Agilia
Intuitive generation

Volumat Agilia

Volumetric infusion pump
Instructions for use

MEDICAL DEVICES

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caring for life

Contents

Valid for software version 1.2.

1. Introduction

Volumat Agilia is the volumetric pump of the Agilia range, our new generation of infusion devices. It is intuitive and easy to learn, like all devices of the Agilia range. Thanks to its various programming modes, infusion modes, customisation capabilities and its extensive set range, Volumat Agilia can be used in any unit of the hospital: general wards, paediatry, critical care, oncology, etc.

Programming modes

Volumat Agilia can be programmed in three different modes.

Mode	Description
No drug name	All infusion parameters must be defined. The drug name is not selected. It works with different infusion modes (see next table).
Drug labelling	The drug name is selected from a predefined drug list during infusion programming and displayed on the screen during infusion.
Vigilant® Drug'Lib	Drug parameters are defined in a drug library: drug name, default flow rate units and values, authorized infusion modes, authorized boluses and bolus parameters, flow rate maximum and soft limit values, etc. The drug library can be customised by the user with the Vigilant® Drug'Lib software and downloaded to the device.

Note: In Drug labelling and Vigilant® Drug'Lib modes, you can select "Drug X (ml/h)" to define all parameters for an unspecified drug (not in the drug list, nor in the drug library) without changing the programming mode.

Infusion modes

The following infusion modes are authorized.

Mode	Description
Volume/time/rate (V/T/R)	Infusion defined by a volume and a time or a flow rate.
Volume/rate	Infusion defined by a volume and a flow rate. In that case, the time is calculated automatically.
Volume/time	Infusion defined by a volume and a time. In that case, the flow rate is calculated automatically.
Time/rate	Infusion defined by a time and a flow rate. In that case, the volume is calculated automatically.
Simple rate	Infusion defined by a flow rate. This mode is only available with the optional drop sensor fixed to the drip chamber and connected to the pump.

Intended use

Volumat Agilia is an infusion pump designed for:

■ Peripheral and central intravenous (IV) administration of drugs, solutions, fluids, parenteral nutrition and transfusion (special set required).

■ Subcutaneous administration of IV fluids (Normal Saline, Dextro 5%, etc.) by following medical prescription and specific medical practices.

It must be used by trained professionals working in healthcare facilities and/or in road ambulances (associated to mandatory accessory Agilia Holder Ambulance).
Volumat Agilia may be used by trained patients and professionals in homecare environment by following specific precautions.

Intended Patients

	Healthcare facility	Homecare
Sex	Male and female	Male and female
Age	Neonates, Paediatrics, Adults, Elderly	Paediatrics, Adults, Elderly

Precautions to be taken

■ When a device is marked with the ⚠ symbol, operators must imperatively review the corresponding Instructions for use prior to using this device. The use of infusion modes by untrained persons may lead to drug administration errors.

■ Volumat Agilia has been tested in accordance with the electromagnetic compatibility standards applicable to medical devices. Its immunity is designed to ensure correct operation. The limitation of the emitted radiations avoids undesirable interference with other equipment such EEG, ECG, etc. If Volumat Agilia is placed near devices like HF surgical equipment, X-rays, mobile phones or Wi-Fi access points, it is essential to observe a minimum distance between the Volumat Agilia and this equipment (see page 43 - Electromagnetic Immunity).

■ Use in a Magnetic Resonance Imaging unit: the pump may be operated safely with the MRI Guard Agilia device only in order to prevent electromagnetic interferences. Please refer to its specific Instructions For Use.

■ Due to use into road ambulances, performances of Agilia IV pump can be modified. Medical staff must remain nearby the Agilia IV pump to react in an appropriate way. Please refer to Agilia Holder Ambulance Instructions For Use.

■ The device must not be used in presence of inflammable anaesthetic agents due to a risk of explosion. It should always be used away from all risk areas.

■ The device can be disturbed by pressure or pressure variations, mechanical shocks, heat ignition sources, etc. If you wish to use the device in specific conditions, please contact our After-Sales Department. The pump must be used in a horizontal and stable position to work correctly.

■ The pump must not be used to administer non-water soluble solutions or unsterile fluids.

■ The physiological effects of medicine can be influenced by the characteristics of the device and the associated disposable (constituent material is commonly listed on the set packaging). Check that they are compatible with prescriptions, the characteristics of trumpet curves and occlusion alarm setting times in relation to the programmed flow rate.

■ The device uses a Lithium-ion rechargeable battery. Incorrect handling of a Lithium-ion battery by non-qualified personnel may cause battery leakage, overheating, smoke, explosion or fire, which could result in deterioration of performance or failure. This may also damage the protection device installed in the battery pack, resulting in damage to the equipment or injury to the user (see page 46 - Use of the internal battery).

■ In case of unexpected situation regarding pump controls or environment, the state of the art safe-design will raise an alarm, stop the infusion and display an error code. Users are invited to be aware of those alarms (see Chapter 6) and in cases where the device is used to deliver life sustaining therapies, like short half-life medications, to consider adequate provisions for back-up therapy delivery solutions.

Precautions to be taken in homecare environments

⚠ Warning: In homecare environments, the user must adhere to the instructions specified in this chapter. Failure to adhere to these instructions may result in damage to the equipment, injury to patients or injury to users.

■ The pump can be used to administer the following fluids and drugs:

- Hydration (typically normal saline), ringer solution, bicarbonate, glucose solutions
- Parenteral nutrition
- Antibiotics, antivirals, antifungals
- Other non-critical drugs for which any interruption of administration would have no consequences within the next 24 hours (e.g. corticoids, immunoglobulins, etc.).

■ Do not use the pump to administer the following fluids unless the pump is under the permanent supervision of a trained healthcare professional:

- Catecholamines
- Morphine
- Chemotherapy
- Other critical drugs

■ The pump must only be used by the following:

- Trained homecare professionals
- Patients or their relatives (in case of inability to correctly react to pump alarms)

Patient or their relatives must receive appropriate training in order to correctly handle the device. Some examples are precautions for use in homecare environments, good hygienic practices or being care not to muffle the device. The patient must also be trained to a limited set of the pump's functions. Refer to the quick reference guide for the patient.

■ It is the healthcare professional's responsibility to warn the patient about the risks associated with the absence of relatives at bedside if the patient has a physical or cognitive disability.

■ The pump must be securely attached to a rolling stand on a flat surface in order to ensure appropriate mobility. The use of a drop sensor is not recommended.

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

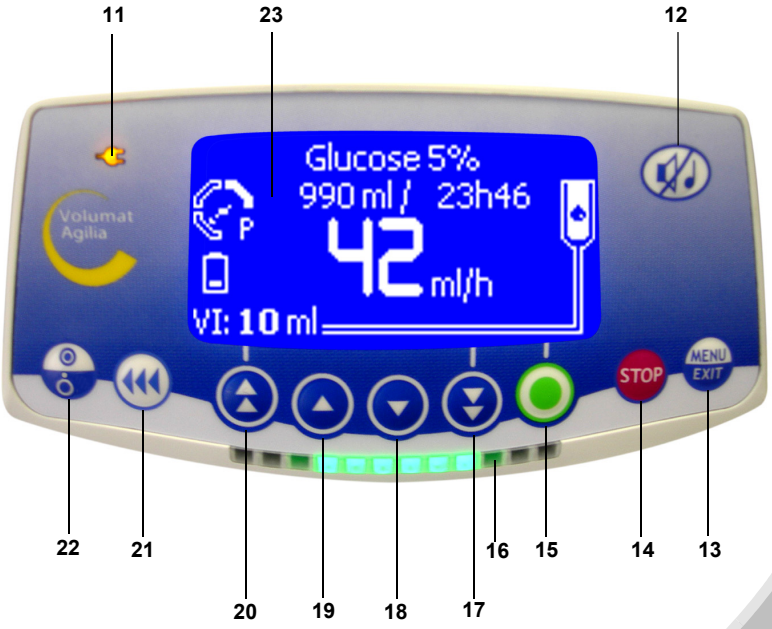
■ Homecare providers must ensure that they can provide backup sets and a backup pump within a short enough time period to avoid interruptions of administration which could have critical consequences in case of pump failure in the patient's home.

■ It is recommended that the healthcare professional configure pump parameters according to the drug prescribed, the administration route and the environment. Some example parameters are KVO rates, pressure limits, air parameters, and display of battery symbol on infusion screen.

■ Two Quick Reference Guides have been created (one for the nurse, one for the patient) in order to describe the typical operations performed at home. We recommend using them and keeping them near the pump.

2. Description

1 -	Handle	**5 -**	Infrared cell	**9 -**	Fixing button
2 -	Pump door	**6 -**	Mains connection	**10 -**	Drop sensor connection socket
3 -	Door lever	**7 -**	Communication port and DC power input-output		
4 -	Assembly bolt	**8 -**	Swinglock clamp		



11 -	Mains indicator	**15 -**	OK / start / enter	**19 -**	Increment
12 -	SILENCE ALARM	**16 -**	Indicator lights (leds)	**20 -**	Fast increment
13 -	MENU / EXIT	**17 -**	Fast decrement	**21 -**	BOLUS or PRIME
14 -	STOP / PAUSE	**18 -**	Decrement	**22 -**	ON / OFF
				23 -	Monitoring screen (see page 13)

3. Installation

Positioning the pump(s)

on a pole

on a rail

on a table

Several Agilia devices can be assembled on a pole in any order

⚠ When devices are stacked together on a pole, the assembly bolts must be in the closed position.

When two Agilia devices are stacked together, the Agilia Duo accessory can be used to centralize the power supply.

Agilia products are easily transportable.
Up to three devices (maximum) can be assembled together during transportation.

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

Using the fixing clamp

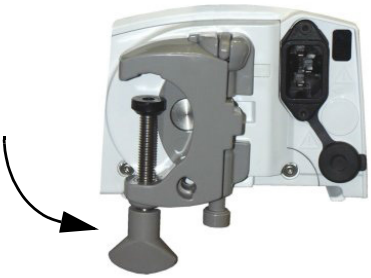
The swinglock clamp is only orientable when closed against the pump. It is maintained in its vertical or horizontal position with the fixing button.

