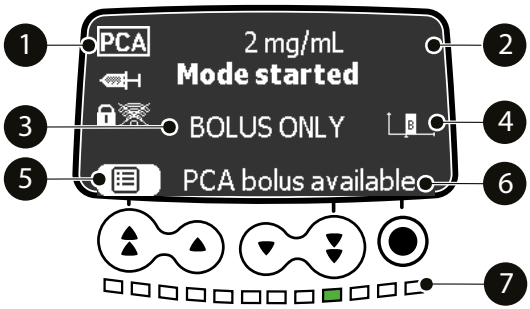
- Monitor a running infusion directly on the screen (see below).
- Press the MENU key to view the total dose infused since the start of infusion.
- Display the history of PCA infusions for patient, see Section 7.19.2, page 64.

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.



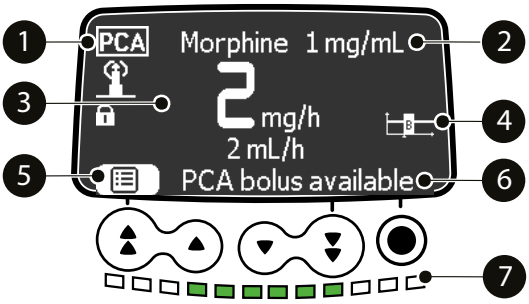
Legend

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

Figure 7.1: PCA infusion in bolus only mode (started but not currently infusing)

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.



Legend

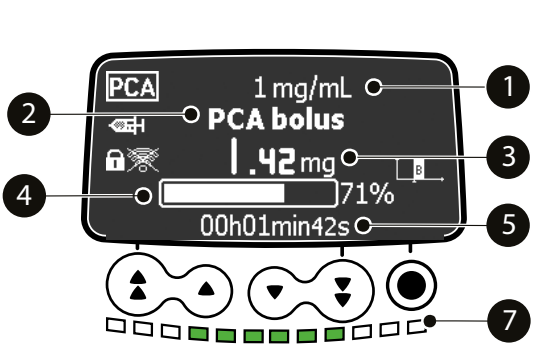
1. PCA therapy indicator
2. Drug name and/or concentration
3. Dose rate and/or flow rate
4. PCA bolus indicator
5. Summary of PCA settings
6. Indication of PCA bolus available or lockout
7. Green LEDs flashing regularly to indicate infusion in progress

Figure 7.2: PCA infusion in progress in bolus + continuous mode - bolus available

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.



Legend

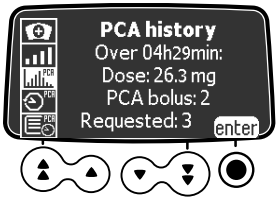
1. Drug name and/or concentration
2. PCA bolus in progress
3. Dose countdown during bolus infusion
4. Progress bar showing percentage of bolus infused
5. Time countdown during bolus infusion
7. Green LEDs flashing fast to indicate bolus in progress

Figure 7.3: PCA bolus in progress

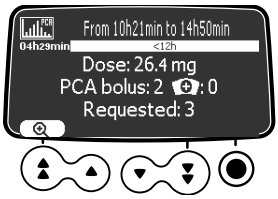
7.19.2 Displaying PCA History

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.

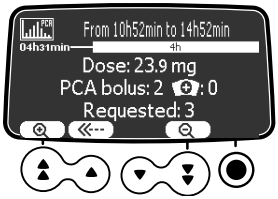
INFORMATION
PCA infusion data is not saved when the pump is turned off.



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.

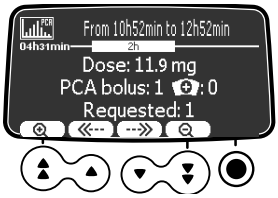


2. Press **enter** to access the detailed PCA history.
   A time scale since the beginning of treatment is displayed above the PCA infusion data. The screen also shows the number of clinician boluses administered, if any, as well as the total number of boluses requested.



3. Press the magnifying glass to zoom in on a narrower time frame.
   The PCA infusion data corresponding to the new time frame is displayed.

4. Use the back and forward double arrow buttons to navigate through the PCA data recorded since the beginning of treatment.



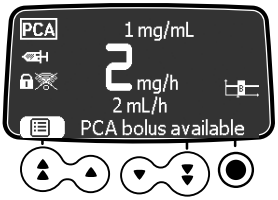
5. Use the magnifying glass to zoom out of the time frame observed.

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

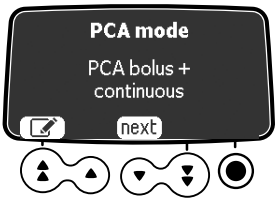
INFORMATION
Dose or Total dose in the PCA history represents the addition of the continuous rate, of clinician and PCA boluses, and of loading doses, if any, over the period displayed.

7.20 Modifying a Running PCA Infusion

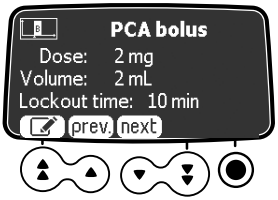
At any time during a PCA infusion, you can modify the infusion settings. You must enter the passcode for PCA therapy if prompted.



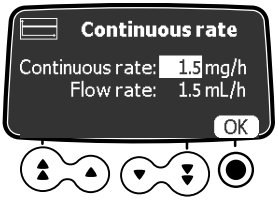
1. Press **Stop** STOP on the keypad to interrupt the PCA treatment.
2. Press the left fast increment key to select the summary of PCA settings (list icon) above it on the screen.
   The current PCA delivery mode is displayed.



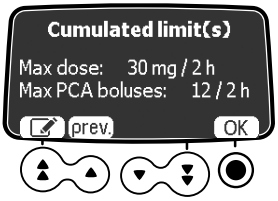
3. Do you want to change the PCA delivery mode?
   - No: select **next**.
     The current PCA bolus settings are displayed. See next step.
   - Yes: press the edit icon .
     See Section 7.11, page 56.



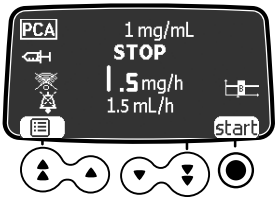
4. Do you want to change the PCA bolus settings?
   - No: select **next**.
     The current continuous rate settings are displayed. See next step.
   - Yes: press the edit icon .
     See Section 7.12, page 56.



5. Do you want to change continuous rate settings?
   - No: press **next**.
     The current cumulated limits settings are displayed. See next step.
   - Yes: press the edit icon .
     See Section 7.13, page 57.



6. Do you want to change the cumulated limits?
   - No: select **OK**.
     The settings review screen is displayed. See next step.
   - Yes: press the edit icon .
     See Section 7.16, page 59.



7. Review and validate the new settings, as explained in Section 7.17, page 60.
8. Press **start** 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.

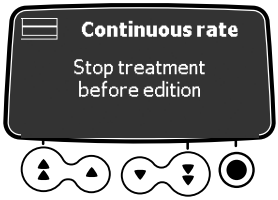


Figure 7.4: Alert message requiring to stop infusion

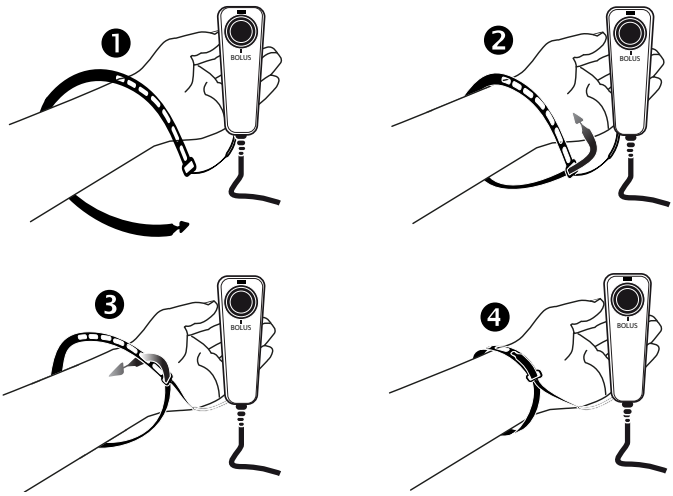
After 3 seconds, the message disappears.

7.21 Administering a Bolus

The patient and the clinician can administer a bolus.

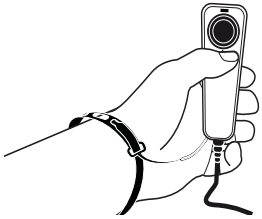
7.21.1 Administering a PCA Bolus

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.

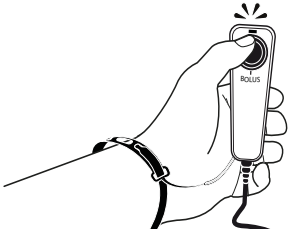


You must explain to the patient how to use the handset.

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

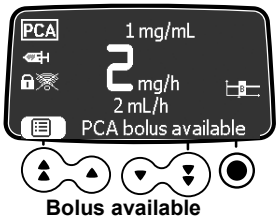


2. To trigger a bolus, press the bolus button on the handset.
The pump beeps and the blue LED above the bolus button flashes for a few seconds (default behavior).

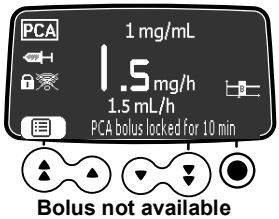


If a PCA bolus is not available due to the lockout period between two consecutive boluses, or because the maximum number of boluses allowed has been reached, on pressing the bolus button, the pump beeps and the LED on the patient handset flashes but the pump does not deliver the bolus.

By default, the pump display shows when a PCA bolus is available. This feature can be disabled in the pump configuration, as explained in Section 11.3, page 111.



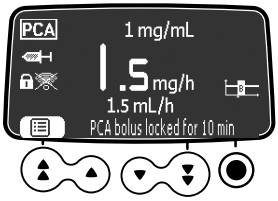
Bolus available



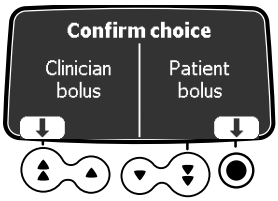
Bolus not available

7.21.2 Administering a Clinician Bolus

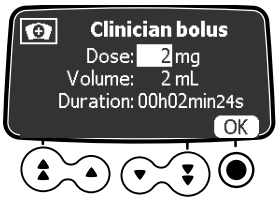
As the clinician, you can administer a bolus during the PCA infusion in progress. In the example below, the patient cannot self-administer a bolus due to the lockout period, but you can administer a clinician bolus.



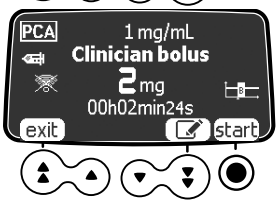
1. Press the Bolus key on the keypad.
   *The screen displays the choice of a **PCA bolus** or **Clinician bolus**.*



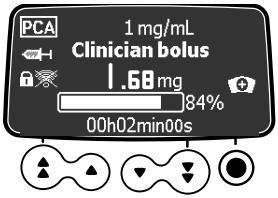
2. Select the clinician bolus using the confirmation key.
3. Enter the passcode for PCA therapy if prompted.



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 confirm the dose.
   See Section 7.22.4, page 71 if the dose to be infused exceeds the maximum dose specified in the cumulated limits.



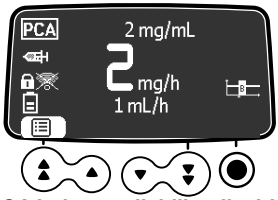
6. Press **start** to administer the bolus, the **edit** key to modify the dose, or **exit** to cancel the clinician bolus.



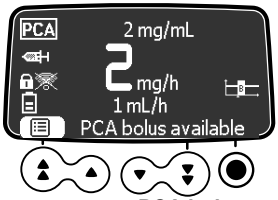
7. Monitor the progress of the bolus on the screen.

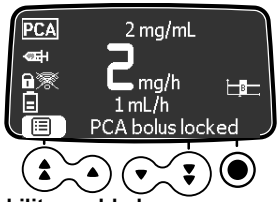
7.21.3 Viewing the Availability of a PCA Bolus

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.



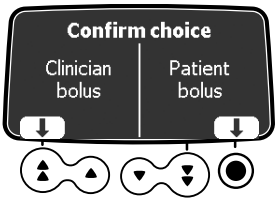
PCA bolus availability disabled



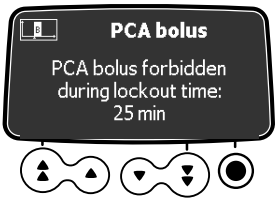


PCA bolus availability enabled

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

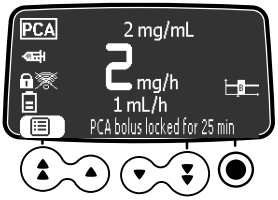


1. Press the Bolus key on the keypad.
   *The screen displays the choice of a **Clinician bolus** or **PCA bolus**.*



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 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 10% of the syringe capacity.

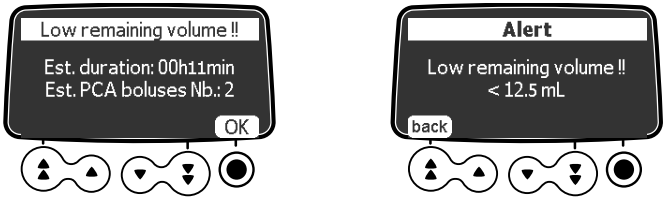


Figure 7.5: Remaining volume too low message

Select **OK** in each screen 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.

