FRESENIUS KABI

Agilia SP TIVA (WiFi)

Syringe Infusion Pumps

Applicable to software version 4.4

Instructions For Use

For Use in Healthcare Facilities



Symbols Description

Symbols used in this document



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



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



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



Information: recommendations to be followed.

Labelling symbols



Warning
(Refer to the Instructions For Use)



Refer to the Instructions For Use

REF — Product reference / part number

SN — Product serial number



Input terminal - connector



Output terminal - connector



Electrical fuses



Alternating Current (AC)



Direct Current (DC)

IP32 — Index of protection against solid foreign objects (> 2.5 mm) and dripping liquids



Not for use in residential areas



Part included in a recycling process



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



Name and address of the manufacturer / Date of manufacture



Name and address of the manufacturing facility



Protection against electric shock: class II



Non-ionizing electromagnetic radiation



Fragile, handle with care



This way up



Keep away from rain



Temperature limitation



Humidity limitation



Atmospheric pressure limitation



General symbol for recyclable material



Eco packaging symbol

CE 0123 — CE mark

MD Medical Device

UDI Unique Device Identifier

CH REP Indicates the authorised representative in Switzerland

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1 Introduction

1.1 Scope

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

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



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

- The software version of the device is displayed on start-up screen.
- The software version described in these Instructions For Use is displayed on the cover page and in the *Release notes* on page 160.

1.2 Principles of Operation

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

The Agilia SP TIVA infusion pump focuses on anesthesia infusions.

The Agilia SP TIVA infusion pump is a transportable and reusable device that can be used everyday.

The size of a syringe can be between 5 mL and 60 mL. For a comprehensive list, refer to the System Components booklet.

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

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

1.3 Intended Purpose

Infusion Pumps and Accessories for Administration of Fluids.

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

1.4 Intended Use

1.4.1 Indications

INFORMATION

- Clearly label Agilia SP TIVA 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 TIVA pumps is available to suit your needs.

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

	Intended Products
Parenteral fluids	■ Standard solutions ■ Colloids ■ Parenteral nutrition
Medication	■ Diluted drugs ■ Antibiotics ■ Chemotherapy ■ Catecholamines ■ Short acting drugs ■ Anesthesia drugs ■ Epidural associated drugs
Blood and blood derivatives	■ Blood ■ Red blood cells ■ Platelets ■ Plasma ■ Albumin

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

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

Do not use the pump for enteral nutrition.

WARNING

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

Administration Routes

The system allows infusion via the following access routes:

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

1.4.2 Contraindications

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

1.4.3 Intended Users

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

Typical initial training duration: 1 hour.

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

For training, contact your Fresenius Kabi sales representative.

1.4.4 Intended Patients

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

	Patient Characteristics
Sex	Male / Female
Age	Regular infusion: Neonates / Young pediatric patients / Adults / Elderly Target Controlled Infusion (TCI): depending on TCI model (*Populations* on page 31)
Weight	Regular infusion: 0.25 kg to 350 kg Target Controlled Infusion (TCI): depending on TCI model (*Populations* on page 31)
Body Surface Area	Regular infusion: 0.05 m^2 to 4.5 m^2 Target Controlled Infusion (TCI): Not applicable
Height	Regular infusion: 20 cm to 250 cm Target Controlled Infusion (TCI): depending on TCI model (*Populations* on page 31)

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

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

1.4.5 Use Environment

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

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

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



WARNING

Do not use the Agilia pumps in the following environments:

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



WARNING

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

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

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



WARNING

The pump can be used in road ambulances exclusively with the Agilia Holder Ambulance accessory. Due to use in road ambulances, performances of the device can be modified. For more information, refer to the Instructions For Use of the Agilia Holder Ambulance accessory.



INFORMATION

- The pump can be used in MRI unit exclusively with the Agilia MRI Guard accessory. For more information, refer to the Instructions For Use of the Agilia MRI Guard accessory.
- 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 benefits of Agilia SP TIVA syringe pump are the following:

- Provide a controlled and accurate system for the infusion of small volumes of products, thus ensuring delivery of medications/fluids within their therapeutic window (volume delivery accuracy of the pump/syringe system is ±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, Target Controlled Infusion [TCI] function).
- Provide users with safety features and relevant alarms that improve infusion safety and prevent unexpected infusion discontinuation (Dynamic Pressure System, pressure monitoring, alarm system compliant with EN/IEC 60601-1-8).
- Prevent infusion-related medication errors (with the use of up-to-date Dose Error Reduction Software [DERS] configured in line with policy/clinical practice of each healthcare facility).

1.6 Side-effects

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

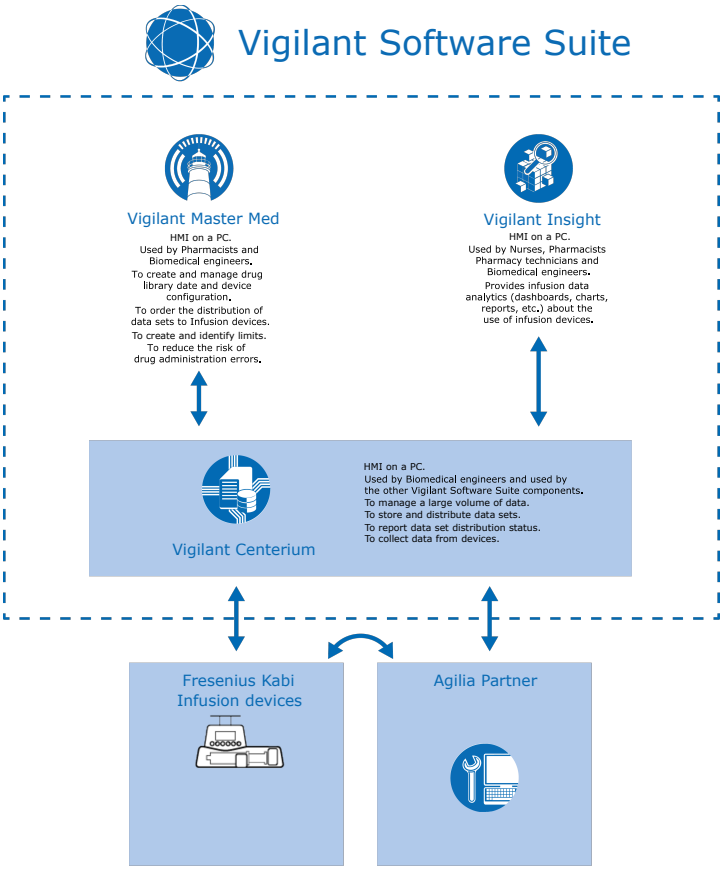
1.7 Risks for patients

Failure to follow all instructions described in this document or loss or degradation of essential performance (*Essential Features* on page 109) may result in: over-delivery, under-delivery, delay of therapy, incorrect therapy, exsanguination, biological/chemical contamination, undetected air infused to patient, traumatic injuries or electrisation.

1.8 Cybersecurity Safety considerations

1.8.1 Agilia SP Infusion System

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



1.8.2 Cybersecurity Recommendations

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

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

- Your premises are secured.
- The device is installed within a secure network perimeter to prevent TCP/IP network access from unauthorized external system(s).
- When not in use, the Agilia SP TIVA WiFi pump is securely stored.
- When not in use, the Agilia SP TIVA WiFi Serial or USB Cables are disconnected and securely stored.
- Secure storage access is restricted to authorized personal only.
- The latest version of the device firmware is installed.

- The device passwords and access codes are changed from their default values. Refer to Technical Manual.
- The Agilia SP TIVA WiFi pump shall enforce the usage of secure communications protocol for TCP/IP data flows exchanged with Vigilant Software Suite. Ensure WPA2 and HTTPS are configured on the Wifi module using Agilia Partner Maintenance Software.

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

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

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

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

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

2 Agilia Connect Infusion System

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

Agilia range		Description
Accessories	Link Agilia Agilia Link Link+ Agilia	**Stacking Rack Systems** Rack systems designed to stack 4, 6 or 8 Agilia infusion pumps. The Link Agilia / Agilia Link devices are designed to centralize the power supply. The Link+ Agilia device is designed to centralize the power supply and to centrally replicate infusion pump signalling.
	Agilia MRI Guard	**MRI-Shielding System** The Agilia MRI Guard accessory is intended to accommodate and power up to four Agilia infusion pumps so that these pumps can be operated in a Magnetic Resonance Imaging unit.
	Agilia Duo	**Two-channel accessory** The Agilia Duo accessory is intended to centralize mains power for two attached Agilia pumps.
	Agilia Holder Ambulance	Accessory intended to be used in road ambulances equipped with AC power source and a horizontal rail in order to fix an infusion pump.
Disposables	Syringes	See *Syringes* on page 105.

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

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

3 Description

3.1 Front View

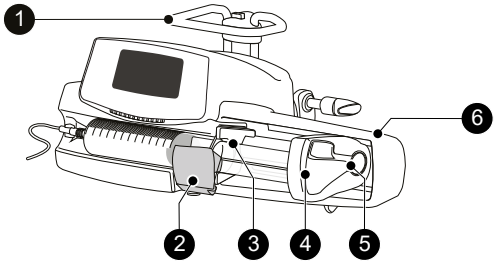


Figure 1: Front View

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

3.2 Bottom View (Device Identification Label)

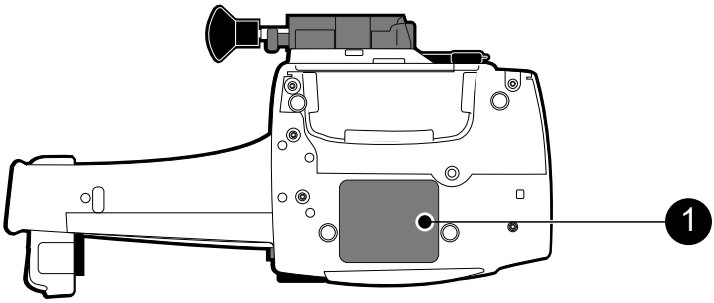


Figure 2: Bottom View

Legend
1 Device Identification Label

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



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

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

3.3 Back View

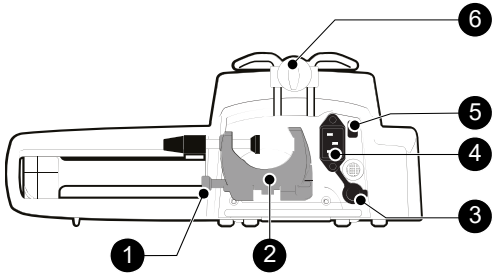


Figure 3: Back View

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

Symbol	Location	Description
	Near Power Cord Inlet	Warning See *Technical Characteristics* on page 122.
	Near RS232 Communication Port	Warning See *Data Communication* on page 92.

3.4 Keypad

3.4.1 Keypad Description

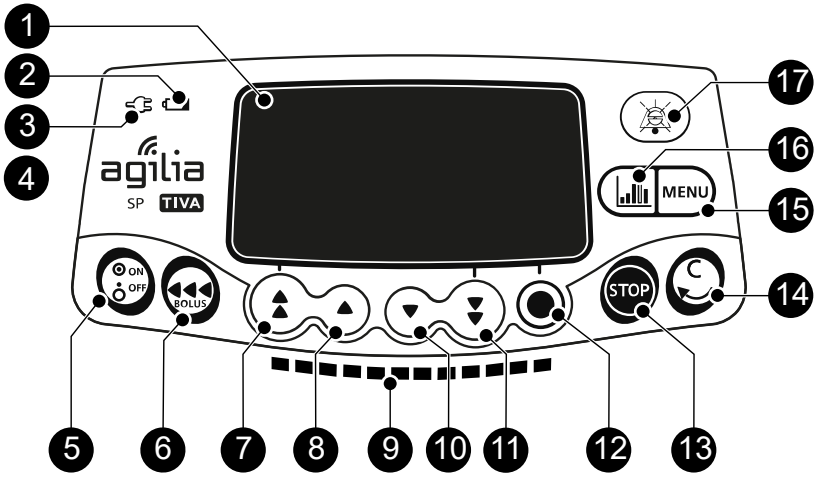
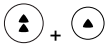
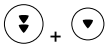


Figure 4: Keypad

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

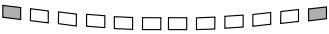
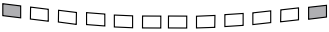
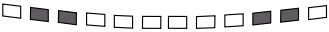
3.4.2 Keypad Details

3.4.2.1 Selection Keys

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

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

3.4.2.2 Infusion Indicator Lights

Indicator	Description
	Infusion in Progress (flashing green)
	TCI therapy in progress with no flow rate delivery (1 constant green light)
	Low-Priority Alarm (constant yellow)
	Medium-Priority Alarm (flashing yellow)
	High-Priority Alarm (flashing red)

NOTE:

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

3.4.2.3 Status Indicators

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

3.5 Display and Symbols

3.5.1 Infusion Status

Symbol	Description
	**Infusion in Progress (Basic & TCI + Custom Profiles with a drug list)** Symbols for infusion in progress.
	**Infusion in Progress (Custom Profiles with a drug library)** This symbol is displayed when the pump is infusing a drug customized with Drug Library Software.
STOPPED	**Infusion Stopped** STOPPED remains in the center of the screen until the user starts the infusion again.

3.5.2 Screen Options

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

3.5.3 Navigation Buttons

Symbol	Description
start	Start
OK	Confirm
enter	Access function
New ?	Access function and clear settings
exit	Exit function
C	Change selection
prog	Program function
☑/☐	Select / Deselect
	Edit settings
i	See more information
/	Zoom in / Zoom out
«--- / ---»	Move the event marker to the left / right

3.5.4 Alarms and Safety Features

Symbol	Description
	Power disconnection
	Alarm silenced
	Pressure increase
	Drop in pressure

NOTE: For more information on alarms, see *Alarms and Safety Features* on page 96.

3.5.5 Infusion Features

Symbol	Description
	**Plasma Control Mode** See *TCI modes in the Agilia SP TIVA* on page 29
	**Effect-site Control Mode** See *TCI modes in the Agilia SP TIVA* on page 29

3.5.6 Data Communication

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

3.6 Packaging

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

	Agilia SP TIVA pump	Instructions For Use	System Components booklet	User information document (multilingual)	Power cord
Z018XXX	✓	✓	✓	-	✓
Z018X01 *	✓	-	-	✓	-

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

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

Packaging weight: Approximately 530 g. Packaging consists of: Recycled cardboard.



INFORMATION

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

4 Fundamentals

4.1 Profiles

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

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

Custom profiles can be created and loaded to the pump with Drug Library Software. Custom profiles feature a specific pump configuration and a drug library.

A pump can manage up to 20 profiles:

- 1 factory profile (Basic & TCI).
- Up to 19 custom profiles.



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

4.1.1 Basic & TCI Profile

Basic & TCI profile allows programming of an infusion whose settings have not been pre-defined with Drug Library Software. To program an infusion with Basic & TCI profile, choose "Basic & TCI" when selecting a profile.

In Basic & TCI, 3 programming modes are available:

- Flow rate (mL/h): the infusion is programmed by flow rate without drug names, see *Infusion Rates* on page 26.
- Dose: the infusion is programmed by dose without drug names, see *Infusion Rates* on page 26.
- TCI: See *Target Controlled Infusion (TCI)* on page 28.

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

4.1.2 Custom Profiles

Custom profiles can be configured and loaded to the pump with Drug Library Software. A custom profile contains the following:

- a specific device configuration (pump settings that control the mechanical functions of the pump such as alarm volume, and so on),
- a comprehensive list of medications and fluids to be infused (optional):
  - a drug library: a list with limits on drug infusion rates, see *Drug Libraries* on page 26,
  - a drug list: a list without limits on drug infusion rates.

Depending on the way it is pre-configured with Drug Library Software, a custom profile may or may not include all of the functionalities described in these Instructions For Use.

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

4.2 Drug Libraries

A drug library is a comprehensive list of drugs that includes limits on drug infusion rates.

INFORMATION

- Each drug library can support up to 200 drug entries that are defined and validated by healthcare professionals according to the drug protocols used at the healthcare facility and/or ward level.
- Drug settings may be adjusted on the pump according to pre-defined programming limits, such as dose limits.
- Infusion modes are not adjustable on the pump for drugs pre-configured with Drug Library Software.

4.3 Drugs

4.3.1 Infusion Rates

A drug can be pre-configured with Drug Library Software according to one of the following rates:

- Flow rate: Infusion of a volume over a period of time.
- Dose: Infusion of a specific amount of a drug corresponding to a dose rate.

4.3.2 Drug X (mL/h)

`Drug X (mL/h)` is an open entry that can be selected if the intended drug is not found in the drug library. It has the following characteristics:

- Fewer limits than the other drugs in the library.
- A full compliment of the Drug Library Software's safeguards are unavailable.

It is strongly recommended to use `Drug X (mL/h)` in a limited number of clinical cases and under close patient monitoring by the clinical staff.

For each custom profile, the healthcare facility can enable or disable `Drug X (mL/h)` using the Drug Library Software.

4.3.3 Hard Limits and Soft Limits

Programming limits can be set for each drug with Drug Library Software. Two types of limits can be set:

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

4.3.4 Infusion Modes

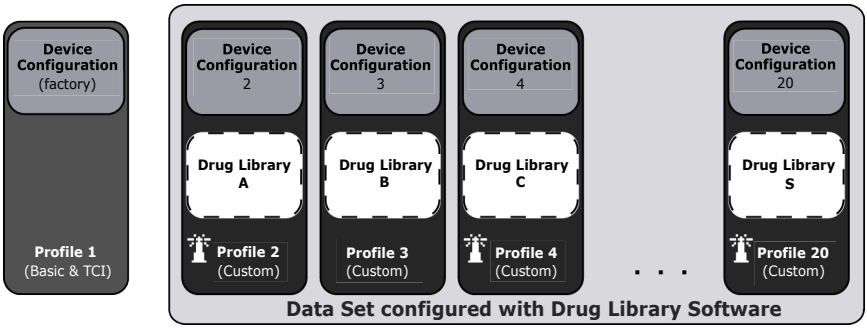
An infusion can be started according to the following modes:

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

INFORMATION
When TCI programming mode is selected, the infusion modes above cannot be selected. For more information on Target Controlled Infusion (TCI), see *Target Controlled Infusion (TCI)* on page 28.

4.4 Data Set

A data set is a combination of custom profiles (up to a maximum of 19) that can be uploaded to Agilia pumps with Drug Library Software.



If there is no data set uploaded to the pump, the pump can be used with the Basic & TCI profile, without the protections of the Drug Library Software.