The following images show how to modify the pump installation, from a pole to a rail position.

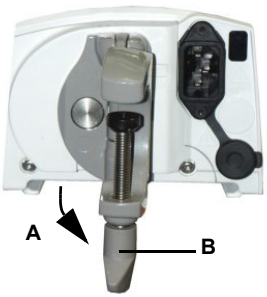
❶ Unscrew the clamp screw (A) and disengage the device from the pole. Push the fixing button (B).

❷ Fold the fixing clamp against the pump. This is the recommended position for the swinglock clamp when the device is placed on a flat surface.

❸ Rotate the fixing clamp downward through 90 degrees.



❹ Move the fixing clamp outward (A). The fixing button is released automatically. Engage the device on the rail and use the clamp screw (B) to secure it.



Installing the device

❶ Position the device securely on the rail, pole or flat surface and connect to the mains supply. The Volumat Agilia can operate with its battery, but the mains supply should be used under normal conditions to ensure the battery charge. The mains supply indicator lights up (yellow) when external or mains power is supplied.

❷ Proceed with the User test, see page 36. The user test performs a complete alarms and safety features check. It is recommended if the device has not been used recently and is mandatory in some countries before each use to fulfill local legal requirements.

Preparing the infusion set

❶ From the Volumat Agilia lines range, choose the infusion set that best suits your protocol.

❷ Prepare the solution container (bag/bottle) with its associated infusion line according to local facility procedures.

Caution:The infusion set and the solution container must be in normal temperature conditions: +18°/+30°C.

It is recommended to purge the infusion set just before starting the administration.

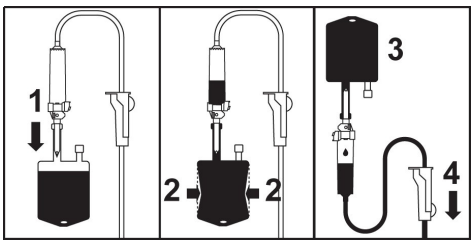
Purging the set used with a bag or a bottle

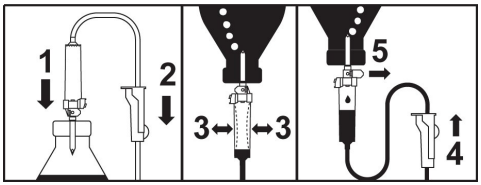
❸ **With a bag...**

1. Introduce the spike right down into the bag (roller clamp open, air inlet closed).
2. Press the bag in order to remove the air, and fill the drip chamber up to 1/2 to 2/3 of its capacity.
3. Hang the bag upside down, and let the liquid flow gently into the set.
4. Once the set is completely primed, close the roller clamp and check absence of air bubble.

... or a bottle

1. Introduce the spike right down into the bottle (roller clamp open, air inlet closed)
2. Close the roller clamp.
3. Hang the bottle upside down then press the drip chamber in order to fill it up to ~ 1/2 of its capacity.
4. Open the roller clamp.
5. Open the air inlet, and let the liquid flow gently into the set.
6. Once the set is primed, close the roller clamp and check absence of air bubble.





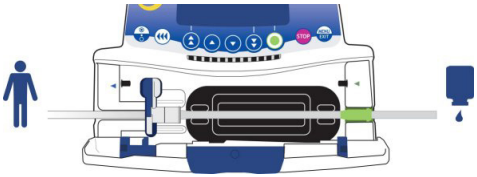
For infusion sets equipped with the K-Nect needle free access, turn this component upside down during priming in order to eliminate bubbles.

Installing the tubing set in the pump (1/2)

❶ Open the pump door by lifting the door lever.
Note: The pump automatically switches on when connected to mains (see Ward option [Par 28], page 35). If not, press the key.

An **auto-test** checks the functionality of the pump. Make sure that all LEDs and buzzers are activated. Once the auto-test is OK, a message is displayed to indicate that you can install the tubing set.

❷ 1. Align the tubing set horizontally along the tube guides so that the green connector is positioned to the right (green) and the blue clamp is positioned in front of the clamp guide (blue).
2. Insert the green connector in the green slot.
3. Position the blue clamp in its blue slot and then push the clamp to locate the spherical hinge into place.
4. Ensure that the tube is in the left tube guide, then push the door lever to close the pump door.

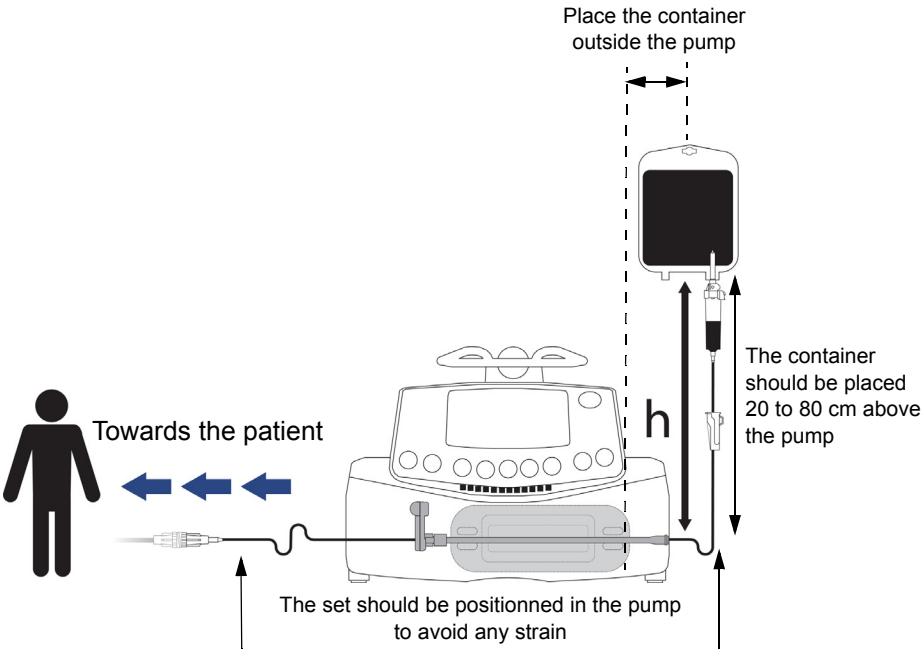


❸ The **Occlusivity Check System** (OCS) automatically clamps the line, activates real pumping, and checks pressure increase. The OCS test verifies the circuit and pump occlusivity to secure the pump against a risk of free flow.

❹ If the OCS test is completed successfully, the infusion mode defined in the options is displayed (to program the infusion, see next page).

Installing the tubing set in the pump (2/2)

The final installation should look like this:

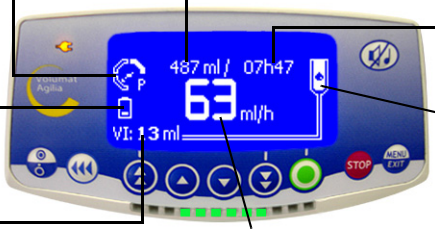


Monitoring screen

Pressure level
The arrow indicates the level of pressure.
For details, go to page page 38.

VTBI: Volume to be infused. It decreases during infusion. To modify it, press <MENU> then select "VTBI".

Infusion **time**. It decreases during infusion.



Infusion in progress.
Drops falling into the drip chamber. Speed is related to flow rate.

Battery level

VI: Volume infused. It increases during infusion. To clear it, press the MENU EXIT key then select "ml?".

Flow rate of infusion in progress.
You can always modify it, whenever necessary, by simply pressing the increment/decrement keys, and then OK.

Volume/time/rate & No drug name modes

The V/T/R infusion mode and No drug name programming mode are described.

For another infusion mode, go to page 15; for another programming mode, go to page 16 or page 17.

1 - Volume selection

■ Use the arrows to select the volume to be infused (VTBI), then press **OK**.

Note: Use the fast increment key to increment VTBI per predefined levels (50 ml, 100 ml, 250 ml, 500 ml, 1000 ml, ...).

Caution: the volume setting must be the closest (less or equal) possible to the actual volume of the container. All added or removed volumes must be taken into account, including the volumes of fluids contained in the set and lost during priming that must be removed from the volume to infuse (~ 25 ml).

2 - Time selection

■ Use the arrows to select the infusion time. The flow rate is automatically calculated and displayed.

■ Press **OK**.

3 - Flow rate selection

■ Use the arrows to modify the flow rate as required, then press **OK**.

Note: If you modify the flow rate, the infusion duration is automatically calculated and readjusted according to the displayed flow rate.

4 - V/T/R start

■ Open the roller clamp. Check that there is no free flow or air remaining inside the infusion line.

■ Connect the set to the patient via the IV infusion set according to local facility procedures.

■ Press **start** to start the infusion or **C** to modify the Volume/Time/ Rate selection.

Other infusion modes (1/2)

The infusion mode set by default is displayed, but you can select another infusion mode (Volume/rate, Volume/time, Time/rate or Simple rate), provided it is preselected in the Ward option [Par 29] (see page 35).

1 - Menu selection

- Press the MENU EXIT key to display the Infusion mode screen. If it does not appear at first place, use the arrows to select "VRT".
- Press **enter**.

2 - Infusion mode selection

- In the Infusion mode screen, use the arrows to select a new infusion mode, then press **OK**.

3 - Volume/rate...

- Select a volume to be infused (VTBI), then press **OK**.
- Select a flow rate and press **OK**.
- Press **start**.

Note: Time is calculated automatically and cannot be modified directly.

or Volume/time...

- Select a volume to be infused (VTBI), then press **OK**
- Select a time and press **OK**.
- Press **start**.

Note: Flow rate is calculated automatically and can be modified directly only during infusion.

Other infusion modes (2/2)

or Time/rate...

- Select a time, then press **OK**.
- Select a flow rate, then press **OK** and **start**.

Note: The volume to be infused (VTBI) is calculated automatically and cannot be modified directly.

... or Simple rate selection

- Select a flow rate, then press **OK** and **start**.