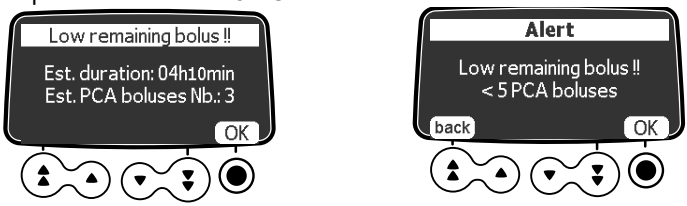


Figure 7.6: Remaining number of boluses too low message

Select **OK** in each screen 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.

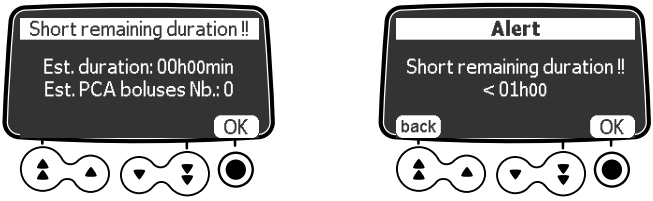
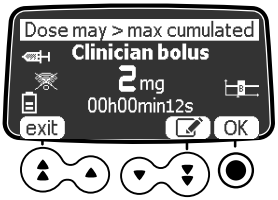


Figure 7.7: Remaining duration too low message

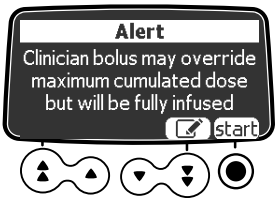
Select **OK** in each screen to acknowledge the alert.

7.22.4 Administering a Clinician Bolus beyond Maximum Dose

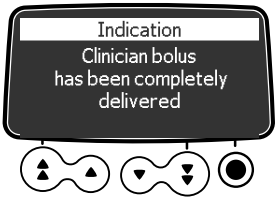
When you program a clinician bolus, before you start the infusion, the pump adds the value of the bolus to the cumulated dose already infused. If the result exceeds the maximum dose authorized, the following alert message is displayed.



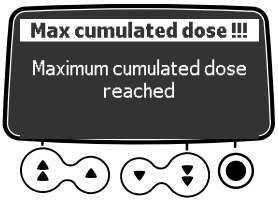
1. Select **OK** to acknoweldge the alert and continue without modifying the dose, or select the edit icon to modify the dose.
   When you select OK, the alert is displayed again.



2. To administer the bolus although the maximum cumulated dose will be exceeded, press start.
   To modify the value of the dose, press the edit icon  .
3. Monitor the progression of the bolus on the screen.



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



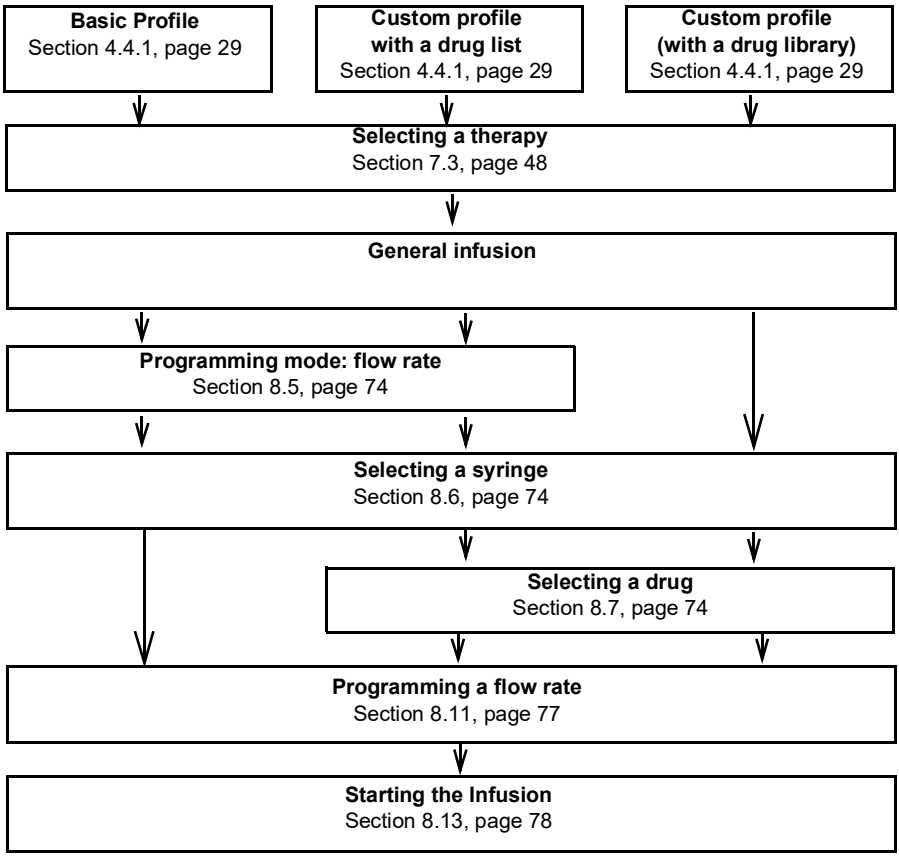
It is followed by a high-priority maximum dose alarm, and the PCA infusion is stopped. See Table 14.6, page 120.

8 Programming a General Infusion

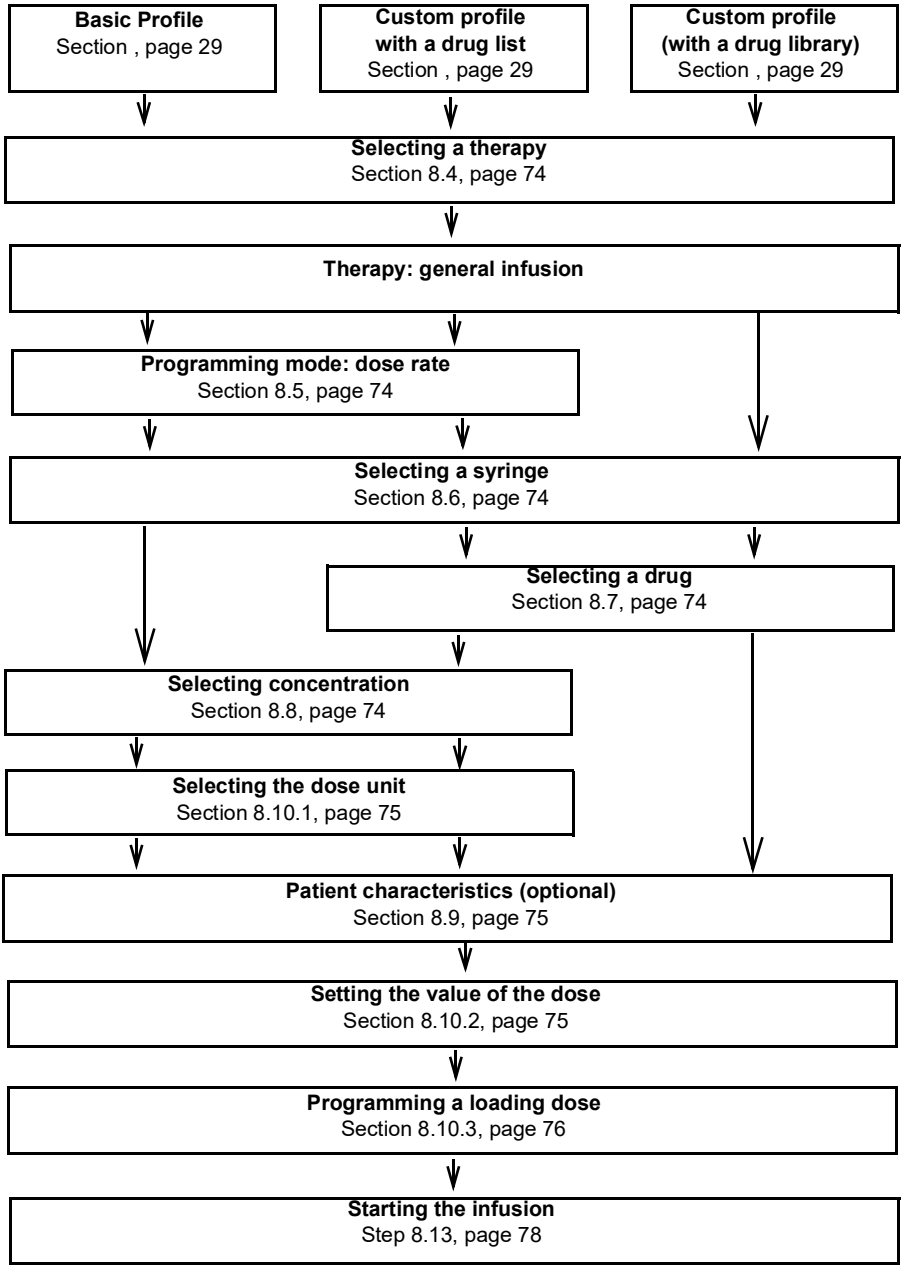
The Agilia SP PCA syringe pump can be used for general infusions as well as for PCA therapy.

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 Section 7.2, page 48 for explanations on how to select a profile.

8.4 Selecting a Therapy

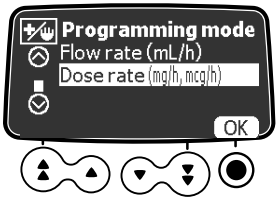
After selecting Basic Profile, the programming interface takes you to the **Select therapy** screen where you must choose **General Infusion**. See Section 7.3, page 48 for detailed explanations.

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.*



1. Use the arrow keys to select the programming mode, and press **OK** 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 Section 7.5, page 49.

WARNING

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

8.7 Selecting a Drug

After you confirm the syringe type, the screen displays a drug selection menu. See Section 7.6, page 50 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 step 8.5 is **Dose rate**, you must specify the drug concentration. See Section 7.7, page 50 for detailed explanations.

If you selected **Flow rate** in step 8.5, go to Section 8.11, page 77.

8.9 Selecting 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 Section 7.8, page 52 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

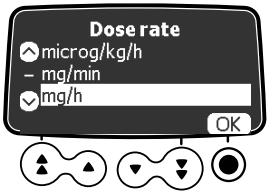
When programming an infusion by dose, you will be prompted, as necessary, to:

- 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 **OK** to confirm.
   The next screen displayed allows you to set the dose to be infused. See Section 8.10.2.

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.

INFORMATION

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 Section 8.17, page 83.

DrugX

Drug from a drug library

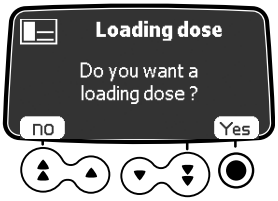
1. Press the arrow keys to program the dose rate value.
2. Press **OK** to confirm.
   *The **Loading dose** screen is displayed. See Section 8.10.3, page 76.*

8.10.3 Programming a Loading Dose

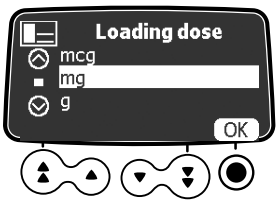
After setting the value of the dose, you can program a **loading dose**.

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 Section 7.9, page 53.

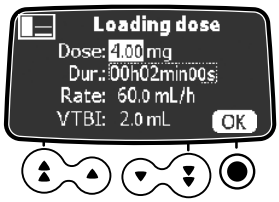
Note: *In custom profiles, the loading dose feature can be deactivated. Therefore, the loading dose screen is not always displayed.*



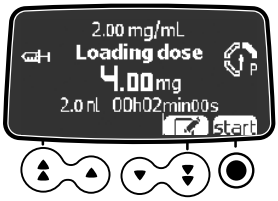
1. On the loading dose screen, press **Yes** if you want a loading dose.
   *If you press **no**, you can start the infusion as explained in Section 8.13, page 78.*



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

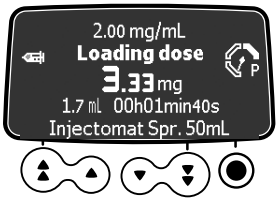


3. Press the arrow keys to enter a value for the dose, and press **OK** to confirm.
4. Press the arrow keys to program the loading dose duration (__ h __ min __), and press **OK** to confirm.
   The VTBI is automatically calculated based on dose and duration settings.
5. Press the arrow keys to program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



7. Before you press **start** to initiate the loading dose, see Section 8.13, page 78 for precautions to take.

   *If needed, press **edit** or the cancel key ⟲ to change the loading dose settings before starting.*



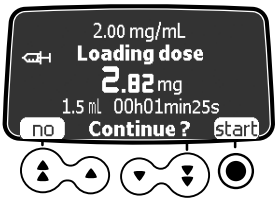
8. Monitor the progression of the loading dose infusion on the screen.
   Once the loading dose is finished, the pump automatically starts the programmed infusion.

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 substracted from the VTBI (or DTBI).

Interrupting a Loading Dose

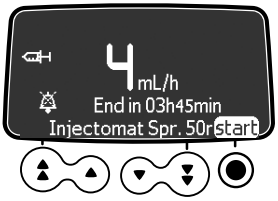


1. To pause the loading dose, press STOP.
   The screen displays ***Continue?***
2. Press **no** or STOP to stop the loading dose and proceed to the programmed infusion.
   Once you have stopped the loading dose, you cannot restart it. Alternatively, press **start** to continue the loading dose.