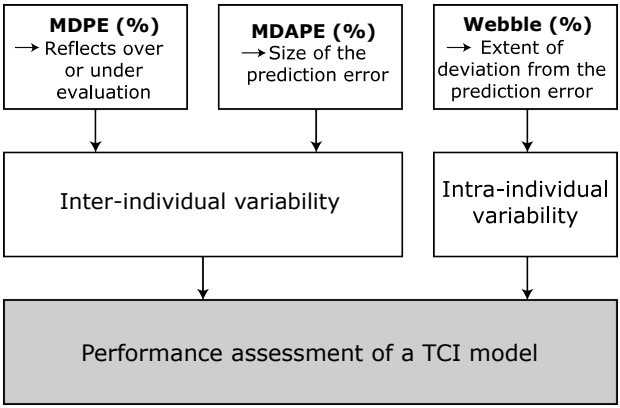
4.5 Target Controlled Infusion (TCI)

4.5.1 Introduction to Pharmacokinetic models

With TCI programming mode, the pump software must determine the infusion rate pattern required to achieve and maintain a target drug concentration in a body compartment or tissue. The mathematical model used to achieve this concentration is called a pharmacokinetic model.

The pharmacokinetic models included in the pump have already been established and validated through clinical studies whose goal was to assess the model's predictive accuracies in various groups of subjects.

A set of standard criteria was proposed for using the Median Predicted Error (MDPE) and the Median Absolute Predicted Error (MDAPE) to assess the predictive performance of computerised infusion pumps:



To calculate these criteria, it is necessary to first calculate the performance error (PE) for each measured drug concentration:

$PE = 100\% \times (C_{meas}-C_{pred})/C_{pred}$

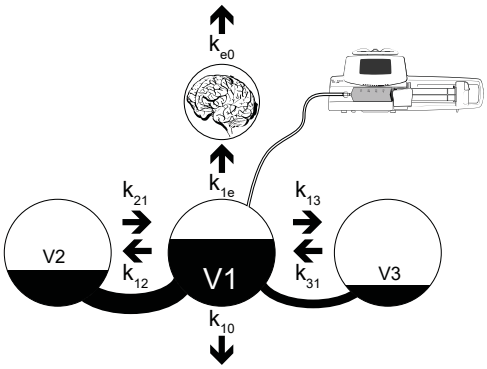
where C_{meas} and C_{pred} are the measured and predicted plasma concentrations, respectively.

A model is considered validated if the following are true:

- MDPE < 20%
- MDAPE < 30%

4.5.2 Target concentration

All pharmacokinetic models included in the pump are 3-compartment models that can be represented as follows:



Legend

V1	Volume of the central compartment (primarily, the blood)
V2	Volume of the fast compartment
V3	Volume of the slow compartment
k_{10}	The partition coefficients that determine the speed at which the drug travels from one compartment to another
k_{10}	A constant representing the rate of elimination from the central compartment
k_{e0}	A constant representing the equilibrium between the plasma and effect sites

- Plasma concentration: concentration of the drug in the central compartment (V1).
- Effect-site concentration: estimation of the concentration in a 4^{th} compartment. This compartment (which represents the site of drug action) has no physical volume, and is virtually linked to the central compartment with a partition coefficient named k_{e0}.

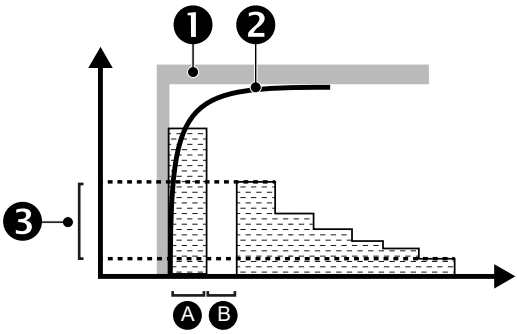
The effect-site concentration and the plasma concentration equilibrate after a period of time that depends on the value of k_{e0}. This value depends on the drug, and has been established by clinical studies that compared the plasma level after equilibration, with the measured effect primarily through an EEG response.

4.5.3 TCI modes in the Agilia SP TIVA

With TCI programming mode, drugs can be infused according to the target control modes below (TCI modes):

- Plasma control mode: control of plasma concentration.
- Effect-site control mode: control of effect-site concentration.

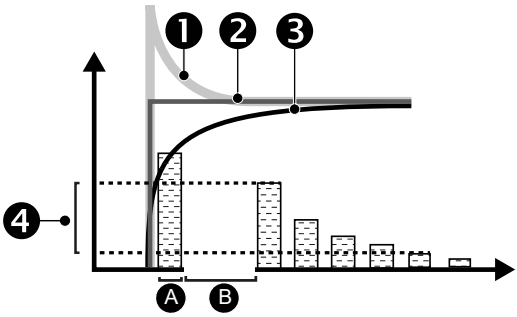
Effect-site control mode differs from plasma control mode by allowing an overshoot of the plasma concentration to rapidly achieve the effect-site concentration. Before using the effect-site control mode, you must evaluate the patient's state of health. Be careful when using the effect-site control on fragile (ASA 3 or 4) or elderly patients.



Legend

1. Target Plasma Concentration (Cpt)
2. Plasma Concentration
3. Flow Rate (range)

Figure 5: Plasma Control Mode



Legend

1. Plasma Concentration
2. Target Effect-site Concentration (Cet)
3. Effect-site Concentration
4. Flow Rate (range)

Figure 6: Effect-site Control Mode

NOTE: With TCI programming mode, the bolus (A) is the initial dose that is delivered to the patient in order to reach the target concentration as quickly as possible. The delay (B) is a wait time that allows the patient's body to absorb the bolus.

NOTE: Target Effect Site Concentration is not available for Kataria and Paedfusor Pharmacokinetic Models.

4.5.4 Pharmacokinetic Models in the Agilia SP TIVA

The pharmacokinetic models included in the Agilia SP TIVA were not developed specifically for a device, but they were established and validated by numerous clinical studies.

Pharmacokinetic models	Drugs	TCI mode	
		Plasma	Effect-site
Eleveld with opioids	Propofol	✓	✓
Eleveld without opioids	Propofol	✓	✓
Modified Marsh (Marsh with low ke0)	Propofol	✓	✓

Pharmacokinetic models	Drugs	TCI mode	
		Plasma	Effect-site
Schnider	Propofol	✓	✓
Kataria	Propofol	✓	x
Paedfusor	Propofol	✓	x
Eleveld	Remifentanil	✓	✓
Minto	Remifentanil	✓	✓
Gepts	Sufentanil	✓	✓
Scott	Alfentanil	✓	✓

For more information on the pharmacokinetic parameters, refer to the published articles in the *Appendix: Pharmacokinetic Models* on page 154.

INFORMATION
Be especially careful when selecting a pharmacokinetic model as this selection leads to different flow rate patterns. Be cautious when selecting the appropriate model to ensure patient safety and optimal dosing.
The Eleveld model comes in two versions: one for concurrent use with an opioid and one without.
The Eleveld pharmacokinetic model delivers a larger initial bolus than the Schnider one. Users are advised to adjust the initial target dose accordingly, especially in vulnerable patients, to ensure patient safety and avoid potential overdose.

4.5.5 Populations

In TCI mode, it is always best to titrate the concentration. This involves finding the proper concentration for your patient by progressively increasing the target until you reach the desired effect.

This table shows the limits regarding patients' characteristics configured in the pump.

Pharmacokinetic Model	Restrictions			
	Age (years)	Weight (kg)	Height (cm)	Body Mass Index (BMI)
Eleveld	1 ➔ 150	1 ➔ 350	20 ➔ 250	Not applicable
Modified Marsh	15 ➔ 100	30 ➔ 200	Not applicable	Not applicable
Schnider	15 ➔ 100	30 ➔ 200	20 ➔ 250	< 35 for women < 42 for men
Minto	15 ➔ 100	30 ➔ 200	20 ➔ 250	< 35 for women < 42 for men
Gepts	15 ➔ 100	30 ➔ 200	Not applicable	Not applicable

Pharmacokinetic Model	Restrictions			
	Age (years)	Weight (kg)	Height (cm)	Body Mass Index (BMI)
Scott	15 ➔ 100	30 ➔ 200	Not applicable	Not applicable
Paedfusor	1 ➔ 16	5 ➔ 60	Not applicable	Not applicable
Kataria	3 ➔ 11	15 ➔ 60	Not applicable	Not applicable

Note that the population range considered in the applicable publications may vary or be more restrictive depending on the model. Refer to the corresponding publications for further information: see *Publications* on page 155.

Age

You must be especially careful with the modified Marsh model, since the pharmacokinetic parameters do not depend on age. For patients aged 55 and older, the Schnider model has proven to be more accurate.

INFORMATION
The Eleveld model comes in two versions: one for concurrent use with an opioid and one without. The version without opioid tends to deliver higher loading doses, and does not reduce doses over time, including for elderly patients.

Weight

For morbidly obese patients, the pharmacokinetic models' accuracy has not been validated, and the TCI modes should be used with caution.

Additionally, the Schnider and Minto models are dependent on Lean Body Mass (LBM), and cannot be selected when the patient parameters give a calculated BMI (Body Mass Index) of more than 42 for male patients and 35 for female patients.

The Lean Body Mass (LBM) and Body Mass Index (BMI) are calculated as follows:

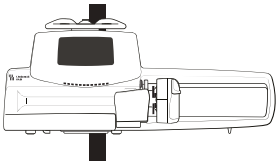
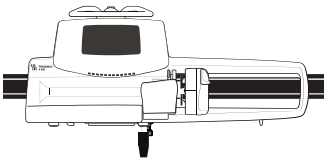
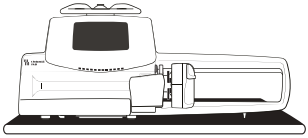
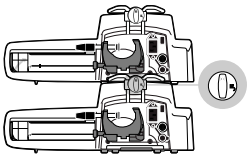
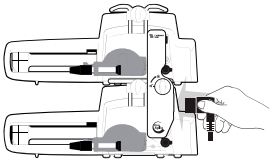
- LBM (Weight in kg, Height in cm, Age in years):
  - Males: $1.1 \times \text{Weight} - 128(\text{Weight}/\text{Height})^2$
  - Females: $1.07 \times \text{Weight} - 148(\text{Weight}/\text{Height})^2$
- BMI (Weight in kg, Height in m): $\text{Weight}/\text{Height}^2$

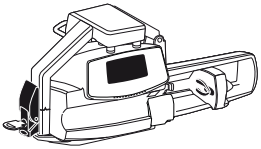
INFORMATION
The pharmacokinetic models have been determined statistically. Due to inter- and intra-individual variability, you must control the flow rate pattern and make sure it corresponds to the pattern you would administer in a non-TCI mode. This is applicable for all infusion startups and ongoing anaesthetic pump procedures.

5 Installation

5.1 Types of Installations

A pump can be installed on any of the following:

Location		Comments
On a Pole		■ See *Attaching to a Pole* on page 35. **Pole specifications:** ■ Diameter: from 15 to 40 mm
On a Rail		■ See *Attaching to a Rail* on page 36. **Rail specifications:** ■ Height: from 25 to 35 mm ■ Depth: from 8 to 10 mm
On the Agilia Link or Link Agilia or Link+ Agilia Rack		■ Refer to the relevant accompanying documents.
On a Table		■ See *Using on a Flat Table* on page 36. Only install a pump on a table if it is not possible to attach it to a pole, a rail or recommended Agilia accessory.
On Another Pump		■ See *Attaching Two Pumps Together* on page 37.
On an Agilia Duo		■ Refer to the Agilia Duo accompanying documents.

Location		Comments
In an Agilia Holder Ambulance		■ Refer to the Agilia Holder Ambulance accompanying documents.

WARNING

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

5.2 Using the Rotating Pole Clamp

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

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

5.2.1 Rotating Pole Clamp Description

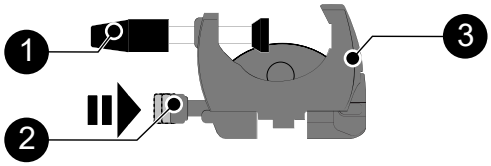


Figure 7: Rotating Pole Clamp System

Legend			
1	Screw Clamp	3	Rotating Pole Clamp
2	Release Button		

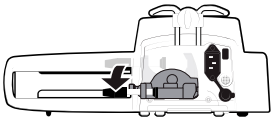
5.2.2 Using the Rotating Pole Clamp

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

5.2.2.1 Folding the Clamp Down (outward)

You can fold the clamp down as follows:

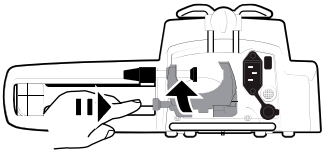
1. Push the release button.
2. Fold the clamp outward.



5.2.2.2 Folding the Clamp Up (inward toward the pump)

You can fold the clamp up as follows:

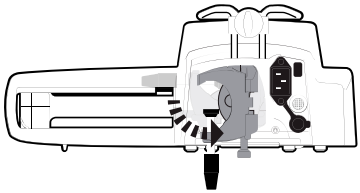
1. Push the release button.
2. Fold the pole clamp inward toward the pump.



5.2.2.3 Rotating the Clamp

You can rotate the clamp as follows:

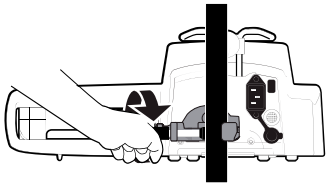
1. Fold the clamp up (see above).
2. Rotate the clamp to a vertical position.
3. If necessary, fold the clamp outward (see above).



5.3 Attaching the pump(s)

5.3.1 Attaching to a Pole

1. Fold the pole clamp down to the horizontal position: see *Folding the Clamp Down (outward)* on page 35.
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.



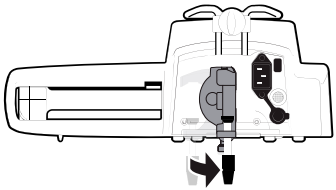
For more information on installing the pump on a pole, consult the pole's Instructions For Use.

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

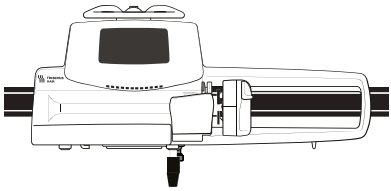
5.3.2 Attaching to a Rail

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

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

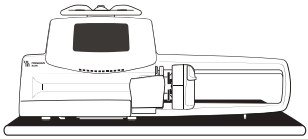


3. Make sure that the pump is securely attached.



5.3.3 Using on a Flat Table

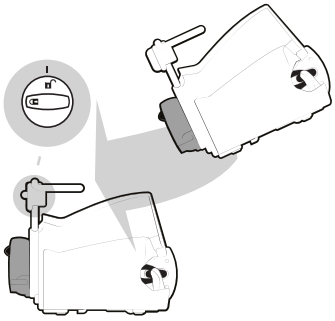
1. Fold the pole clamp up: see *Folding the Clamp Up (inward toward the pump)* on page 35.
2. Place the pump far enough from the table's edges to prevent it from accidentally being pushed off.



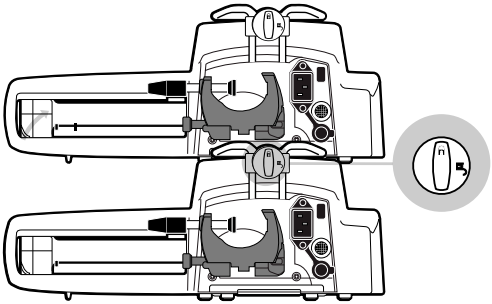
5.3.4 Attaching Two Pumps Together

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

1. Fold both pumps' pole clamps up: see *Folding the Clamp Up (inward toward the pump)* on page 35.
2. Slide the slot on the bottom of the upper pump onto the handle of the lower pump.



3. Turn the attachment lock knob on the lower pump handle clockwise until the locked symbol lines up with the marker.
4. Make sure the two pumps are securely attached together.
5. If needed, fold the two pole clamps down and secure them tightly to the pole.

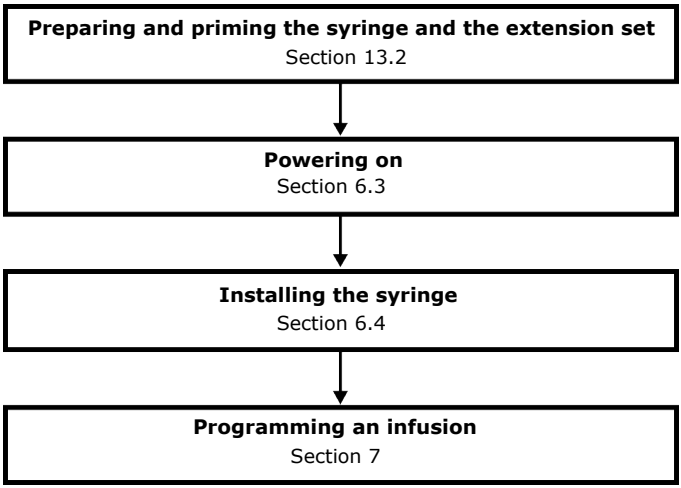


Symbol	Location	Description
	Attachment Lock Knob	Locked Position
	Attachment Lock Knob	Unlocked Position

6 Getting Started

6.1 Flowchart

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



INFORMATION

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

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

6.2 Using the Pump for the First Time

1. Make sure the pump is correctly installed at the bedside. See *Installation* on page 33.
2. Plug the pump into the AC power supply. See *AC Power Supply Precautions* on page 120.
3. Before starting the pump for the first time, you must charge the battery for approximately 6 hours.

   Wait until the pump is fully charged. Do not use the pump during the first charge.
4. Power on the pump. See *Powering on* on page 39.
5. Install a syringe into the pump. See *Installing a Syringe* on page 40.

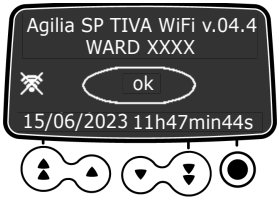
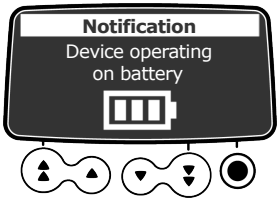
6.3 Powering on

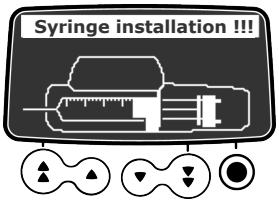
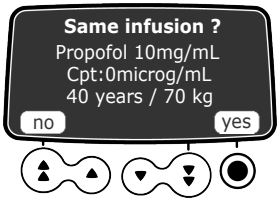
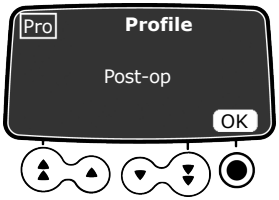
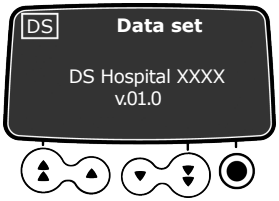
CAUTION
The pump can operate using the battery; however, we recommend that the pump be connected to a power supply as often as possible during use in order to ensure that the battery remains charged.