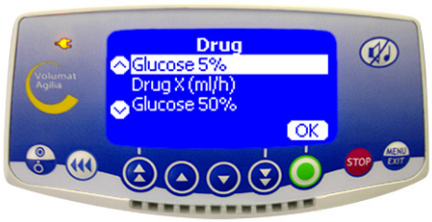
Note 1: This infusion mode only works with the **drop sensor** fixed on the drip chamber and connected to the pump (for installation, see page 23). If not, a warning message appears when you select this mode in the Infusion mode screen. Shut-down the pump, set the drop sensor, and restart the pump.

Note 2: When no more drops are detected, it indicates that the container is empty. The infusion will be stopped and an alarm generated.

Drug labelling mode

Caution: Drug labelling is available only if authorized in the Ward option [Par 22] (see page 35) and preselected in the User option [User 9] (see page 33).

1 - Drug selection



- Start-up the pump. The Drug screen appears.
- Use the arrows to select a name in the Drug list, then press **OK**.

Note: Select "Drug X (ml/h)" if the drug name is not in the predefined Drug list.

2 - Define the infusion

- Infusion adjustments can be made as described in Operations on page 14.

Vigilant Drug'Lib mode

Vigilant® Drug'Lib is the safest and simplest mode to administrate a drug via the Volumat Agilia.
You need to select a drug from a drug library in which the drugs have been predefined with all their infusion parameters. (To define a drug library, see Vigilant® Drug'Lib for Agilia operator's guide.)
Caution: Vigilant DrugLib is available only if authorized in the Ward option [Par 22] (see page 35) and preselected in the User option [User 9] (see page 33).

1 - Drug selection

- Start-up the pump. The Drug screen appears.
- Use the arrows to select a drug name in the Drug library, then press **OK**.

Note: The Drug library is preselected in the Ward option [Par 17] (see page 34).

2 - Drug information

- Depending on the drug selected, an informative screen may appear. If the information confirms the patient's needs and the infusion provided, press **OK**.

- Infusion adjustments can be made as described in Operations on page 14.

Note: Fields and selected values may be limited according to drug parameters defined by the Vigilant® Drug'Lib.

3 - Drug Lib modification

- The screen displays predefined values for volume to be infused (VTBI), time and flow rate. You can use the arrows to select a volume to be infused (VTBI), then press **OK**.

Note 1: The selection of "Furosemide" has switched the device to micro mode (values with one decimal).

Note 2: Depending on the predefined infusion mode, some parameters cannot be modified.

General operations

The following operations can be repeated and/or modified during the infusion process.

Note: For information on leds, see Indicator lights in chapter “Display and symbols”, page 24.

Stop

■ To stop the infusion, press the STOP key.

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

■ To restart the infusion, you must confirm (or modify) the volume, time and flow rate values, by pressing **OK** for each value, and finally **start**.

Pause

■ To program a pause, press the STOP key twice, define a pause duration

■ If desired, press the checkbox button to activate the "Start infusion at the pause end" option for an automatic start.

■ **Note**: If you do not check the "Start infusion at the pause end" option, an audible alarm is generated at the end of the pause duration.
A manual **start** is required to continue the infusion.

VTBI selection during infusion

- During infusion it is possible to adjust the VTBI.
- Press the MENU EXIT key to access the menu and select VTBI. Modify the VTBI with the selection keys and press OK.

Pressure management

- The pressure parameters for the infusion can be defined from the pressure management menu.
- Press the MENU EXIT key, use the selection keys and <enter> button to access the Pressure management parameters.

Maximum pressure

- Use the selection keys to define the upper pressure limit and press OK.
- The Dynamic Pressure System calculates pressure differences to anticipate possible occlusion or disconnection problems.

DPS

- To activate the DPS, use the <check box> button.
- To continue the infusion, press OK.

Manual bolus

■ To start a bolus, press the ⏪ twice: one short press, then one continuous press (activates bolus ☞ check infused volume on screen. This volume is taken into account in the VTBI).

■ To stop the bolus, release the ⏪ key.

■ To change the bolus rate, keep the bolus key pressed for at least 3 seconds and modify the bolus rates with the selection keys.

Note 1: This operation is available only if preselected in the Ward option [Par 19] (see page 35).

Note 2: During bolus, occlusion pressure level is set to maximum value (750 mmHg)

Changing a tubing set

1. Press the STOP key to hold the infusion.
2. **Close the roller clamp**.
3. Press the 🔇 key to silence the audible signal for 2 minutes.
4. Open the pump door.
5. Disengage the tubing set from the pump.
6. Disconnect the tubing set from the container.
7. Disconnect the tubing set from the IV device according to local facility procedures.
8. Follow instructions as described from pages 9 to 14 (set installation and infusion adjustments).

Programming the infusion

The Volumat Agilia can be pre-programmed before installing the tubing set.

Switch on the device (door closed and without set) and select the <prog> button.

Infusion adjustments can be made as described in Operations on page 14.

When the parameters are logically entered, the <exit> and <C> options are displayed as optional actions.

<C> will allow parameter modifications and <exit> validates the program parameters and the device will display the "Install set" screen.

When the tubing set is installed, the device self -tests and the programmed parameters are displayed.

Press <start> to start the infusion or <C> to modify the parameters.

Note: The parameters are stored in the device and are displayed when the machine is turned ON.

End of infusion pre alarm

Prior to the end of an infusion, an End of infusion pre-alarm is automatically triggered. An audible alarm is triggered, and an alarm message appears on the pump screen. The infusion indicator lights flash yellow.

■ Press the key to silence the alarm.

The infusion will continue until the VTBI reaches zero.

End of infusion pre alarm settings are configurable in the Ward option [Par 31].

End of infusion alarm

When the VTBI reaches zero, the infusion is complete. If KVO is disabled, the infusion indicator lights flash red, and the pump stops infusing.

If KVO is enabled, an audible alarm is triggered. An alarm message appears on the pump screen. The infusion indicator lights flash yellow. The pump continues at the **KVO** (Keep Vein Open) rate.

■ Press the key to silence the alarm.

Prepare a new container, and adjust the settings for a new infusion.

Locking / unlocking keyboard

■ Press the key to access the menu, and use the selection keys to select .

■ Press the **enter** button to access the Locking keyboard menu, and select to lock the keyboard.

■ Press **OK** to confirm.

The , and keys remain functional during infusion when the keyboard is locked.

The keyboard can be unlocked from the Locking keyboard menu.

Switch-off

■ Press the key to interrupt the infusion.

■ Press the key continuously, until the Switch off screen disappears.

■ Disconnect mains plug first when taking out the supply lead.

Special features

The first two features are available only if preselected in the Ward option [Par 19] (see page 35).

Prime set

- Press the key to start-up the pump.

The infusion mode defined in the options is displayed after the OCS screen.

- Press the key. Make sure that the set is not connected to the patient, as indicated on screen.
- Press **OK**.
- Press the key continuously and release the key to finish priming.

See air bubble

Note: This feature is available only when an **air alarm** is triggered (air volume exceeded or air bubble in front of the air detector). The air bubble is removed without having to open the pump door.

- Press the key to reach <See air bubble> function
- Press **OK** to confirm, or **C** to cancel the selection.
- Press the key continuously to force the air bubble out of the pump.

Note: This feature allows you to advance the air bubble at the same set rate for a volume equal to the volume of air defined in the alarm setting.

- **Caution**: It is recommended to ask for medical advice to assess if the infusion can be re-started because air is still present. If the air bubble exceeds an acceptable size, or if the pump cannot be re-started because air is still present, the set should be removed from the pump and disconnected from the patient according to facility procedures for set priming or set exchange.
- **Note:** During prime set function, occlusion pressure level is set to maximum value (750 mmHg) and **air alarm** is inhibited.

Drop sensor (optional)

The drop sensor allows you to work in **Simple rate** infusion mode (for more details, see pages 16) and to detect if the container is empty. Using a drop sensor is recommended if the actual volume of the container (bag or bottle) is not known accurately.

1. Connect the drop sensor plug to the connection socket on the back of the pump **before** switching on the pump.
2. For a standard drip chamber, fix the drop sensor to the upper part of the drip chamber by aligning the vertical part of the drop sensor with the air inlet of the drip chamber room as indicated on the photograph.

Standard drip chamber (example: VL ST00)

For a drip chamber with central ring, fix the drop sensor to the upper part of the drip chamber positioned above the ring.

Drip chamber with central ring (example: VL ON42)

Caution: Check the right positioning of the drip chamber and check there are no drops on the drip chamber walls. Check that the drop sensor and the drip chamber are in a vertical position.

When the drop sensor is connected, check that the symbol is displayed on the screen.

Note: With the drop sensor, the maximum flow rate is restricted to 1100 ml/h.

5. Display and symbols

Volumat Agilia displays the infusion parameters in progress through specific symbols.

Continuous display	**Infusion in progress**		A drop falling into the drip chamber (see also Indicator lights for infusion in progress).
	Pause		STOP remains in the center of the screen until the pause is over.
	Vigilant® Drug'Lib		The device is operating with Vigilant® Drug'Lib.
	Battery life		Appears when the device is operating on battery. Three different levels of charge are symbolized.
Indicator lights	**Mains**		When the device is attached to an active mains supply, the icon is a constant yellow. In all other conditions the LED is unlit.
	Infusion in progress	 flashing green	Main indicator lights provide information about the infusion: in progress, in pre-alarm, or in alarm.
	Pre-alarm	 flashing orange	
	Alarm	 flashing red	
Help	**Start**		These symbols help the user in programming the pump.
	Validation		
	Access to function		
	Change selection		
	Selected		
	Not selected		
	See drug information		

Alarm and safety features	**Mains disconnection alarm**		Main symbols for alarm and safety features.
	Pressure increase		
	Pressure drop		
	Upper soft limit exceeded	High flow rate	
	Lower soft limit exceeded	Low flow rate	
Selection keys			Keys for selecting volume, time, flow rate and other values. **Note**: Fast increment and decrement keys have been programmed with different levels corresponding to standardized volumes of bags and bottles.
	Fast increment key		
	Increment key		
	Decrement key		
	Fast decrement key		
	Fast access to maximum value		
	Fast access to minimum value		

MENU	**Volume infused**	ml?	The menu gives access to infusion options that are selected by the user.
	Infusion mode	V R T	
	Pressure		
	Volume to be infused	VTBI	
	Battery life		
	Macro/micro	µ/M	
	Data log event		
	Programming mode		
	Maintenance		
	Sound level		
	Date/time		
	Keyboard locked		
	Pause		
	Drug library		
	Night mode		

6. Alarms and safety features

Volumat Agilia has a continuous inspection system that operates as soon as the pump is in use.

