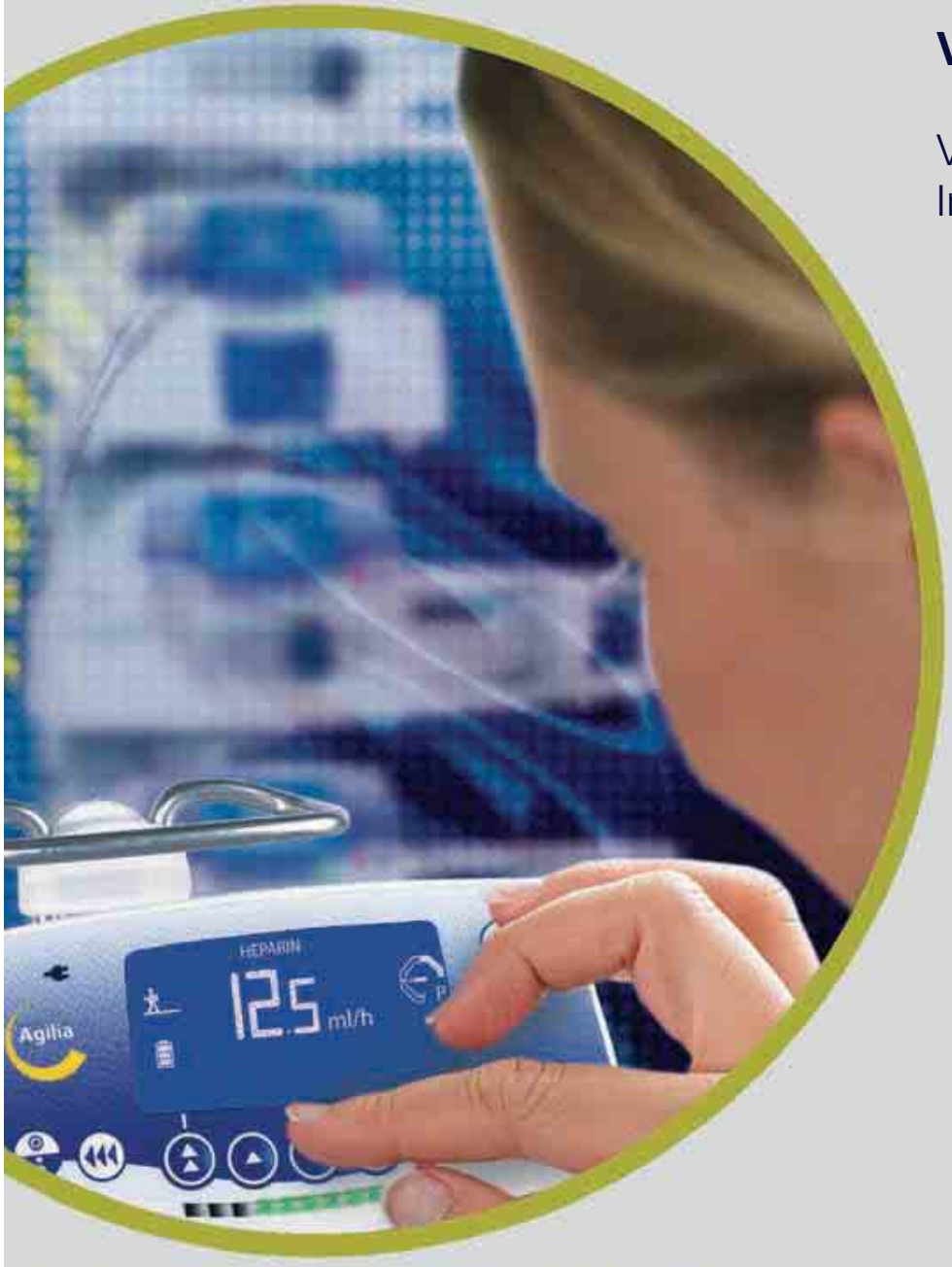
Agilia
Intuitive generation

Volumat MC Agilia

Volumetric infusion pump
Instrutions for use



MEDICAL DEVICES

FRESENIUS KABI
caring for life

Contents

1. Introduction

Volumat MC Agilia is the volumetric pump of the Agilia range, incorporating advanced features such as Dose rate, Ramp mode, Sequential mode, etc. It is intuitive and easy to learn, like all devices of the Agilia range. Thanks to its various programming modes, infusion modes, customization capabilities and its extensive set range, Volumat MC Agilia can be used in any unit of the hospital: general wards, paediatry, intensive care, oncology, etc.

Programming modes

Volumat MC 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, maximum flow rate and soft limit values, etc. The drug library can be customized 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)" or "Drug X (dose)" to define all the parameters of an undefined drug (neither in the drug list, nor in the drug library) without changing the programming mode.

Infusion modes

When flow rate mode in ml/h or dose rate mode are selected, the following infusion modes are authorized.

ml/h	Dose rate	Infusion mode	Description
X	**X**	**Volume/Time/Rate**	Infusion defined by a volume and a time or a flow rate.
X	**X**	**Volume/Rate**	Infusion defined by a volume and a flow rate. In that case, the time is calculated automatically.
X	**X**	**Volume/Time**	Infusion defined by a volume and a time. In that case, the flow rate is calculated automatically.
X	**X**	**Time/Rate**	Infusion defined by a time and a flow rate. In that case, the volume is calculated automatically.
X	**X**	**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.
X		**Ramp**	Infusion defined by a total volume, a total infusion time, a ramp up and ramp down time and a plateau flow rate. This mode allows the flow rate to be increased gradually by intermediate stages in order to reach the plateau flow rate.
X		**Sequential**	Infusion by sequences defined by volume to be infused and the infusion flow rate for each sequence.
X		**Secondary**	Infusion which enables to deliver the content of a secondary bag / bottle, by means of a secondary line connected to the main line called primary line.

ml/h	Dose rate	Infusion mode	Description
X	X	**Programmed bolus**	Bolus defined by its volume (or dose) and flow rate.
	X	**Loading dose**	Initial dose defined by a time and delivered before a dose rate.
X		**Drops per minute**	Infusion defined by a flow rate expressed in drops per minute.

Intended use

■ Volumat MC Agilia is an infusion pump designed for intravenous (IV), administration of drugs, solutions, fluids, parenteral nutrition and transfusion (special set required). It must be used only by professionals (hospital staff or caregivers).

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 MC 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 MC Agilia is placed near devices like HF surgical equipment, X-rays, NMR, mobile phones or Wi-Fi access points, it is essential to observe a minimum distance between the Volumat MC Agilia and this equipment (see page 60 - Electromagnetic Immunity).

■ 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.