INFORMATION

- When the pump is connected to the power supply, check that the power supply indicator lights up green, and that the power cord and the wall plug are accessible.
- When plugged into a power supply, the pump automatically powers on when the disengagement lever is pushed. You can deactivate this option in the pump options. For more information, refer to the technical manual.

1. Press or push the pump disengagement lever.
   An auto-test checks the functionality of the pump.
2. Immediately after powering on the pump, make sure that all LED lights blink.
3. If needed, select the language and enter the date. If the selection is incorrect, contact your biomedical department to reset the pump to its initial configuration.
4. Successively acknowledge the screens listed in the table below.

Screen After Powering on	Description
	Startup screen: the following information is displayed: ■ Product name / Ward name ■ Wi-Fi module status (if applicable) ■ Date & time
	■ Displayed if the pump is operating on battery. ■ The symbol shows three different charge levels: – < 30% battery charge – 30% - 70% battery charge – > 70% battery charge

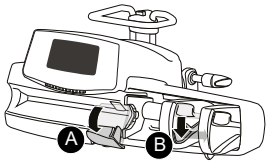
Screen After Powering on	Description
	■ No syringe is installed on the pump. ■ `Syringe installation !!!` is displayed on top of the screen. ☞ Install a syringe. See *Installing a Syringe* on page 40.
	■ Maintenance reminder message (optional).
	■ Same infusion screen (optional). Press ◉ to select **yes** in order to keep the previous infusion settings.
	■ Profile confirmation screen (optional). Press ◉ to select **OK** in order to confirm the profile. **NOTE:** This screen is associated with the "same infusion" function above.
	■ Data Set information (optional)

5. Check that the device is parametrized as expected.

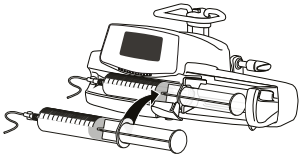
6.4 Installing a Syringe

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

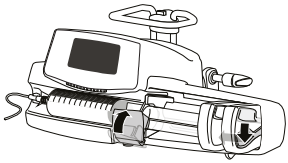
1. Open the syringe barrel clasp [A].
2. Push the disengagement lever [B] down and move the plunger driver to the right.



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



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



6.5 Pump Height

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

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

Precautions for pump position

CAUTION

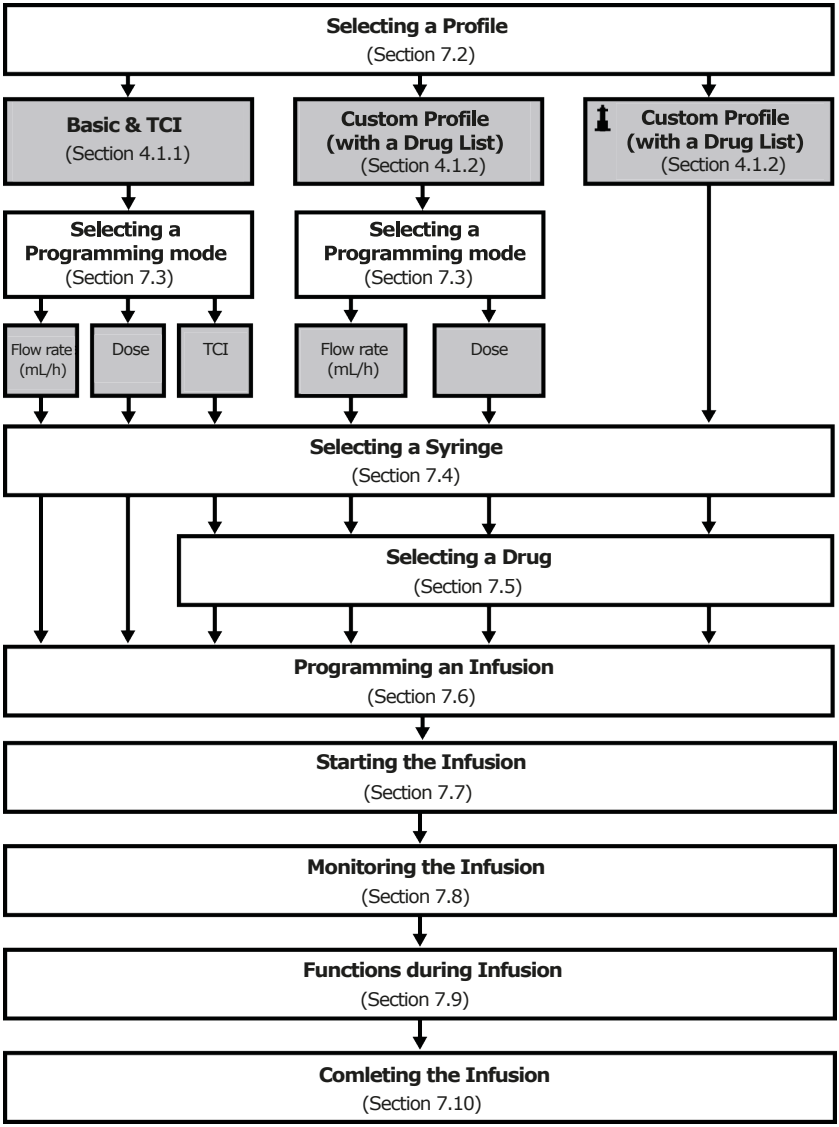
- If multiple syringe pumps are used and it is not clinically feasible to position all of them at the same level as the distal tip of the catheter (or the fluid delivery site), prioritize placing high-risk or life-sustaining medications as close as possible to the distal tip of the catheter. When infusing several high-risk or life-sustaining medications, consider positioning the ones infusing at the lowest flow rates as close as possible to the level of the distal tip of the catheter.

- Minimize the height difference between the pump and the patient and avoid changes in the height of the pump (example: during transport of critically ill patients) to prevent unintended fluctuations in the flow rate.

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

7 Operation

7.1 Flowchart

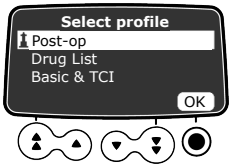


7.2 Selecting a Profile

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

You can switch to another a profile without turning off the pump. See *Profile* on page 69.

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

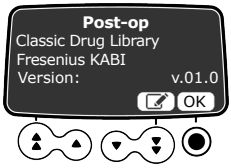


2. Press the arrow keys to select a profile that corresponds to your needs.

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

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

   The selected profile information is displayed.

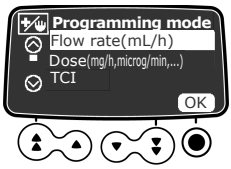


4. Press ◉ to select **OK** in order to confirm the drug library version, or press the arrow key to select ✎ to change the profile.
   The drug library is loaded for the profile selected.

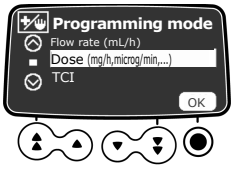
7.3 Selecting the Programming Mode

This step occurs just after selecting Basic & TCI profile, or a custom profile with a drug list.

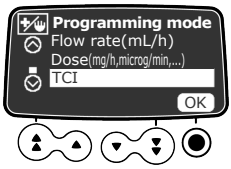
NOTE: The infusion rates for each drug of a drug library are pre-defined with Drug Library Software.



Flow rate



Dose

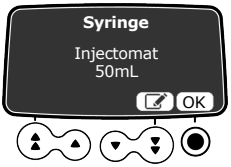


TCI

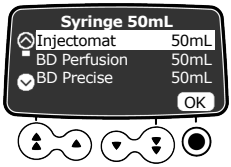
1. Press the arrow keys to select a new programming mode.
2. Press ◉ to select **OK** in order to confirm.

7.4 Selecting a Syringe

The pump automatically detects the size of the installed syringe.



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



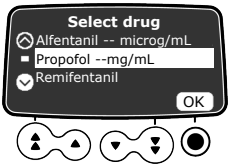
2. If you have chosen to select another syringe, press the arrow keys to select a new syringe.
3. Press to select **OK** in order to confirm the new syringe.
   A clinical advisory message may appear, if one is configured for the selected syringe.
4. Press to select **OK** to acknowledge the clinical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

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

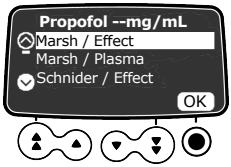
7.5 Selecting a Drug

7.5.1 Basic & TCI Profile

NOTE: In Basic & TCI, the drug selection step is only applicable with TCI programming mode.



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

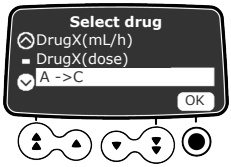


2. Press the arrow keys to select the Pharmacokinetic model / TCI mode (Plasma / Effect-site), and press ◉ to select **OK**.
   An information is displayed about the use of the Pharmacokinetic model and TCI mode selected.
3. Press ◉ to select **OK**.

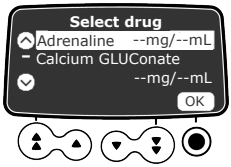
7.5.2 Custom Profiles

Drugs are sorted alphabetically by the first letter of their names:

- A ➔ C
- D ➔F
- G ➔ I
- J ➔ L
- M ➔ O
- P ➔ R
- S ➔ U
- V ➔ Z
- Drug X (mL/h)
- Drug X (Dose)



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



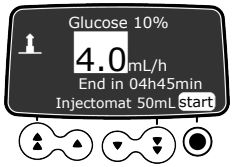
2. Press the arrow keys to scroll to the drug's name, and press ◉ to select **OK**.
   A clinical advisory message may appear, if one is configured for the selected drug.
3. Press ◉ to select **OK** to acknowledge the clinical advisory message and continue programming or C to change the drug.

7.6 Programming an Infusion

- This section describes the programming of an infusion with the Simple Rate infusion mode.
- You can also program an infusion with the following modes:

– Volume/Time (or Dose/Time), see *Volume/Time & Dose/Time* on page 63.
– Volume Limit, see *Volume Limit* on page 64.

7.6.1 Programming an Infusion by Flow Rate



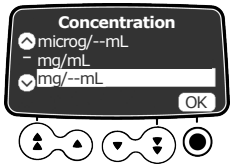
1. Press the arrow keys to program the flow rate.
2. Press ◉ to select **start** to start the infusion.

7.6.2 Programming an Infusion by Dose

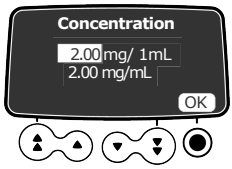
7.6.2.1 Selecting the Drug Concentration

Profile	Drug Concentration Selection Procedure
Basic & TCI profile	*A- Basic & TCI profile and Custom Profile (with a Drug List)* on page 47.
Custom Profile (with a drug list)	
Custom Profile (with a drug library)	*B- Custom Profiles* on page 48.

A- Basic & TCI profile and Custom Profile (with a Drug List)



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



2. Press the arrow keys to select a mass value, and press ◉ to select **OK**.
3. Press the arrow keys to select a volume value, and press ◉ to select **OK**.
   The concentration is automatically calculated and displayed in the unit selected above.
4. Press ◉ to select **OK** in order to confirm.

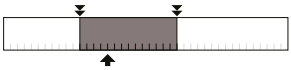
B- Custom Profiles

The selected drug is configured in Drug Library Software to allow adjustments to its concentration in one of the following ways:

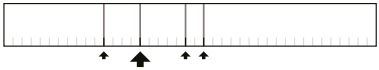
- Within an authorized range
- At authorized finite values (up to 5)

If no adjustment of the concentration is allowed, see *Selecting the Patient's Characteristics* on page 49.

Authorized Concentration Range



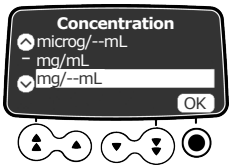
Authorized Finite Concentrations



Legend

Unauthorized Range	Hard Limits
Authorized Range	Default Value
	Finite Values

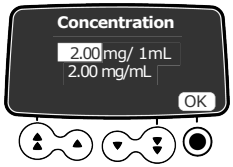
Selecting the Drug Concentration



Concentration Setting

If a Concentration unit is selected:

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

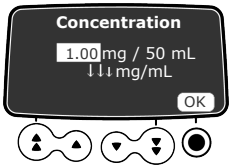


Dilution Setting

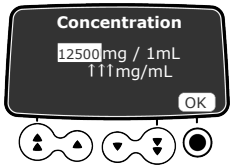
If a Dilution unit is selected:

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

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



Concentration below the Drug Library Software hard limit

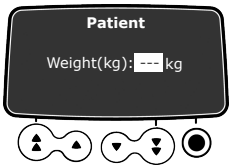


Concentration above the Drug Library Software hard limit

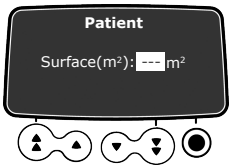
NOTE: User will not be able to proceed to the next screen until he changes the Dose or Volume settings in order to have an authorized concentration value.

7.6.2.2 Selecting the Patient's Characteristics

NOTE: This step is only applicable with custom profiles that contain a drug library.



Weight



Body Surface Area

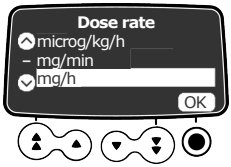
1. Press the arrow keys to enter the patient's weight or body surface area.
2. Press ◉ to confirm.

INFORMATION

- The weight entry screen only appears if the selected drug uses weight for dose rate calculations.
- The body surface area entry screen only appears if the selected drug uses body surface area for dose rate calculations.
- A pre-populated default weight or body surface area will be configured with the Drug Library Software.

7.6.2.3 Selecting the Infusion Unit

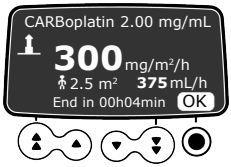
NOTE: This step is only applicable with Basic & TCI profile and custom profiles that contain a drug list. The infusion units for each drug of a drug library are pre- defined with Drug Library Software.



1. Press the arrow keys to select the infusion unit.

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

7.6.2.4 Programming the Infusion



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

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

7.6.2.5 Programming an Induction Dose

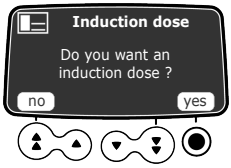
NOTE: This feature can be activated or deactivated in Drug Library Software (custom profiles).

INFORMATION
The induction 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 induction dose again.

If enabled for the selected drug, you can program an induction dose after programming an infusion defined by dose.

The screens below will appear prior to starting the infusion.

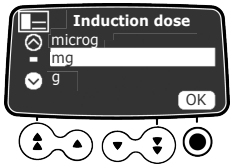
Selecting an Induction Dose



On the induction dose screen:

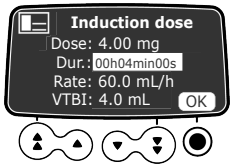
- Press the arrow key to select **no** to return to the programming screen.
- Press ◉ to select **yes** to program an induction dose prior to starting the primary infusion.

Selecting the Induction Dose Unit



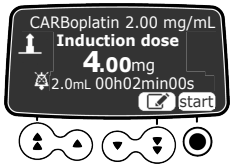
1. Press the arrow keys to select the induction dose unit.
2. Press ◉ to select **OK** in order to confirm.

Programming an Induction Dose



1. Press the arrow keys to enter a value for the dose, and press ◉ to select **OK** to confirm.
2. Press the arrow keys to program the induction dose duration (__ h __min __sec), and press ◉ to select **OK** to confirm.
   The VTBI is automatically calculated based on dose and duration settings.
3. Press the arrow keys to program the flow rate.
   The duration and the rate are interdependant.
4. Press ◉ to select **OK** to confirm the induction dose settings.

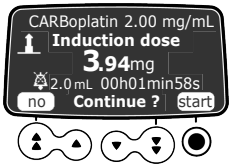
   If needed, press the arrow key to select  or ↺ to change the induction dose settings before starting.



5. Press ◉ to select **start** to initiate the induction dose.
   Once the induction dose is finished, the pump automatically starts the programmed infusion.

INFORMATION
In Volume/Time (or Dose/Time) mode, the volume of the induction dose is substracted from the VTBI (or DTBI)

Interrupting an Induction Dose

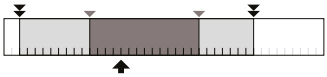


1. To pause the induction dose, press STOP.
   The screen displays `Continue?`
2. Choose one of the following options:
   - Press the arrow key to select `no` or STOP to stop the induction dose and proceed to the programmed infusion.
   - Press ◉ to select **start** to continue with the induction dose.

7.6.3 Programming Beyond Soft Limits

NOTE: This step is only available with custom profiles that contain a drug library.

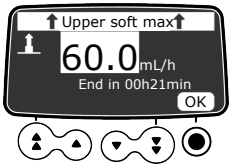
You can override soft limits, and adjust flow rate and dose within the authorized ranges. You cannot override a hard limit.



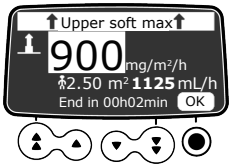
Legend			
	Unauthorized Range	⏬	Hard Limits
	Programmable Range (warning and confirmation)	▼	Soft Limits
	Authorized Range	▲	Default Value

7.6.3.1 Overriding a Soft Limit

1. If you reach a soft limit when programming an infusion, the pump displays a message at the top of the screen:
   - `Upper soft max` = the upper soft limit is exceeded
   - `Lower soft min` = the lower soft limit is exceeded



Flow rate

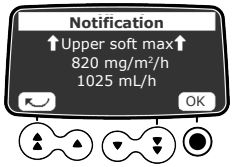


Dose

2. If the displayed settings correspond to the intended flow rate or dose, press ◉ to select **OK**.



Flow rate



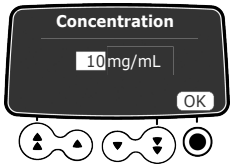
Dose

3. Carefully review the program settings.
   The original infusion settings continue until you confirm the new settings.

4. Press ◉ to select **OK** or **start** in order to confirm the soft limit override.
   During infusion, the upper or lower soft limit message will alternate with the drug name and concentration at the top of the screen.