If an alarm occurs, the infusion stops, visual (red leds) and sound signals are emitted. A clear message is expressed by means of words and pictograms. The  key is effective for two minutes. When the cause of the alarm has been fixed, the red lights are turned off, but the message remains displayed at the top of the screen as a reminder of the cause of the alarm.

If the pre-alarm or a warning occurs, the infusion continues, a visual (orange leds) and sound signals are emitted. The  key is effective with no time limit.

System	Message	Type	Infusion stop	Activation / ☞ Action
Installed set	**Install set**	Alarm	YES	At start-up: Tube set not installed or door open ☞ Install tube set and close door.
	Door opened	Alarm	YES	During infusion or stop mode: door is open. ☞ Check set installation and close the door.
	Set air installation	Alarm	YES	Tube is mis-positionned in front of air sensor. ☞Check set installation in front of air sensor and close the door.
	Air bubble	Alarm	YES	At start-up or stop mode: air bubble detected ☞Remove air bubble by priming set.
	Air alarm	Alarm	YES	During infusion: air bubble detected. ☞Remove air bubble by priming set.
OCS	**OCS failed**	Alarm	YES	The OCS control system has detected a failure. ☞ Check set installation, check door integrity, check set integrity. If the problem cannot be solved, contact the after-sales department.
Infusion	**Flashing flow rate**	Warning	NO	The flow rate has been modified from the keys but has not been confirmed. ☞ Check flow rate and confirm with **OK**
	End of infusion pre-alarm	Pre-alarm	NO	Remaining VTBI is less than 5% of initial VTBI set up or 5 minutes or 5ml left before initial VTBI is reached. ☞ check if remaining volume in container is in accordance with remaining VTBI. If needed, prepare container for a new infusion sequence. If operating with drop sensor, the end of the infusion pre-alarm is inhibited and can be set in ward option [par 31] page 35.
	End of Infusion pre-alarm is disabled	Warning	NO	The "End of Infusion Pre-Alarm" has been disabled in ward option [Par 31]. ☞ Press **OK** to acknowledge.
	End of infusion alarm	Alarm	Stop/KVO	VTBI completed. KVO activated according to configuration, see User option [User 5], page 33. ☞ Press Stop to set new infusion parameters (if required).

System	Message	Type	Infusion stop	Activation / ☞ Action
Pressure	**Pressure increase (DPS)**	Warning	NO	The pressure is increasing in the line. This warning can be selected as an option [User 4] see page 33. ☞ Check if the infusion line is occluded (stop-cock, catheter, folded line,...).
	Occlusion pre-alarm	Pre-alarm	NO	In-line pressure has reached 50 mmHg below the programmed threshold. ☞ Check the infusion line. Set the correct pressure threshold.
	Downstream occlusion	Alarm	YES	The pressure in the line has reached the threshold level (see page 19) ☞ Check if infusion line is occluded (stop-cock, catheter, folded line). If necessary, readjust pressure threshold in relation to flow rate.
	Upstream occlusion	Alarm	YES	The pressure in the upstream line is too low. ☞ Check the roller clamp. Check the container and line. Check the container height. Check air inlet cap (if a bottle is used) folded line.
	Pressure drop (DPS)	Warning	NO	Pressure drop in infusion line. This warning can be selected as an option. ☞ Check the downstream luer lock connection and full line integrity.
Battery	**Battery pre-alarm**	Pre-alarm	NO	Low battery. ☞Connect to mains supply.
	Battery alarm	Alarm	YES	Discharged battery. ☞The pump will turn OFF automatically within 5 minutes. Connect the pump to the mains supply immediately.
	Empty battery	Alarm	YES	Connect to mains supply and wait for battery to be charged.
Mains	**Mains disconnection**	Warning	NO	Mains supply disconnection. ☞ Press silence to acknowledge and check battery life is sufficient for the expected infusion duration. If the disconnection is unintentional, check the mains connection.
	Mains Supply Failure	Warning	NO	Mains supply failure is inconsistent. ☞ Contact your technical support.

System	Message	Type	Infusion stop	Activation / ☞ Action
Drop sensor	**Connect drop sensor**	Alarm	YES	Only if drop sensor is compulsory (see page 35). At start-up: drop sensor not connected ☞ connect drop sensor to the pump and drip chamber (see page 23).
	No drop sensor	Alarm	YES	Only if drop sensor is compulsory (see page 35). During infusion or stop mode: drop sensor not connected ☞ connect drop sensor to the pump and drip chamber (see page 23).
	Underflow	Alarm	YES	Flow rate detected by drop sensor is below the set flow rate. ☞Check container. Check roller clamp. Check fluid drip forms ~20 drops/ ml. Check the drip chamber is hold in a vertical position. Check the drop sensor is fixed as recommended in page 23.
	Overflow	Alarm	YES	Flow rate detected by drop sensor is above the set flow rate. ☞Open the door and check the set positioning. Check drop sensor positioning. Check the fluid temperature. Check fluid drip forms ~20 drops/ ml.
	Uncontrolled flow	Alarm	YES	At start-up or stop mode: free flow detected by drop sensor ☞ Close roller clamp. Check drop sensor and set installation
Vigilant® Drug'Lib	**High flow rate**	Warning	NO	Upper soft limit exceeded according to drug parameters defined in drug library.
	Low flow rate	Warning	NO	Lower soft limit exceeded according to drug parameters defined in drug library.
Technical error	**Er - message (Er01, Er02, etc.)**	Alarm	YES	Technical alarm. ☞Contact your qualified technician or our after-sales department.

Remarks:
When a value is selected, it must be confirmed. If this value is not confirmed, the value will flash three seconds after last key press and a sound will be triggered 12 seconds later.
The maximum volume that may be infused under single fault condition is 1 ml.
When using a drop sensor, the flow rate is controlled at -50%, +100%.
In case of a malfunction alarm, note the error message (ErXX). Close the roller clamp, disconnect from the mains and stop the device by pressing the key (10 to 15 seconds can be necessary). If the alarm persists when the device is switched on again, without use on patient, contact the qualified technicians in your establishment or our After-Sales Department.

7. Menu

Operation	Key
Access menu or escape menu	
Select	
Confirm	 (corresponds to enter on the screen)
Selected ☒ / Not selected ☐	

Permanent menu

Function	Description	Operation	Symbol
Volume to be infused	Adjustment of VTBI during infusion	■ New setting	
Volume infused	Total infused volume	■ Clearing of infused volume	
Pressure	Pressure limit adjustment and DPS mode activation	■ Pressure limit ■ DPS mode activation	
Battery life	Battery life display	■ Hours and minutes left for a selected flow rate	
Pause	Pause duration adjustment	■ Hours and minutes adjustment and activation of delayed VTBI start-up	
Keyboard locked	Keyboard locking and unlocking	■ Locking keyboard	

Menu selected in option mode

Function	Description	Operation	Symbol
Maintenance	Information on maintenance, version, functioning duration, etc.	■ Maintenance date ■ SN (serial number) ■ Software version, etc.	
Data log event	Recording of up to 1500 events	■ Pressure limit ■ Flow rate, etc.	
Sound level	Audible level adjustment	■ 7 accessible levels	
Macro/micro Function accessible in STOP mode only	Type of displayed values	■ Macro (integer values) ■ Micro (values with one decimal)	
Date/time	Date and time programming	■ dd/mm/yyyy ■ h/min	
Night mode	Reduces the brightness of the display and light indicators	■ For night mode configuration, see Ward options [par 18] page 34.	
Programming mode Only if preselected in Ward option [Par 22]	Selection of another programming mode	■ Drug labelling ■ Vigilant Drug'Lib	
Drug library Function accessible in STOP mode only	Information on preselected drug library	■ Library name, author, drugs number ■ List of drugs with predefined parameters	
Volume/Time/Rate selection	Choose the required infusion mode	■ Volume/Time/Rate ■ Volume/Rate ■ Volume/Time ■ Time/Rate ■ Simple Rate	

CAUTION: the menu can change depending on selected Ward and User options (see "Options", page 32).

8. Options

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

Operation	Key
Options access	+ (when device is turned off, press simultaneously on both keys, <ON> and <MENU>)
Option selection	
Confirm	(corresponds to enter on the screen)
Selected ☒ / Not selected ☐	
Selected current values are memorized when the device is turned off after programming. To return to the normal menus switch off the device	

User options are selected according to authorized Ward options (see Ward table next page).