8.11 Programming an Infusion by Flow Rate

If the programming mode you selected in step 8.5 is **Flow rate**, the Flow rate screen is displayed to allow you to set the value.

INFORMATION
At this stage in the worflow, 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 Section 8.17, page 83.



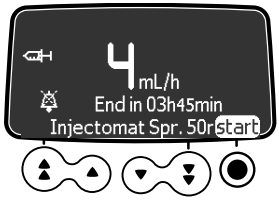
1. Use the arrow keys to set the value of the flow rate.
2. Before you press **start**, see Section 8.13, page 78 for precautions to take.

8.12 Programming an Infusion Beyond Soft Limits

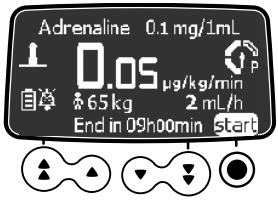
A drug that is part of a drug library can have predefined limits on flow rate and dose settings. For information on the limits that can be defined, see Section 4.4.4, page 30.

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 Section 7.15, page 58.

8.13 Starting an Infusion



Flow rate



Dose

1. Check that there is no air in the syringe or in the extension set.
   For information on priming the extension set, see Section 7.9, page 53.
2. Connect the syringe's extension set to the patient's access device.
3. Check the integrity of the delivery path.
4. Check the infusion settings prior to starting the infusion.
5. Press **start** to start the infusion.
   The keypad is automatically locked.

WARNING

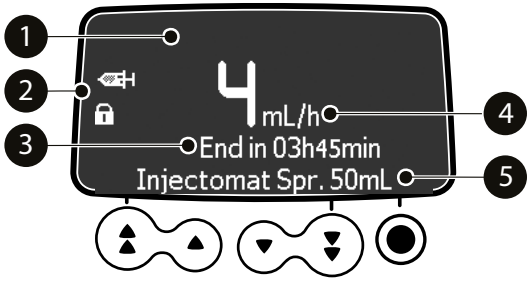
- When connecting the syringe's extension set to the patient's access device, always use aseptic technique according to your healthcare facility policy.
- During programming and prior to starting an infusion, verify that the syringe size and model on the syringe pump's display screen matches the syringe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

WARNING

If the protective cover is necessary, before actually starting the infusion, you must close it and remove the key.

8.14 Monitoring an Infusion

8.14.1 Monitoring an Infusion Programmed by Flow Rate



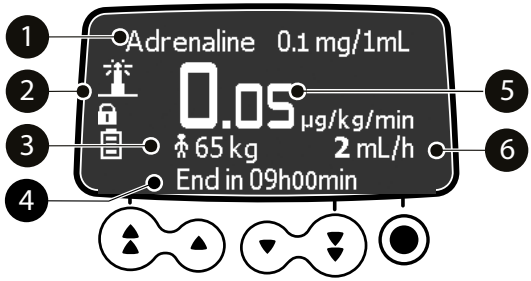
Legend

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 curent rate
4. Flow rate (displayed with largest font size)
5. Syringe name / ward name (configurable)

Figure 8.1: Infusion programmed by flow rate in progress

INFORMATION
- To change the flow rate during infusion, see Section 8.15, page 80.
- Display of infusion remaining time depends on the predefined settings for this drug.

8.14.2 Monitoring an Infusion Programmed by Dose



Legend

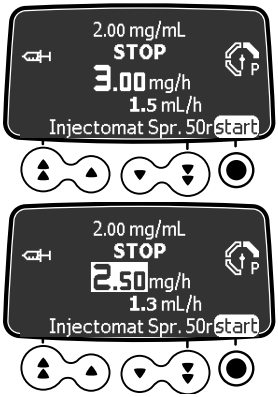
1. Drug name and/or concentration
2. Lighthouse indicates drug selected from drug library
3. Patient characteristics
4. Syringe name / ward name (configurable)
5. Flow rate (displayed with largest font size)
6. Infusion flow rate

Figure 8.2: Infusion programmed by dose in progress

INFORMATION
- To change the dose during infusion, see Section 8.15, page 80.
- 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.



1. If required, stop the infusion by pressing STOP, as explained in Section 9.1, page 86.
2. Press the arrow keys to modify the flow rate or dose.
3. Press **start** 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, using the bolus key BOLUS
- Programmed bolus, using the bolus key BOLUS or the menu key MENU

During bolus administration, the occlusion pressure level is set to its maximum value: 900 mmHg / 120 kPa / 17.4 PSI.

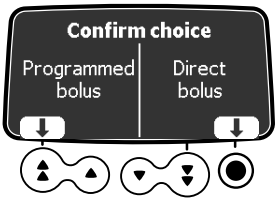
INFORMATION

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

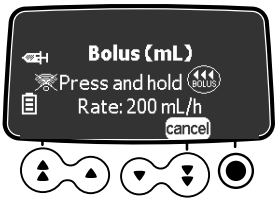
8.16.1 Direct Bolus

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

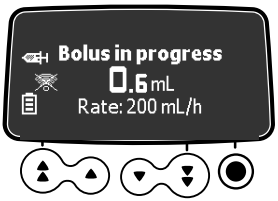
Note*: This feature can be deactivated in Basic Profile (see the Technical manual) and in custom profiles. Therefore, the* ***Bolus*** *screen is not displayed for all drugs.*



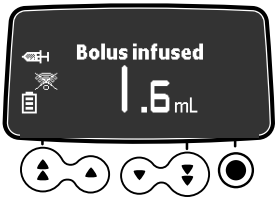
1. During the infusion, press the bolus key (BOLUS).
2. Select **Direct bolus** on the screen to access the bolus function.
   The screen shows the infusion rate for the bolus.



3. Following the instructions on the screen, press and hold the bolus key (BOLUS) to administer a direct bolus.
   The bolus starts and the screen shows the volume (or dose) infused.



4. While holding the bolus key, monitor the volume *(or dose)* infused displayed on the screen.
5. Release the bolus key when you reach the volume *(or dose)* desired.



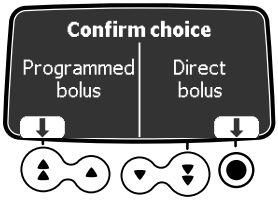
The volume *(or dose)* infused is displayed for a few seconds on the screen. The infusion resumes its previous rate after the bolus is delivered.

8.16.2 Programmed Bolus

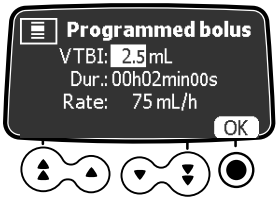
At any time during infusion, you can program a bolus in one of the following ways.

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

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.*

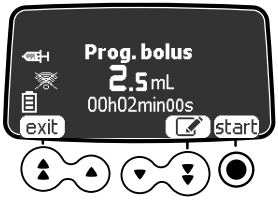


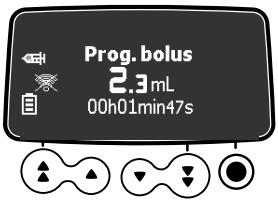
1. During the infusion, press the bolus key (BOLUS).
   The bolus screen is displayed.
2. Select **Programmed bolus** on the screen to access the programmed bolus function.
   *The **Programmed bolus** screen is displayed.*



3. Press the arrow keys to program the bolus volume or dose, and press **OK** to confirm.
4. Press the arrow keys to program the bolus duration (__ h __ min __), and press **OK** to confirm.
   The flow rate is calculated automatically.
5. Press the arrow keys to program the flow rate.
   The duration and the rate are interdependant.
6. Press **OK** to confirm the programmed bolus settings.
7. At this stage, you can:

- Press **start** to administer the bolus immediately.
- Press **exit** to save the settings without administering the bolus.
- Press **edit** to change the bolus settings.

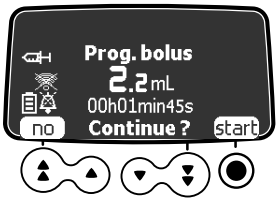




8. Monitor the progression of the bolus infusion on the screen.
   The infusion resumes its previous rate after the bolus has been delivered.

INFORMATION
If you press the bolus key (BOLUS) again, and select Programmed bolus, the settings of the last bolus are displayed.

Interrupting a Programmed Bolus



1. Press (STOP) to interrupt the bolus.
2. Answer the question: **Continue?**

- Press **no** or (STOP) to stop the bolus and resume the infusion.
- Press **start** to continue the programmed bolus.

8.17 Advanced Infusion Programming Modes

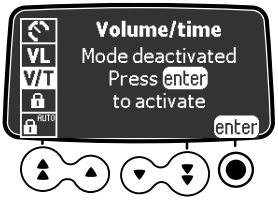
The Agilia SP PCA pump offers the following advanced programming modes:

- Volume/Time and Dose/Time
- Volume limit

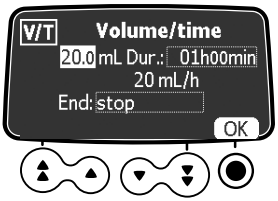
Note: The availability of these infusion modes depends on the pump configuration and the selected drug. They are not available for PCA therapy.

8.17.1 Volume/Time and Dose/Time

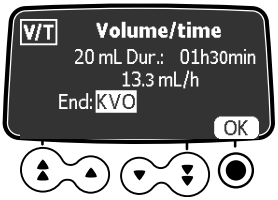
You can use this infusion mode to program a volume or dose to be infused (VTBI or DTBI) over a programmed period of time. When the VTBI / DTBI is reached, an alarm is triggered.



1. Press the menu key (MENU), then press the arrow keys to select V/T (or D/T).
2. Press **enter**.
   The Volume/time (or Dose/time) screen is displayed.



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



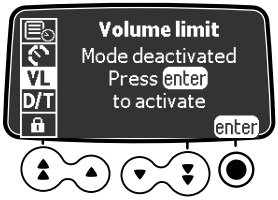
5. Press the arrow keys to configure the end of infusion settings and press **OK** to confirm.

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

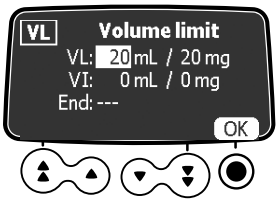
6. Press **start** to start the infusion.
   If the loading dose screen is displayed, see Section 8.10.3, page 76. The loading dose is included in the volume or the dose that you programmed.
   When the infusion starts the remaining VTBI and remaining time are displayed on the screen and updated every minute.

8.17.2 Volume Limit

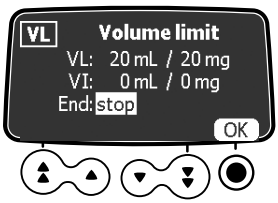
You can use this infusion mode to set a limit to the volume infused. When the limit is reached, an alarm is triggered.



1. Press the menu key (MENU), then press the arrow keys to select VL .
2. Press **enter**.
   The Volume limit screen is displayed.



3. Press the arrow keys to set the volume to be infused, and press **OK**.



4. Press the arrow keys to configure the end of infusion setting and press **OK** to confirm.
   - *Stop:* The infusion stops when the VTBI is completed.
   - *Keep Vein Open (KVO):* After the VTBI is completed, the infusion continues at a preset flow rate to keep the access device open.
   - *Continuous:* After the VTBI is completed, the infusion continues at the programmed flow rate.

5. Press the arrow keys to set the value of the flow rate or dose rate, and press **OK**.
6. Press **start** to start the infusion.
   If the loading dose screen is displayed, see Section 8.10.3, page 76. The loading dose is included in the volume limit that you programmed.
   When the infusion starts, the volume infused over the programmed volume limit is displayed.

INFORMATION

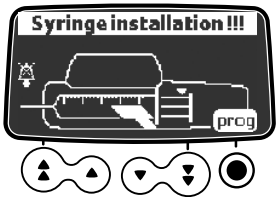
- If you program a volume limit that exceeds the actual volume in the syringe, you must replace the syringe when it is empty, as explained in Section 15.3.2, page 128.
- The volume already infused (VI) before accessing the volume limit mode is taken into account.

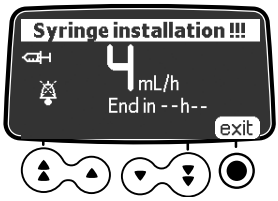
8.18 Pre-programming the Pump

If necessary, you can program the pump before installing the syringe.

Note: You cannot pre-program the pump for PCA therapy. This programming mode is available for general infusion only.

You can program the pump before installing the syringe:





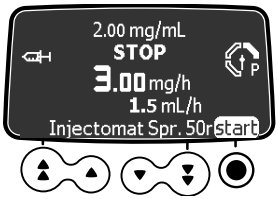
1. Press ⏻ to power on the pump.
   `Syringe installation !!!` is displayed on top of the pump screen.
2. Make sure the syringe barrel clasp is folded up against the pump.
   *The **prog** symbol is displayed.*
3. Program the infusion.
   See Section 8.5, page 74.
4. Press **exit** to confirm.
5. When ready, install the syringe.
6. Confirm or correct the syringe type.
   See Section 8.6, page 74.
7. Press **start** 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 STOP.
   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 **start** to resume 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:

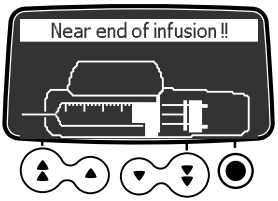
- An audible alarm is triggered.
- An alarm message appears on the pump screen.
- The infusion indicator lights flash yellow.