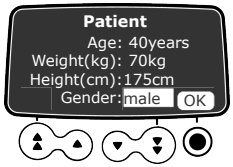
7.6.4 Programming an Infusion (TCI Programming Mode)

7.6.4.1 Selecting the Drug Concentration



1. Press the arrow keys to program the concentration.
2. Press ◉ to select **OK** in order to confirm.

7.6.4.2 Selecting the Patient's Characteristics

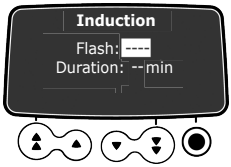


1. Press the arrow keys to enter the patient's age and press ◉ to select **OK**.
2. Press the arrow keys to enter the patient's weight and press ◉ to select **OK**.
3. Press the arrow keys to enter the patient's height and press ◉ to select **OK** (if available).
4. Press the arrow keys to enter the patient's gender and press ◉ to select **OK** (if available).

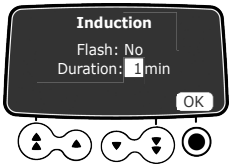
7.6.4.3 Setting the Induction Time

NOTE: This step is only applicable for plasma control mode.

The induction time is a period of time during which the target concentration progressively increases, to finally reach the programmed value. The induction time can be set to flash (the shortest, fastest possible induction dose) or adjusted from 1 to 60 minutes.



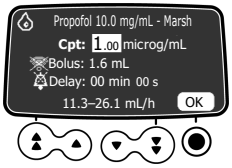
1. Press the arrow keys to enable ("Yes") / disable ("No") the flash induction time, then press to select **OK**.



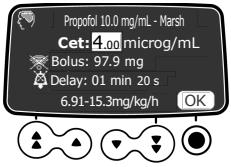
2. If Flash is set to "No", press the arrow keys to set the induction time.
3. Press ◉ to select **OK**.

7.6.4.4 Programming the Infusion

NOTE: For more information on the elements displayed on the TCI programming screen (target concentration, bolus, delay, flow rate range), see *TCI modes in the Agilia SP TIVA* on page 29.

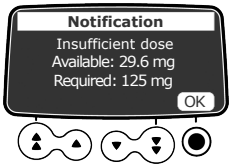


Plasma



Effect-site

1. Press the arrow keys to program the target concentration and press ◉ to select **OK**. If the remaining volume in the syringe is too low for the adjusted target, an alert message is displayed.



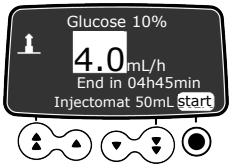
- Available dose: Dose remaining in the syringe.
- Required dose: Dose necessary to reach the target concentration.

2. Press ◉ to select **OK** to continue the infusion, or choose one of the following options:

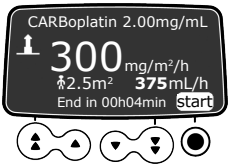
- Press C to modify the target concentration.
- Replace the syringe.

7.7 Starting an Infusion

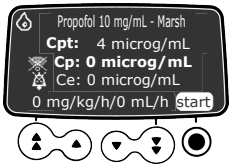
NOTE: Depending on the programming mode you selected, the screens below may appear.



Flow rate



Dose



TCI

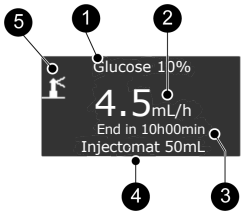
CAUTION
Check the complete infusion line from the syringe to the catheter prior to starting the infusion.

1. Check that there is no air in the syringe or in the extension set.
2. Confirm that the syringe is correctly installed in the pump.
3. Connect the syringe's extension set to the patient's access device.
4. Check the infusion settings prior to starting the infusion.
5. Press ◉ to select **start** in order to start the infusion.

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

7.8 Monitoring an Infusion

7.8.1 Monitoring an Infusion when Programmed by Flow Rate



Legend

1. Drug Name (Custom profiles only)

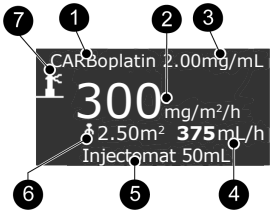
❷ Infusion Flow Rate (mL/h)
To change the flow rate during an infusion, see *Adjusting Infusion parameters: Rate Titration / Target Modification* on page 58.
The flow rate is displayed with the largest font size.

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

❹ Syringe Name / Ward Name (configurable)

❺ Infusion in Progress Symbol (see *Infusion Status* on page 22)

7.8.2 Monitoring an Infusion when Programmed by Dose



Legend

❶ Drug Name & Concentration (Custom profiles only)

❷ Dose
To change the dose during an infusion, see *Adjusting Infusion parameters: Rate Titration / Target Modification* on page 58.
Dose is displayed with the largest font size.

❸ Drug Concentration

❹ Infusion Flow Rate

❺ Syringe Name / Ward Name (configurable)

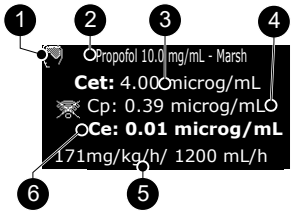
❻ Patient Characteristics

❼ Infusion in Progress Symbol (see *Infusion Status* on page 22)

7.8.3 Monitoring an Infusion when Programmed with TCI

During a Target Controlled Infusion (`TCI`), you can press to switch from the numerical view to the graphical view.

7.8.3.1 Numerical View

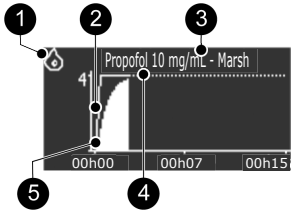


Legend	
1	TCI Mode Plasma / Effect-site
2	Drug Name & Concentration - Pharmacokinetic Model / Wake up Concentration & Wake up Duration
3	Target Concentration (Cet/Cpt) Cet: Target Effect-site Concentration ; Cpt: Target Plasma Concentration
4	Plasma Concentration (Cp) Evolution
5	Dose / Flow rate
6	Effect-site Concentration (Ce) Evolution

NOTE:

- In Plasma Control Mode, plasma concentration evolution (Cp) is displayed in bold.
- In Effect-site Control Mode, effect-site concentration evolution (Ce) is displayed in bold.

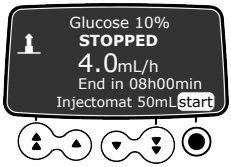
7.8.3.2 Graphical View



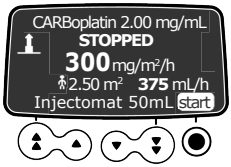
Legend	
1	TCI Mode Plasma / Effect-site
2	Plasma Concentration (Cp) Evolution
3	Drug Name & Concentration - Pharmacokinetic Model / Dose & Flow rate / Target Concentration (Cet /Cpt)
4	Predicted Plasma Concentration (Cp) Curve
5	Effect-site Concentration (Ce) Evolution

7.9 Functions During Infusion

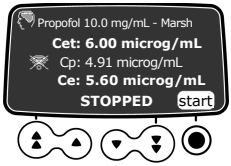
7.9.1 Stop



Flow rate



Dose



TCI

To stop the infusion, press STOP.

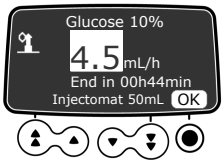
After 2 minutes, an alarm is generated as a reminder that the infusion is stopped.

To restart the infusion, first confirm or modify the programming settings, then start the infusion. See *Programming an Infusion* on page 46.

7.9.2 Adjusting Infusion parameters: Rate Titration / Target Modification

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

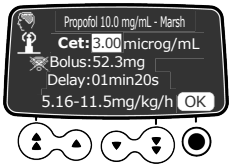
1. If required, stop the infusion, see *Stop* on page 58.
2. Press the arrow keys to modify the infusion rate or the target concentration.
3. Press the ◉ key to select **OK** in order to confirm.



Flow rate



Dose



TCI

7.9.3 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 an infusion:

- Direct bolus
- Programmed bolus

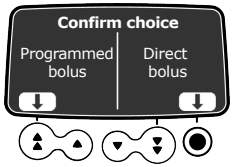
	Direct Bolus	Programmed Bolus
Access Key	BOLUS	BOLUS or MENU
Occlusion Pressure Level	Set to its maximum value: 900 mmHg / 120 kPa / 17.4 PSI	

INFORMATION

- The bolus volume is added to the Volume Infused (VI).
- The BOLUS key is not active when the menu screen is displayed.
- This feature is not available with TCI programming mode.

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

1. Press the Bolus key BOLUS on the keypad.

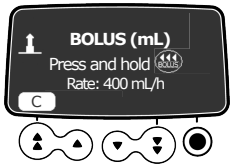


2. Select **Programmed bolus** using the arrow key or **Direct bolus** using the ◉ key.
3. Then, see *Direct Bolus* on page 59 or see *Programmed Bolus* on page 59.

7.9.3.1 Direct Bolus

NOTE: This feature can be activated or deactivated in Drug Library Software (custom profiles) or in the pump options (Basic & TCI configuration).

1. During the infusion, press the bolus BOLUS key.
2. Press ◉ to confirm access to bolus function.



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

7.9.3.2 Programmed Bolus

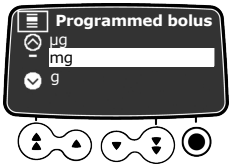
NOTE: This feature can be activated or deactivated in Drug Library Software (custom profiles) or in the pump options (Basic & TCI configuration).

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

- Press BOLUS, then the arrow key to select **Programmed bolus**.

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

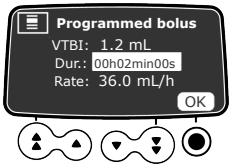
Programming a Bolus



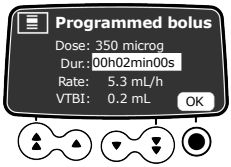
1. Press the arrow keys to select the programmed bolus unit, and press ◉ to select **OK**.

   NOTE: This step is only applicable with Basic & TCI profile and custom profiles that contain a drug list. The infusion units for each drug of a drug library are pre-defined with Drug Library Software.

2. Press the arrow keys to program the bolus volume or dose, and press ◉ to select **OK** in order to confirm.
3. Press the arrow keys to program the bolus duration (__ h __ min __ s), and press ◉ to select **OK** in order to confirm.
   The flow rate is calculated automatically.
4. Press the arrow keys to program the flow rate.
   The duration and the rate are interdependant.

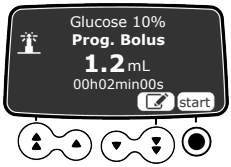


Flow rate

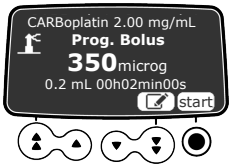


Dose

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



Flow rate



Dose

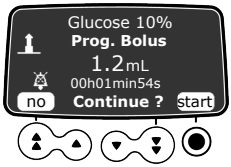
6. At this stage, you can:
   - Press the ◉ key to select **start** in order to administer the bolus immediately.
   - Press the C key in order to save the settings without administering the bolus.
   - Press the arrow key to select ✎ in order to change the bolus settings.

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

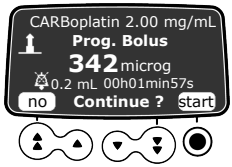
   If you press BOLUS again then select **Programmed bolus**, a screen is displayed with the settings of the last bolus.

Interrupting a Programmed Bolus

1. Press STOP to interrupt the bolus.



Flow rate



Dose

2. Answer the question: `Continue?`

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

7.10 Completing an Infusion

7.10.1 Near End of Infusion Alert

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

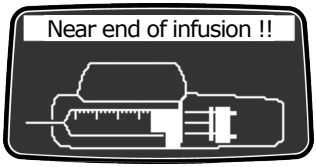
- An audible alarm is triggered.
- An alarm message appears on the pump screen.
- The infusion indicator lights flash yellow.

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

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

Near end of infusion alert settings are configurable with Drug Library Software (custom profiles), or in the pump options (Basic & TCI configuration). For more information, refer to the technical manual.

Silencing Near End of Infusion Alert



1. Press to silence the alarm.
2. If required, press to select **OK** in order to confirm the empty syringe mode. Depending on the pump configuration, the following happens:
   - The infusion continues at the programmed rate until the plunger reaches the tip of the syringe. The syringe is not completely emptied (regular end of infusion).
   - The infusion continues until the syringe is completely emptied. The flow rate decreases when the plunger reaches the tip of the syringe (empty syringe - only in Simple Rate mode).

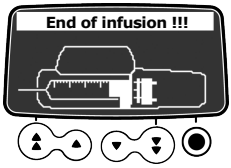
7.10.2 End of Infusion

When the infusion is complete, the following happens:

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

End of infusion settings are configurable with Drug Library Software (custom profiles), or in the pump options (Basic & TCI configuration). For more information, refer to the technical manual.

Silencing the Alarm



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

7.11 Infusion Modes

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

7.11.1 Simple Rate

1. Press the arrow keys to select the infusion rate.

2. Press ◉ to select **OK**.

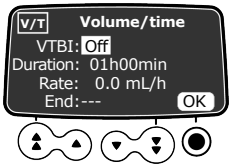
For more information, see *Programming an Infusion* on page 46.

7.11.2 Volume/Time & Dose/Time

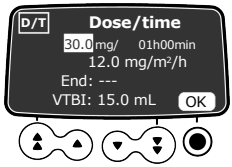
You can use this infusion mode to program a volume or dose to be infused (VTBI or DTBI) over a programmed period of time.

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

1. Access the Volume/Time or Dose/Time, see *Volume/Time & Dose/Time* on page 79.



Volume/Time



Dose/Time

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

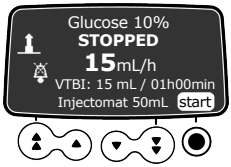
INFORMATION
If you program a volume to be infused that is greater than the actual volume in the syringe, make sure to replace the syringe when it is empty, see *Changing a Syringe* on page 107.

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

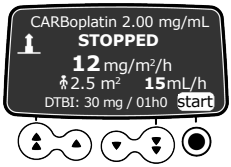
4. Press the arrow keys to configure the end of infusion settings and press ◉ to select **OK** in order to confirm.
   - `Stop`: The infusion stops when the VTBI is completed.
   - `Keep Vein Open (KVO)`: After the VTBI is completed, the infusion continues at a preset flow rate to keep the access device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

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

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



Volume/Time



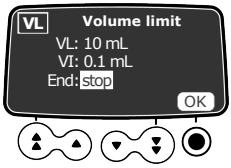
Dose/Time

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

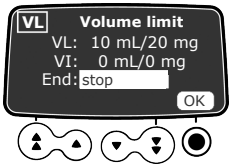
7.11.3 Volume Limit

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

1. Access the Volume Limit menu, see *Volume Limit* on page 79.



Flow rate



Dose

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

INFORMATION

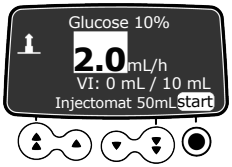
- If you program a volume limit that exceeds the actual volume in the syringe, make sure to replace the syringe when it is empty, see *Changing a Syringe* on page 107.
- The volume already infused (VI) before accessing the volume limit mode is taken into account.

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

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

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

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



Flow rate



Dose

4. Press ◉ to select **start** in order to start the infusion.

7.12 Other Functions

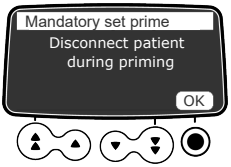
7.12.1 Priming the Syringe and the Extension Set

The prime function can be configured with Drug Library Software (custom profiles) or in the pump options (Basic & TCI):

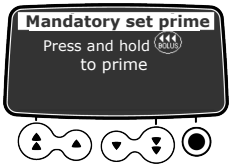
- `Mandatory`: A message is displayed and the user is required to prime the line before infusion.
- `Advised`: A message is displayed to encourage the user to prime the line before infusion.
- `Not displayed`: The pump does not remind the user to prime the line before infusion.

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

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



1. Press ON/OFF to power on the pump.
2. Press BOLUS.
3. Make sure the extension set is not connected to the patient, as indicated on screen.
4. Press the ◉ key to select **OK** in order to proceed.



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

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

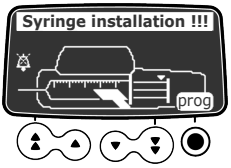
Quick-start is designed to decrease the delay of therapy when the pump's prime function is not used. When quick-start is triggered, the infusion starts at a high flow rate (120 mL/h) until the pump's plunger driver starts pushing the syringe plunger head. The flow rate then automatically switches to 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	■ Not triggered
Not displayed	■ Triggered if flow rate is equal or inferior to 50 mL/h and the automatic priming is not done. ■ Not triggered if the automatic priming is done by the user.

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

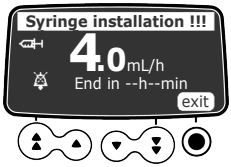
This function can be disabled according to the pump's configuration.

7.12.2 Pre-programming the Pump

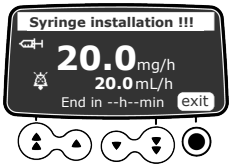


You can program the pump before installing the syringe.

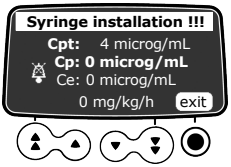
1. Press ⏻ to power on the pump.
   `Syringe installation !!!` is displayed on top of the pump screen.
2. Make sure the syringe barrel clasp is folded up against the pump.
   The **prog** symbol is displayed.
3. Press the ◉ key to select **prog**.
4. Program the infusion.
   See *Programming an Infusion* on page 46.



Flow rate



Dose



TCI

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

7.12.3 Powering off

1. If an infusion is running, press STOP to stop the infusion.
2. Close line.
3. Press and hold ⏻ until the pump powers off.

8 Menus

8.1 Overview

8.1.1 Commands

Operation	Key
Access menu or exit menu	MENU
Select	(correspond to arrow keys)
Confirm	(corresponds to **enter** on the screen)
Select ☑ / Deselect ☐	

8.1.2 Menu Description

Menu	Symbol	Stop Infusion Required	Associated Procedure
Profile	Pro	No	■ *Profile* on page 69.
Pressure		No	■ *Pressure* on page 70.
Keypad lock status		No	■ *Keypad Lock Status* on page 72.
Keypad automatic lock	AUTO	No	■ *Keypad Automatic Lock* on page 74.
Battery life		No	■ *Battery Life* on page 75.
Volume Infused	mL?	No	■ *Volume Infused / Dose Infused* on page 75.
Dose Infused			
Pause		Yes	■ *Pause* on page 76.
Patient		No	■ *Patient* on page 77.
Day/Night mode		No	■ *Day/Night Mode* on page 78.
Programmed bolus		No	■ *Programmed Bolus* on page 77.
Volume/Time	V/T	Yes	■ *Volume/Time & Dose/Time* on page 79.
Dose/Time	D/T	Yes	
Volume limit	VL	Yes	■ *Volume Limit* on page 79.