Option	Function	Choice	Description
User	**[User 1] Screen options** Choice of different symbols that can be displayed on the screen	■ Battery	Permanent display of battery symbol
		■ Pressure	Display of pressure symbol
		■ Priority for Vigilant logo	Vigilant logo is prior to pressure symbol
	[User 2] Menu options Choice of different options accessible by the <menu>key	■ Sound level	Sound level adjustment
		■ Maintenance	Maintenance information display
		■ Data log event	Display log events
		■ Date/time	Date/time adjustment
		■ Drug library	Display of drug library
		■ Macro/micro	Macro or micro mode selection
		■ Programming mode	Programming mode selection
		■ Infusion mode	Display of infusion modes
	[User 3] Contrast	■ Screen contrast adjustment. Use (fast) increment and decrement keys	

Option	Function	Choice	Description
User	**[User 4] Pressure**		
	Mode	■ **Variable** mode: One initial pressure value that can be adjusted during infusion	■ **3 levels** mode: 3 fixed pressure limits that can be selected during the infusion
	DPS (Dynamic Pressure System)	■ YES/NO	■ YES: DPS can be activated during infusion
	Maximum pressure for Micro/Macro mode	■ Defines the pressure parameters for Micro (300 to 750 mmHg) and Macro (500 to 750 mmHg) Modes	■ This defines the maximum pressure allowed during the infusion
	Storage limit	■ The checkbox is used to validate the storage of the pressure parameters	■ The storage of last adjustment pressure limit during infusion is memorised automatically for the next start-up or must be manually entered for the next start-up
	If DPS = YES: Drop threshold	■ Select a pressure level, an indication is generated when the pressure is below this level.	
	If DPS = YES: Incr. threshold	■ Select a pressure level, an indication is generated if pressure is above this level compared to the average pressure of the set.	
		■ **Note:** For details and values, see "Pressure management", page 38	
	DPS storage	■ The checkbox is used to validate the storage of the DPS function	■ The storage of last DPS adjustment during infusion is memorized automatically for the next start-up or must be manually entered for the next start-up
	[User 5] KVO (Keep Vein Open)	■ KVO: OFF, 1 to 20 ml/h	■ Silence duration (5 min to 12h): time during which the pump is silenced after pressing the Silence key.
	[User 7] Date/time	■ Date selection: dd/mm/yyyy	■ Hour selection: h/min
	[User 8] Language	■ Français / English / Deutsch	
	[User 9] Programming mode	■ Press **enter** to select default programming mode at start-up	■ Press **OK** to validate default programming mode at start-up
	[User 10] Infusion mode	■ Press **enter** to select default infusion mode at start-up	■ Press **OK** to validate default infusion mode at start-up
	[User 11] Macro/micro	■ Press **enter** to select default mode at start-up	■ Press **OK** to validate default mode at start-up

Ward options are authorized options that you can select or not in User options (see previous table).

Option	Function	Choice		
Ward	**Ward code**	■ Code: 0000 (0200 by default) Use increment and/or decrement keys, then **OK** for each digit		
	[Par 1] Beep sound	■ 1 tonality	■ 2 tonalities	■ Key beep
		■ For preventive silence		
		■ Silence duration between 2 alarm beeps (0 to 5 seconds)		
	[Par 2] Sound level	■ 7 sound levels available		
	[Par 3] Initial parameters	■ **Drug and parameters**: last drug name and parameters are displayed at start-up ■ **Same infusion screen**: once activated, last infusion parameters (VTBI, Time, Rate, VI) are recalled at switch ON for the set duration ■ **Volume infused**: clear (VI=0 at switch ON), stored (VI cumulated at switch ON)		
	[Par 4] Maximum rates	■ Macro infusion (ml/h)	■ Micro infusion (ml/h)	
	[Par 9] Bolus rates	■ Maxi. macro (ml/h)	■ Maxi. micro (ml/h)	■ Storage: select option to store last bolus rates
		■ Macro flowrate (ml/h)	■ Micro flowrate (ml/h)	
	[Par 10] Ward name	■ Press increment and/or decrement keys to select alphanumeric characters. Press **OK** after each selection		
	[Par 11] Biomedical name			
	[Par 12] User code	■ 2-digit mandatory code to set code to user menu		
	[Par 13] Mains supply disconnection alarm	■ Mains supply disconnection warning activated or not		
	[Par 17] Drug library	■ Selection of a drug library among four (maximum)		
	[Par 18] Night mode	■ Screen brightness low	■ Green lights low	■ Key beep off
		■ Manual mode: manual switch from one mode to another	■ Auto mode: automatic switch from one mode to another according to the time range settings	
		■ Select night mode. Use the button to change mode	■ From (hh:mm) ■ To (hh:mm)	

Option	Function	Choice		
Ward	**[Par 19] Authorised functions**	■ Manual bolus	■ Prime set	■ See air bubble
	[Par 21] Mode displayed	■ Last mode: At switch ON, the device will operate using the previous programming mode	■ Question mode: At switch ON, the device will ask which programming mode is to be used	
	[Par 22] Authorised modes	■ Drug labelling (or)	■ Vigilant Drug'Lib	
	[Par 24] Macro/micro mode	■ Macro: infusion defined by increments of 1 ml	■ Micro: infusion defined by increments of 0.1 ml	■ Storage: the last choice is used at switch ON
	[Par 27] Air parameters	■ Macro parameters (see below)	■ Micro parameters (see below)	
		- Total volume/15 min (µl): above this volume of air, the alarm is triggered. - Bubble filter (µl): minimum bubble size taken into account.		
	[Par 28] Auto switch on at door opening	■ Automatic switch on at door opening (select/deselect) when device on mains supply		
	[Par 29] Infusion mode	■ Defines available infusion mode		
		■ Volume/time/rate	■ Volume/rate	
		■ Volume/time	■ Time/rate	
		■ Simple rate	■ Storage : stores the last infusion mode	
	[Par 30] Drop sensor	■ Compulsory (select/deselect)		
	[Par 31] Pre alarm end VTBI	■ Defines the pre-alarm parameters **Note**: The parameters of the pre-alarms can be readjusted. Nevertheless, the following situation should be carefully considered: the end of infusion pre-alarm should not be deactivated in case of short half-life drugs or for infusion with rigid bottles.		
		■ Duration: from 0 to 30 min before the end of the infusion **Note**: Adjusting down to 0 (disabling) is possible with Partner Agilia software only.	■ % Volume: from 0 to 15% of remaining VTBI	
		■ Volume: from 0 to 50 ml of remaining VTBI	■ With drop sensor: Activate or deactivate pre-alarm when using drop sensor	
Maint.	**Maintenance**	■ Code: XXXX (please contact our technical team)		

9. User test

This protocol allows a quick check of pump functionality.

Volumat Agilia **serial number (ID/N):** _____	**Name:** _____ **Ward:** _____ **Date:** _____

Actions	YES ☒ NO ☐
1. Check the state of the device: - absence of impact marks and noises (turn the device upside down), - presence of all labels as well as their legibility, mains lead.	☐
2. Without connecting the device to the mains, press the key: - check the functionning of the display and luminous indicators. - functioning on the battery is signaled.	☐
3. Install set without liquid: - close the door and check message: "air bubble"	☐
4. Remove set. Fill set with liquid. Install set incorrectly with pumping segment outside the pump. - check message: "Install set"	☐
5. Re-install set correctly as described in the user guide: - check that the OCS test is OK	☐
6. Set infusion parameters - 500 ml/h (no patient connected) - start infusion.	☐
7. Clamp the upstream line with the roller clamp: - check that the upstream occlusion alarm occurs in less than 15 seconds, - check visual and audible alarm	☐
8. Open roller clamp.	☐
9. Start infusion (500 ml/h) and clamp the downstream line: - check occlusion alarm (less than 15 seconds).	☐
10. Unclamp the downstream line. Open the door: - check that there are no more than 3 drops falling in the drip chamber.	☐
11. Connect the device to the mains supply: - check the "mains" indicator.	☐
The device is operational when all controls are OK.	☐
Signature	

Note: if one or more tests do not conform, please contact the appropriate department, our After-Sales Service or our Customer service.

10. Performances

Rates range

	Modes	Rates range	
Infusion rate (ml/h)	**Macro**	From 1 to 1200 ml/h, with 1 ml/h increments	Maximum infusion rate can be configured in Ward option [par4] page 34
	Micro	From 0.1 to 100 ml/h, with 0.1 ml/h increment	
Manual Bolus rate (ml/h)	**Macro**	From 200 to 1200 ml/h, with 50 ml/h increments (0 = deactivation)	Maximum infusion rate can be configured in Ward option [par9] page 34 Manual bolus inhibition: 0 ml/h
	Micro	From 200 to 1200 ml/h, with 50 ml/h increments (0 = deactivation)	
Prime rate (ml/h)	**All modes**	Maximum rate (1200 ml/h)	

Volume to be infused

The volume to be infused in macro mode can be set from 1 to 9999 ml.
The volume to be infused in micro mode can be set from 0.1 to 1000 ml.

KVO Rate (Keep Vein Open)

Default: 1mL/h (adjustable from 0 to 20 mL/h). Activated when VTBI is reached.
Note: if KVO is higher than programmed rate, then infusion continues at programmed rate.

Infusion time

From 0h01 to 168h00.

Drug library

Up to four libraries can be stored in the device. Each one can contain up to 240 drugs. This total capacity can be limited by the number of comments and the other fields. These libraries are configured with the Vigilant® Drug'Lib software.

Air detection

Default setting: 250 µl detected as a single bubble or cumulated volume air over a period of 15 minutes, from bubble sizes above 50 µl.
Resolution of sensor: ~ 10 µl.
For fragile patients (critical patients, neonates etc.), we recommend lowering the air detection threshold, or using an air eliminating filter attached to or part of the Volumat line.

Set replacement interval

The mechanical properties of the set in association with the pump are designed to maintain pumping performances for 10 L maximum within a time limit of 96 hours. Nevertheless, we recommend replacing the administration set every 24 hours for microbiological reasons, unless local policy or regulation may be applicable. The set should be disconnected from the IV site according to local facility procedures.

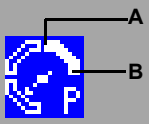
Accuracy

Flow rate accuracy	± 5 % over 96h with a maximum of 10 liters infusion	Following NF EN/IEC 60601-2-24 standard.
Manual bolus	± 5 % or ± 0.2 ml	
Accuracy with back pressure of ±13.33 kPa	± 5% over 96h with an infusion of 10 liters maximum	

Programmable pause

Programmable pause	From 1 minute to 24 h	1 minute increments.

Pressure management

Variable mode 	Maximum pressure (B)	From 50 to 750 mmHg	25mmHg increment (50-250 mmHg) 50mmHg increment (250-750 mmHg). Defines the authorized maximum pressure during infusion.
	Pre-alarm level (A)	50 mmHg below maximum pressure	**Note**: If max. pressure is set to 50 mmHg, then the pre-alarm is not activated.
3 levels mode	High	750 mmHg	These values are given as an example and configurable in User option [User 4], page 33.
	Middle	400 mmHg	
	Low	100 mmHg	
DPS (Dynamic Pressure System)	Pressure increase	Anticipates an occlusion during infusion.	
	Pressure decrease	A pressure decrease may indicate a disconnection or a leak in the line.	
	Accuracy: the accuracy on the pressure threshold activation is 75 mmHg or ± 15%. **Note**: 1 bar = 750 mmHg = 1000 hPa.		