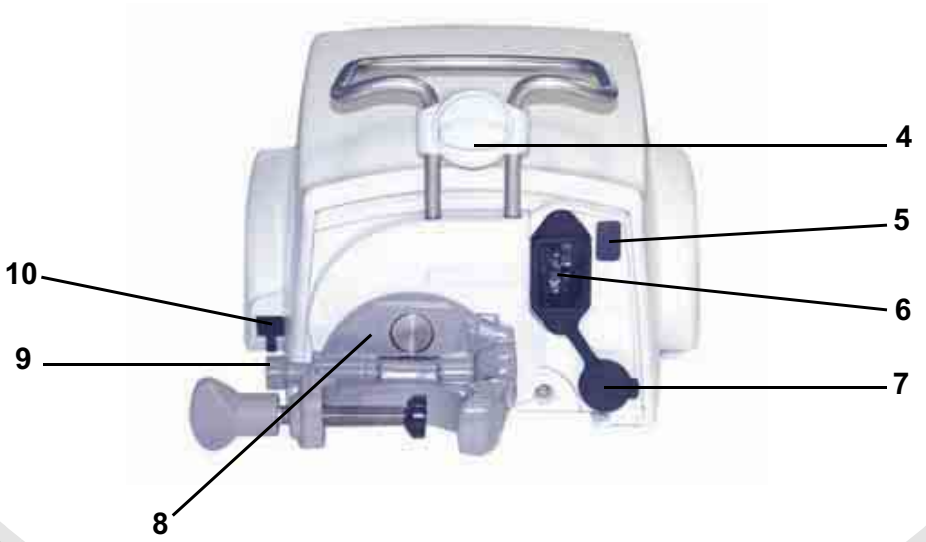
■ The device can be disturbed by pressure or pressure variations, mechanical shocks, heat ignition sources, etc. If you wish to use the device in specific conditions, please contact our After-Sales Department. The pump must be used in a horizontal and stable position to work correctly.

■ The 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.

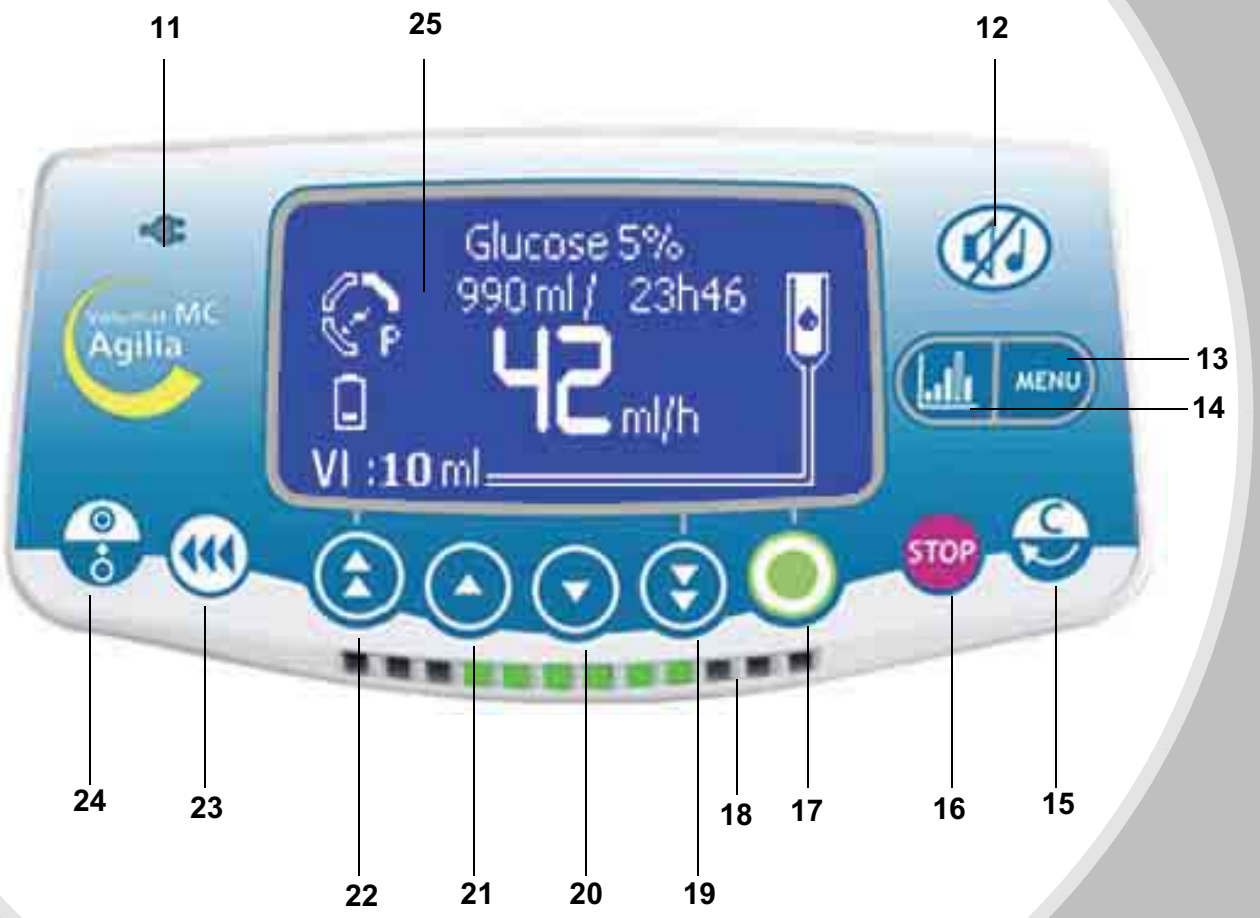
■ The device uses a Lithium-ion rechargeable battery. Incorrect handling of a Lithium-ion battery by non-qualified personnel may cause battery leakage, overheating, smoke, explosion or fire, which could result in deterioration of performance or failure. This may also damage the protection device installed in the battery pack, resulting in damage to the equipment or injury to the user (see page 63 - 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.

2. Description



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



11 -	Mains indicator	**17 -**	OK/Start/Enter	**23 -**	BOLUS or PRIME
12 -	SILENCE ALARM	**18 -**	Indicator lights (LEDs)	**24 -**	ON/OFF
13 -	MENU	**19 -**	Fast decrement	**25 -**	Monitoring screen (see page 12)
14 -	Graphic Function	**20 -**	Decrement		
15 -	Correction/Back	**21 -**	Increment		
16 -	STOP/PAUSE	**22 -**	Fast increment		

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.