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 **OK** 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.

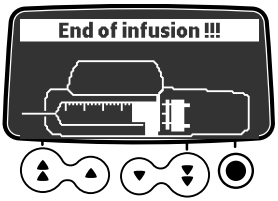
9.2.2 End of Infusion

When the infusion is complete, an **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 red.

End of infusion settings are configurable in Basic Profile (see the Technical Manual) and in custom profiles.

Silencing the Alarm

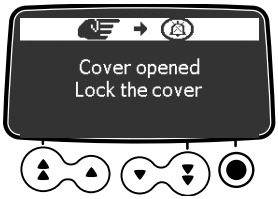


1. Press (🔕) to silence the alarm.
2. Prepare a new syringe, and adjust the settings for a new infusion.

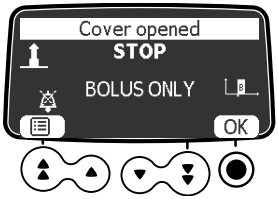
9.3 Unlocking the Pump Keypad

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

- By using the keypad lock status menu, as explained in Section 10.4, 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 progresss, press STOP.
2. Use the key to open the protective cover.
3. If necessary, press the key to silence the cover open alarm.

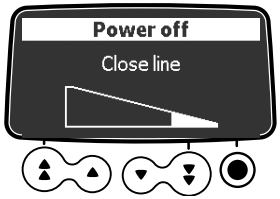


4. Press and perform the task that requires the keypad to be unlocked.

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 Section 10.4, 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	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 menu displayed depends on the pump configuration. For information on factory configuration, refer to Appendix: Factory Configuration, page 170.

Menu	Symbol	Stop Infusion Required	Associated Procedure
Profile	Pro	NO	▪ Displaying active profile information, page 91
Pressure		NO	▪ Modifying the pressure limit, page 91
Keypad lock status		NO	▪ Locking / Unlocking the keypad, page 93
Keypad automatic lock	AUTO	NO	▪ Activating / Deactivating the keypad automatic lock, page 95
Battery life		NO	▪ Viewing the battery life, page 96
Volume Infused Dose Infused	mL?	NO	▪ Viewing and clearing the volume or dose infused, page 96
Pause		YES	▪ Programming a pause, page 97
Programmed bolus		NO	▪ Programming a bolus, page 98
Clinician bolus		YES	▪ Programming a clinician bolus, page 98
PCA history	PCA	NO	▪ Viewing PCA history, page 104
PCA treatment	PCA	NO	▪ Viewing PCA treatment information, page 105
PCA event log	PCA	NO	▪ Viewing PCA event log, page 105

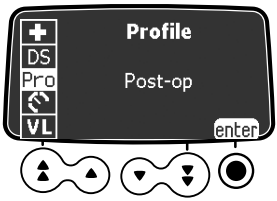
Menu	Symbol	Stop Infusion Required	Associated Procedure
Patient		NO	▪ Changing a patient's weight or body surface area, page 99
Day/Night mode		NO	▪ Switching between day mode and night mode, page 100
Volume/Time	V/T	YES	▪ Programming a Volume/Time or Dose/Time infusion, page 101
Dose/Time	D/T	YES	
Volume limit	VL	YES	▪ Programming a Volume Limit infusion, page 101
Alarm volume		NO	▪ Adjusting the alarm volume, page 102
Volume-Dose history		YES	▪ Viewing the infusion history, page 102
View flow rate history		NO	▪ Viewing flow rate history, page 103
View pressure history		NO	▪ Viewing pressure history, page 104
Syringe		NO	▪ Displaying on-pump syringe information, page 107.
View event log		NO	▪ Viewing the event log, page 106
Date / Time		NO	▪ Setting the date and time, page 107
Maintenance		NO	▪ Displaying maintenance information, page 107
Library information		NO	▪ Displaying drug library information, page 108
Clinical information		NO	▪ Viewing time remaining before clinical information is displayed, page 108
Data Set	DS	NO	▪ Displaying active data set information, page 109

10.2 Profile

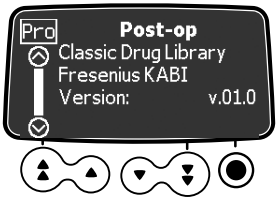
Symbol	Pro
Procedure	Displaying active profile information

INFORMATION
The Profile function is not available in PCA therapy.

You can display the active profile name as follows:



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



10.3 Pressure

Symbol	
Procedure	Modifying the pressure limit

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

- **3 levels** (low 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.

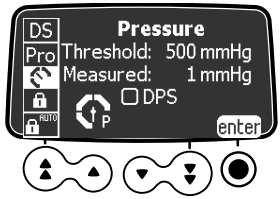
To consult the pressure settings, see Section 16.9, page 134.

WARNING

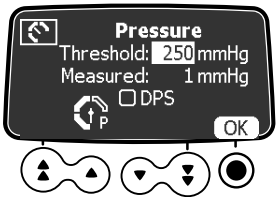
When addressing or clearing an occlusion:

- 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 health care professional should weigh the relative risks of disconnection with the risks of an unintended bolus of drug.
- Be aware that using larger size syringes on a high plunger force setting may produce a larger post occlusion bolus due to excessive syringe plunger head compliance.

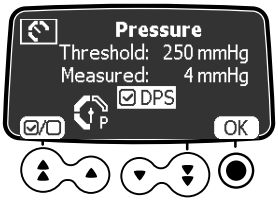
You can modify the pressure limit as follows:



1. Press the menu key (MENU), then press the arrow keys to select .
2. Press **enter** to access the pressure limit settings.



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



5. Press (☑/☐) to enable or disable the DPS function (optional).
6. Press **OK** to confirm.

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.

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 (less than 5 mL per hour, and especially less than 0.5 mL per hour):

- Consider occlusion pressure threshold setting and adjust it, as necessary. The lower the occlusion pressure threshold setting, the shorter the occlusion detection time. However, when infusing viscous or thick fluids (e.g., lipids), the occlusion pressure threshold setting may need to be adjusted to reduce false alarms.
- Use the smallest compatible syringe size necessary to deliver the fluid or medication. This minimizes the amount of friction and compliance (i.e., stiffness) of the syringe plunger head. Because syringe pumps infuse fluids by precisely controlling the plunger, smaller syringes provide more precise fluid delivery than larger syringes.
- Use the prime feature on the pump when changing a syringe and/or tubing.
- Use extension sets which have the smallest internal volume or deadspace (e.g., use microbore tubing when infusing at low rates, shorter length of tubing, etc.).

10.4 Keypad Lock Status

Symbol	
Procedure	Locking / Unlocking the keypad

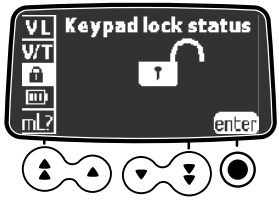
You can use this feature to avoid inadvertent key presses.

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

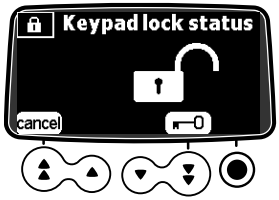
- Automatic lock: the keypad will lock automatically at infusion start, or after a time-out.
- Unlock code: the user must enter a code to unlock the keypad.

Locking the Keypad

You can lock the keypad as follows:



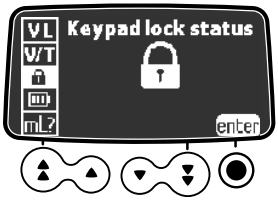
1. Press MENU.
2. Press the arrow keys to select .
3. Press **enter**.



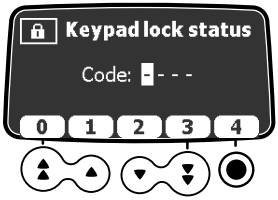
4. Press to lock the keypad.
   The keypad is locked and the screen displays .
5. Press **OK** to confirm.

Unlocking the Keypad

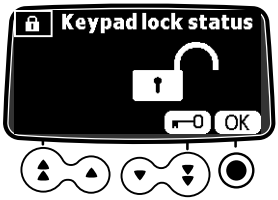
You can unlock the keypad as follows:



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



3. If a code is required, press the keys to enter the unlock code.
   The keypad is unlocked.



4. If no code is required, press .
   The keypad is unlocked and the screen displays .
5. Press **OK** to confirm.

INFORMATION

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

10.5 Keypad Automatic Lock

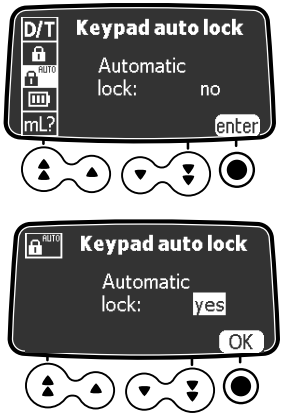
Symbol	AUTO
Procedure	Activating / Deactivating the keypad automatic lock

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

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

Activating the Keypad Automatic Lock

You can activate the keypad automatic lock as follows:



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

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

Deactivating the Keypad Automatic Lock

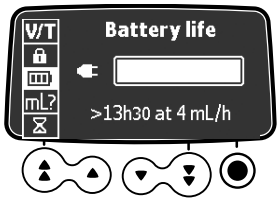
To deactivate the keypad automatic lock:

1. Unlock the keypad: see Unlocking the Keypad, page 94.
2. Press MENU.
3. Press the arrow keys to select AUTO .
4. Press **enter**.
5. Press the arrow keys to set the Automatic lock to "no".
6. Press **OK**.

10.6 Battery Life

Symbol	
Procedure	Viewing the battery life

You can view the battery life as follows:



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

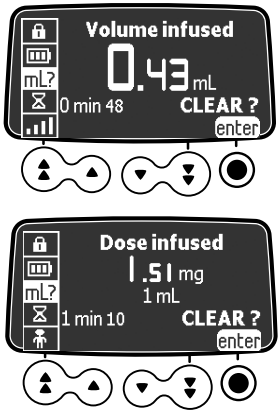
The bar graph shows a visual representation of battery life. The symbol displayed shows the following:

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

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 MENU.
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 **enter**.
4. Press **OK** to confirm.

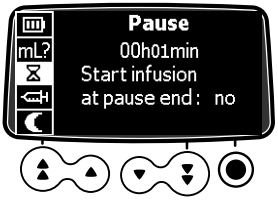
INFORMATION
When the pump is powered off or a new drug is selected, the volume or dose infused is cleared.

10.8 Pause

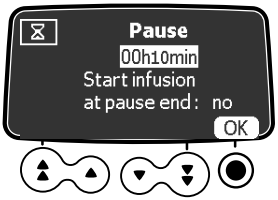
Symbol	⧖
Procedure	Programming a pause

INFORMATION
The Pause function is not available in PCA therapy.

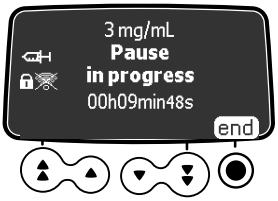
You can program a pause as follows:



1. Press STOP to stop the infusion.
2. Press MENU, then press the arrow keys to select ⧖ .
3. Press **enter**.



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



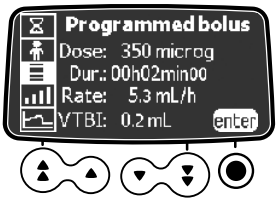
7. To restart the infusion before the end of the pause period, press end and then **start**.

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

10.9 Programmed Bolus

Symbol	
Procedure	Programming a bolus

INFORMATION
The programmed bolus function is not available in PCA therapy.

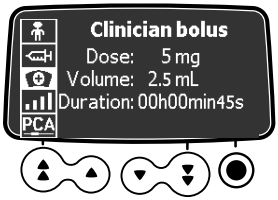


1. Press MENU, then press the arrow keys to select .
2. To program a bolus, see Section 8.16.2, page 82.

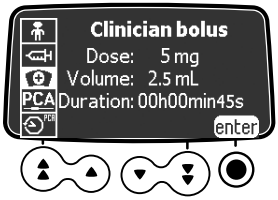
10.10 Clinician Bolus

Symbol	
Procedure	Programming a clinician bolus

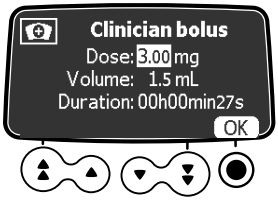
You can program and start a clinician bolus as follows.



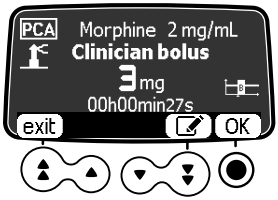
1. Press MENU, then press the arrow keys to select .
The screen displays the default settings for a clinician bolus, or the values programmed in the last clinician bolus administered.



2. To modify the settings, unlock the keypad, as explained in Section 10.4, 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 **enter**.



5. Set the value of the dose.
The volume is automatically adjusted.
6. Press **OK** to confirm the settings.
The clinician bolus start screen is displayed.