Occlusion alarm response time

The occlusion times have been obtained by creating an occlusion with a three-way-stopcock situated immediately after a VL ST10 set. Occlusion times may vary if the occlusion occurs at a different place in the line or if another model of infusion set is used.

Rate	Occlusion alarm threshold			
	100 mmHg	300 mmHg	400 mmHg	750 mmHg
1 ml/h	7’	22’	34’	58’
25 ml/h	15"	45"	56"	1’ 52"
100 ml/h	2"	9"	12"	27"
These values can vary by +/- 20 % depending on the device and the tubing set.				

Bolus volume at occlusion release

Rate	Bolus volume
< 100 ml/h	< 0.2 ml
> 100 ml/h	< 0.3 ml

Calculation rules

	First parameters set up after switch on and in stop mode	During infusion: press on selection keys
V/T	Modify V, T is calulated according to T = V / R	R is modifed and T is calculated according to T = V / R
	Modify T, R is calculated according to R = V / T	
V/R	Modify V, T is calulated according to T = V / R	R is modifed and T is calculated according to T = V / R
	Modify R, T is calulated according to T = V / R	
T/R	Modify T, V is calculated according to V = R x T	R is modifed and T is calculated according to T = V / R
	Modify R, V is calculated according to V = R x T	
V/T/R	Modify V, T is calulated according to T = V / R	R is modifed and T is calculated according to T = V / R
	Modify T, R is calculated according to R = V / T	
	Modify R, T is calculated according to T = V / R	

V = Volume to be infused
T = Infusion time
R = Rate

Note 1: The calculated value for macro infusion is displayed rounded according to the following rules.

Calculated Value		Example
V	Rounded up to nearest ml	Calculated V = 1.3 ml, Displayed V = 2 ml
T	Rounded up to nearest minute	Calculated T = 1 h 12 min 32 sec, Displayed T = 1h13
R	Rounded at ± 0.5 ml/h	Calculated R = 42.52 ml/h, Displayed R = 43 ml/h Calculated R = 42.39 ml/h, Displayed R = 42 ml/h Real infusion rate = calculated rate
Note: For micro infusion, calculated rate is rounded at +/- 0.05 ml/h		

11. Technical characteristics

⚠ Electrical power

Use the main lead supplied with Volumat Agilia.

Mains power	Mains supply :	100 V - 240 V ~ / 50-60 Hz with functional earth.
	Maximum power consumption:	15 VA
	Protective fuses:	2 x 1AT accessible in the battery compartment .
External power	9 Volts continuous ⎓ / Power > 15 Watts. Via a specific Fresenius Kabi accessory connected to an 8-pin connector.	

⚠ Battery

Disconnect battery before opening device. Avoid short circuits and excessive temperatures.

If the device is not used over an extended period, all of its parameters are stored permanently, except the date that is erased after 3 months. When the pump is switched on, you are invited to set the date again.

Characteristics	7.2 V 2.2 Ah - Li-ion battery.
Weight	Approximately 100 g
Battery life	8 h min at the intermediate rate of 25 ml/h, and at any rates lower than 125 ml/h.
Battery recharge	Pump OFF: < 6 h. Pump ON: < 20 h.

⚠ Communication port

The connector situated at the back of the device allows different functions using the communication, mains power and nurse call cables.

Nurse call	Nurse call relay output command.
Serial cable	TTL output.
External power	9 VDC / 15 W input.
Power output	5 VDC / 150 mA to power Nurse Call or Serial Link accessories.

Infrared communication

Volumat Agilia is equipped with an infrared cell located at the back of the device. It is used for data communication with the Agilia link rack. Data can then be transmitted by dedicated communication cables.

Compliance

CE 0459	Conform to the 93/42/CE Medical Directive.	**IP22** Protection against splashing liquid. Protection against leakage current: Defibrillation-proof type CF applied part. Protection against electric shocks: class II. Functional earth.
Safety of ElectroMedical Equipments	Conform to EN/IEC 60601-1 and EN/IEC 60601-2-24.	
EMC (ElectroMagnetic Compatibility)	Conform to EN/IEC 60601-1-2 and EN/IEC 60601-2-24.	
	The functional earth is directly connected to the mains socket. It reduces residual current that may disturb ECG or EEG devices.	

Dimensions - Weight

H / W / D	135 x 190 x 170 mm
Weight	Approximately 2 kg
Screen size	70 x 35 mm

Trumpet curves

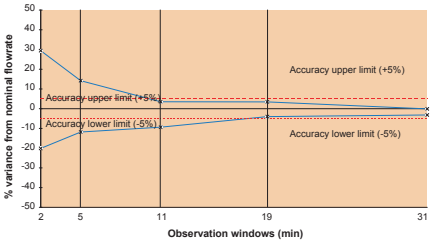
Trumpet curves demonstrate the evolution of the minimum and maximum variance of the pump / set combination versus flow rate.

The test protocol used to obtain these results is described in the EN/IEC 60601-2-24. For further information, please refer to this publication.

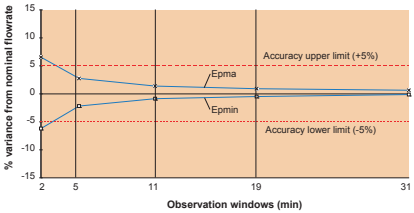
Use these curves to determine the accuracy depending upon your infusion protocol/drug/dilution. These graphs are representative of VL Volumat tubing sets.

Trumpet curves for 2, 5, 11, 19, 31 minutes observation windows

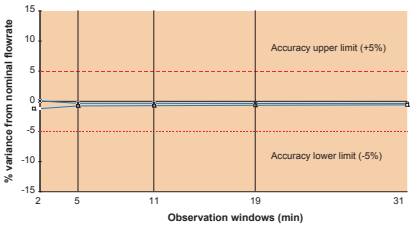
1 ml/h



25 ml/h

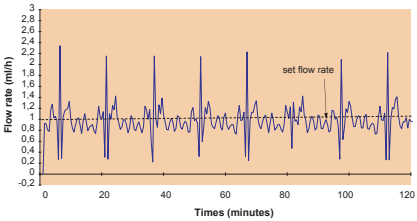


100 ml/h

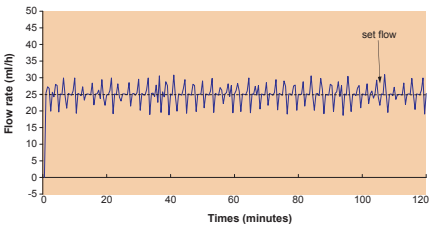


Flow rate/time curves: start-up and instantaneous flow rate (volume is measured every 30 seconds)

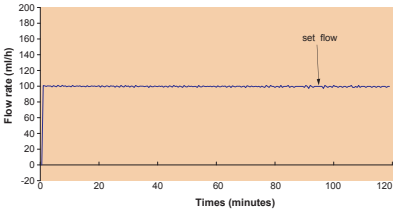
1 ml/h



25 ml/h



100 ml/h



12. Guidance and manufacturer's declaration on EMC

The guidance below is valid for pumps used outside of the MRI Guard Agilia.

For use in MRI environment with the MRI Guard Agilia, please refer to the MRI Guard Agilia instructions for use.

Electromagnetic emissions - Table 201

Volumat Agilia is intended for use in the electromagnetic environment specified below. The user of Volumat Agilia should make sure it is used in such an environment.

Emissions test	Compliance obtained by the device	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	Volumat Agilia uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	Volumat Agilia is suitable for use in all establishments, including domestic and hospital establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations Flicker emissions IEC 61000-3-3	Does not apply	

Electromagnetic immunity - Table 202

Volumat Agilia is intended for use in the electromagnetic environment specified below. The user of Volumat Agilia should make sure it is used in such environment.

Immunity test	IEC 60601-1-2 IEC 60601-2-24 Test level	Compliance level obtained by the device	Electromagnetic environment - guidance
Electrostatic Discharge (ESD) IEC 61000-4-2	± 8 kV contact ± 15 kV air	± 8 kV contact ± 15 kV air	Coatings of the floors out of wooden, tilling, and concrete, with a relative humidity level at least 30 %, make it possible to guarantee the level of necessary conformity. If it is not possible to guarantee this environment, additional precautions must be taken, such as: anti-static material usage, preliminary user discharge and the wearing of anti-static 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	Mains power quality should be that of a typical domestic, commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV differential mode ± 2 kV common mode	± 1 kV differential mode ± 2 kV common mode	Mains power quality should be that of a typical domestic, commercial or hospital 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 cycle	< 5 % Ut (> 95 % dip in Ut) for 0,5 cycle	Mains power quality should be that of a typical domestic, commercial or hospital environment. For short and long interruptions (< than battery life) of power mains, the internal battery provides the continuity of service. **Note**: Ut is the a/c. main voltage prior to application of the test level.
	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	400 A / m	400 A / m	If necessary, the power magnetic field should be measured in the intended installation location to assure that it is lower than compliance level. If the measured field in the location where the Volumat Agilia is used exceeds the applicable magnetic field compliance level above, the Volumat Agilia should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or re-locating Volumat Agilia, or install magnetic shielding.

Electromagnetic immunity - Table 204

Volumat Agilia is intended for use in the electromagnetic environment specified below. The user of Volumat Agilia should make sure it is used in such an environment.

Immunity test	IEC 60601-1-2 IEC 60601-2-24 Test level	Compliance level obtained by the device	Electromagnetic environment - guidance
			Portable and mobile RF communications equipment should be used no closer to any part of the Volumat Agilia including cables, than the recommended separation distance calculated from the equation applicable to the frequency of transmitter. Recommended separation distance:
Conducted RF IEC 61000-4-6	10 Vrms 150 kHz to 80 MHz	10 Vrms	$D = 0.35 \sqrt{P}$, for a frequency of 150 kHz to 80 MHz
Radiated RF IEC 61000-4-3	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 Where 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 meter (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 1: At 80 MHz and 800 MHz, the highest frequency range applies.