Using the fixing clamp

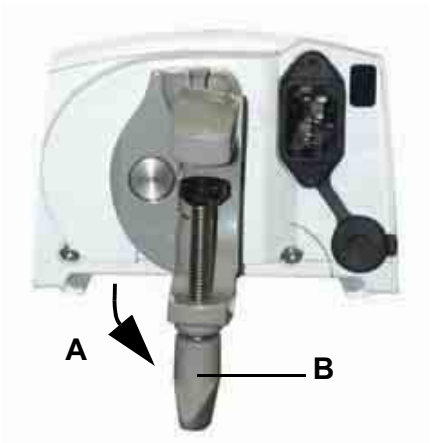
The fixing clamp is only orientable when closed against the pump. It is maintained in its vertical or horizontal position with the fixing button.
The following images show how to modify the pump installation, from a pole to a rail position.

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 fixing 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.



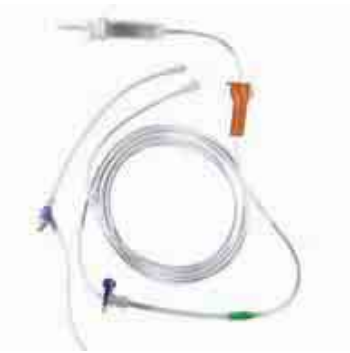
Installing the device

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

❷ Proceed with the User test, see page 50. 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 to fulfill local legal requirements before each use.

Preparing the infusion set

❶ From the Volumat 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.

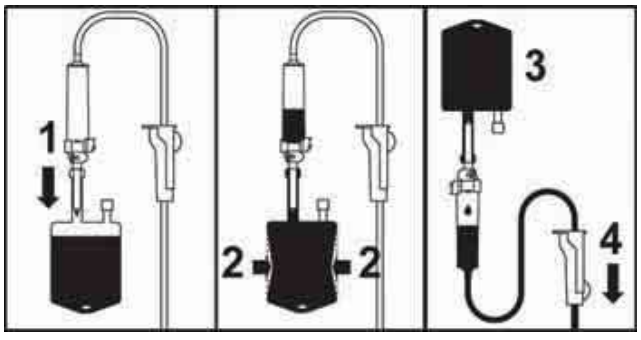
Purging the set used with a bag or a bottle

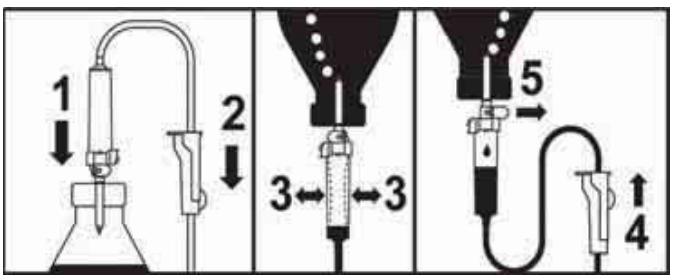
❸ **With a bag...**

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 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 into the set.
6. Once the infusion set is primed, close the roller clamp and check absence of air bubble.





Installing the tubing set in the pump

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 48). 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.

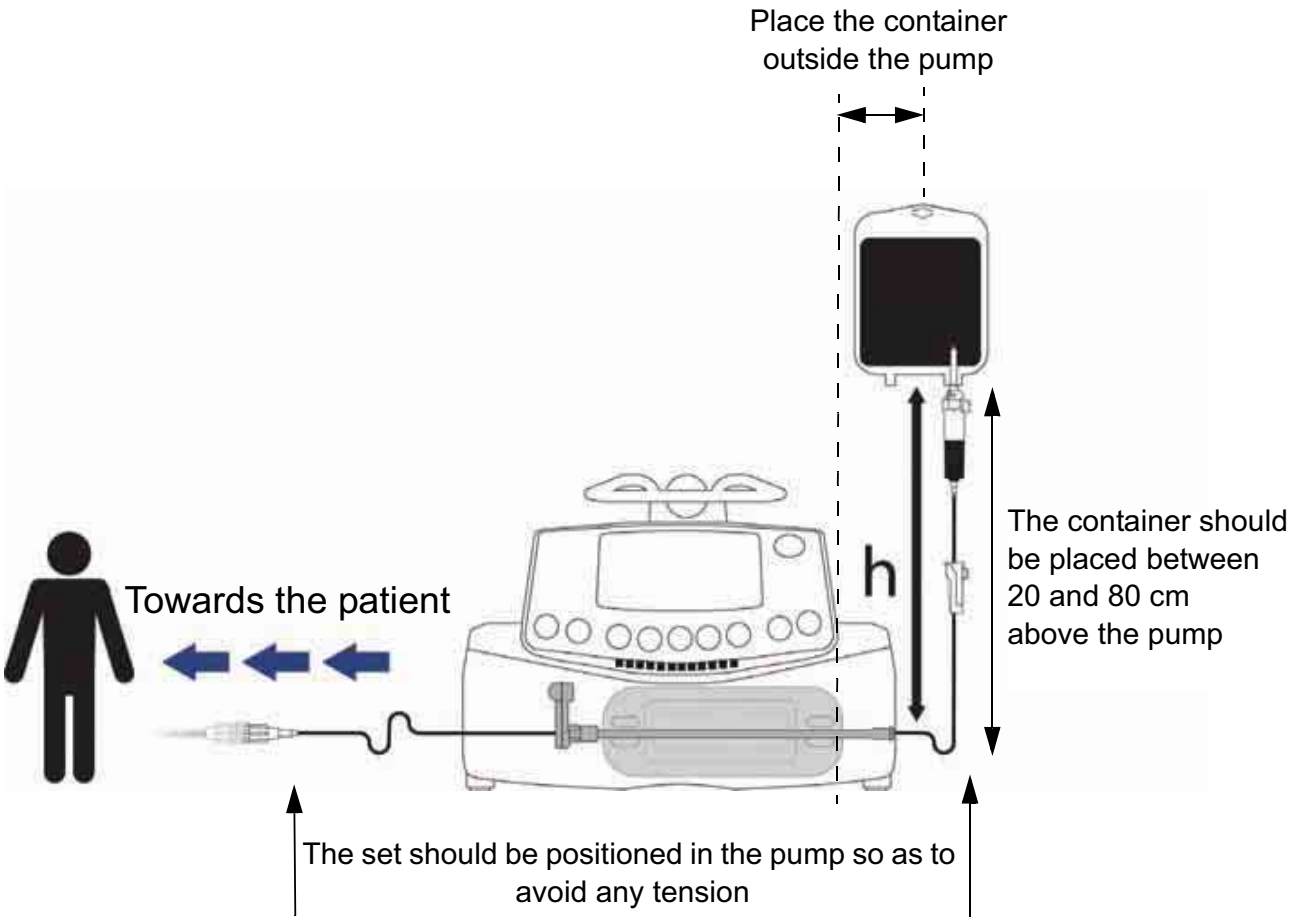
❷ 1. Align the tubing set horizontally along the tube guides so that the green connector is positioned to the right (green) and the blue clamp is positioned in front of the clamp guide (blue).
2. Insert the green connector in the green slot.
3. Position the blue clamp in its blue slot and then push the 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 the rise in pressure. The OCS test verifies the circuit and pump occlusivity to secure the pump against a risk of free flow.