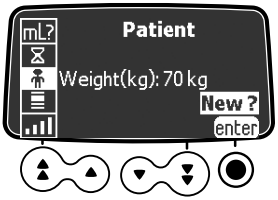
7. Choose one of the options:
   - Press **start** to start infusion of the clinician bolus
   - Press **exit** to save the settings without administering the bolus
   - Press **edit** symbol to modify the settings.

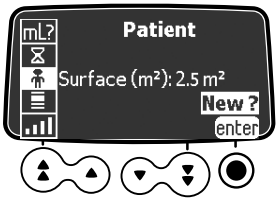
10.11 Patient

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 MENU, then press the arrow keys to select .
2. Press **enter**.
3. Press **OK** to change the patient's weight or body surface area.
4. Press **OK** to confirm the infusion settings.

10.12 Day/Night Mode

Symbol	☾
Procedure	Switching between day mode and night mode

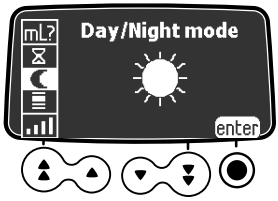
This function switches between day mode ☀ and night mode ☾.

The default night mode settings are as follows:

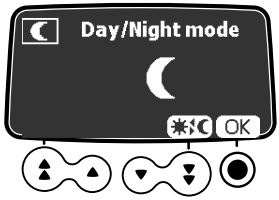
- The key-press beep is silenced.
- Infusion indicators and screen brightness are dimmed.

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

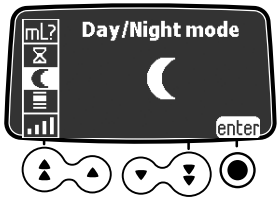


1. Press MENU.
2. Press the arrow keys to select ☾.
3. Press **enter**.

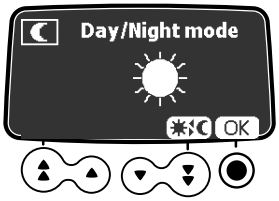


4. Press ☀/☾ to activate night mode.
   The screen displays ☾.
5. Press **OK** to confirm.

Switching from Night Mode to Day Mode



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

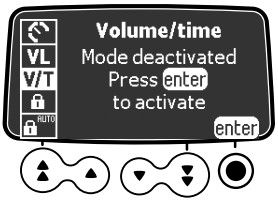


4. Press ☀/☾ to activate day mode.
   The screen displays ☀.
5. Press **OK** to confirm.

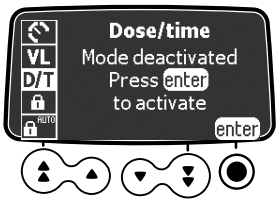
10.13 Volume/Time and Dose/Time

Symbols	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.



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

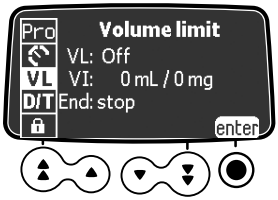


4. To program a Volume/Time or Dose/Time infusion, see Section 8.17.1, page 83.

10.14 Volume Limit

Symbol	VL
Procedure	Programming a Volume Limit infusion

INFORMATION
The VL function is not available in PCA therapy.

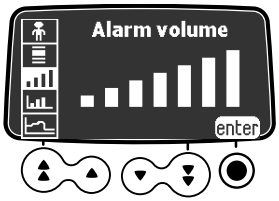


1. Press MENU, then press the arrow keys to select VL .
2. Press **enter**.
3. To program a volume limit infusion, see Section 8.17.2, page 84.

10.15 Alarm Volume

Symbol	
Procedure	Adjusting the alarm volume

You can adjust the alarm volume as follows:

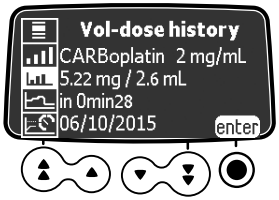


1. Press MENU, then press the arrow keys to select .
2. Press **enter**.
3. Press the arrow keys to select the alarm volume.
   The pump emits an alarm at the selected volume level.
4. Press **OK**.

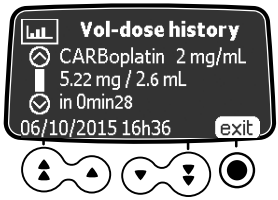
10.16 Volume-Dose History

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 MENU, then press the arrow keys to select .
2. Press **enter**.



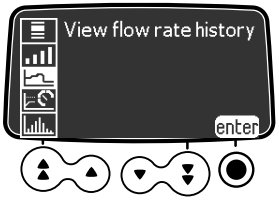
3. Press the arrow keys to select an infusion.
   The selected infusion's details are displayed:
   - Drug name and drug concentration
   - Volume or dose infused
   - Infusion total duration
   - Infusion date & time
4. Press **exit** to return to the menu.

10.17 View Flow Rate History

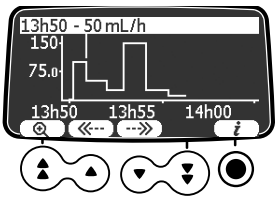
Symbol	
Procedure	Viewing flow rate history

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 MENU, then press the arrow keys to select .
2. Press **enter**.
   The following information is displayed:
   - An event marker (cursor)
   - The event details (time and flow rate)
   - The measured flow rate (solid line)



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

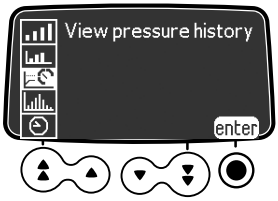
INFORMATION

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

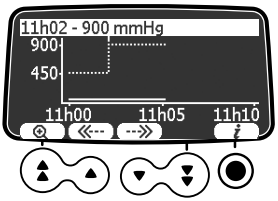
10.18 View Pressure History

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



3. Press the (<<--) and (-->>) buttons to browse the events.
4. Press (i) to view information about the selected event.

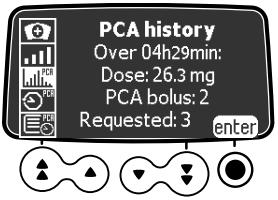
INFORMATION

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

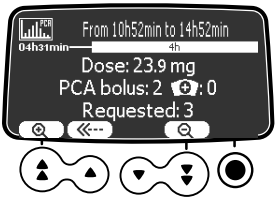
10.19 View PCA History

Symbol	
Procedure	Viewing PCA history

You can view the PCA infusion history as follows:



1. Press (MENU), then the arrow keys to select .
   The data for the time period specified in the cumulated limits is displayed.
2. Press **enter** for details on treatment in progress.
   The time scale since beginning of treatment is displayed above the PCA infusion data.

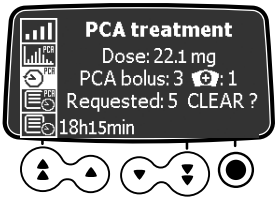


3. Use the arrow buttons or the zoom in and zoom out buttons to display previous time periods, or a different length of time, as explained in Section 7.19.2, page 64.

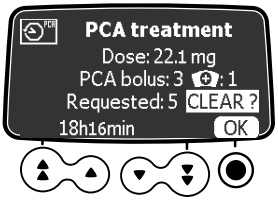
10.20 View PCA Treatment Information

Symbol	
Procedure	Viewing PCA treatment information

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



1. Press MENU, then 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.*



2. 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.

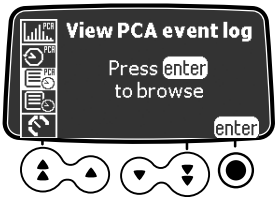
10.21 View PCA Event Log

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.

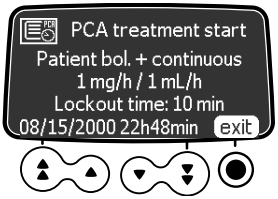
Note: *When the AC power is disconnected for a period of time, or when the batteries are not operating, the log file is kept in a non-volatile memory for approximately 10 years.*

You can view the PCA event log as follows:



1. Press MENU, then the arrow keys to select .
   A list of events is displayed.
2. Press **enter**.
   The first event in the list is highlighted.

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



5. Press **exit** to return to the event list. Press MENU or C twice to return to the infusion screen.

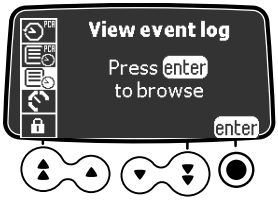
10.22 View Event Log

Symbol	
Procedure	Viewing the event log

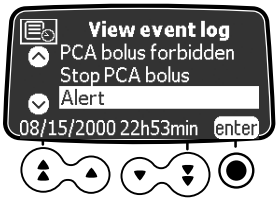
The event log displays details of the last events that occurred on the pump. The log can store up to 1500 events. When it is full, older events are overwritten. Events are stored in the log even after the pump is powered off and on again.

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.*

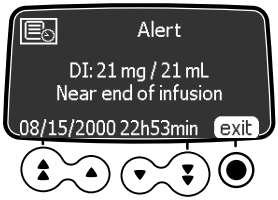
You can view the event log as follows:



1. Press MENU, then press the arrow keys to select .
2. Press **enter**.



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

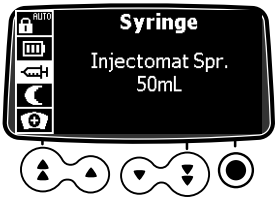


5. Press **exit** to return to the previous screen.

10.23 Syringe

Symbol	
Procedure	Displaying on-pump syringe information

You can display on-pump syringe information as follows:



1. Press MENU, then press the arrow keys to select .

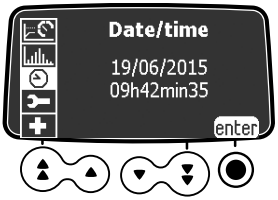
The following information is displayed:
- Syringe capacity
- Syringe brand / name

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.

You can set the date and time as follows:

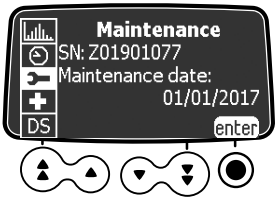


1. Press MENU, then press the arrow keys to select .
2. Press **enter**.
3. Press the arrow keys to set the day, month, year, hours, and minutes.
4. Press **OK** to confirm each setting.

10.25 Maintenance

Symbol	
Procedure	Displaying maintenance information

You can display maintenance information as follows:

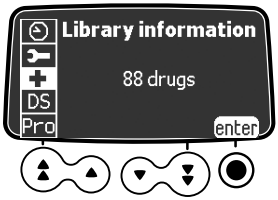


1. Press MENU, then press the arrow keys to select .
2. Press **enter**.
3. Press the arrow keys to scroll through the maintenance information: pump serial number, next maintenance date (dd/mm/yyyy), pump model, software version, total operating time since last maintenance.

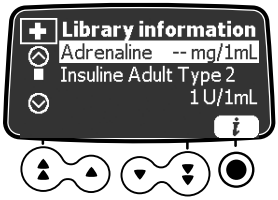
10.26 Library Information

Symbol	✚
Procedure	Displaying drug library information

You can display drug library information as follows:



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

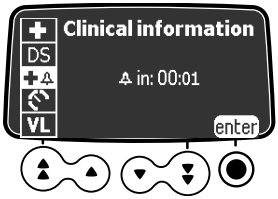


3. Press the arrow keys to select a drug.
4. Press i to view information on the selected drug.

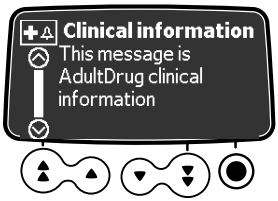
10.27 Clinical Information

Symbol	✚🔔
Procedure	Viewing time remaining before clinical information is displayed

For drugs selected from a custom profile, clinical information messages can be displayed. You can view the time remaining before clinical information is displayed, as follows:



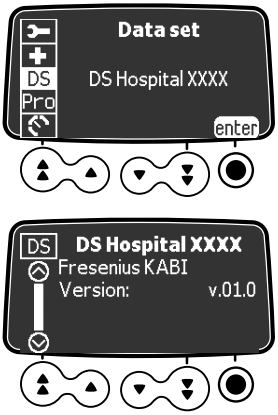
1. Press MENU, then press the arrow keys to select ✚🔔.
   The screen shows the remaining time before clinical information is displayed.
2. Press **enter**.
   The clinical information message is displayed.



10.28 Data Set

Symbol	DS
Procedure	Displaying active data set information

You can display active data set information as follows:



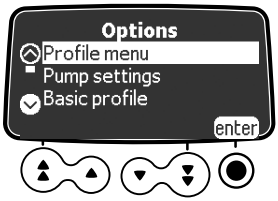
1. Press MENU, then press the arrow keys to select DS .
2. Press **enter**.
   The active data set information is displayed.

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:



1. Starting with the pump off, simultaneously press ON/OFF + MENU.
   *The **Options** screen is displayed. See Section 11.3, page 111 for details on the **Pump settings** options. For information on other options, refer to the technical manual.*

Using the Keypad

Operation	Key
Options access	ON/OFF + MENU
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 display the user menus, after programming, power off then power on again.

11.2 Option Groups

Four different option groups are available on the pump. This manual describes the "Pump Settings" group.

Option	Access code?	Description location
Pump Settings	Optional	Section 11.3, page 111
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.

11.3 Pump Settings

You can use the functions listed below to customize your Agilia SP PCA pump.