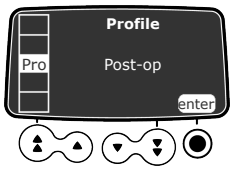
Menu	Symbol	Stop Infusion Required	Associated Procedure
Alarm volume		No	■ *Alarm Volume* on page 80.
Volume-Dose history		Yes	■ *Volume-Dose History* on page 80.
View flow rate history		No	■ *View Flow Rate History* on page 81.
View pressure history		No	■ *View Pressure History* on page 81.
View concentration history	TCI	No	■ *Concentration History* on page 82.
Syringe		No	■ *Syringe* on page 83.
View event log		No	■ *View Event Log* on page 83.
Date / Time		No	■ *Date / Time* on page 84.
Maintenance		No	■ *Maintenance* on page 85.
Library information		No	■ *Library Information* on page 85.
Clinical information		No	■ *Clinical Information* on page 86.
Data Set	DS	No	■ *Data Set* on page 86.
Wake up concentration		No	■ *Wake up Concentration* on page 87.
TCI setup	TCI	No	■ *TCI Setup* on page 88.

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

For more information on factory configuration, refer to *Appendix: Factory Configuration* on page 152.

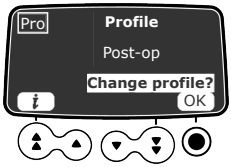
8.2 Profile

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

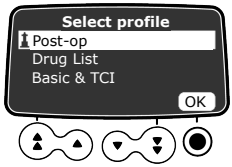


You can display the active profile name as follows:

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



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



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

8.3 Pressure

Symbol	
Procedure	Modifying the pressure limit

Agilia pumps control the pressure inside the infusion line. If the infusion line is partially or totally blocked (called an "occlusion") for any reason, the pressure level inside the line increases. This triggers the occlusion alarms. The pressure limit that triggers these alarms can be configured as shown below.

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

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

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

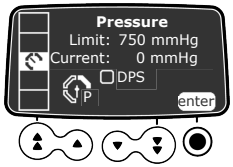
- `Variable` P

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

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

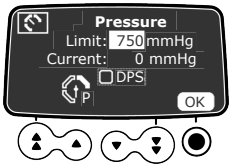
To consult the pressure settings, see *Pressure Management* on page 112.

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



You can modify the pressure limit as follows:

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



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

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

- Consider adjusting the pressure thresholds according to the route of administration and to the infused medication to minimize the occlusion detection time and the time to trigger the related alarms, especially at flow

rates below 1 mL/h. The lower the occlusion pressure threshold is, the shorter the occlusion detection time will be.

- Use the smallest compatible syringe size to deliver the intended medication, especially when infusing life-sustaining drugs. This minimizes the amount of friction and compliance of the syringe plunger head, optimizes pump accuracy and reduces post-occlusion bolus volumes.
- Use extension set which have the smallest internal volume or deadspace (e.g., use microbore tubing when infusing at low rates, shorter length of tubing, etc.).

INFORMATION

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

8.4 Keypad Lock Status

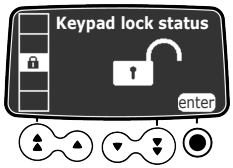
Symbol	🔒
Procedure	Locking / Unlocking the keypad

You can use this feature to avoid inadvertent key presses.

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

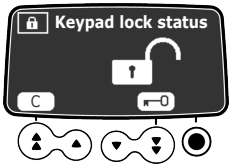
- Unlock code: The user must enter a code to unlock the keypad.

Locking the Keypad



You can lock the keypad as follows:

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

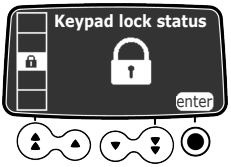


4. Press 0 to lock the keypad.

   The keypad is locked and the screen displays 🔒.

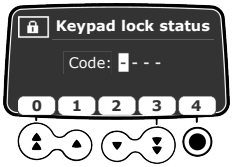
5. Press ◉ to select **OK** in order to confirm.

Unlocking the Keypad

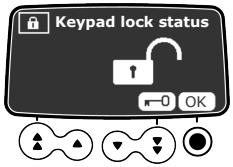


You can unlock the keypad as follows:

1. Press MENU.
2. Press ◉ to select **enter**.



Unlock code enabled



Unlock code disabled

3. Unlock the keypad as follows:
   - If a code is required, press the keys to enter the unlock code. The keypad is unlocked.
   - If no code is required, press 0, and press ◉ to select **OK** to confirm.

   The keypad is unlocked and the screen displays 🔓.

INFORMATION

- The STOP and 🔔 keys remain functional when the keypad is locked.
- During keypad lock, the ◉ key is functional when the infusion is stopped.
- During keypad lock, the 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.

8.5 Keypad Automatic Lock

Symbol	AUTO
Procedure	Activating / Deactivating the keypad automatic lock

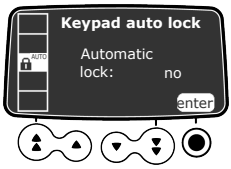
You can use this feature to avoid inadvertent key presses. Depending on the device configuration, the keypad automatic lock feature may or may not be available.

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

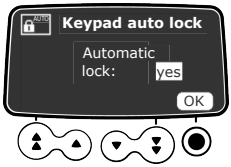
Activating the Keypad Automatic Lock

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 ◉ to select **enter**.



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

Deactivating the Keypad Automatic Lock

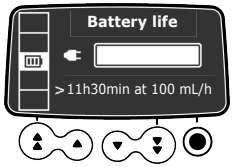
To deactivate the keypad automatic lock:

1. Unlock the keypad: see *Unlocking the Keypad* on page 73.
2. Press MENU.
3. Press the arrow keys to select AUTO
4. Press ◉ to select **enter**.

5. Press the arrow keys to set the Automatic lock to `no`.

8.6 Battery Life

Symbol	
Procedure	Viewing the battery life



You can view the battery life as follows:

1. Press MENU.

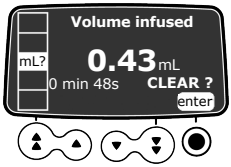
2. Press the arrow keys to select .
The time remaining under current flow rate conditions is displayed.

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

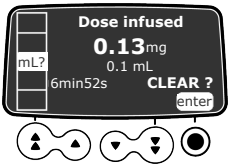
- : The pump is plugged into the AC power supply.
- : The pump is operating on battery.

8.7 Volume Infused / Dose Infused

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



Volume infused



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, induction doses and boluses. The length of time over which they were infused is also displayed.

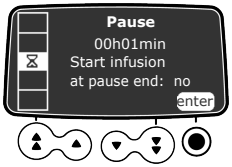
3. To clear the volume or dose infused, press ◉ to select **enter**.
4. Press ◉ to select **OK** in order to confirm.

INFORMATION

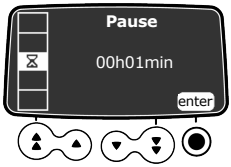
- When the pump is powered off or a new drug is selected, the volume or dose infused is cleared.
- In TCI mode, clearing the dose infused is not allowed.

8.8 Pause

Symbol	⧖
Procedure	Programming a pause



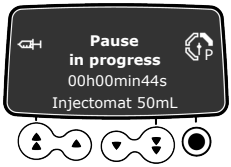
Flow rate and Dose



TCI

You can program a pause as follows:

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



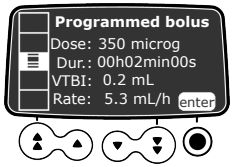
8. To restart the infusion before the end of the pause period, press twice ◉.

INFORMATION

- If you do not activate the "Start infusion at pause end" option, an audible alarm is generated at the end of the pause. The infusion must be started manually to continue the infusion.
- The "Start infusion at pause end" option is not available in TCI Mode. Pause feature is not available during an infusion in TCI Mode.

8.9 Programmed Bolus

Symbol	
Procedure	Programming a bolus



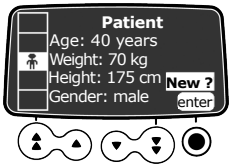
To program a bolus, see *Programmed Bolus* on page 59.

8.10 Patient

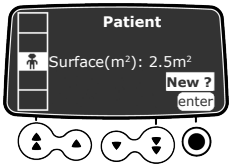
Symbol	
Procedure	Changing a patient's weight or body surface area

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.



Weight



Body Surface Area

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

1. Press MENU.

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

8.11 Day/Night Mode

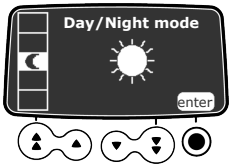
Symbol	
Procedure	Switching between day mode and night mode

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

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

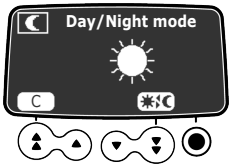
Depending on your pump configuration, the switch between day and night mode may be managed either through this menu (manual mode), or according to pre- defined settings (auto mode). For more information, refer to the technical manual.

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



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

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

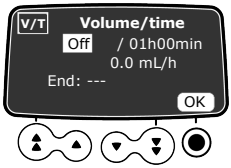


4. Press to activate night mode (the screen displays) or day mode (the screen displays).

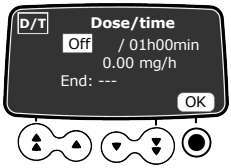
5. Press ◉ to select **OK** in order to confirm.

8.12 Volume/Time & Dose/Time

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



Volume/Time

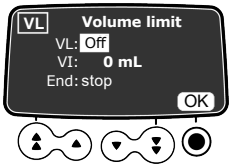


Dose/Time

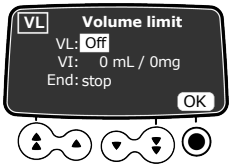
1. Press MENU.
2. Press the arrow keys to select V/T or D/T.
3. Press ◉ to select **enter**.
   For more information on how to program a Volume/Time or Dose/Time infusion, see *Volume/Time & Dose/Time* on page 63.

8.13 Volume Limit

Symbol	VL
Procedure	Programming a Volume Limit infusion



Volume/Time

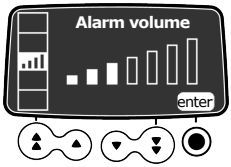


Dose/Time

1. Press MENU.
2. Press the arrow keys to select VL.
3. Press ◉ to select **enter**.
   For more information on how to program a Volume Limit infusion, see *Volume Limit* on page 64.

8.14 Alarm Volume

Symbol	
Procedure	Adjusting the alarm volume



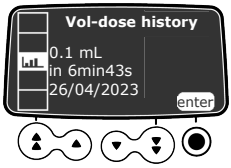
You can adjust the alarm volume as follows:

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

8.15 Volume-Dose History

Symbol	
Procedure	Viewing the infusion history

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



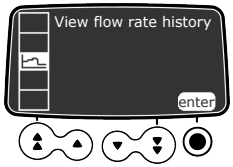
You can view the infusion history as follows:

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

8.16 View Flow Rate History

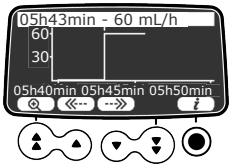
Symbol	
Procedure	Viewing flow rate history

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



4. Press the arrow keys to select «--- and ---» in order to browse the events.
5. Press ◉ to select i in order to view information about the selected event.

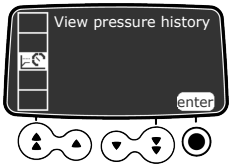
INFORMATION

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

8.17 View Pressure History

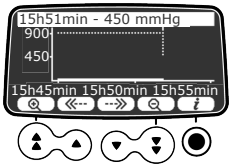
Symbol	
Procedure	Viewing pressure history

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



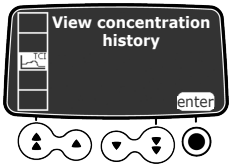
4. Press the arrow keys to select «-- and --» in order to browse the events.
5. Press ◉ to select *i* in order to view information about the selected event.

INFORMATION

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

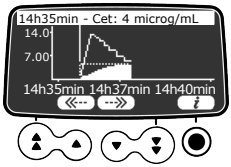
8.18 Concentration History

Symbol	TCI
Procedure	Viewing concentration history



You can view concentration history as follows:

1. Press MENU.
2. Press the arrow keys to select TCI.
3. Press ◉ to select **enter**.
   The following information is displayed: an event marker (cursor), the event details (time and target concentration), the target concentration (dotted line), the plasma concentration (Cp) evolution (solid line), the effect-site concentration (Ce) evolution (solid form).



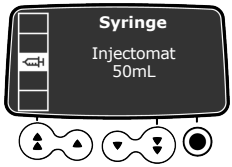
4. Press the arrow keys to select «-- and --» in order to browse the events.
5. Press ◉ to select i in order to view information about the selected event.

INFORMATION

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

8.19 Syringe

Symbol	
Procedure	Displaying on-pump syringe information



You can display on-pump syringe information as follows:

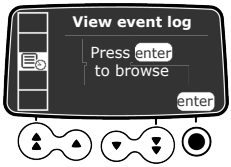
1. Press MENU.
2. Press the arrow keys to select .
   The following information is displayed: syringe capacity, syringe brand / name.

8.20 View Event Log

Symbol	
Procedure	Viewing the event log

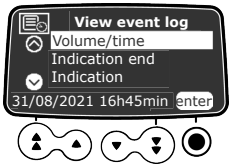
The event log displays details of the last events that occurred on the pump. Events are stored in the log even after the pump is powered off and on again. The log can store up to 1500 events. Older events are overwritten.

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



You can view the event log as follows:

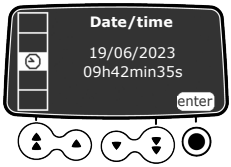
1. Press MENU.
2. Press the arrow keys to select .
3. Press ◉ to select **enter** in order to browse the events.



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

8.21 Date / Time

Symbol	
Procedure	Setting the date and time



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

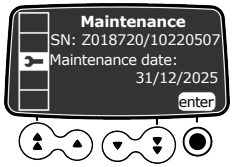
You can set the pump date and time as follows:

1. Press MENU.

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

8.22 Maintenance

Symbol	🔧
Procedure	Displaying maintenance information

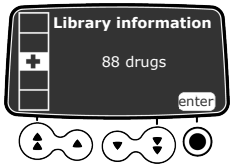


You can display maintenance information as follows:

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

8.23 Library Information

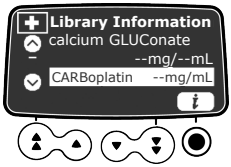
Symbol	✚
Procedure	Displaying drug library information



You can display drug library information as follows:

1. Press MENU.
2. Press the arrow keys to select ✚.
   The number of drugs contained in the drug library is displayed.

3. Press ◉ to select **enter**.
   All the drugs contained in the drug library are displayed.

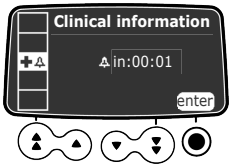


4. Press the arrow keys to select a drug.
5. Press ◉ to select (i) to view information on the selected drug.

8.24 Clinical Information

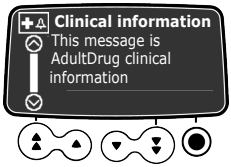
Symbol	✚🔔
Procedure	Viewing remaining time before clinical information display

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



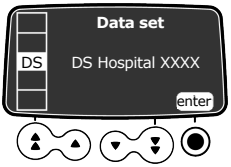
You can view the remaining time before clinical information display as follows:

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



8.25 Data Set

Symbol	DS
Procedure	Displaying active data set information



You can display active data set information as follows:

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



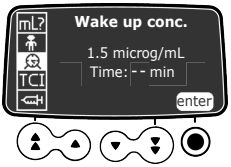
8.26 Wake up Concentration

Symbol	
Procedure	Modifying the wake up concentration / Viewing the wake up duration

Wake up concentration is the estimated drug concentration at which the patient will wake up.

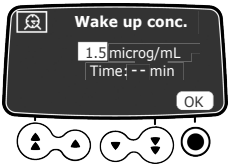
Wake up duration is the time left to reach the wake up concentration.

The pump automatically calculates the wake up duration, in accordance with the information entered in this menu. The wake up duration is only displayed if relevant.



You can modify the wake up concentration as follows:

1. Press MENU.
2. Press the arrow keys to select .
3. Press the arrow keys to modify the wake up concentration.
   The wake up duration is automatically calculated.

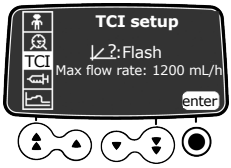


4. Press ◉ to select **OK** in order to confirm.

8.27 TCI Setup

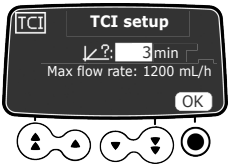
Symbol	TCI
Procedure	Modifying or viewing the induction time

You can modify the induction time before the infusion start (plasma mode only). Once the infusion has started, you can only display the programmed induction time.



You can modify the induction time as follows:

1. Press MENU.
2. Press the arrow keys to select TCI.



3. Press the arrow keys to modify the induction time.
4. Press ◉ to select **OK** in order to confirm.

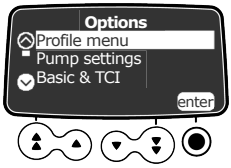
9 Options

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

9.1 Accessing the Pump Configuration Options

Display the pump configuration options as follows:

➪ Pump off, simultaneously press (ON/OFF) + [MENU].
The **Options** screen is displayed. See *Pump Settings* on page 90 for details on the **Pump settings** options. For information on other options, refer to the Technical manual.



9.2 Commands

Operation	Key
Option selection	▲▲ ▲ ▼ ▼▼
Confirm	◉ (corresponds to **enter** on the screen)
Select ☑ / Deselect ☐	▲▲

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

9.3 Option Groups

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

Option	Access Code?	Description Location
Profile menu	Yes	Technical Manual
Pump settings	Yes Default code: 0100	*Pump Settings* on page 90.
Basic & TCI Configuration	Yes	Technical Manual
Maintenance	Yes	Technical Manual

INFORMATION
If the wrong access code is entered, `error` is displayed.
The Default access code may be modified using Agilia Partner Maintenance Software.