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

Installing the tubing set in the pump

The final installation should look like this:



Monitoring screen

Pressure level
The arrow indicates the pressure level.
For details, go to page 53.

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. Infusion indicator. Speed is related to flow rate.

Battery level

Drop sensor presence indicators. Turns off when a drop is detected.

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

Infusion flow in progress. You can always modify it, whenever necessary, by simply pressing the increment/ decrement keys, and then **OK**.

4. Operations

No drug name and flow rate ml/h modes

The V/R infusion mode and No drug name programming mode are described. For another infusion mode, go to page 14; for another programming mode, go to page 25 or page 26.

1 - Flow rate/Start...

■ Choose flow rate ml/h mode (for Dose rate mode, refer to page 20) then press **OK**.

2 - 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 (1 ml, 10 ml, 20 ml, 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 be infused (~ 25 ml).

3 - Flow rate selection

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

Note: The infusion time is calculated automatically and adjusted according to the displayed flow rate.

4 - Starting the infusion

■ 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/Rate selection.

Other infusion modes in flow rate ml/h

The infusion mode set by default is displayed, but you can select another infusion mode (Volume/Time/Rate, Volume/Time, Time/Rate, Simple rate, Ramp, Sequence or Drops/min), provided it is preselected in the Ward option [Par 29] (see page 48).

Note: The infusion mode menu is accessible before starting the infusion and in <STOP> mode.

1 - Menu selection

■ Press the MENU key to display the Infusion mode screen. If it does not appear at first, use the arrows to select "ml/h".

■ Press **Enter**.

2 - Infusion mode selection

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

Note: New ? is displayed on the screen if you choose the current mode. Press this key to set new parameters.

3 - Volume/Time/Rate

■ Select a volume to be infused (VTBI), then press **OK**.

■ Select a time and press **OK**.

■ Select a flow rate and press **OK**.

■ Press **Start**.

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

or Volume/Time

■ Select a volume to be infused (VTBI), then press **OK**.

■ Select a time and press **OK**.

■ Press **Start**.

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

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.

Simple rate

- 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 35). 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.

Drops/minute mode

This infusion mode allows to convert the traditional prescription of rate in drops per minute into flow rate in ml/h.

- Check the equivalent quantity of drops per ml, then press **OK**.
- Select a volume to be infused (VTBI), then press **OK**.
- Select a flow rate or a number of drops per minute and press **OK** according to the service option [Par 33] (page 49).
- Press **start**.
- **Note**: The default value is based on the mathematical conversion 1 drop/min = 3 ml/h (20 drops per ml). This value can differ according to the choice of drug.

Ramp mode

This infusion mode allows, with a simple adjustment of the rise and fall times, the infusion flow rate to be increased gradually by 10 intermediate stages until the maximum plateau flow rate is reached. At the end of the infusion, the flow rate will be gradually reduced to zero.
Note: This mode is accessible only in flow rate ml/h mode.

- Adjust the total volume to be infused with ⏫ 🔼 🔽 ⏬. Confirm by pressing **OK**.
- Adjust the total infusion time in minutes with 🔼 and 🔽, in hours with ⏫ and ⏬.

Confirm by pressing **OK**.

- Adjust the rise time in minutes and in hours with the arrows. Confirm by pressing **OK**.
- Do the same for the fall time.
- Adjust the plateau flow rate with the arrows. Confirm by pressing **OK**.
- Press **start** to start the infusion.

1 - Infusion stop

- Press STOP during the infusion.

3 actions are then possible:

- Press D\ to start the ramp-down.
- Press STOP to stop the infusion.
- Press **C** to continue the infusion.

Note: This screen is accessible only during the plateau. Else, pressing STOP leads directly to the infusion stopping.

2 - Ramp-down

- Check the ramp-down values, then press **OK**.

Sequential mode

Up to 20 infusion sequences can be programmed, each with their own volumes to be infused and infusion flow rates. Pause (Stop) or Keep Vein Open (KVO) periods can also be programmed in sequential mode.

Note: This mode is accessible only in flow rate ml/h mode.

- Regulate the volume of the first sequence with ⏫ 🔼 🔽 ⏬. Confirm by pressing **OK**.
- Adjust the flow rate of the first sequence with the arrows. Confirm by pressing **OK**.
- Choose whether or not to beep at the end of the sequence with the arrows. Confirm by pressing **OK**.
- Select the following sequence with 🔽. Adjust the volume. Confirm by pressing **OK**.
- Adjust the following sequence(s) in the same way.
- Adjust the last sequence by selecting **end** for the last volume to be infused.
- Check the sequential programming and confirm with **OK**.
- Press **start** to start the infusion.

Changes made in a sequential program become effective only for sequences which have not yet been executed or when the entire sequential program is restarted. A sound beep can be programmed at the end of each sequence.

Note: To modify a future sequence, press the STOP key, change the parameters of the future sequence, then press **start** to confirm. The sequential program is not modified.

If a sequential program is modified during a sequential infusion, only future sequences will be modified.

Description of specific functions

End: End of the programming sequences

Stop: Programming of a pause between two sequences

KVO: Programming a KVO sequence

Repeat: Up to 20 repetitions of the already programmed sequences (limited by the total VTBI).

Secondary mode

This infusion mode enables to deliver the content of a secondary bag / bottle, by means of a secondary line (second line of the VL SP22 / VL ON10 / VL ON20 / VL ON30, or secondary line connected to the VL ST22 / VL ST42 / VL TR22 / VL TR42 / VL PA92 / VL ON42) connected to the main line called primary line. Once the secondary infusion is completed, the user can either continue another secondary infusion, or resume the primary infusion (initial infusion) which parameters are restored.

Note: this mode is only accessible in ml/h rate mode (except : ramp, sequential and drops/min modes).

- Press the MENU key to select the secondary mode.
- Close the primary line.
- Press **OK** to confirm the parameters of the primary mode and access the secondary mode.

1 - Define the infusion

- In V/R mode, use the arrows to select the secondary volume to be infused. Confirm by pressing **OK**.
- Use the arrows to select the secondary flow rate. Confirm by pressing **OK**.

Note: the current volume infused becomes the volume infused during the secondary infusion. It is displayed in bold at the bottom of the screen.