Function	Choice	Default pump setting
[User 1]: Screen options	▪ Enable/Disable framing of editable values	Enabled
[User 2]: Menu items	▪ Maintenance: display or hide maintenance	Hidden
	▪ Date / Time: display or hide date/time menu	Hidden
[User 3]: Contrast	▪ Adjustment of screen contrast using the fast increment and decrement keys	Medium level
[User 7]: Date/Time	▪ Date selection: dd/mm/yyyy	Production plant date and time
	▪ Time selection: __ h __	
[User 8]: Language	▪ A scrolling list with all available languages	Official language of the target country
[User 14]: Wi-Fi module	▪ Enable/Disable the Wi-Fi module	Enabled
[Par 5]: Syringe selection	▪ Enable/Disable selected syringe confirmation screen	Enabled
[Par 6]: Syringes	▪ Checkbox list with the names of available syringes, and other syringes sizes	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 power on with disengagement	Enabled
[Par 35]: Dose display format	▪ Enable/Disable removal of trailing 0 (display of the decimal "0" after a dose value)	Enabled
	▪ Enable/Disable removal of trailing 0 during programming (display of the decimal "0" after a dose value)	Disabled
[Par 37]: Alarm system	▪ Enable/Disable preventive silence for alarm system	Enabled

12 Data Communication

12.1 Overview

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

INFORMATION

- Ensure that all hospital information systems have been approved by Fresenius Kabi. 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.

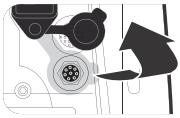
12.2 Communication via Agilia Cables

12.2.1 Data Communication Cables

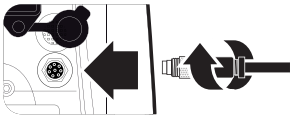
INFORMATION

- 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 Section 11.3, page 111.
For more information on the Wi-Fi module, refer to the technical manual.

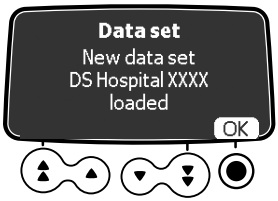
INFORMATION

WiFi 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 **OK** to acknowledge.
   The data set information is displayed.

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

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

WARNING

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

14.2 Alarm Descriptions

There are several levels of alarm priorities:

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

Alarm Priority	Required operator response	Description
High (!!!)	Immediate response	▪ The infusion stops. ▪ The infusion indicator lights flash **red**. ▪ The pump emits audible alarm signals. ▪ An alarm description is displayed on the pump screen. ▪ The (🔕) key silences the alarm for 2 minutes. End of Volume Limit and End of Volume Time are acknowledged. For detailed description of each alarm, please refer to List of Alarms, 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, please refer to List of Alarms, page 117.
Low (!)	Awareness	
Information signals	Awareness	▪ The infusion continues. ▪ An information message is displayed on the pump screen.

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

Table 14.1: 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 a duration of 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 a duration of 2 minutes.
`Disengagement mechanism !!!`	High (!!!)	Yes	Disengaged mechanism. ☞ Check the syringe installation. Note: The (🔔) key silences the alarm for a duration of 2 minutes.
`Remove completely syringe !`	Low (!)	No	Preventive auto-test on potential failure of plunger head. ☞ Remove and reinstall the syringe. Note: The (🔔) key acknowledges the alarm.

Table 14.2: 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 a duration of 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 a duration of 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.
`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.

Table 14.3: 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.

Table 14.4: 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 until the volume limit has dropped to 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 duration from 1 minute to 12 hours.

Table 14.5: 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 has dropped to less than 10 % of the syringe capacity. Note: The (🔔) key silences the alarm for no time limit.

Message	Priority	Stops Infusion?	Problem / Resolution
`Near end of dose/time !!`	Medium (!!)	No	The time remaining is less than the defined time duration (adjustable between 1 and 30 minutes), and the remaining VTBI has dropped to less than 10 % of the syringe capacity. Note: The (🔔) key silences the alarm for no time limit.
`End of volume/time !`	Low (!)	No	The VTBI is completed and the end of infusion setting is set as "KVO" or "continuous". Note: The (🔔) key silences the alarm for a duration from 1 minute to 12 hours.
`End of dose/time !`	Low (!)	No	The VTBI is completed and the end of infusion setting is set as "KVO" or "continuous". Note: The (🔔) key silences the alarm for a duration from 1 minute to 12 hours.

Table 14.6: Infusion Alarms

Message	Priority	Stops Infusion?	Problem / Resolution
`End of infusion !!!`	High (!!!)	Yes	The infusion is completed (simple rate). The syringe is empty. Note: The (🔔) key silences the alarm for a duration of 2 minutes.
`Max cumulated dose !!!`	High (!!!)	Yes	In PCA therapy, the maximum dose specified in the cumulated limits is reached or, in the case of a clinician bolus, exceeded. ☞ 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 a duration of 2 minutes.

Message	Priority	Stops Infusion?	Problem / Resolution
`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 avalaible 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.
`Maximum cumulated dose nearly reached !!`	Medium (!!)	No	In PCA therapy, the maximum dose specified in the cumulated limits is nearly reached. ☞ Wait until the time a PCA bolus becomes avalaible 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 a duration of 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 a duration of 2 minutes.

Message	Priority	Stops Infusion?	Problem / Resolution
`Waiting start !!`	Medium (!!)	No	The infusion settings have been entered, but have not been confirmed with **start**. ☞ Check the infusion settings, and press **start** to start the infusion. Note: The (🔔) key silences the alarm for a duration of 2 minutes.
`End of clinician bolus!`	Low (!)	Yes	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.
`Reached hard limit`	Information signal	No	The upper or lower hard limit is reached.

Table 14.7: 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 Section 10.3, page 91. Note: The (🔔) key silences the alarm for a duration of 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.

Message	Priority	Stops Infusion?	Problem / Resolution
`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.

Table 14.8: 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 a duration of 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 a duration of 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.

Table 14.9: 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. ☞ Check that the battery life is sufficient for the expected infusion duration. ☞ If the disconnection was unintentional, check the power connection.

Table 14.10: Keypad Alarms

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

Table 14.11: 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 a duration of 30 seconds.
`High internal temperature !`	Low (!)	No	Temperature increase. ☞ Check device environment. Note: The (🔔) key silences the alarm for a duration of 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 ON/OFF key.

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

Table 14.12: Audio-only Information Signals

Type	Comment	Stops Infusion?	Activation
Power on or 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
Non validation beep	1 beep	No	For each key pressed
Direct bolus	1 beep	No	Repeated for each mL infused
Syringe prime	1 beep	N/A	When purge reached end after 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 and Extension Sets

15.1 Syringe List

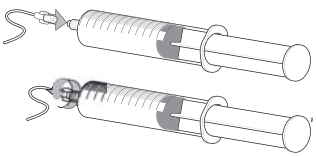
WARNING

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

INFORMATION

- The pump offers a maximum of 100 syringes of different types, brands and sizes. For a list of compatible syringes, and for ordering information, refer to the System Components booklet.
- The list of available syringes on your pump is accessible from the pump options.
- For general information on syringes (such as expiration date, storage, sterility), refer to the syringe manufacturer's instructions.

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.

INFORMATION

- The fluid in the syringe and the syringe must be within normal operating temperature conditions: +18 °/+30 °C.
- It is recommended to prime the set immediately before starting the infusion.
- Do not use in conjunction with positive pressure infusion devices that could generate back pressure higher than 2000 hPa (1500 mmHg): doing so will damage the administration set and the pump.
- Some extension sets may have components such as a filter that require special instructions.
- 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 consummables 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 yellow color-coded consummables and extension sets without injection port.

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

15.3 Operations for Syringes

15.3.1 Removing a Syringe

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

15.3.2 Changing a Syringe

1. Remove the syringe. See section 15.3.1, page 128.
2. Prepare a new syringe and follow the steps described in the flowchart. See section 6.1, page 38.
3. After the new syringe is installed, respond to the **Same therapy?** prompt (optional screen).

WARNING

Electronically prime the syringe pump system after replacing a near-empty syringe with a replacement syringe to avoid the presence of air and minimize the amount of time it takes the pump to recognize an occlusion and generate an alarm while infusing at low rates.

- Verify the fluid flow to the patient is OFF, and if available, use the prime function on the syringe pump to remove any mechanical slack in the system.
- Using the syringe pump's prime feature engages the mechanical components of the pump and decreases the syringe's friction and compliance (i.e., stiffness) to minimize startup delays and delivery inaccuracies, especially at low infusion rates.

Failure to use the prime feature on the syringe pump after every syringe change and/or tubing change can significantly delay the infusion delivery startup time and lead to delivery inaccuracies.

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.

15.4 Gravity Infusion in Parallel with a Pump

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

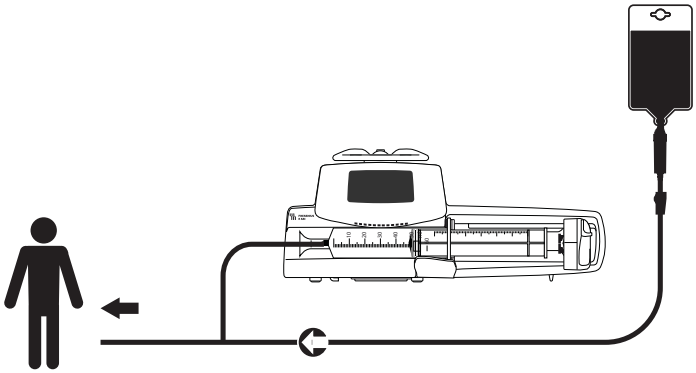


Figure 15.1: Gravity Infusion (in parallel with a pump)

INFORMATION

- Fresenius Kabi recommends the use of a back check valve or positive pressure infusion devices when an infusion on the pump is connected to a gravity line. This will prevent the back-up of IV fluid or medication into the gravity line.
- If there is no back check valve on a gravity infusion line during a multi-line infusion, it will be impossible to detect patient-side occlusions. Such an occlusion could cause the pumped drug to back up into the gravity line, and later be infused in an uncontrolled manner when the occlusion is released.
- Be careful about drugs interactions and incompatibilites during a multi-line infusion. Fresenius Kabi recommends infusing the critical drugs first.

16 Specifications

This chapter describes all of the parameters that you can use to program an infusion with the Agilia SP PCA 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.

16.1 Essential Features

In standard operating conditions (see Section 1.4.5, page 13), the pump's essential features are:

Feature	Refer to
Flow Rate Accuracy	Section 16.2.1, page 130 and Section 19.9, page 147
Time to Detect Occlusion	Section 19.10, page 149
Bolus Volume After Occlusion Release	Section 19.10, page 149
Management of High-priority Alarms	Section 14, page 116

16.2 Pump Accuracy

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

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

16.2.1 Flow Rate Accuracy

	Accuracy
Flow Rate	± 3%

Test conditions: *Flow rate*: 5mL/h

16.2.2 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 (Deviation From Mean Values)
+ 39.9 kPa (299.3 mmHg)	~ - 3%
+ 13.33 kPa (100 mmHg)	~ - 1.5%
- 13.33 kPa (100 mmHg)	~ + 1.5%

16.2.3 Bolus Volume Accuracy

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

		Target Volume	
		0.1 mL	**1.8 mL**
Direct Bolus	**Average** Min deviation Max deviation	**0.11 mL** -7 % +18 %	**1.83 mL** -0.02 % +0.04 %
Programmed Bolus	**Average** Min deviation Max deviation	**0.09 mL** -30 % +3 %	**1.8 mL** -0.03 % +0.02 %

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

16.2.4 Pressure Accuracy

	Below 500 mmHg	Above 500 mmHg
Accuracy	± 75 mmHg	± 15 %

16.3 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 (0.10 → 9.99) 0.1 (10.0 → 99.9) 1 (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 (0.10 → 9.99) 0.1 (10.0 → 99.9) 1 (100 → 1200)
Priming	mL/h	1200	600	600	350	250	Not adjustable
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 defaut value = 1 mL/h.

16.4 Volume To Be Infused (VTBI) Settings

	Unit	Range of Settings	Default Value	Minimum Increment
Volume Limit	mL	0.1 → 999	N/A	0.1 (0.1 → 99.9) 1 (100 → 999)
Volume/Time	mL	0.1 → 99.9	N/A	0.1
PCA bolus Clinician bolus PCA loading dose	mL	0.1 → 99.9	N/A	0.01
Direct bolus	mL	0.1 → 60	N/A	0.1
Programmed bolus Loading dose	mL	0.1 → 99.9	N/A	0.01

Applicable for all syringe sizes.

16.5 Dose To Be Infused (DTBI) Settings

	Unit	Range of Settings	Default Value	Minimum Increment
Dose	All	0.01 ➔ 9999	N/A	0.001 (0.010 ➔ 0.999) 0.001 (1.00 ➔ 9.99) 0.01 (10.0 ➔ 99.9) 1 (100 ➔ 9999)
Programmed bolus **PCA bolus** **Clinician bolus** **PCA loading dose** **Loading Dose**	All	0.01 ➔ 9999	N/A	0.001 (0.010 ➔ 0.999) 0.001 (1.00 ➔ 9.99) 0.01 (10.0 ➔ 99.9) 1 (100 ➔ 9999)

Applicable for all syringe sizes.