9.4 Pump Settings

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

Function	Choice	Default Pump Setting
`[User 1]: Screen option`	■ V/T D/T programming in view list	Enabled
	■ Enable/Disable framing of editable values	Enabled
`[User 2]: Menu items`	■ Maintenance: display or hide maintenance menu	Disabled
	■ Date / Time: display or hide date/time menu	Disabled
`[User 3]: Contrast`	■ Adjustment of screen contrast using the fast increment and decrement keys	Medium level
`[User 7]: Date/Time`	■ Date selection: dd/mm/yyyy	Production plant date and time
	■ Time selection: __ h __min	
`[User 8]: Language`	■ A scrolling list with all available languages	Official language of the target country
`[User 14]: Wi-Fi module`	■ Enable/Disable the Wi-Fi module	Enabled
`[Par 5]: Syringe selection`	■ Enable/Disable selected syringe confirmation screen	Enabled
`[Par 6]: Syringes`	■ Checkbox list with the syringes sizes and the names of available syringes	Specific to product code
`[Par 13]: AC power disconnection alert`	■ Enable/Disable `AC power disconnection` message and `Device operating on battery` message at power on	Enabled
`[Par 28]: Automatic power on with disengagement`	■ Enable/Disable automatic device powering on at disengagement lever push	Disabled
`[Par 35]: Dose display format`	■ Enable/Disable display of the decimal "0" after a dose value	Remove trailing 0 (Disabled) / Remove trailing 0 during programming (Disabled)
`[Par 37]: Alarm system`	■ Enable/Disable preventive silence for alarm system	Enabled

Function	Choice	Default Pump Setting
[Par 38]: Keypad unlock code	■ Set or disable keypad unlock code (4-digit). Disable value: 0000	0000 (Disabled)

10 Data Communication

10.1 Overview

Important cybersecurity recommendations

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

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

Cable Communication	Wi-Fi Communication
Connection of 1 pump to a PC for the following purposes: ■ Data set upload (via Drug Library Software) ■ Maintenance (via Agilia Partner) 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 Fresenius Kabi systems are compatible with the facilty information system. For more information, contact your technical services representative.
- Before connecting the pump to a hospital information system, ask your IT or biomedical department to configure the device.

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

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

10.2 Communication via Agilia Cables

10.2.1 Data Communication Cables

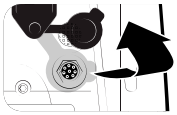
INFORMATION

- Only use recommended Agilia cables.
- All connections and disconnections must be performed by qualified and appropriately trained staff.

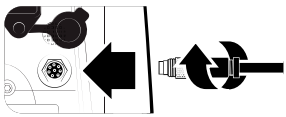
- All IT devices (including computers, hubs and switches) inside the patient area (< 1.5 m) must comply with IEC/EN 60601-1 (leakage current).
- IT devices connected outside the patient area (> 1.5 m) must be at least IEC/EN 60950 compliant.

10.2.2 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.

10.3 Communication via Wi-Fi

The Wi-Fi option allows the pump to connect to a hospital information system without cables. To know if your pump is equipped with a Wi-Fi module, check for the presence of the Wi-Fi logo on the pump's keypad.

See *Keypad Description* on page 20.

Wi-Fi pump

Non Wi-Fi pump

To activate or deactivate the Wi-Fi module, see *Pump Settings* on page 90. For more information on the Wi-Fi module, refer to the technical manual.

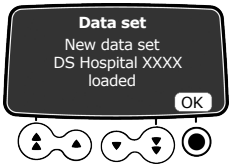
Wi-Fi pumps can be configured with Wi-Fi module enabled or disabled.

10.4 Data Set Upload

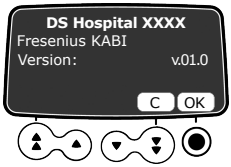
A new data set may be uploaded to the pump while it is infusing. The new data set will be installed at the next pump start-up.

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

1. Power on the pump.



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



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

INFORMATION
It is the hospital's responsibility to define a data set and upload it to the Server Software for distribution to the device.

11 User Test

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

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

12 Alarms and Safety Features

12.1 Introduction

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

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

CAUTION

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

12.2 Alarm Descriptions

There are several different levels of alarm priorities:

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

Alarm Priority	Required Operator Response	Description
High (!!!)	Immediate response	■ The infusion stops. ■ The infusion indicator lights flash **red**. ■ The pump emits audible alarm signals. ■ An alarm description is displayed on the pump screen. ■ Depending on the alarm, the  key silences the alarm for no time limit or for a defined duration. For detailed description of each alarm, see *List of Alarms* on page 97.
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 no time limit or for a defined duration. For detailed description of each alarm, see *List of Alarms* on page 97.

Alarm Priority	Required Operator Response	Description
Low (!)	Awareness	■ The infusion continues. ■ The infusion indicator lights (LEDs) **yellow** are ON. ■ The pump emits audible alarm signals. ■ Depending on the alarm, the key silences the alarm for no time limit or for a defined duration. For detailed description of each alarm, see *List of Alarms* on page 97.
Information Signals	Awareness	■ The infusion continues. ■ An information message is displayed on the pump screen. ■ For detailed description of each alarm, see *List of Alarms* on page 97.

12.3 General Remarks

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

12.4 List of Alarms

12.4.1 Syringe Alarms

Message	Priority	Stops Infusion?	Problem / Resolution
`Syringe installation !!!`	High (!!!)	Yes	The syringe is not installed correctly (plunger driver, syringe barrel clasp or flange detection). ☞ Check the syringe installation. **NOTE:** the key silences the alarm for 2 minutes.

Message	Priority	Stops Infusion?	Problem / Resolution
Plunger head alarm !!!	High (!!!)	Yes	The plunger head is missing or incorrectly inserted. ☞ Check the syringe installation. **NOTE:** the  key silences the alarm for 2 minutes.
Disengagement mechanism !!!	High (!!!)	Yes	Disengaged mechanism. **NOTE:** ☞ Check the syringe installation. **NOTE:** the  key silences the alarm for 2 minutes.
Remove completely syringe !	Low (!)	No	☞ Remove and reinstall the syringe. **NOTE:** the  key silences the alarm for 2 minutes.

12.4.2 Volume Limit Alarms

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

12.4.3 Volume/Time & Dose/Time Alarms

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

12.4.4 Infusion Alarms

Message	Priority	Stops Infusion?	Problem / Resolution
`End of infusion !!!`	High (!!!)	Yes	The infusion is completed (simple rate). **NOTE:** the key silences the alarm for 2 minutes.
`Near end of infusion !!`	Medium (!!)	No	The time remaining is less than the defined time duration (adjustable between 1 and 30 minutes), and the remaining volume of fluid in the syringe has dropped to less than 10 % of the syringe capacity. **NOTE:** the key silences the alarm for no time limit.
`Check settings !!`	Medium (!!)	No	An infusion value has been modified using the keys, but has not been confirmed. ☞ Check this value and press **OK** to confirm. **NOTE:** the key silences the alarm for 2 minutes.

Message	Priority	Stops Infusion?	Problem / Resolution
Waiting settings !!	Medium (!!)	No	A value must be entered. ☞ Enter a value and press **OK** to confirm. **NOTE:** the  key silences the alarm for 2 minutes.
Waiting start !!	Medium (!!)	No	The infusion settings have been entered, but the infusion has not been started with **start** key. ☞ Check the infusion settings, ☞ Press **start** to start the infusion. **NOTE:** the  key silences the alarm for 2 minutes.
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.
High concentration	Information signal	No	The upper soft limit for concentration is exceeded, according to the drug settings defined in the drug library.
Low concentration	Information signal	No	The lower soft limit for concentration 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.
Insufficient dose	Information signal	No	In TCI mode, the remaining volume/dose in the syringe is insufficient to reach the target.

12.4.5 Pressure Alarms

Message	Priority	Stops Infusion?	Problem / Resolution
Occlusion alarm !!!	High (!!!)	Yes	The pressure in the infusion line has reached the threshold level. ☞ Check whether the infusion line is occluded. If necessary, readjust the pressure threshold in relation to the flow rate. See *Pressure* on page 70. **NOTE:** the  key silences the alarm for 2 minutes.

Message	Priority	Stops Infusion?	Problem / Resolution
`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 250 mmHg) or ■ 50 mmHg / 5 kPa / 1 PSI below the programmed threshold (over 250 mmHg) ☞ Check the infusion line. ☞ Set the correct pressure threshold. **NOTE:** the  key silences the alarm for no time limit.
`Pressure increase !`	Low (!)	No	The pressure is increasing in the infusion line. ☞ Check for occlusions in the infusion line. **NOTE:** the  key acknowledges the alarm.
`Drop in pressure !`	Low (!)	No	The pressure is decreasing in the infusion line. ☞ Check the downstream Luer lock connection and the integrity of the entire line. **NOTE:** the  key silences the alarm for no time limit.

12.4.6 Battery Alarms

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

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

12.4.7 Power Alarms

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

12.4.8 Keypad Alarms

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

12.4.9 Technical Error Alarms

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

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

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



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

12.5 Audio Only Information Signals

Type	Comment	Stops Infusion?	Activation
Switch off	Beep until key is released	No	Beep starts when action is not allowed
End of induction dose	3 beeps	No	At the end of the induction dose
End of programmed bolus	3 beeps	No	At the end of a programmed bolus

Type	Comment	Stops Infusion?	Activation
Start infusion at the end of pause	3 beeps	N/A	At the end of a pause, when the infusion automatically starts
End of pause	4 beeps	N/A	At the end of pause - repeated
AC power connection	1 beep	No	When power is connected
Forbidden key	1 beep	No	Repeated until key is released
Key beep	1 beep	No	For each key pressed
Other non validation beep	1 beep	No	For each key pressed
Direct bolus	1 beep	No	Repeated for each mL infused
Syringe prime	Beep until key is depressed	N/A	When purge reached end after 5ml

13 Syringes

13.1 Syringe List

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

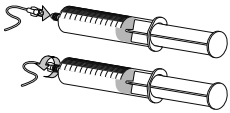
INFORMATION

- The Agilia SP TIVA pump offers a maximum 100 syringes of different types, brands and sizes. For a list of compatible syringes, and for ordering information, refer to the System Components booklet.
- The list of available syringes on your pump is accessible from the pump options.

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

13.2 Preparing a Syringe

1. Prepare the fluid to be infused according to your healthcare facility's protocol.
2. Select a syringe.
3. Check the syringe and access device integrity.
4. Connect the extension set to the syringe according to local practices.



5. If necessary, fill the syringe and check that it is watertight.
6. Manually prime the extension set according to your healthcare facility's protocol.
7. Confirm that there is no air in the syringe or in the extension set.

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

INFORMATION

- It is recommended to prime the set immediately before starting the infusion.

- Do not use in conjunction with positive pressure infusion devices that could generate back pressure higher than 2000 hPa (1500 mmHg): doing so will damage the administration set and the pump.
- Certain drugs may require specific extension sets.
- For infusions with TCI mode, it is recommended to use an extension set with a back check valve and a small dead volume.
- Connect the infusion line in accordance with procedures in your healthcare facility using good medical practices. It is recommended to use a Luer lock system to reduce the risk of disconnection, leakage, air-in-line, or contamination.
- Manually prime the syringe and extension set to remove all air, before connecting to the pump.

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

Precautions for the use of extension sets

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

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

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

13.3 Operations for Syringes

13.3.1 Removing a Syringe

1. Press STOP to stop the infusion.
2. Disconnect the patient.
3. Open the syringe barrel clasp.
4. Push the disengagement lever down and remove the syringe from its cradle.
5. Disconnect the syringe from its extension set.

6. Disconnect the extension set from the access device in accordance with healthcare facility protocol.

13.3.2 Changing a Syringe

1. Remove the syringe. See *Removing a Syringe* on page 106.
2. Prepare a new syringe and follow the steps described in the flowchart. See *Flowchart* on page 38.
3. After the new syringe is installed, acknowledge the "same therapy" screen (optional screen).

INFORMATION
Properly dispose of used syringes.

13.3.3 Syringe Replacement Interval

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

13.4 Gravity Infusion in Parallel with a Pump

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

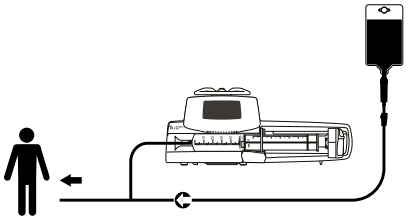


Figure 8: Gravity Infusion (in parallel with a pump)

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

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

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

14 Device Storage

14.1 Precautions for Storage

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

14.2 Storage and Transport Conditions

Observe the following conditions for storage and transport:

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

14.3 Preparing the Device for Storage

Prepare the device for storage as follows:

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

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

14.4 Using the Device After Storage

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

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

We recommend charging the battery for at least 6 hours.

We recommend that the "User test" is performed when the device is installed after storage, and before being used on a patient, see *User Test* on page 95.

15 Specifications

INFORMATION
The range of settings and default values described in this section correspond to the factory configuration.
Range of settings and default values may be adjusted in the pump options (Basic & TCI configuration).

15.1 Essential Features

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

Feature	Refer to
Flow Rate Accuracy	*Flow Rate Accuracy* on page 113. *Trumpet and Start-up Curves* on page 125.
Time to Detect Occlusion	*Occlusion Alarm Accuracy and Bolus Volume at Occlusion Release* on page 113.
Bolus Volume After Occlusion Release	*Occlusion Alarm Accuracy and Bolus Volume at Occlusion Release* on page 113.
Management of High-priority Alarms	*Alarms and Safety Features* on page 96.

15.2 Flow Rate

	Format	Syringe					Minimum Increment
		50 mL/ 60 mL	30 mL	20 mL	10 mL	5mL	
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*	mL/h	50 ➔ 1200	50 ➔ 600	50 ➔ 600	50 ➔ 350	50 ➔ 250	50
Priming	mL/h	1200	600	600	350	250	N/A
Programmed Bolus	mL/h	0.1 ➔ 1200	0.1 ➔ 600	0.1 ➔ 600	0.1 ➔ 350	0.1 ➔ 250	0.01 (0.10 ➔ 9.99) 0.1 (10.0 ➔ 99.9) 1 (100 ➔ 1200)
KVO**	mL/h	0.1 ➔ 5	0.1 ➔ 5	0.1 ➔ 5	0.1 ➔ 5	0.1 ➔ 5	0.01 (0.1 ➔ 5)
Induction 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)

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

** KVO defaut value = 1 mL/h.

15.3 Volume To Be Infused (VTBI)

	Format	Range of Settings	Default Value	Minimum Increment
Volume Limit	mL	0.1 ➔ 999	N/A	0.01 (0.01 ➔ 9.99) 0.1 (10.0 ➔ 99.9) 1 (100 ➔ 999)
Volume/Time	mL	0.1* ➔ 99.9*	0*	0.01 (0.1 ➔ 9.99) 0.1 (10.0 ➔ 99.9)
Direct Bolus	mL	0.1* ➔ 60**	N/A	N/A
Programmed Bolus	mL	0.1* ➔ 99.9*	0.1*	0.1
Loading Dose	mL	0.1* ➔ 99.9*	0.1*	0.1

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

** 60 mL with drug, 10 mL without drug

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

15.4 Dose To Be Infused (DTBI)

	Unit	Range of Settings	Default Value	Minimum Increment
Dose	All	0.01* ➔ 9999*	0*	0.01 (0.01 ➔ 9.99) 0.1 (10.0 ➔ 99.9) 1 (100 ➔ 9999)
Programmed Bolus	All	0.01* ➔ 9999*	0.01*	0.01 (0.01 ➔ 9.99) 0.1 (10.0 ➔ 99.9) 1 (100 ➔ 9999)
Induction Dose	All	0.01* ➔ 9999*	0.01*	0.01 (0.01 ➔ 9.99) 0.1 (10.0 ➔ 99.9) 1 (100 ➔ 9999)

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

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

15.5 Infusion Time

	Format	Range of Settings	Default Value	Minimum Increment
Infusion Time	__ h __min	00h01min ➔ 96h00min	N/A	00h01min
Programmed Bolus	__ h __min__s	00h00min01sec ➔ 24h00min00sec	N/A	00h00min01sec 00h00min00sec ➔ 00h59min59sec 00h01min00sec 1h00min00sec ➔ 24h00min00sec
Induction Dose	__ h __min__s	00h00min01sec ➔ 24h00min00sec	N/A	00h00min01sec 00h00min00sec ➔ 00h59min59sec 00h01min00sec 1h00min00sec ➔ 24h00min00sec
KVO Silence Alarm Duration	__ h __min	00h01min ➔ 12h00min	01h00min*	N/A
Pause	__ h __min	00h01min ➔ 24h00min	N/A	00h01min

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

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

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

15.6 Concentration

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

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

15.7 Patient Data

	Format	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	m²	0.05 ➔ 4.5	N/A	0.01

15.8 Pressure Management

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

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

* These values are in mmHg

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

15.9 Accuracy

WARNING
Accuracy (flow rate, time, volume infused, pressure) can be influenced by syringe model, syringe configuration, extension set configuration, fluid viscosity, and fluid temperature. Accuracy may be reduced when the infusion flow rate is below 1 mL/h.

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

15.9.1 Flow Rate Accuracy

	Accuracy
Flow Rate	± 3%

15.9.2 Effects of Pressure Variations on Accuracy

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

15.9.3 Occlusion Alarm Accuracy and Bolus Volume at Occlusion Release

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

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

** Syringe: BD Precise

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

* Test condition: Back pressure: 0 mmHg

** Syringe: BD Precise 50 mL

NOTE:

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

15.9.4 Volume Accuracy

	Accuracy
Direct Bolus*	≤ 10 mL: ± 0.2 mL > 10 mL: ± 3%
Programmed Bolus*	

* Test condition: Back pressure: 0 mmHg

15.9.5 Pressure Accuracy

	Accuracy
Pressure	≤ 500 mmHg: ± 75 mmHg > 500 mmHg: ± 15%

15.10 Units and Conversion Rules

15.10.1 Concentration Units

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

15.10.2 Dose Units

	Units
Dose Units	nanog/h, nanog/kg/min, nanog/kg/h
	microg/min, microg/h, microg/kg/min, microg/kg/h
	mg/min, mg/h, mg/24h, mg/kg/min, mg/kg/h, mg/kg/24h, mg/m²/h, mg/m²/24h
	g/h, g/kg/min, g/kg/h, g/kg/24h
	mmol/h, mmol/kg/h, mmol/kg/24h
	mUnit/min, mUnit/kg/min, mUnit/kg/h
	Unit/min, Unit/h, Unit/kg/min, Unit/kg/h
	kcal/h, kcal/24h, kcal/kg/h
	mEq/min, mEq/h, mEq/kg/min, mEq/kg/h
	mL/kg/min, mL/kg/h, mL/kg/24h

15.10.3 Conversion Rules

Conversion Rules	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	
	$mL/h = \frac{\text{unit/kg/h (dose) x kg (weight)}}{\text{unit/mL (concentration)}}$	Conversion of a dose including the unit/kg into volume flow rate (mL/h)
	$mL/h = \frac{\text{unit/m}^2\text{/h (dose) x m}^2\text{(body surface area)}}{\text{unit/mL (concentration)}}$	Conversion of a dose including the unit/m² into volume flow rate (mL/h)
	$mL/h = \frac{\text{unit/h (dose)}}{\text{unit/mL (concentration)}}$	Expression of a volumetric flow rate
	$mL = \frac{\text{unit/kg (dose) x kg (weight)}}{\text{unit/mL (concentration)}}$	Conversion of a dose including the unit/kg into volume (mL)
	$mL = \frac{\text{unit/m}^2\text{(dose) x m}^2\text{(body surface area)}}{\text{unit/mL (concentration)}}$	Conversion of a dose including the unit/m² into volume (mL)

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

16 Cleaning and Disinfecting

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

WARNING

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

INFORMATION

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

Quick Cleaning Only

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

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

1. Check that the keypad is locked in order to avoid unintended modification of the infusion parameters. Do not move the pump.
2. Use ready-to-use wipes to wipe down all exposed surfaces of the pump.
3. At the end of the infusion, perform the complete cleaning protocol, see *Cleaning Instructions* on page 118.