Note: the volume infused during the primary infusion is displayed above the current volume infused.

2 - Secondary infusion start

- Check the primary line is closed, check the secondary line is connected and opened. Press **start** to start the infusion or **C** to modify the Volume/ Rate selection

3 - End of secondary infusion

■ Once the secondary infusion is completed, press the key.

■ Press **Yes** to continue a secondary infusion. Go back to step 1.

■ Press **No** to go back to the primary infusion.

4 - Start again primary infusion

■ Check the secondary line is closed, re-open the primary line.

■ Press the key to go back to the last parameters of the primary infusion.

Note: at the end of the secondary infusion, the end-of-infusion pre-alarm is not activated, it is therefore recommended to adjust carefully the VTBI of the secondary infusion.

Note: in case the drop sensor is used, it has to be positioned onto the right drip chamber. The ward option [Par 30] (see page 48) allows defining the type of line managed by the drop sensor.

Note: the current volume infused becomes the volume infused during the primary infusion. It is displayed in bold at the bottom of the screen.

No drug name and dose rate mode

V/R infusion mode is described. For another infusion mode, see page 14.

1 - Start-up screen

- Choose dose rate mode, then press **OK**.

2 - Dilution units

- Use the arrows to select the dilution units.

Note: You can select "unit/ml" or "unit/Xml". For the list of units, see page 55. These units are preselected in the Ward option [Par 20] (see page 48).

- Press **OK** to validate your choice.

3 - Dilution values

- Select the dilution values.
- Press **OK** to validate your choice.

4 - Flow rate units

- Select the flow rate units.
- Press **OK** to validate your choice.

5 - Patient

Note: This screen only appears if you have selected a flow rate unit of "mg/**kg**/h" (Weight adjustment) or "mg/**m²**/h" (Surface area adjustment) type.

The default weight is set in the Ward option [Par 23] (see page 48).

- Select a value.
- Press **OK** to validate your choice.

6 - Volume selection

- Select the volume to be infused (VTBI), then press **OK**.

7 - Flow rate selection

- Select the dose rate, then press **OK**.

Note: The flow rate in ml/h is calculated automatically according to the Patient parameters and the dilution.

8 - Starting the infusion

- Open 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.

Loading dose

Once the parameters are entered, a loading dose can be infused.

Note: This operation is available in dose rate mode only if it is selected in the service option [Par 19] (refer to page 48).

9 - Loading dose question

- Answer the question: "Do you want a loading dose?"
- If you press **no**, return to step 8. Press **start** to go directly to the infusion.
- If you press **yes**, go to step 10.

10 - Loading dose unit

- Select the loading dose unit.
- Press **OK** to validate your choice.

11 - Loading dose settings

■ Set up the loading dose parameters and press **OK**.

12 - Loading dose start

■ Press **C** to change the loading dose parameters. Return to step 10.

■ Press **start** to start the loading dose.

13 - Loading dose interruption

■ Press the STOP key to interrupt the loading dose.

Note: If you press the STOP key twice, the loading dose is deleted. Press **start** to continue with the infusion.

■ Answer the question: "Continue?"

- If you press **no**, the loading dose is deleted. Press **start** to continue with the infusion.
- If you press **start**, the loading dose is confirmed and the infusion continues until at the end of the loading dose. At the end of the loading dose, the infusion continues with the values programmed initially at stage 8.

Note: During the infusion, you can check the volume infused by pressing the MENU key. The infusion screen returns automatically or press the MENU key again.

Other infusion modes in dose rate

The infusion mode set by default is displayed, but you can select another infusion mode (Volume/Time/Rate, Volume/Time, Time/Rate, Simple rate), provided it is preselected in the Ward option [Par 29] (see page 48).

Note: The infusion mode menu is accessible before starting the infusion and in <STOP> mode.

Menu selection

■ Press the MENU key to display the Infusion mode screen. If it does not appear at first place, use the arrows to select "DR".

■ Press **Enter**.

Infusion mode selection

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

Volume/Time/Rate...

■ Select a volume to be infused (VTBI), then press **OK**.

■ Select a time and press **OK**.

■ Select a dose rate value and press **OK.**

■ Press **Start**.

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.

Time/Rate

- Select a time, then press **OK.**
- Select a dose rate, then press **OK** and **Start**.

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

Simple rate

- Select a dose rate, then press **OK** and **Start**.

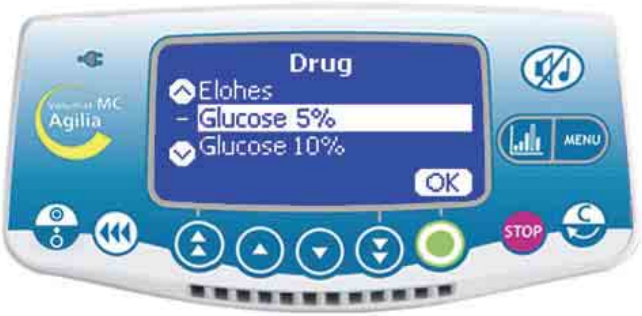
Note 1: This infusion mode only works with the **drop sensor** fixed on the drip chamber and connected to the pump (for its installation, see page 35). If not, a warning message appears when you select this mode in the Infusion mode screen. Shut-down the pump, set the drop sensor, and restart the pump.

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 the Ward option [Par 22] (see page 48) and preselected in the User option [User 9] (see page 46).

1 - Drug selection



- Start 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)" or "Drug X (dose)" 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 13.

Vigilant Drug'Lib mode

Vigilant® Drug'Lib is the safest and simplest mode to administrate a drug via the Volumat MC 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, use Vigilant® Drug'Lib for Agilia software.

Caution: Vigilant DrugLib is available only if authorized in the Ward option [Par 22] (see page 48) and preselected in the User option [User 9] (see page 46).

1 - Drug selection

- Start 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 47).

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 13.

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

3 - Parameters adjustments

- The screen displays predefined values for volume to be infused (VTBI), time and flow rate. You can use the arrows to modify the adjustable parameters.
- Press **OK** to validate the parameters

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.

4 - High flow rate / Low flow rate

- During parameters adjustments, if the calculated flow rate is higher than the limit predefined in the drug library, the warning **High flow rate** is displayed.
- To launch the infusion, this high flow rate must be confirmed by a press on **start**.

Note : Identically, the warning **Low flow rate** is displayed if the calculated flow rate is lower than the limit predefined in the drug library.

Special features

Programmed bolus

Via <BOLUS> key

- Press the ⏪ key:
- Press **prog**. The "Programmed bolus" screen appears. Go to step 1.

Via <MENU> key

- Press the MENU key.
- Select "Programmed bolus" in the menu.
- Press **Enter**.