16.6 Infusion Time Display

	Format	Range of Settings	Default Value	Minimum Increment
Infusion Rate	__h__ min__sec	00h00min01sec ➔ 96h00min00sec	N/A	00h00min01sec
Programmed bolus **PCA bolus** **Clinician bolus** **PCA loading dose** **Loading Dose**	__h__ min__sec	00h00min01sec ➔ 24h00min00sec	N/A	00h00min01sec
KVO Silence Alarm Duration	__h__ min__sec	00h01 ➔ 12h00	N/A	00h01min00sec
Pause	__ h __	00h01 ➔ 24h00	N/A	00h01min00sec
Lockout time	__h__ min	1 ➔ 360min	N/A	00h01min

Applicable for all syringe sizes.

16.7 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	0.001 (0.010 ➔ 0.999) 0.001 (1.00 ➔ 9.99) 0.01 (10.0 ➔ 99.9) 1 (100 ➔ 9999)
Volume of Diluent	mL	1 ➔ 60	N/A	1

Applicable for all syringe sizes.

16.8 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

16.9 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 setting is stored in memory for the next startup.	Enabled / Disabled	Disabled
DPS Stored	The last DPS setting is stored in memory for the next startup.	Enabled / Disabled	Disabled

		Unit	Range of Settings	Default Value	Minimum Increment
3 Levels	**Low**	mmHg	50 ➔ 300	100	50
	Medium	mmHg	150 ➔ 700	250	50
	High	mmHg	250 ➔ 900	500	50
Variable	**Full Range**	mmHg	50 ➔ 900	50 ➔ 900	25 (50 ➔ 250) 50 (250 ➔ 900)
	Maximum Limit	mmHg	500 ➔ 900	750	50
DPS	**Raise Threshold**	mmHg	50 ➔ 400	100	50
	Drop Threshold	mmHg	100 ➔ 400	100	50

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

16.10 Units and Conversion Rules

16.10.1 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

16.10.2 Concentration Units

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

16.10.3 Dose Rate Units

The table below shows all the dose rate units available on the pump.

	min	h	24h
Default units for PCA mode in Basic Profile	-	microg/h mg/h	-
nanog **nanog/kg**	- nanog/kg/min	nanog/h nanog/kg/h	
microg **microg/kg**	microg/min microg/kg/min	microg/h microg/kg/h	
mg **mg/kg** **mg/m²**	mg/min mg/kg/min -	mg/h mg/kg/h mg/m²/h	mg/24h mg/kg/24h mg/m²/24h
g **g/kg**	- g/kg/min	g/h g/kg/h	- g/kg/24h
mmol **mmol/kg**	- -	mmol/h mmol/kg/h	- mmol/kg/24h
mUnit **mUnit/kg**	mUnit/min mUnit/kg/min	- mUnit/kg/h	
Unit **Unit/kg**	Unit/min Unit/kg/min	Unit/h Unit/kg/h	
kcal **kcal/kg**	- -	kcal/h kcal/kg/h	kcal/24h -
mEq **mEq/kg**	mEq/min mEq/kg/min	mEq/h mEq/kg/h	
mL/kg	mL/kg/min	mL/kg/h	mL/kg/24h

16.10.4 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

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

17 Cleaning and Disinfection

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

WARNING

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

17.1 Recommended and Prohibited Agents

We recommend the following cleaning and disinfection agents:

Table 17.1: Recommended Agents

	Recommended Active Agent	Example of product
Cleaning	Didecyldimethylammonium chloride	Wip'Anios Excel ready-to-use wipes by *Anios*
Disinfecting	Didecyldimethylammonium chloride	Wip'Anios Excel ready-to-use wipes by *Anios*

The following cleaning and disinfection agents are prohibited:

- Trichloroethylene
- Abrasive detergents
- Undiluted alcohol

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

17.2 Quick Cleaning Procedures

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

17.2.1 Quick Cleaning for the Pump

WARNING

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

INFORMATION

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 Section 17.4.1, page 140.

17.2.2 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 Section 17, page 138.

1. Press the stop key STOP 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 Section 17.4.1, page 140.

17.3 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.

17.4 Instructions for Cleaning and Disinfection

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

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

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

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

17.4.1 Cleaning Instructions

Prerequisites

- The pump is powered off.
- The power cord and all other cables (including the patient handset) are unplugged.
- The ambiant air temperature is between 20 and 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 device to dry completely at room temperature.

17.4.2 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 ambiant air temperature is between 20 and 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 disinfection 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.

18 Power Management

18.1 AC Power Supply Precautions

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

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

WARNING

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

18.2 Battery Precautions

The device uses a Lithium-ion rechargeable battery.

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

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

INFORMATION

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

18.3 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.

19 Technical Characteristics

19.1 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 mm^2.

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

19.2 Battery

Disconnect the battery before opening the device. Avoid short circuits and extreme temperatures.
If the device is not used for more than 3 months, the date is erased (all other settings are stored permanently). When you power on the pump, you must set the date again.

Characteristics	7.2 V 2.2 Ah - Li-ion Smart battery	
Weight	Approximately 100 g	
Battery life*	**Wi-Fi enabled**	**Wi-Fi disabled or not used**
	> 6 h	> 11 h
Battery recharge	Pump OFF: < 6 h / Pump ON: < 20 h	

**For a flow rate of 5 mL/h*

19.3 Power Consumption

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

19.4 Communication Port

The connector located at the back of the pump 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

19.5 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

19.6 Sound Levels

Table 19.1: Operating Pump Sound Levels (without alarms)

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

Note: These values are provided for information purposes only.

Table 19.2: Alarm Sound Levels

Alarm Priority	Sound Level (dBA)	
	min	Max
High-priority	55	63
Medium-priority	50	57
Low-priority	45	52

19.7 Compliance

ElectroMedical Equipment Safety	Compliant with the following standards: ▪ IEC 60601-1 ▪ IEC 60601-1-8	**IP 22** (pump) **IP 27** (handset except connector)	Index of protection against ingress of water or particulate matter
EMC (Electromagnetic compatibility)	Compliant with the following standard: ▪ IEC 60601-1-2		Protection against leakage current: Defibrillation-proof type CF applied part*
Particular Standards	▪ 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.*

19.8 Dimensions and Weight

Table 19.3: 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

Table 19.4: Pump dimensions and weight with protective cover

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

Table 19.5: 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 65g

19.9 Trumpet and Start-up Curves

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

Trumpet curves are presented below for a number of representative flow rates. The test protocol used to obtain these results is described in IEC60601-2-24:2012.

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

Syringe used: BD Precise 50 mL
Fluid used: distilled water

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

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

19.9.1 Flow rate: 1 mL/h

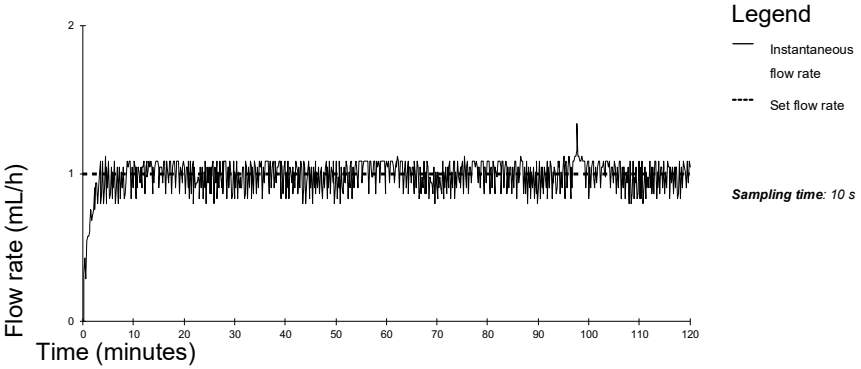


Figure 19.6: Start-up and instantaneous flow rate (1 mL/h over 2 hours)

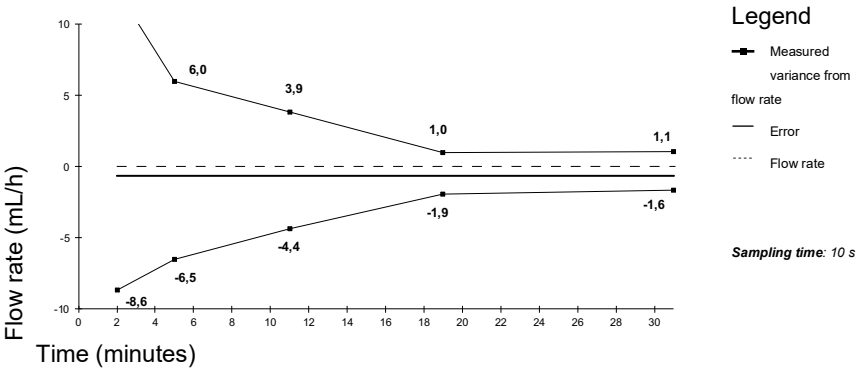


Figure 19.7: Trumpet curves for 2, 5, 11, 19, 31 minutes observation windows (1 mL/h over 2 hours)

19.9.2 Flow rate: 5 mL/h

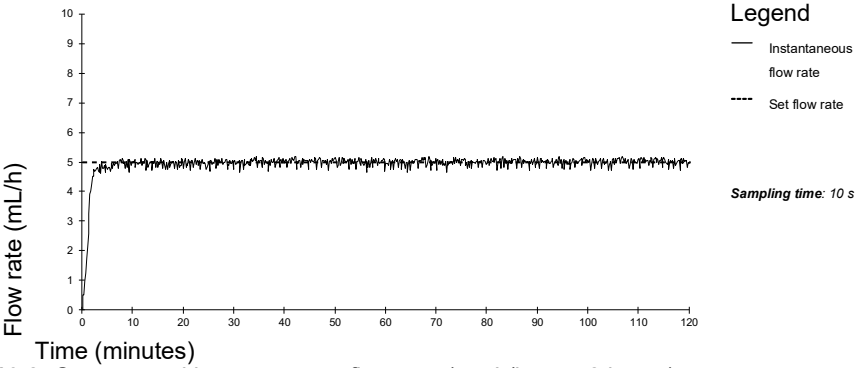


Figure 19.8: Start-up and instantaneous flow rate (5 mL/h over 2 hours)

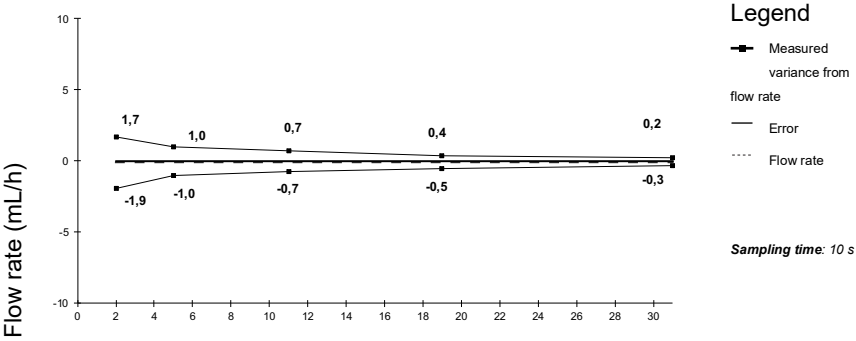


Figure 19.9: Trumpet curves for 2, 5, 11, 19, 31 minutes observation windows (5 mL/h over 2 hours)

19.10 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.

		Pressure 50 mmHg	Pressure 900 mmHg
50mL syringe	**0.1 mL/h** **1 mL/h** **5 mL/h**	< 5 hours < 30 minutes < 7 minutes	< 28 hours < 3 hours < 30 minutes
20mL syringe	**0.1 mL/h** **1 mL/h** **5 mL/h**	< 4 hours < 20 minutes < 5 minutes	< 14 hours < 75 minutes < 15 minutes

Test conditions: *Temperature:* 20 °C, *Extension set length:* 150 cm, *Syringe*: BD Precise

	Volume			
Bolus Volume at Occlusion Release*	**Syringe****	**Rate**	**Bolus Volume at Occlusion Release**	
			50 mmHg	**900 mmHg**
	50 mL	5 mL/h	-0.05 ≤ X ≤ 0.35 mL	-0.05 ≤ X ≤ 0.35mL

*Test conditions: *Back pressure:* 0 mmHg,

***Syringe*: BD Precise 50 mL

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

20 Wi-Fi

20.1 General Information

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

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

The 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 transmitters with the following IDs:

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

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

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

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.

20.2 Technical Specifications

Technology	IEEE 802.11 a/b/g/n
Frequency Band	▪ 2.400 ➔ 2.500 GHz (2.4 GHz is ISM band) ▪ 4.900 ➔ 5.850 GHz (High Band)
Modulation	OFDM with BPSK, QPSK, 16-QAM, and 64-QAM 802.11b with CCK and DSSS
Wireless Security	WPA/WPA2-Entreprise, WPA/WPA2-PSK
Network Protocols	TCP, IPv4, DHCP, HTTP
Typical Transmit Power (± 2 dBm)	▪ 17 dBm for 802.11b DSSS ▪ 17 dBm for 802.11b CCK ▪ 15 dBm for 802.11g/n OFDM ▪ 12 dBm in 802.11a mode

20.3 Electromagnetic Compatibility

For information on electromagnetic compatibilty, see section 25, page 157.