16.1 When to Clean and Disinfect the Pump

Thoroughly clean and disinfect the pump in the following cases:

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

16.2 Recommended and Prohibited Agents

CAUTION

Recommended agents

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

CAUTION
The following cleaning and disinfecting agents are prohibited:

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

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

16.3 Instructions for Cleaning and Disinfecting

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

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

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

Only trained staff can clean and disinfect the pump.

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

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

16.3.1 Cleaning Instructions

Prerequisites

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

Protocol

1. Place the pump on a clean surface or disposable underlay.
2. Use a ready-to-use wipe to remove any major grime.
3. Thoroughly wipe down all exposed surfaces (housing, keyboard, syringe barrel area, syringe guard, plunger driver, disengagement lever, syringe barrel clasp, etc.) of the pump, from top to bottom. You can use the silver handle to lift and move the pump.
   - When wiping down the sides, avoid wetting the connector sockets.
   - Do not allow liquids to run, leak, or drip into the pump housing.

4. Make sure the pump remains damp for at least 1 minute.
5. Set down the pump, and wipe down the silver handle, the attachment lock knob, the screw clamp and the release button.
6. Use a fresh ready-to-use wipe to gently wipe down the back side of the syringe barrel clasp and all exposed surfaces in the syringe barrel area.
7. Make sure the pump remains damp for at least 1 minute to dissolve all organic matter.
8. Use a swab to gently scrub the exposed surfaces of the pump. Be sure to scrub along the seams and edges of the control panel, and the narrow or hard-to-reach areas.
9. Wipe down the power cord and any pump accessories.
10. Allow the pump to dry completely at room temperature.

16.3.2 Disinfecting Instructions

Prerequisites

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

Protocol

1. Place the previously cleaned pump on a clean surface or disposable underlay.
2. Use a ready-to-use wipe to wipe down all exposed surfaces of the pump, making sure to cover all cracks, crevices, and hard-to-reach areas. You can use the silver handle to lift and move the pump.
   - When wiping down the sides, avoid wetting the connector sockets.
   - Do not allow liquids to run, leak, or drip into the pump housing.
3. Set down the pump, and wipe down the silver handle, the attachment lock knob, the screw clamp and the release button.
4. Use a fresh ready-to-use wipe to gently wipe down the back side of the syringe barrel clasp and all exposed surfaces in the syringe barrel area.
5. Using a fresh ready-to-use wipe, repeat steps 2 to 4.
6. Leave the disinfecting agent on the pump for at least 3 minutes.
7. Wipe down the power cord and any pump accessories.
8. Allow the pump to dry completely at room temperature.

17 Power Management

17.1 AC Power Supply Precautions

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

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

CAUTION

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

17.2 Battery Precautions

The device uses a Lithium-ion rechargeable battery.

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

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

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

17.3 Battery Operating Mode

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

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

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

18 Technical Characteristics

18.1 Power Supply

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

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

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

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

18.2 Battery

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

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

The device is equipped with one of these batteries:

- 7.2 V 2.2 Ah
- 7.34 V 2.75 Ah

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

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

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

✓ = Wi-Fi enabled

x = Wi-Fi disabled or not used

18.3 Power Consumption

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

18.4 Communication Port

The connector located at the back of the device allows data communication with a PC.

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

18.5 Infrared Communication

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

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

18.6 Sound Levels

18.6.1 Operating Pump Sound Levels (without alarms)

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

NOTE: These values are provided for information purposes only.

18.6.2 Alarms Sound Levels

Alarm Priority	Range for sound alarm volume adjusted at minimum (see *Alarm Volume* on page 80)			Range for sound alarm volume adjusted at maximum (see *Alarm Volume* on page 80)		
	Range values		Measured values	Range values		Measured values
High	55	70	63.7	70	80	75.4
Medium	54	64	58.8	64	75	70.2
Low	52	62	57.3	59	70	64.5

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

18.7 Compliance

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

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

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

18.8 Dimensions and Weight

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

18.9 Trumpet and Start-up Curves

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

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

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

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

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

Syringe used: BD Precise 50 mL

Fluid used: distilled water

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

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

18.9.1 Flow Rate: 1 mL/h

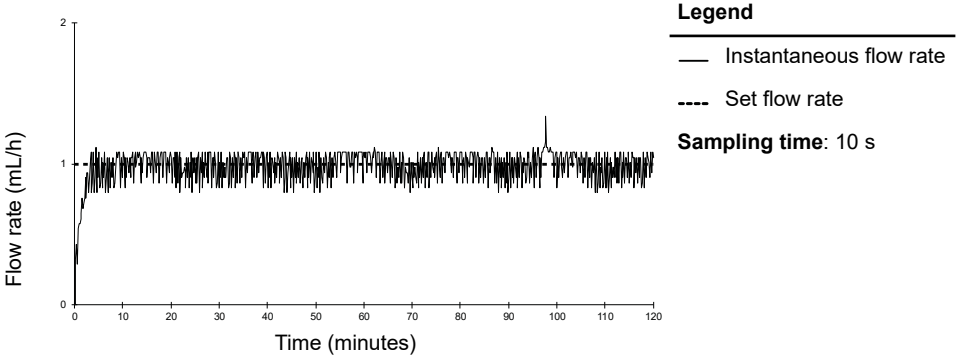
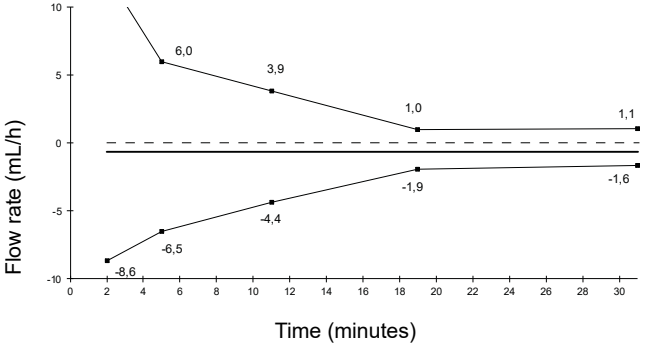


Figure 9: Start-up and instantaneous flow rate (1 mL/h over first 2 hours on 96 hours)



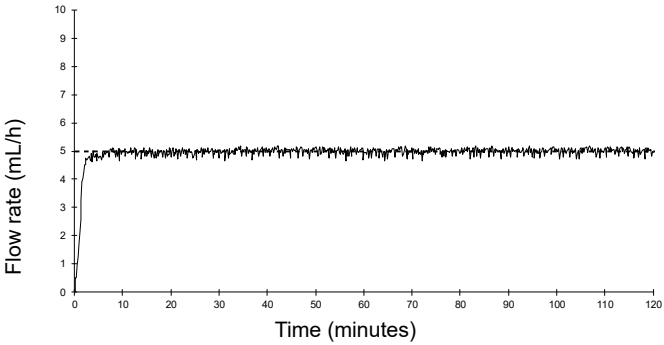
Legend

- Measured variance from flow rate
- Error
- Flow rate

Sampling time: 10 s

Figure 10: Trumpet curves for 2, 5, 11, 19, 31 minutes observation windows (1 mL/h over first 2 hours on 96 hours)

18.9.2 Flow Rate: 5 mL/h



Legend

- Instantaneous flow rate
- Set flow rate

Sampling time: 10 s

Figure 11: Start-up and instantaneous flow rate (5 mL/h over first 2 hours on 96 hours)

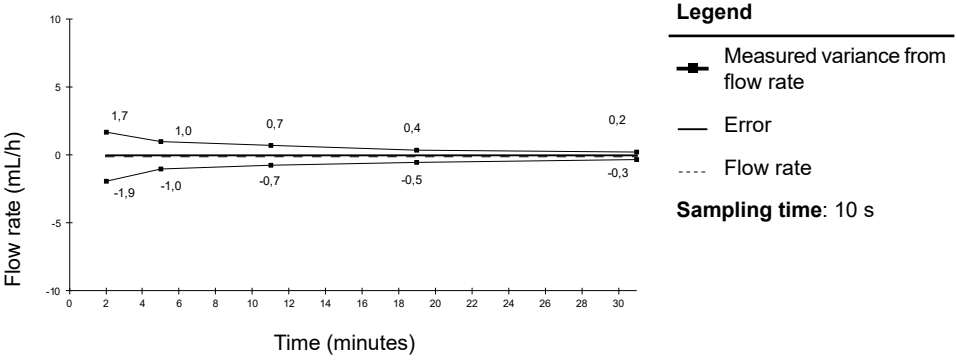


Figure 12: Trumpet curves for 2, 5, 11, 19, 31 minutes observation windows (5 mL/h over first 2 hours on 96 hours)

19 Wi-Fi

19.1 General Information

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

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

INFORMATION
For more information on differentiation between WiFi and non WiFi pumps, see *Communication via Wi-Fi* on page 93.

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

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

Agilia infusion pumps contain transmitter with the following IDs:

- FCC ID: Z64-CC3235MOD
- IC ID: 451I-CC3235MOD

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

Agilia infusion pumps support a hidden network.

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

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

19.2 Specifications

19.2.1 Technical Specifications

	Description
Technology	IEEE 802.11 a/b/g/n

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

19.2.2 Electromagnetic Compatibility

For information on electromagnetic compatibilty, see *Guidance and Manufacturer's Declaration on EMC* on page 134.

19.2.2.1 USA - FCC Notice

The users manual or instruction manual for an intentional or unintentional radiator shall caution the user that changes or modifications not expressely approved by the party responsible for compliance could void the user's authority to operate the equipment.

19.2.2.2 Europe - RED

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

19.2.3 Protocols and Standards

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

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

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

20 Troubleshooting

Issue	Recommended Actions
The pump is unstable when mounted.	■ Check that the rotating pole clamp is fastened.
The pump is damaged, or you notice something abnormal (unusual noise, abnormal heat or smoke).	■ Remove the power cord. ■ Contact your biomedical department or your Fresenius Kabi sales representative immediately.
The pump has been dropped or was subjected to a force that may have produced internal damage.	■ Do not use the pump. ■ Contact your biomedical department or your Fresenius Kabi sales representative.
The pump cannot be installed or removed from the Link Agilia or Agilia Link or Link+ Agilia device.	■ Check the rotating pole clamp position. ■ Contact your biomedical department or your Fresenius Kabi sales representative.
The pump does not start after pressing ON OFF.	■ Connect the pump to the AC power supply to see if the battery is fully discharged. ■ Contact your biomedical department or your Fresenius Kabi sales representative.
Data communication cables cannot be connected or removed from the pump.	■ Check the cable connector. ■ Check the pump connector. ■ Contact your biomedical department or your Fresenius Kabi sales representative.
Flow rate variance is higher than flow rate accuracy.	■ Check the infusion line configuration. ■ Check the fluid viscosity. ■ Check that the fluid temperature is within the recommended range. ■ Contact your biomedical department or your Fresenius Kabi sales representative.
Keypad problem (keys, LEDs).	■ Check the general condition of the keypad. ■ Check the contrast. ■ Contact your biomedical department or your Fresenius Kabi sales representative.
The power supply indicator does not light up.	■ Connect the pump to the AC power supply. ■ Contact your biomedical department or your Fresenius Kabi sales representative.
The pump powers off on its own.	■ Connect the pump to the AC power supply. ■ Contact your biomedical department or your Fresenius Kabi sales representative.
The battery alarm is ON even though the pump has been correctly charged.	■ Check the AC power voltage. ■ Contact your biomedical department or your Fresenius Kabi sales representative.

Issue	Recommended Actions
The pump powers off when it is disconnected from the AC power supply.	■ The battery is completely discharged: charge the battery. ■ Contact your biomedical department or your Fresenius Kabi sales representative.
Wi-Fi communication error.	■ Contact your IT or biomedical department, or your Fresenius Kabi sales representative.
At start-up, the pump displays: "Software is upgrading...".	■ Connect the pump to the AC power supply. Then, wait few minutes without touching the keypad until the message disappears and the pump starts as usual. ■ Contact your biomedical department or your Fresenius Kabi sales representative.

21 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.

22 Warranty

22.1 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.

22.2 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.

22.3 Warranty Conditions for Accessories

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

23 Guidance and Manufacturer's Declaration on EMC

23.1 Electromagnetic Compatibility



DANGER
Do not use Agilia pumps in an MRI environment unless in an Agilia MRI Guard.



WARNING

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

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

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

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

23.2 Electrostatic Discharge (ESD)



CAUTION

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

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

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

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

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

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

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

23.3 Electromagnetic Compatibility and Interference Guidance

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

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

WARNING

- Use of the Agilia pump adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.
- Maintain a minimum distance of 30 cm between Agilia pumps and any portable radiofrequency (such as smartphones, antennas…). For RTLS tags use, see *Real Time Location System Tag* on page 147. Electromagnetic perturbations may damage the Agilia devices and alter their performance if this distance is not maintained.
- Maintain a minimum distance of 30 cm between Agilia pumps and:
  - Electro-surgical equipment,
  - Electro-encephalography (EEG) devices,
  - Electro-cardiography (ECG) devices.

  Electromagnetic perturbations may damage the Agilia devices and alter their performance if this distance is not maintained.
- Do not expose the Agilia pumps directly to ultrasonic devices. Mechanical perturbations may damage the devices and alter their performance it the distance is not maintained.
- Use of accessories, transducers and cables other than those specified or provided by the manufacturer of the Agilia pump could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.
- Prolonged exposure to X-ray environments can damage the electronic components of the device and influence the flow rate accuracy. For a safe usage, we recommend to:
  - always put the device at the maximum distance from the patient and the source,
  - limit the presence of the device in such environments.

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

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

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

23.4 EMC and essential performances

In the case of electromagnetic disturbances, if the essential performance, *Section 15.1, page 127*, is lost or degraded, the consequences for the patient are as follows: over-delivery, under-delivery, delay of therapy, undetected air infused to patient, traumatic injuries, exsanguination.

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



WARNING

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

Emission Test	Compliance Obtained by the Device	Electromagnetic Environment - Guidance
RF emissions CISPR 11	Group 1	The Agilia pump only uses RF energy for its internal operation. Its RF emissions are therefore very low and are not likely to cause any interference in nearby electronic equipment.

Emission Test	Compliance Obtained by the Device	Electromagnetic Environment - Guidance
RF emissions CISPR 11	Class B	The Agilia pump is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC61000-3-2	Class A	
Voltage fluctuations Flicker emissions IEC 61000-3-3	Compliant	
Conducted emissions 150 kHz - 108 Mhz CISPR25	Class 5	The Agilia pump is suitable for use in automotive environments.
Radiated emissions 150 kHz - 2.5 Ghz CISPR25	Class 3	

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

WARNING

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

Immunity Test	IEC 60601-1-2 Ed3 - - - - - - - - - IEC 60601-2-24 Test Level	Compliance Level Obtained by the Device	Electromagnetic Environment - Guidance
Electrostatic Discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air - - - - - - - - - ± 8 kV contact ± 15 kV air	± 8 kV contact ± 15 kV air	Floor coverings made from wood, tiles and concrete, with relative humidity level at least 30%, make it possible to guarantee the necessary level of conformity. If it is not possible to guarantee this environment, additional precautions must be taken, such as: use of anti-static equipment, preliminary user discharge and the wearing of antistatic clothing.
Electrical fast Transient / burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input output lines	± 2 kV for power supply lines ± 1 kV for input output lines	AC power quality should be that of a typical commercial or healthcare facility environment.

Immunity Test	IEC 60601-1-2 Ed3 - - - - - - - - - IEC 60601-2-24 Test Level	Compliance Level Obtained by the Device	Electromagnetic Environment - Guidance
Surge IEC 61000-4-5	± 1 kV differential mode ± 2 kV common mode	± 1 kV differential mode ± 2 kV common mode	AC power quality should be that of a typical commercial or healthcare facility environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	< 5% Ut (> 95% dip in Ut) for 0.5 cycles	< 5% Ut (> 95% dip in Ut) for 0.5 cycles	AC power quality should be that of a typical commercial or healthcare facility environment. For short and long interruptions (< than battery life) of AC power, the internal battery provides continuity of service.
	40% Ut (60% dip in Ut) for 5 cycles	40% Ut (60% dip in Ut) for 5 cycles	
	70% Ut (30% dip in Ut) for 25 cycles	70% Ut (30% dip in Ut) for 25 cycles	
	< 5% Ut (> 95% dip in Ut) for 5 s	< 5% Ut (> 95% dip in Ut) for 5 s	
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m - - - - - - - - - 400 A/m	400 A/m	If necessary, the power of the magnetic field should be measured in the intended installation location to ensure that it is lower than compliance level. If the measured field in the location where the Agilia pump is used exceeds the applicable magnetic field compliance level above, observe the Agilia pump to verify that it is operating normally. If you notice abnormal performance, additional measures may be necessary, such as reorienting or relocating the Agilia pump, or installing magnetic shielding.

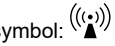
NOTE: "Ut" is the AC Power voltage prior to applying the test level.

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

WARNING

- The Agilia pump and its accessories are intended to be used in the electromagnetic environments specified below.

- The customer or the user of the Agilia pump should ensure that it is used in such environments.