1 - Bolus unit

- Select the bolus unit.

Note: This screen is displayed only in Dose rate mode.

2 - Bolus parameters

- Adjust the bolus parameters.
- Select a volume or a dose, then press **OK**.
- Select a flow rate value (ml/h) then press **OK**.

3 - Bolus start

■ Press C to modify the bolus values. Return to step 1.

■ Press **start** to start the bolus.

Note: If you press the ⏪ key again, this screen appears directly with the last bolus parameters.

Note: To save the bolus parameters, press on the diskette icon.

4 - Bolus interruption

■ Press the STOP key to interrupt the bolus.

Answer the question: "Continue?"

- If you press **no**, the bolus is deleted.
- If you press **start**, the bolus continues.

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

Manual bolus

■ To start a bolus, press twice on the key: one short press, then one continuous press (activates bolus ⏪ ; check volume infused 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: This operation is available only if preselected in the Ward option [Par 19] (see 48). During the bolus, the occlusion pressure level is set to its maximum value (750 mmHg).

Note: This function is not accessible with Ramp and Sequential modes.

The first two features are available only if preselected in the Ward option [Par 19] (see page 48).

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 end priming.

Note: Priming is accessible as long as the infusion has not started.

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 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 restarted because air is still present. If the air bubble exceeds an acceptable size, or if the pump cannot be restarted 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 priming, the occlusion pressure level is set to its maximum value (750 mmHg), and the air alarm is disabled.

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 36.

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**.

Switch-off

- Press the STOP key to interrupt the infusion.
- Press the key continuously, until the Switch off screen disappears.
- To disconnect the pump, disconnect the mains supply, then the power lead.

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 pause end" option for an automatic start.

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

VTBI selection during infusion

- During infusion it is possible to adjust the VTBI.
- Press the MENU 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 key, use the selection keys and **enter** button to access the Pressure management parameters.

Maximum pressure

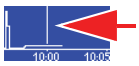
- Use the selection keys to define the upper pressure limit and press **OK**.
- The Dynamic Pressure System (DPS) calculates pressure differences to anticipate possible occlusion or disconnection problems.

DPS

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

History

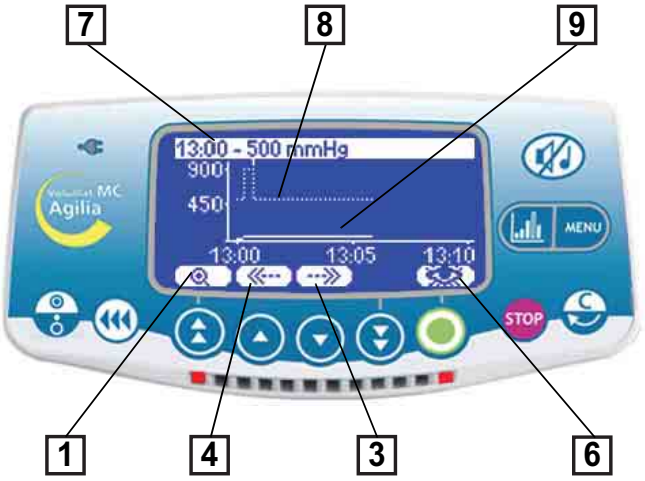
To display the history when the infusion is in progress, press the graphic key. This key also allows the numerical and graphical infusion screen to be selected. Press the button with short press until you reach the history menu. Choose the history with the selection value keys.

Symbols		Definitions
Circle		Pressure history
Curve		Flow rate history
Loop +		❶ Go to more detailed period
Loop -		❷ Go to less detailed period
Right arrow		❸ Displace the event marker to the right side
Left arrow		❹ Displace the event marker to the left side
Vertical line		❺ Time / event marker
Eye		❻ Time / event details where the marker is placed

Note 1: To refresh the history, exit and select the history again. Refresh is not automatically performed when remaining in the history screen.

Note 2: The history is not stored after switch off

Pressure history (in mmHg)



❼ The date and user pressure limit is displayed on the upper line.

❽ The dotted curve represents the limit. The limit is adjustable in User Menu [User 4: pressure] (see page 46).

It is also adjustable during infusion in the Pressure section of the menu.

❾ The continuous curve represents the real pressure during infusion.

The history is cancelled on drug change and patient change.

The history runs over 2 hours.

Note: On boluses and purge the pressure limit alarms are increased to their maximum level.

Example of an occlusion view

Example of the detailed screen of the event

This screen appears when pressing the eye key. User limit indicates the limit set by the user. Current limit is the pressure on infusion in the line.

Flow/Dose rate history

The history runs over 12 hours.

The upper line indicates the flow or dose rate.

Changing an infusion 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 infusion set from the pump.
6. Disconnect the infusion set from the container.
7. Disconnect the infusion set from the IV device in accordance with local facility procedures.
8. Follow instructions as described from pages 11 to 13 (set installation and infusion adjustments).

Pre-programming the infusion

The Volumat MC 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 13.

When the parameters are logically entered and confirmed by pressing **OK**, 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.

Warning function

Function activation

■ Press the key to access the menu and select . Press **enter.**

■ Select an offset period to set an alarm activation time.

Note 1: The activation time is calculated according to the device time, which is indicated at the bottom of the screen.

Note 2: If the device has been switched off during the warning time, a warning message is displayed when switching on the device.

Function deactivation

■ Press the key to access the menu and select . Press **enter.**

■ To deactivate the function, set the offset period to OFF.

Drop sensor (optional)

Note: The drop sensor allows you to work in **Simple rate** infusion mode (for more details, see page 15 and page 25) and to detect the container end. 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. 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.

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

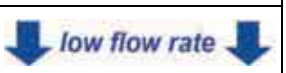
Caution: Check the right positioning of the drip chamber and check there are no drops on the drip chamber walls. Check that the drop sensor and the drip chamber are in a vertical position.