Note 2: These guidelines may not apply to all situations. Absorption and reflection from structures, objects and people affect electromagnetic propagation.

(a) Field strengths from fixed transmitters, such as base stations for radio (cellular / cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast 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 Volumat Agilia is used exceeds the applicable RF compliance level above, Volumat Agilia should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or re-locating Volumat Agilia, or install magnetic shielding.

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

Recommended separation distances between portable and mobile RF communication equipment and Volumat Agilia - Table 206

Volumat Agilia is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The user of Volumat Agilia can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and Volumat Agilia as recommended below, according to the maximum output power of the communication equipment.

Rated maximum output power of transmitter (W)	Separation distance according to frequency of transmitter in meters (m)		
	150 kHz to 80 MHz $d = 0.35 \sqrt{P}$	80 MHz to 800 MHz $d = 0.35 \sqrt{P}$	800 MHz to 2,5 GHz $d = 0.7 \sqrt{P}$
0.01	0.04	0.04	0.07
0.1	0.11	0.11	0.22
1	0.3	0.3	0.7
10	1.1	1.1	2.2
100	3.5	3.5	7

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

Note 1: At 80 MHz and 800 MHz, the separation distance for the highest frequency range applies.

Note 2: These guidelines may not apply to all situations. Absorption and reflection from structures, objects and people affect electromagnetic propagation.

The use of accessories and cables, other than those specified, can result in increased emissions or decreased immunity of the device.

The device should not be used adjacent to other equipment and that if adjacent use is necessary, the device should be observed to verify normal operation in the configuration in which it will be used (pump with a mains cable, an RS232 cable).

13. Cleaning and use conditions

Cleaning and disinfecting

■ Volumat Agilia is part of the patient's immediate environment. It is advisable to clean and disinfect the device's external surfaces regularly and especially before connecting a new patient and before any maintenance operation in order to protect patient and staff.

1. Prepare the detergent-disinfectant solution.
2. Disconnect the device from the power supply.
3. Moisten the disposable cloth with the detergent-disinfectant solution, carefully wring out the cloth. Repeat at each stage of the cleaning process.
4. Start by cleaning the bottom side of the device. Then carefully turn the device upside down without touching the mobile parts. Put down the device on a clean surface.
5. Continue the cleaning on sides of the device without wetting the sockets.
6. Clean the keyboard.
7. Complete the cleaning of the most exposed surfaces, the most critical zones and the mains cord.
8. Do not rinse, leave to dry.
9. Protect and keep the device clean before reuse.
10. Validate the maintenance protocol by simple bacteriological checking.

■ Do not place in an AUTOCLAVE or IMMERSE the device. Do not let liquids enter the device's casing.

■ **DO NOT USE**: TRICHLOROETHYLENE-DICHLOROETHYLENE - AMMONIA - AMMONIUM CHLORIDE - CHLORINE and AROMATIC HYDROCARBON - ETHYLENE DICHLORIDE-METHYLENE CHLORIDE - CETONE. These aggressive agents could damage the plastic parts and cause device malfunction.

■ Take care also with ALCOHOL BASED SPRAYS (20% - 40% alcohol). They lead to tarnishing and create small cracks in the plastic, and do not provide the necessary cleaning prior to disinfecting. Disinfecting SPRAYS may be used, in accordance with the manufacturer recommendation, from a distance of 30 cm of the device, avoid the accumulation of the product in liquid form.

■ Please contact the appropriate service, responsible for cleaning and disinfecting products, in your establishment for further details.

Environmental conditions

The device should be stored in a dry and cool place. Do not expose to sunlight or heat sources. Keep away from animals or any objects that could potentially damage the device. In case of prolonged storage, the battery should be disconnected. This should be done by a qualified technician who can access the battery via the battery access flap situated underneath the device.

■ **Storage conditions and carrying**

Temperature: - 10°C to +60°C.
Pressure : 500 hPa to 1060 hPa.
Humidity : 10% to 90%, no condensation

■ **Use conditions**

Temperature: 5°C to 40°C.
Pressure : 700 hPa to 1060 hPa.
Humidity : 20% to 90%, no condensation.

Transport conditions

Before transport, make sure the battery is sufficiently charged in the Battery life menu. Disconnect the pump's mains cord.

Press silence to acknowledge. Handle the pump with care during transport.

After transport, reconnect the mains cord. A beep is emitted.

Use of the internal battery

This device is provided with a Li-ion battery. When the device is disconnected from the mains, it automatically switches to battery mode.

Before starting for the first time, charge the battery for approx. 5 hours by connecting the power supply cord without using the device.

If the device is not used during an extended period (longer than 2 months), it is recommended to remove the battery from the device and store it as indicated in the storage instructions. If it is not possible to remove the battery or during a short period (less than 2 months), it is recommended to charge the battery at least once a month, by leaving the device connected to the mains for at least 8 hours (device off).

You can also recharge a Lithium-ion battery whenever convenient, without observing the full charge/discharge cycle that is required to get full capacity when fully charged.

In order to maximise battery lifetime and performance:

- Use and store in a cool place.

- During operation, leave the device connected to the mains to maintain the charge of the battery and the maximum capacity when possible.

Lithium-ion rechargeable battery - to be handled with care!

- Do not incinerate or place near an open flame.
- Do not drop, crush, puncture, modify or disassemble battery.
- Do not use the battery that is severely scarred or deformed.
- Do not short terminals.
- Do not expose to high temperature.
- Do not replace by a battery other than that specified by manufacturer.
- Do not charge or discharge otherwise than in the device.

Recommendations

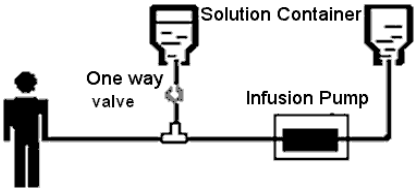
- ***Fresenius Kabi*** will not be liable for any damages or claims, medical or otherwise, of any nature whatsoever, whether direct or consequential, caused by improper use of this device.
- In order to insure that all the safety features of the device are activated, the pump should be switched ON prior to being connected to the patient.
- Special attention must be paid to the stability of the device. Use the device in horizontal position, on a table, or with the incorporated clamp for using on a pole.
- ***Fresenius Kabi*** recommends not placing the pump higher than 1,3 meter above patient.
- Container must be placed on a range of 50 cm above the pump ± 30 cm.
- 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 with your protocol (see configuration menu); the time to detect a downstream occlusion being conversely proportional to the flow rate, it is recommended to lower the pressure limit in order to gain in time to detect an occlusion. For the infusion of very short half-life drugs at flow rate below 5 ml/h, we recommend the use of syringe pumps that usually offer better performances of instant flow rates. Checks instant flow rate curves and trumpet curves.
- The pump may only be connected to the mains with the power cord supplied by the manufacturer. Check that the mains voltage corresponds with the value indicated on the label placed underneath the device. Do not exceed the permitted voltage on the different external connections.
- The pump should be used with accessories listed on page 50 only.
- High inline depression may create free flow.
- Only use luer lock connection to prevent disconnection due to infusion pressure.
- Do not use in conjunction with positive pressure infusion devices that could generate back pressure higher than 2 000 hPa susceptible to damage infusion disposable and the device.
- During the use without drop sensor, the adjusted volume to be infused must be less or equal to the volume actually contained into the bag, bottle or burette. The right adjustment of the volume to be infused contributes to the air injection risk reduction.

Special recommendations linked to the use of Volumat Lines:

■ During all manipulations on the pump or on the set (set installation, door opening, set removal), close the roller clamp and make sure the line is closed near to the injection device with a clamp or a stopcock. If they are not available, we recommend a back check valve to be assembled on the injection device in order to avoid any pressure variations that may occur due to the compliance of the line.

■ **Use only** disposable proposed in this Operator's Guide in accordance with local standard operating procedures and good clinical practices. Using non recommended disposable could lead to serious hazards such as free flow or pump degradation. After the disposable is primed, check the integrity of the connected disposable to patient (no leak, no air, especially after the air bubble sensor).

■ ***Fresenius Kabi*** recommends the use of one way valves or positive pressure infusion devices for multi-line infusions.



■ If there is no one way valve on a gravity infusion line during a multi-line infusion, this will make it impossible to detect occlusions on the patient side, and could result in accumulation of the drug being infused in the gravity line, which could later be infused in an uncontrolled manner when the occlusion is released.

■ Place the connection between the gravity line and the pump-driver line as near to the start of the set as possible in order to minimize the dead space and consequently the impact of any change in flow rate on the gravity line.

■ The filter size and the materials used in the infusion set are mentionned in its individual packaging: check they are suitable with the fluid or drug to be administered.

■ The infusion set may be equipped with ports (K-nect needle-free access, or 3-way stopcock). These ports should be accessed by respecting aseptic procedures and the pump is on hold.

■ The upstream ports (above the pump) must not be used to deliver a manual bolus into the line. They should be used only to connect a secondary infusion line.

■ The downstream ports (below the pump) must not be used to connect a secondary line.

■ The downstream ports (below the pump) may be used to administer a manual bolus by means of a luer lock syringe into the line: when administering a bolus, we recommend to hold the infusion.

■ Use of the Volumat Lines with two spikes or with secondary lines: we do not recommend to keep the two lines open. Only the line from which the fluid is supposed to be administered should be open, the others must not be open.

14. Services

Conditions of guarantee

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.

To benefit from the materials and workmanship guarantee from our After-Sales Service or agent authorized by ***Fresenius Kabi***, the following conditions must be respected:

- The device must have been used according to the instructions in this Operator's Guide.
- The device must not have been damaged when in storage, at the time of repair, or show signs of improper handling.
- The device must not have been altered or repaired by non-qualified personnel.
- The internal battery of the device must not have been replaced by a battery other than that specified by manufacturer.
- The serial number (ID/N°) must not have been altered, changed, or erased.
- In case of non-respect of these conditions, ***Fresenius Kabi*** will prepare an estimate for repair covering the parts and labor required.
- When return and repair of a device is necessary, please contact ***Fresenius Kabi*** Customer or After-Sales Department.