Immunity Test	IEC 60601-1-2 Ed3 --------- IEC 60601-2-24 Test Level	Compliance Level Obtained by the Device	Electromagnetic Environment - Guidance
			Portable and mobile RF communication equipment should be used no closer to any part of the Agilia pump (including cables), than the recommended separation distance calculated from the transmitter frequency equation.
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz --------- Not applicable	3 Vrms	Recommended separation distance: $D = 0.35 \sqrt{P}$, for a frequency of 150 kHz to 80 MHz
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz --------- 10 V/m 80 MHz to 2.5 GHz	10 V/m	$D = 0.35 \sqrt{P}$, for a frequency of 80 MHz to 800 MHz $D = 0.7 \sqrt{P}$, for a frequency of 800 MHz to 2.5 GHz P is the maximum output power rating of the transmitter in Watts (W) according to the transmitter manufacturer, and D is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey (a), should be less than compliance level (b). Interference may occur in the vicinity of equipment marked with the following symbol: 

NOTE:

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

- (b) Over the frequency range of 150 kHz to 80 MHz, field strengths should be less than 10 V/m.

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

INFORMATION

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

Rated Maximum Output Power of Transmitter (W)	Separation Distance According to Transmitter Frequency in Meters (m) IEC 60601-1-2 Ed3		
	150 kHz to 80 MHz $D = 0.35 \sqrt{P}$	80 MHz to 800 MHz $D = 0.35 \sqrt{P}$	800 MHz to 2.5 GHz $D = 0.7 \sqrt{P}$
0.01	0.04	0.04	0.07
0.1	0.11	0.11	0.22
1	0.3	0.3	0.7
10	1.1	1.1	2.2
100	3.5	3.5	7

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

INFORMATION

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

23.4.5 EMC test deviations and supplementary tests

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

Immunity test	IEC 60601-1-2 IEC 60601-2-24 Test level	Compliance level obtained by the device	Electromagnetic environment – guidance
Discharge (ESD) IEC 61000-4-2	± 8 kV contact ± 15 kV air	± 8 kV contact ± 15 kV air	Wooden, tiled or concrete flooring, with a relative humidity level at least 30%, makes it possible to guarantee the level of necessary conformity. If it is not possible to guarantee this environment, the additional precautions must be taken, such as: use of anti-static material, preliminary user discharge and wearing anti-static clothing.
Radiated RF - IEC 61000-4-3	10 V/m, 80 MHz to 2.7 GHz For radio conformity according to IEC 301489-1 and IEC 30189-17: 3 V/m, 2.7 GHz to 6 GHz	10 V/m, 80 MHz to 2.7 GHz 3 V/m, 2.7 GHz to 6 GHz	Portable and mobile RF communications equipment should be used no closer to any part of the Agilia pump, including cables, than the recommended separation distance calculated from the equation applicable to the frequency and power of transmitter. For standard communication services and equipment, the specific frequencies were tested for a minimum approach distance of 30 cm.

Immunity test	IEC 60601-1-2 IEC 60601-2-24 Test level	Compliance level obtained by the device	Electromagnetic environment – guidance
Near field radiated RF IEC 61000-4-3 test method	385 MHz, PM 18Hz, 27 V/m 450 Mhz, 1 KHz, 28 V/m 710 MHz, PM 217 Hz, 9 V/m 745 MHz, PM 217 Hz, 9 V/m 780 MHz, PM 217 Hz, 9 V/m 810 MHz, PM 18 Hz, 28 V/m 870 MHz, PM 18 Hz, 28 V/m 930 MHz, PM217 18 Hz, 28V/m 1720 MHz, PM 217 Hz, 28 V/m 1845 MHz, PM 217 Hz, 28 V/m 1970 MHz, PM 217 Hz, 28 V/m 2450 MHz, PM 217 Hz, 28 V/m 5240 MHz, PM 217 Hz, 9 V/m 5500 MHz, PM 217 Hz, 9 V/m 5785 MHz, PM 217 Hz, 9 V/m	385 MHz, PM 18Hz, 27 V/m 450 Mhz, 1 KHz, 28 V/m 710 MHz, PM 217 Hz, 9 V/m 745 MHz, PM 217 Hz, 9 V/m 780 MHz, PM 217 Hz, 9 V/m 810 MHz, PM 18 Hz, 28 V/m 870 MHz, PM 18 Hz, 28 V/m 930 MHz, PM217 18 Hz, 28V/m 1720 MHz, PM 217 Hz, 28 V/m 1845 MHz, PM 217 Hz, 28 V/m 1970 MHz, PM 217 Hz, 28 V/m 2450 MHz, PM 217 Hz, 28 V/m 5240 MHz, PM 217 Hz, 9 V/m 5500 MHz, PM 217 Hz, 9 V/m 5785 MHz, PM 217 Hz, 9 V/m	For minimal distance approach 30 cm (12 inches) Portable and mobile RF communications equipment should be used no closer to any part of the Agilia pump, including cables, than the recommended minimal separation distance (30 cm) for these frequencies
Electrical Fasttransient / Burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input output lines 100 KHz repetition	± 2 kV for power supply lines ± 1 kV for input output lines 100 KHz repetition	Electricity power quality should be that of a typical domestic, commercial or hospital
Surge IEC 61000-4-5	± 1 kV differential mode ± 2 kV common mode	± 1 kV differential mode ± 2 kV common mode	Electricity power quality should be that of a typical domestic, commercial or hospital environment. For very exposed establishments or buildings with the lightning, a protection must be installed on electricity power. Class II product and no earth connexion.
Conducted RF IEC 61000-4-6	3 Vrms 150 KHz to 80 MHz And 6 Vrms in the ISM and amateur radio bands	3 Vrms 150 KHz to 80 MHz And 6 Vrms in the ISM and amateur radio bands	Portable and mobile RF communications equipment should be used no closer to any part of the Agilia pump including cables, than the recommended separation distance calculated from the equation applicable to the frequency and power of transmitter (see table 6)

Immunity test	IEC 60601-1-2 IEC 60601-2-24 Test level	Compliance level obtained by the device	Electromagnetic environment – guidance
Power frequency (50 / 60 Hz) magnetic field IEC 61000-4-8	30 A / m	400 A / m	If necessary, the power magnetic field should be measured in the intended installation location to make sure it is lower than the compliance level. If the measured field in the location where the Agilia pump is used exceeds the applicable magnetic field compliance level above, the Agilia pump should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Agilia pump, or installing magnetic shielding.

Immunity test	IEC 60601-1-2 IEC 60601-2-24 Test level	Compliance level obtained by the device	Electromagnetic environment – guidance
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0% Ut (100% dip in Ut) for 0,5 cycle at 0°, 45°, 90°, 135°,180°, 225°, 270° and 315° 0% Ut (100% dip in Ut) for 1 cycle 70% Ut (30% dip in Ut) for 25 cycles at 50 Hz for 30 cycles at 60 Hz at 0°	0% Ut (100% dip in Ut) for 0,5 cycle at 0°, 45°, 90°, 135°,180°, 225°, 270° and 315° 0% Ut (100% dip in Ut) for 1 cycle 70% Ut (30% dip in Ut) for 25 cycles at 50 Hz for 30 cycles at 60 Hz at 0°	Electricity power quality should be that of a typical domestic, commercial or hospital environment. For short and long interruptions (< than battery autonomy) of electricity power supply, the internal battery provides the continuity of service. For very long (> than battery autonomy) interruptions of electricity power supply, the Agilia pump must be powered from an external Uninterruptible Power Supply (UPS). Note: Ut is the a/c mains voltage prior to application of the test level.
Proximity magnetic field IEC 61000-4-39 Test method	134.2 KHz Pulse modulation 2.1 KHz 13.56 MHz Pulse modulation 50 KHz 30 KHz Modulation CW	65 A/m 7.5 A/m 8 A/m	The RFID Immunity phenomena should be in the frequency range 9 KHz to 13.56 MHz.

24 Servicing

24.1 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.

24.2 Maintenance Requirements

WARNING
Perform preventive maintenance at least once every 6 years. Failure to comply with these maintenance procedures could damage the device and result in altered performances.

WARNING
Do not use a device that has been dropped or that doesn't operate as expected. Contact your biomedical department or your Fresenius Kabi representative.

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

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

- Preventive maintenance should be performed by trained and qualified technical personnel in compliance with the technical manual and procedures. Only authorized service personnel should attempt to repair the device.
- Internal inspection of the device requires compliance with special procedures to avoid damage to the device.
- When replacing components, only use spare parts from Fresenius Kabi.

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

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

24.3 Quality Control

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

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

24.4 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

25 Real Time Location System Tag

25.1 Tag Installation

WARNING
The positioning of the RTLS tag must be strictly respected to avoid any perturbations that may impact the pump performances.

CAUTION
Remove the RTLS tag if the pump does not behave as expected when it is attached to the pump.

1. Locate a 44 x 34 mm area on the side panel of the pump.
   The tag must be positioned in the greyed area as shown below.

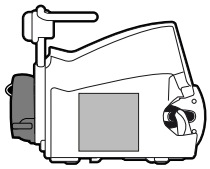


Figure 13: Agilia SP range of pumps (left panel)

CAUTION
The installation of the RTLS tag on the pump must respect the integrity of the pump housing. Any modification may damage the pump and/or its internal components and make it unusable. Only use biocompatible material to position a RTLS tag on Agilia pumps.

2. Stick the double-sided tape supplied with the tag in the location defined above.
3. Stick the tag ❶.

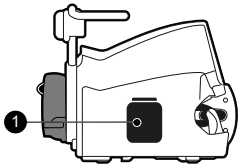


Figure 14: Location for Agilia SP range of pumps

25.2 Use environment

The RTLS tags must be used in the same operational conditions as for the Agilia pump. See *Use Environment* on page 12.

25.3 Tag Compliance

CAUTION
Be sure that used RTLS tags are in compliance with latest local radio equipments and electrical safety directives and standards. Incompatible tags may impact pump performances.

Radio, EMC (Electromagnetic compatibility)	FCC Part 15 Subpart C class B subpart B EN/IEC 300-328, EN/IEC 301-489 Radio Equipment Directive 2014/53/EU (RED) Radio Equipment S.I2017/2016 (RED) RoHS 2 Directive 2011/65/EU, RoHS 2 Directive S.I.2012/3032 Safety: CE, UKCA
Safety	EN62368/UL62368/IEC62368, Japan 201-200209

A Glossary of Terms

Term	Description
A	Amperes
AC	Alternating Current
Ah	Ampere-hours
AM	Amplitude Modulation
A/m	Amperes per meter
ASA	American Society of Anesthesiologists
BMI	Body Mass Index
BSA	Body Surface Area
Cmeas	Measured Concentration
Cpred	Predicted Concentration
CDC	Centers for Disease Control
CE	Effect-site Concentration
CERT	Computer Emergency Response Team
CET	Target Effect-site Concentration
CISPR	Special International Committee on Radio Interference
CP	Plasma Concentration
CPT	Target Plasma Concentration
CT Scan	Computed Tomography
CVD	Coordinated Vulnerability Disclosure
dB(A)	Decibels
DC	Direct Current
DCOM	Distributed Component Object Model
DECT	Digital Enhanced Cordless Telecommunications
DI	Dose Infused
DPS	Dynamic Pressure System
DTBI	Dose to Be Infused
ECG	Electrocardiogram
ECMO	ExtraCorporeal Membrane Oxygenation

Term	Description
EEG	Electroencephalogram
EMC	Electromagnetic compatibility
ErXX	Error message
ESD	Electrostatic Discharge
FM	Frequency Modulation
FTP	File Transfer Protocol
GTIN	Global Trade Item Number
H/W/D	Height / Width / Depth
HF	High Frequency
hPa	Hectopascals
HTTP	HyperText Transfer Protocol
HTTPS	HyperText Transfer Protocol over TLS
Hz	Hertz
IEC	International Electrotechnical Commission
IT	Information Technology
IV	Intravascular
kg	Kilograms
KVO	Keep Vein Open
LBM	Lean Body Mass
LED	Light Emitting Diode
mA	Milliamperes
MDAPE	Median Absolute Predicted Error
MDPE	Median Predicted Error
mL/h	Milliliters per hour
MOS	Metal Oxyde Semiconductor
MRI	Magnetic Resonance Imaging
N/A	Not Applicable
NFS	Network File System
NMR	Nuclear Magnetic Resonance
OLE	Object Linking and Embedding

Term	Description
OPC	Open Platform Communications
OTS	Off-The-Shelf
PC	Personal Computer
PE	Performance Error
REF	Product reference / part number
RF	Radio Frequency
RFID	Radio Frequency IDentification
RPC	Remote Procedure Call
RS232	Serial interface connector
SN	Serial Number
SIR	Asynchronous Serial Infrared
SQL	Structured Query Language
TCI	Target Controlled Infusion
TLS	Transport Layer Security
TIVA	Total Intravenous Anaesthesia
UDI	Unique Device Identifier
USB	Universal Serial Bus
Ut	Test specification level
V	Volts
V/m	Volts per meter
VA	Volt-Amperes
VDC	Volts Direct Current
VI	Volume Infused
VLAN	Virtual Local Area Network
VPN	Virtual Private Network
Vrms	Root Mean Square Voltage
VTBI	Volume to Be Infused
W	Watts
WPA	Wi-Fi Protected Access
XSS	Cross-Site Scripting

B Appendix: Factory Configuration

Menus

Feature	Basic & TCI			Feature	Basic & TCI		
	Flow rate	Dose	TCI		Flow rate	Dose	TCI
Profile	x	x	x	View flow rate history	x	x	x
Pressure management	✓	✓	✓	View pressure history	x	x	x
Keypad lock status	✓	✓	✓	View concentration history	x	x	✓
Battery life	✓	✓	✓	Syringe	✓	✓	✓
Volume infused / Dose infused	✓	✓	✓	View event log	✓	✓	✓
Pause	✓	✓	x	Date / Time	✓	✓	✓
Programmed bolus	x	x	x	Maintenance	x	x	x
Patient	✓	✓	✓	Library information	x	x	x
Day/Night mode	✓	✓	✓	Clinical information	x	x	x
Volume Limit	✓	✓	x	Data Set	x	x	x
Volume/Time - Dose/Time	✓	✓	x	Wake up concentration	x	x	✓
Alarm volume	✓	✓	✓	TCI setup	x	x	✓
Volume-Dose history	✓	✓	✓				

Infusion Modes

Feature	Basic & TCI			Feature	Basic & TCI		
	Flow rate	Dose	TCI		Flow rate	Dose	TCI
Simple Rate	✓	✓	x	Volume Limit	✓	✓	x
Volume/Time - Dose/Time	✓	✓	x	TCI	x	x	✓

Infusion Features

Feature	Basic & TCI			Feature	Basic & TCI		
	Flow rate	Dose	TCI		Flow rate	Dose	TCI
Direct Bolus	✓	✓	x	KVO	x	x	x

Feature	Basic & TCI			Feature	Basic & TCI		
	Flow rate	Dose	TCI		Flow rate	Dose	TCI
Programmed Bolus	✓	✓	x	Prime Set	✓	✓	✓
Induction Dose	✓	✓	x	Dynamic Pressure System (DPS)	✓	✓	✓

✓ = Features activated with factory configuration (Basic Profile & TCI).

x = Features not activated with factory configuration. Can be enabled in the pump options or with Drug Library Software. Otherwise, they can be enabled on request.

TCI Model IV Drug	Vd (L)	k10 (min-1)	k12 (min-1)	k13 (min-1)	k21 (min-1)	k31 (min-1)	ke0 (min-1)
Modified Marsh [a, b] Propofol	0.228 × Weight	0.119	0.112	0.0419	0.055	0.0033	1.21
Schnider [c, d] Propofol	4.27	[1.89 + 0.0456 x (weight-77) - 0.0681 x (LBM - 59) + 0.0264 x (Height - 177)] / Vd	1.29 - 0.024 × (Age - 53) / Vd	0.836 / Vd	[1.29 - 0.024 x (Age - 53)] / [18.9 - 0.391 x (Age - 53)]	0.836 / 238	0.456
Minto [e] Remifentanil	5.1 - 0.0201 × (Age - 40) + 0.072 × (LBM - 55)	[2.6 - 0.0162 × (Age - 40) + 0.0191 × (LBM - 55)] / Vd	[2.05 - 0.0301 × (Age - 40)] / Vd	[0.076 - 0.00113 × (Age - 40)] / Vd	[2.05 - 0.0301 × (Age - 40)] / [9.82 - 0.0811 × (Age - 40) + 0.108 × (LBM - 55)]	[0.076 - 0.00113 × (Age - 40)] / 5.42	0.595 - 0.007 × (Age - 40)
Gepts[f, g] (for Ke0) Sufentanil	14.3	0.0645	0.1086	0.0229	0.0245	0.0013	0.112
Scott[h] Alfentanil	2.185	0.091	0.656	0.113	0.214	0.017	0.7702
Paedfusor[i, k] (for ke0) Propofol	0.458 × Weight * (-0.0576 × Age + 1.1485) × Weight **	0.1527 × Weight-0.3 * 0.0678 *** 0.0792 **** 0.0954 ***** 0.119 ******	0.114	0.0419	0.055	0.0033	0.91
Kataria[j, k] (for ke0) Propofol	0.52 × Weight	0.066	0.113	0.051	0.059	0.0032	0.41
Units: Weight: in kg Height: in cm Age: in year		For Paedfusor: * if patient age < 13 years ** if patient age is between 13 and 16 years *** if patient age = 13 years **** if patient age = 14 years ***** if patient age = 15 years ****** if patient age = 16 years					

The Eleveld model is designed for a wide range of patients, so the parameters must be calculated based on individual covariates such as weight, height, age and gender. Specifically, the Ke0 is calculated as follows:

- For Eleveld propofol (with or without opioids):

  $Ke0 = 0.146 \times F_{size}^{-0.25}$, where F_{size} = weight / 70

- For Eleveld remifentanil:

  $Ke0 = 1.09 \times F_{age}(-0.0289)$, where $F_{age}(x) = \exp(-x \times (age - 35))$

Therefore, there are no fixed values for the Eleveld TCI model that can be disclosed in a table as with other TCI models. Please refer directly to the publications from Eleveld and colleagues (mark *l* and *m*).

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Release notes

Date	Software version	Description
October 2023	4.2	Creation
July 2024	4.3	Cover: Removed "Caring for life" from Fresenius Kabi logo § 1.8.2: Updated Cybersecurity recommendations § 4.5.4, 4.5.5 and Appendix C: added Eleveld pharmacokinetic model § 18.6.2: Updated Alarms sound levels § 19: Updated WiFi specifications
September 2025	4.4	§ 4.5.5: Updated restrictions data for Schnider and Minto models § 16.2: Modified list of prohibited agents for cleaning and disinfecting § 19.2.1: Modified description for wireless security

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