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

5. Display and symbols

Volumat MC 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.
	Validation		
	Access to function		
	Change selection		
	Selected		
	Not selected		
	See drug information		

Alarms and safety features	**Mains disconnection alarm**		Main symbols for alarm and safety features.
	Pressure increase		
	Pressure drop		
	Upper soft limit exceeded		
	Lower soft limit exceeded		
	Maximum volume infused exceeded		
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**		The menu gives access to the infusion options selected by the user.
	Flow rate mode (ml/h)		
	Dose rate mode		
	Ramp programming screen		
	Sequential programming screen		
	Programmed bolus		
	Primary/Secondary		

MENU	**Pressure**		The menu gives access to the infusion options selected by the user.
	Volume to be infused		
	Patient		
	Battery life		
	Macro/Micro		
	History		
	Programming mode		
	Maintenance		
	Sound level		
	Date/time		
	Locking keyboard		
	Pause		
	Drug library		
	Night mode		
	Warning		
OTHER	**Drops per minute**		This symbol expresses a set flow rate in drops per minute.
	Secondary mode		
	Loading dose		

6. Alarms and safety features

Volumat MC 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: Infusion set not installed or door open ☞ Install infusion 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-positioned 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 5 ml 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].
	End of infusion alarm	Alarm	Stop/KVO	VTBI completed. KVO activated according to configuration, see User option [User 5], page 46. ☞ 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 46. ☞ Check if 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 31). ☞ Check if the infusion line is occluded (stop-cock, catheter, folded line). If necessary, readjust pressure threshold in relation to flow rate.
	Upstream occlusion	Alarm	YES	Only without drop sensor. 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 if battery life is sufficient for the expected infusion duration. If the disconnection is unintentional, check the mains connection.

System	Message	Type	Infusion stop	Activation / ☞ Action
Drop sensor	**Connect drop sensor**	Alarm	YES	Only if drop sensor is compulsory (see page 48). At start-up: drop sensor not connected ☞ Connect the drop sensor to the pump and the drip chamber (see page 35).
	No drop sensor	Alarm	YES	Only if drop sensor is compulsory (see page 48). During infusion or stop mode: drop sensor not connected ☞ Connect the drop sensor to the pump and the drip chamber (see page 35).
	Underflow	Alarm	YES	Flow rate detected by drop sensor is below the set flow rate. ☞ Check container. Check roller clamp. Check that the liquid actually forms ~ 20 drops/ml and that the drip chamber is maintained in a vertical position. Check that the drop sensor is fixed as indicated in page 35.
	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 that the 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 selection and an audible alarm is activated.
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	VTBI
Volume infused	Total infused volume	■ Clearing of volume infused	ml?
Pressure	Pressure limit adjustment and DPS mode activation	■ Pressure limit ■ DPS mode activation	
Battery life	Display of battery life	■ Hours and minutes left for a selected flow rate	
Pause	Pause duration adjustment	■ Hours and minutes adjustment and activation of delayed VTBI start-up	
Locking keyboard	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.	
History	Recording of up to 1500 events	■ Pressure limit ■ Flow rate, etc.	
Sound level	Sound level adjustment	■ 7 accessible levels	
Macro/Micro Function accessible in STOP mode only	Type of displayed values	■ Macro flow rate from 1 to 1500 ml/h (integer values) ■ Micro flow rate from 0.1 to 100 ml/h (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 47.	
Programming mode	Selection of another programming mode	■ No drug name ■ Drug labelling ■ Vigilant Drug'Lib ■ Flow rate (ml/h) ■ Dose rate	
Flow rate (ml/h)	Choose the required infusion mode	■ Volume/Time/Rate ■ Volume/Rate ■ Volume/Time ■ Time/Rate ■ Simple rate ■ Ramp ■ Sequence ■ Drops/min	
Dose rate	Choose the required infusion mode	■ Volume/Time/Rate ■ Volume/Rate ■ Volume/Time ■ Time/Rate ■ Simple rate	
Programmed bolus	Programming a bolus	■ Volume or dose ■ Rate	

Function	Description	Operation	Symbol
Primary/Secondary	Programming a secondary infusion	■ The parameters to set are the same than in primary mode	
Patient	Information on Patient parameters. Choice of a new patient	■ Weight when the unit is in kg ■ Body surface when the unit is in m^2	
Drug library Function accessible in STOP mode only	Information on preselected drug library	■ Library name, author, drugs number ■ List of drugs with predefined parameters	
Time warning	Time warning adjustment	■ Offset adjustment ■ Activation / Deactivation	

CAUTION: the menu can change depending on selected Ward and User options (see "Options", page 45).

8. Options

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

Operation	Key
Options access	 +  (when the 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 page 47).

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
		■ History	Display log events
		■ Date/time	Date/time adjustment
		■ Warning	Set of a warning
		■ Drug library	Display of drug library
		■ Macro/Micro	Macro or micro mode selection
		■ Programming mode	Programming mode selection
		■ Flow rate (ml/h)	Selection of flow rate ml/h mode
		■ Dose rate	Selection of dose rate mode
		■ Programmed bolus	Adjusting a programmed bolus
		■ Patient	Information on the patient
		■ Primary/Secondary	Selection of Primary / Secondary infusion
	[User 3] Contrast	■ Adjustment of screen contrast. Use fast increment and decrement keys	

Option	Function	Choice	
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
		■ The storage of the last activation of DPS is memorized automatically for the next start-up	
	Maximum pressure for Macro/Micro 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 memorized 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: Increase 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 53	
	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)
	[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
	[User 12] Graphical history	■ Flow rate history	■ Pressure history

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**: deleted (VI=0 at switch ON), stored (VI cumulated at switch ON)		
	[Par 4] Maximum rates	Choose for primary and secondary mode: ■ Macro infusion (ml/h) ■ Micro infusion (ml/h)		
	[Par 9] Bolus and loading dose rates			
	Manual bolus	■ Maxi. macro (ml/h)	■ Maxi. micro (ml/h)	
		■ Storage: select option to store last bolus rates		
		■ Macro flow rate (ml/h)	■ Micro flow rate (ml/h)	
	Programmed bolus and loading dose	■ Maxi. macro	■ Maxi. micro	
	[Par 10] Ward name	■ Press the 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	■ See air bubble	■ Prime set
		■ Loading dose	■ Programmed bolus	
	[Par 20] Authorised units	■ Dilution units (Select/Deselect) ■ Dose rate units (Select/Deselect)		
	[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 23] Patient parameters	■ Select the patient's default parameters		
	[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 25] Same therapy screen	■ 'Same therapy' screen appears to restart infusion with last parameters at the end of infusion. This function is available in Dose Rate mode.		
	[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 (Adjustable from 10 to 2000 µl). - Bubble filter (µl): Minimum bubble size taken into account (Adjustable from 0 to 250 µl).		
	[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 the available infusion modes in flow rate ml/h and in dose rate		
		■ Volume/Time/Rate	■ Volume/Rate	
		■ Volume/Time	■ Time/Rate	
		■ Simple rate	■ Storage: stores the last infusion mode	
		■ Drops/min (in ml/h)	■ Ramp (in ml/h)	■ Sequential (in ml/h)
	[Par 30] Drop sensor	■ Compulsory (select/deselect)	For Primary/Secondary mode: ■ Drop sensor on primary (select/deselect) ■ Drop sensor on secondary (select/deselect)	

Option	Function	Choice		
	[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	
	[Par 33] Drops/min.	■ Volumic flow rate	■ Allows selection of adjustable flow rates	■ Drops/min flow rate
	[Par 34] Rate modification	■ Allows modification of the flow rate in STOP mode only		
Maint.	**Maintenance**	■ Code: XXXX (please contact our technical team)		

9. User test

This protocol allows a quick check of pump functionality.