USA - FCC Notice

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

Europe - Radio Equipment Directive

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

20.4 Protocols and Standards

This wireless functionality is compliant with the following protocols and standards:

- IEEE 802.11a/b/g/n standard
- WPA/WPA2-Entreprise, WPA/WPA2-PSK (Wi-Fi protected access) is a long-term security solution for wireless networks. For more information, refer to the IEEE 802.11.
- TCP (Transmission Control Protocol / Internet Protocol), IPv4 (Internet Protocol Version 4), DHCP (Dynamic Host Configuration Protocol) and HTTP (Hypertext Transfer Protocol) 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). Wireless transactions are initiated by the pump and are periodic. The absence of connection (for example, out of range) does not affect the device ability to infuse. Pending data 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.

21 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 **Fresenius Kabi** support 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 **Fresenius Kabi** support.
The pump cannot be installed or removed from the Agilia Link.	▪ Check the rotating pole clamp position. ▪ Contact your biomedical department or **Fresenius Kabi** support.
The power supply indicator does not light up when the pump is racked into the Agilia Link.	▪ Check that the Agilia Link is connected to the mains. ▪ Check the pump is correctly slotted in the Agilia Link. 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 **Fresenius Kabi** support.
The lock on the pump for the protective cover is jammed.	▪ Contact your biomedical department or **Fresenius Kabi** support.
The pump cannot be removed from the pole.	▪ Make sure the lock on the pole clamp is unlocked. ▪ Contact your biomedical department or **Fresenius Kabi** support.
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 **Fresenius Kabi** support.
Data communication cables cannot be connected or removed from the pump.	▪ Check the cable connector. ▪ Check the pump connector. ▪ Contact your biomedical department or **Fresenius Kabi** support.
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 **Fresenius Kabi** support.
Keypad problem (keys, LEDs).	▪ Check the general condition of the keypad. ▪ Check the contrast. ▪ Contact your biomedical department or **Fresenius Kabi** support.

Issue	Recommended Actions
The power supply indicator does not light up.	▪ Connect the pump to the AC power supply. ▪ Contact your biomedical department or **Fresenius Kabi** support.
The pump powers off on its own.	▪ Connect the pump to the AC power supply. ▪ Contact your biomedical department or **Fresenius Kabi** support.
The battery alarm is ON even though the pump has been correctly charged.	▪ Check the AC power voltage. ▪ Contact your biomedical department or **Fresenius Kabi** support.
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 **Fresenius Kabi** support.
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 pump to see if the problem persists. ▪ Contact your biomedical department or **Fresenius Kabi** support.
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 **Fresenius Kabi** support.
Wi-Fi communication error.	▪ Contact your IT or biomedical department, or **Fresenius Kabi** support.
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 **Fresenius Kabi** support.

22 Device Storage and Transport

22.1 Precautions for Storage

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

WARNING

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

22.2 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

22.3 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.

22.4 Using the Device After Storage

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

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

We recommend charging the battery for at least 6 hours.

We recommend that the "User test" is performed when the device is installed after storage, and before being used on a patient, see section 13, page 115.

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

WARNING

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

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

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

Points (for example, screws or battery contacts) and surfaces that are only accessible for maintenance also require precautions.

25.2 Electrostatic Discharge (ESD) and Precautions To Be Taken

INFORMATION

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

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

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

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

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

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

For maintenance 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 Performance

In standard operating conditions (see Section 1.4.5, page 13), the essential performance of the Agilia pump is defined in Section 16.1, 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: overdose, underdose, delay of therapy, electric shock.

It is the responsibility of the customer or user to check the equipment before use as described in Section 13, page 115, and to consider the EMC guidance of Section 25.4, page 158.

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.

Agilia SP PCA 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.
- Use of accessories, transducers and cables other than those specified or provided by the manufacturer of the Agilia pump could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.
- Portable RF communications equipment (including peripherals such as antenna cables, internal and external antennas) should be used no closer than 10 cm for cell phones and 30 cm for other equipments, to any part of the Agilia pump, including cables specified by the manufacturer. Otherwise, degradation of the essential performances of Agilia pump could result. Electrosurgical equipment (including base unit, cables, electrodes) should be used no closer than 30 cm to any part of the Agilia pump, including cables specified by the manufacturer. Otherwise, degradation of the essential performance of Agilia pump could result.

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

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

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

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

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

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

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 3 years. This includes replacing the battery.
- When using the device on a patient, no maintenance action must be performed.

WARNING

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

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

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

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

INFORMATION

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

26.3 Quality Control

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

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

INFORMATION

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

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:

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

www.fresenius-kabi.com

27 Cybersecurity

27.1 Cybersecurity and IT-Network environment

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

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

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

WARNING

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

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

Policy recommendations

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

IT-Network recommendations

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

Software used to maintain or operate medical devices may be deployed on different host computers: desktop, laptop, servers, …
However, such software deployment shall comply with the same use conditions as those for healthcare facility network deployment. Ideally, the host computer will belong to the healthcare facility network, and therefore will be protected in the same manner as the network.

INFORMATION

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

27.2 Inherent design

Agilia system pumps design includes security mechanisms. Communication with software application are secured, Wi-Fi communication can be protected using WPA2 encryption, integrity and availability of data is verified, user interface can be locked on demand, Agilia pumps only communicate at their initiative on a configurable manner.
Fresenius Kabi strongly recommends reading and implementing the good practices included in Section 27.3, page 164.

27.3 Information regarding cybersecurity

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

WARNING

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

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

WARNING

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

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

WARNING

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

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

INFORMATION

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

Network configuration

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

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

WARNING

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

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

Login and passwords

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

Hardening

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

WARNING

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

27.4 Firewall configuration

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

27.5 Potential vulnerabilities

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

Vulnerability	Typical Threat Events
Communication and network configuration vulnerabilities	
Improperly configured or non-existent firewall or logical protective barrier	A lack of properly configured firewall could permit unnecessary data to pass between networks, such as device and facility networks, allowing adversary or malware to spread between networks, making critical or sensitive data susceptible to monitoring, eavesdropping and to be subjected to Man-in-the-Middle attack.
Standard, well-documented plain text communication protocol	Adversaries can use a protocol analyzer (commercially available) or other utilities to decode the data transferred by protocols, such as telnet, FTP, HTTP and NFS. It is relatively easier for adversaries to perform attacks on these communications.
Lack of integrity checking	Adversaries could manipulate communications undetected.
Inadequate authentication between wireless clients and access points	Strong mutual authentication between wireless clients and access points is needed to ensure that clients do not connect to a rogue access point deployed by an adversary.
Inadequate data protection between wireless clients and access points	Sensitive data between wireless clients and access point should be protected using strong encryption to ensure that adversaries cannot gain unauthorized access to the unencrypted data. Ensure protection from fraudulent Wi-Fi access points (Evil Twin) that appear to be legitimate but are set up to eavesdrop on wireless communications.
Poor remote access controls	Remote access capabilities must be adequately controlled to prevent unauthorised individuals from gaining access to the system.
Inadequate firewall and router logs	Without proper and accurate logs, it might be impossible to determine what cause a security incident to occur.
Unprotected ports or services	Unused ports (such as ForgotDoor) and services must be closed or turned off.
Physical Access	
Unauthorised personnel have physical access to devices	▪ Physical theft or damage of data ▪ Unauthorised personnel add, remove or change resources of devices ▪ Install unauthorised utilities (undetectable interception of data)

Vulnerability	Typical Threat Events
Unsecured physical ports	▪ Flash/thumb drivers ▪ Keystroke logger ▪ Other unauthorised utilities to exploit unsecure physical ports
Network Configuration and Communication	
A flat network with no zones (no segregation between corporate and device networks)	▪ Unauthorised access to medical devices through facility's IT-network ▪ Distribute malware across facility's IT-networks ▪ Intercept or manipulate unencrypted messages (plain text)
Improperly selected and configured firewall (weak firewall rules)	▪ Phishing attack (spear phishing, mobile phishing) ▪ Identity spoofing ▪ Firewall bypassed ▪ Man-in-the-middle attacks
Malware protection not installed or not up-to-date	▪ Disseminate virus, ransomware among networks ▪ Plant spyware (for monitoring and eavesdropping) ▪ Audit log manipulation or destruction
Software vulnerabilities	
Inadequately assess security of OTS	A wide variety of security implications and vulnerabilities have been identified with various OTS operating systems or control protocols such as OLE, DCOM, RPC, OPC, etc.
Database vulnerabilities	Databases with web interfaces may be vulnerable to typical web attacks like XSS, SQL injection. The information contained in database makes them high-value targets for any attacker.
Security Policies and Procedures	
Lack of or inadequate authentication, authorisation, access control policies and incident detection and response plan or procedure	▪ Vulnerabilities regarding authentication, authorisation, access control policies, incident detection and response plan or procedure could lead to multiple threat events (attacks) or more likely. ▪ For example incident detection (such as unusual CPU usage due to Cryptojacking) and response plans, procedures and methods are necessary for rapidly detecting incident, minimizing loss and destruction, preserving evidence for later forensic examination, mitigating the weakness that were exploited, and restoring system services. ▪ Having an inadequately shared network between Medical Device Network and Corporate Network (for example, it does not have dedicated VLAN for medical devices) could make it possible for virus and worm to spread to medical devices.

28 Glossary of Terms

A

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

B

BPSK Binary Phase Shift Keying
BSA Body Surface Area

C

cal Calorie
CCK Complementary Code Keying
CDC Centers for Disease Control
CISPR Special International Committee on Radio Interference
CT Scan Computed Tomography

D

dBA Decibels
dBm Decibels-Milliwatts
DC Direct Current
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

E

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

F

FCC Federal Communications Commission
FM Frequency Modulation
ft Feet
FTP File Transfer Protocol

G

GPL General Public License
GTIN Global Trade Item Number

H

H/W/D Height / Width / Depth
HF High Frequency
hPa Hectopascals
HTTP HyperText Transfer Protocol
Hz Hertz

I

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

K

kg Kilograms
KVO Keep Vein Open

L

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

M

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

N

N/A Not Applicable
NFS Network File System
NMR Nuclear Magnetic Resonance

O

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

P

PC Personal Computer
PCA Patient Controlled Analgesia
PSI Pounds per Square Inch
PSK Phase Shift Keying

Q

QAM Quadrature Amplitude Modulation
QPSK Quadrature Phase Shift Keying

R

REF Product reference / part number
RF Radio Frequency
RFID Radio Frequency IDentification
RPC Remote Procedure Control
RS232 Serial interface connector

S

SN Serial Number
SELV Safety Extra Low Voltage
SIR Asynchronous Serial Infrared
SQL Structured Query Language

T

TCP Transmission Control Protocol

U

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

V

V Volts
V/m Volts per meter
VA Volt-Amperes
VDC Volts Direct Current
VI Volume Infused
VLAN Virtual Local Area Network
VPN Virtual Private Network
Vrms Root Mean Square Voltage
VTBI Volume to Be Infused

W

W Watts
WPA Wi-Fi Protected Access

X

XSS Cross-Site Scripting

Appendix: Factory Configuration

	Feature	Default setting
Menus	Profile	Disabled
	Pressure	Enabled
	Keypad lock status	Enabled
	Battery life	Enabled
	Volume infused / Dose infused	Enabled
	Pause	Enabled
	Programmed bolus	Enabled
	Clinician bolus	Enabled
	Patient	Disabled
	Day/Night mode	Enabled
	Volume/Time Dose/Time	Enabled
	Volume Limit	Enabled
	Alarm volume	Enabled
	Volume-Dose history	Enabled
	View flow rate history	Enabled
	View pressure history	Disabled
	Syringe	Disabled
	View event log	Disabled
	View PCA event log	Enabled
	PCA treatment	Enabled
	Date / Time	Disabled
	Maintenance	Disabled
	Library information	Disabled
	Clinical information	Disabled
	Data Set	Disabled

	Feature	Default setting
PCA modes	Continuous only	Enabled
	PCA bolus only	Enabled
	PCA bolus + continuous	Enabled
	PCA bolus + variable	Disabled
	Clinician bolus	Enabled
	PCA loading dose	Disabled
General infusion modes	Simple Rate	Disabled
	Volume/Time Dose / Time	Disabled
	Volume Limit	Disabled
General infusion features	Loading Dose	Disabled
	Programmed Bolus	Enabled
	Direct bolus	Enabled
	KVO	Enabled
	Prime Set	Disabled
	Empty syringe	Disabled
	Dynamic Pressure System (DPS)	Enabled
	Near end of max dose	Enabled
Cover	Install mandatory	Enabled
	lock mandatory	Enabled
	Auto-lock keyboard at cover close	Enabled
	Auto-unlock keyboard at cover open	Enabled
Patient handset	Sound for PCA bolus request	Enabled
	Blinking light for PCA bolus	Enabled
Flow rate	Continuous rate	N/A
	PCA bolus PCA loading dose	200 mL/h
	Direct bolus Programmed bol.	200 mL/h
	KVO	1mL/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
January 2021	3.3	Creation.
March 2021		Table 14.3 - Improvement of battery alarm messages
April 2022		Epidural feature ; MDR compliance ; Cybersecurity recommendations are added.

This document may contain inaccuracies or typographical errors.
Modifications may thus be made, and included in later editions.
Due to the evolution of standards, and of legal texts and materials, the characteristics indicated in the text and images of this document are applicable only to the device with which it is included.

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

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www.fresenius-kabi.com

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Local Contacts for Servicing

15148-2_IFU_Agilia_SP_PCEA_AUS

FRESENIUS KABI

caring for life

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

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