Quality control

Upon the hospital request, a control check of the device may be performed every 12 months.

A regular control check (not included in the guarantee) consists of various inspection operations listed in the Technical manual. These control checks must be performed by an experienced technician and are not covered by any contract or agreement provided by ***Fresenius Kabi***.

Preventive maintenance

To ensure normal performance of the device, it is recommended that preventive maintenance is performed every 3 years. This includes battery and pumping membrane replacement. These actions should be performed by a qualified technician with the help of technical manual.

The qualified technicians in your establishment or our After-Sales Service should be informed if the device is dropped or if any of malfunctions occurs. In this case, the device must not be used.

In case of component replacement, only use ***Fresenius Kabi*** spare parts.

WARNING: Failure to comply with these maintenance procedures can damage the device and lead to a functional failure. Internal inspection of the device requires the respect of particular procedures to avoid damages to the pump or user.

Servicing

For further information concerning the device servicing or use, please contact our After-Sales Service or our Customer service.

If a device is returned to our After-Sales Department, it is essential to clean and disinfect it, then, pack it very carefully, if possible in its original packaging, before sending it.

Fresenius Kabi is not liable for loss or damage to the device during transport to our After-Sales Department.

⚠ **Recycling of obsolete batteries, devices and disposables:**
Before disposal, remove battery from the device. Batteries and devices with this label must not be disposed of with the general waste. They must be collected separately and disposed of according to local regulations. For further information pertaining to waste processing regulation, contact your local Fresenius Kabi.
Homecare providers are responsible for elimination of infusion sets and bags used at home according to current standards in order to limit the risk of harm and infection.

Maintenance requirements

- Maintenance must be performed by qualified and trained technical personnel using the technical manual and procedures.
- Homecare providers are responsible for periodic maintenance of pumps used at home.

Data racks, accessories and maintenance tools

Volumat Agilia is compatible with the range of Agilia accessories.

Use only recommended accessories delivered with the device or described below. Please refer to its specific instructions for use.

For operating with these accessories or any further information, please contact our Sales Department.

Duo Agilia	2 channels accessory for power supply centralisation	073495
Nurse call Agilia	Nurse call cable (4000 V isolated)	073496
Link 4 Agilia	Rack 4 slots for power centralisation	(Z)0740XX
Link 6 Agilia	Rack 6 slots for power centralisation	(Z)0760XX
Link 8 Agilia	Rack 8 slots for power centralisation	(Z)0780XX
Link 4 + Agilia	Rack 4 slots for power centralisation and communication capabilities	(Z)0745XX
Link 6 + Agilia	Rack 6 slots for power centralisation and communication capabilities	(Z)0765XX
Link 8+ Agilia	Rack 8 slots for power centralisation and communication capabilities	(Z)0785XX
MRI Guard Agilia	Transportable device that can accomodate up to 4 Agilia pumps in MRI environment	(Z)0749XX
Agilia Holder Ambulance	Can support and fix 1 Agilia pump in a road ambulance environment	(Z)0732XX
Drop sensor	Fixed to the drip chamber of the set to use the pump in "Simple rate" mode and to detect empty container.	Z073200
Infusion Pump Rolling stand	Can support and fix 1, 2 or 3 Agilia pumps	(Z)073150
Multichannel Rolling stand	Can support and fix up to 8 Agilia pumps mounted individually or onto Link 4 Agilia, Link 6 Agilia or Link 8 Agilia	(Z)073160
Twin-Link Rolling Stand	Can support and fix up to 16 Agilia pumps mounted on 2 racks Link Agilia (Link 4 Agilia, Link 6 Agilia, or Link 8 Agilia)	(Z)073170

Disposables

This sets list is indicative of most current product codes. To know the exact list of your product code, please contact our Sales Department or refer to the catalogue of Volumat Lines.

VL ST00	Standard set for infusion, 15 µm filter	M46441000
VL ST10	Standard set for infusion, 15 µm filter, rotating luer lock, Flow stop cap	M46441300
VL ST01	Standard set for infusion, 15 µm filter, 1 Injection site	M46441600
VL ST02	Standard set for infusion, 15 µm filter, 1 K-Nect needle-free access	M46441900

VL ST22	Standard set for infusion, 15 µm filter, 2 K-Nect needle-free accesses	M46442500
VL TR00	Set for transfusion, 200 µm filter	M46442800
VL TR12	Vented set for transfusion, 200 µm filter, 1 K-Nect needle-free access	M46442700
VL TR22	Primary set for transfusion and infusion, 200 µm filter, 2 K-Nect needle-free accesses	M46443000
VL TR43	Vented set for transfusion and infusion, 200 µm filter, 2 K-Nect needle-free accesses	M46444500
VL SP22	Dual set for transfusion and infusion, 200 µm filter, 1 K-Nect needle free access	M46443100
VL SP62	Set for infusion of drugs incompatible with PVC, 15 µm filter, 1 K-Nect needle-free access	M46443400
VL SP90	PVC-free set for infusion of drugs incompatible with PVC, light protecting, 15 µm filter	M46443500
VL SP92	PVC-free set for infusion of drugs incompatible with PVC, light protecting, 15 µm filter, 1 K-Nect needle free access	M46443600
VL PN20	Parenteral Nutrition set, 15 µm filter, upstream Luer lock connection	M46443700
VL PN00	Parenteral Nutrition set, 1.2 µm air eliminating filter	M46444300
VL PN00 FX	Parenteral nutrition set for Freeflex® bags, 1.2 µm air eliminating filter	M46442300
VL PN02	Parenteral nutrition set, 1.2 µm air eliminating filter, 1 K-Nect needle-free access	M46444400
VL PN02 FX	Parenteral nutrition set for Freeflex® bags, 1.2 µm air eliminating filter, 1 K-Nect needle-free access	M46442400
VL ON10	Oncology set for infusion of drugs in closed system, 1 side line, 15 µm filter	M46445500
VL ON11	Oncology set for multi infusion of drugs in closed system, 1 K-Nect needle-free access, 15 µm filter	M46443900
VL ON12	Oncology set for multi infusion of drugs incompatible with PVC in closed system,1 K-Nect needle-free access, 15 µm filter	M46444800
VL ON12 FX	Oncology set for Freeflex® bags for multi infusion of drugs in closed system,2 K-Nect needle-free access, 15 µm filter	M46444850
VL ON20	Oncology set for multi-infusion of drugs in closed system, 2 side lines, 15 µm filter	M46445700
VL ON30	Oncology set for multi-infusionof drugs in closed system, 3 side lines, 15 µm filter	M46445900
VL ON21	Oncology set for multi infusion of drugs incompatible with PVC in closed system,2 K-Nect needle-free accesses, 15 µm filter	M46444200
VL ON22	Oncology set for multi infusion of drugs incompatible with PVC in closed system,2 K-Nect needle-free accesses, 15 µm filter	M46444200

VL ON22 OP	Oncology set for multi infusion of light sensitive drugs incompatible with PVC in closed system, 2 K-Nect needle-free accesses, 15 µm filter	M46446000
VL ON22 FX	Oncology set for Freeflex® bags for multi infusion of drugs in closed system,3 K-Nect needle-free accesses, 15 µm filter	M46444250
VL ON40	Oncology set for multi infusion of drugs in closed system, 3 side lines, 2 spikes, 15 µm filter	M46445100
VL ON42	Oncology set for multi infusion of drugs in closed system, 4 K-Nect needle-free accesses, 15 µm filter	M46444000
VL ON42 OP	Oncology set for multi infusion of light sensitive drugs in closed system, light protecting, 4 K-Nect needle-free accesses, 15 µm filter	M46445800
VL ON42 FX	Oncology set for Freeflex® bags for multi infusion of drugs in closed system, 5 K-Nect needle-free accesses, 15 µm filter	M46444050
VL ON70	Oncology set for infusion of drugs, 0.2 µm filter	M46444600
VL ON72	Oncology set for infusion of drugs, 0.2 µm filter, 1 K-Nect needle free access	M46444100
VL ON90	PVC-free set for infusion of light sensitive drugs, light protecting, 15 µm filter	M46444900
VL ON90 FX	PVC-free set for Freeflex® bags for infusion of light sensitive drugs, light protecting, 2 K-Nect needle-free accesses, 15 µm filter	M46444960
VL PA02	Paediatric Infusion set, 60 drop/mL, 15 µm filter, 1 K-Nect needle-free access microbore tube	M46442200
VL PA92	Infusion set with 150 ml graduated burette, 20 drop/mL, 15 µm filter, 2 K-Nect needle-free access	M46445200
VL PA93	Infusion set with 150 mL graduated burette, 20 drop/mL, 2 K-Nect needle-free accesses, 15 µm filter	M46443800
VL PA94	Infusion set with 150 mL graduated burette, 20 drop/mL, 2 K-Nect needle-free accesses, 15 µm filter	M46445300

Data management

RS 232 cable for Agilia	Communication cable for RS 232 connection (4000V isolated)	073493
USB cable for Agilia	Communication cable for USB connection (4000V isolated)	073491

Maintenance CD & tools

Partner Agilia	Maintenance CD	067037

This user guide may contain inaccuracies or typographical errors.
Modifications may thus be made and will be included in later editions.
Because of the evolution of the standards, lawful texts and material, the characteristics indicated by the text and the images of this document are applicable only for the device that it accompanies.

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CE 0459

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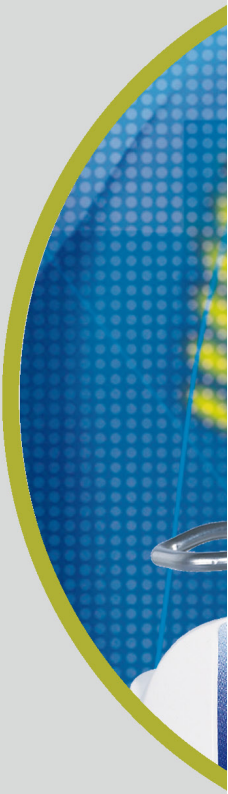

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