Volumat MC 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 functioning 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	

10. Performance

Rates range

	Modes	Rates range	
Infusion rate (ml/h)	**Macro**	From 1 to 1500 ml/h, with 1 ml/h increments	Maximum infusion rate can be configured in Ward option [Par 4] page 47
	Micro	From 0.1 to 100 ml/h, with 0.1 ml/h increments	
Manual Bolus rate (ml/h)	**Macro**	From 200 to 1500 ml/h, with 50 ml/h increments	Maximum infusion rate can be configured in Ward option [Par 9] page 47
	Micro	From 200 to 1500 ml/h with 50 ml/h increments	
Programmed bolus and loading dose	**Macro**	From 1 to 1500 ml/h with 1 ml/h increments	The adjustment is common to both modes. Maximum infusion rate can be configured in Ward option [Par 9] page 47.
	Micro	From 0.1 to 1500 ml/h, by increments of 0.1 ml/h from 0.1 to 100 ml/h and 1 ml/h from 100 to 1500 ml/h	
Infusion rate for a Secondary infusion	**Macro**	From 1 to 1000 ml/h, with 1 ml/h increments	Maximum infusion rate can be configured in ward option [Par 4], page 47.
	Micro	From 0.1 to 1000 ml/h, with 0.1 ml/h increments from 0.1 to 99.9 ml/h and 1ml/h increments from 100 to 1000 ml/h	
Special case: Minimum plateau flow rate in Ramp mode	**Macro**	2 ml/h	Non-adjustable
	Micro	2 ml/h	
Prime rate (ml/h)	**All modes**	Maximum rate (1500 ml/h)	

Volume to be infused (VTBI)

	Modes	Volume range
Volume to be infused in ml and dose rate mode	**Macro**	From 1 to 9999 ml, with 1 ml increments
	Micro	From 0.1 to 1000 ml, by increments of 0.1 ml from 0.1 to 99.9 ml and 1 ml from 100 to 1000 ml
Volume to be infused for a secondary infusion	**Macro**	From 1 to 2000 ml with 1 ml increments (Maximum value can be configured with a computer)
	Micro	From 0.1 to 1000 ml with 0.1 ml increments from 0.1 to 99.9 ml and 1 ml increments from 100 to 1000 ml (Maximum value can be configured with a computer)
Programmed bolus and loading dose	**Macro**	From 1 to 100 ml, with 1 ml increments
	Micro	From 0.1 to 50 ml, by increments of 0.1 ml

KVO (Keep Vein Open) rate

Activated when the volume to be infused is reached. KVO Rate: 1 ml/h or set flow rate (flow rate below 1 ml/h).

Dose range

	Setting range
Patient data	
Weight (kg)	■ Increment of 0.01 from 0.25 to 0.99 ■ Increment of 0.1 from 1 to 9.9 ■ Increment of 1 from 10 to 250
Surface (m^2)	■ Increment of 0.01 from 0.05 to 4.5
Height (cm)	■ Increment of 1 from 20 to 250
Dilution (Units/X ml)	
X ml	■ Increment of 1 from 1 to 9999 (Maximum value can be configured with a computer)
Units	■ Increment of 0.01 from 0.01 to 9.99 ■ Increment of 0.1 from 10 to 99.9 ■ Increment of 1 from 100 to 9999
Dose rate	■ Increment of 0.01 from 0.01 to 9.99 ■ Increment of 0.1 from 10 to 99.9 ■ Increment of 1 from 100 to 9999

Infusion time

	Infusion time range
Loading dose	From 00 min 01 to 59 min 59
Programmed bolus	No limit. Beyond 1h, the display no longer indicates the exact time but '>1h'
Ramp mode	From 0h01 to 48h00
Other programming modes	From 0h01 to 168h00

Drug library

Up to four drug 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.

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.

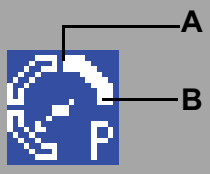
Accuracy

Nominal flow rate accuracy	± 5% on 96h with an infusion of 10 liters maximum	In accordance with the NF EN/IEC 60601-2-24 standard.
Manual bolus	± 5% or ± 0.2 ml	
Accuracy with back pressure of ±13.33 kPa	± 5% on 96h with an infusion of 10 liters maximum	

Programmable pause

Programmable pause	From 1 minute to 24 h	Increments: 1 minute.

Pressure management

<table>
<tr><td rowspan="2">Variable mode
 
</td><td>Maximum pressure (B)</td><td>From 50 to 750 mmHg</td><td>25mmHg increment (50-250 mmHg)
50mmHg increment (250-750 mmHg).
Defines the authorized maximum pressure during infusion.</td></tr>
<tr><td>Pre-alarm level (A)</td><td>50 mmHg below maximum pressure</td><td>Note: If max. pressure is set to 50 mmHg, then the pre-alarm is not activated.</td></tr>
<tr><td rowspan="3">3 levels mode</td><td>High</td><td>750 mmHg</td><td rowspan="3">These values are given as examples and can be configurable in the User option [User 4], page 46.</td></tr>
<tr><td>Middle</td><td>400 mmHg</td></tr>
<tr><td>Low</td><td>100 mmHg</td></tr>
<tr><td rowspan="3">DPS (Dynamic Pressure System)</td><td>Pressure increase</td><td colspan="2">Anticipates an occlusion during infusion.</td></tr>
<tr><td>Pressure drop</td><td colspan="2">A pressure decrease may indicate a disconnection or a leak in the line.</td></tr>
<tr><td colspan="3">Accuracy: the accuracy on the pressure threshold activation is 75 mmHg or ± 15%.
Note: 1 bar = 750 mmHg = 1000 hPa.</td></tr>
</table>

Occlusion alarm response time

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 infusion 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 calculated according to T = V/R	R is modified 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 calculated according to T = V/R	R is modified and T is calculated according to T = V/R
	Modify R, T is calculated according to T = V/R	
T/R	Modify T, V is calculated according to V = R x T	R is modified 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 calculated according to T = V/R	R is modified 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

In Ramp mode, each ramp flow rate represents X*1/10 of the plateau flow rate (for X from 1 to 10).

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

Calculated Value		Examples
V	Rounded up to the nearest ml	Calculated V = 1.3 ml, displayed V = 2 ml
T	Rounded up to the nearest minute	Calculated T = 1h 12 min 32 sec, displayed T = 1h 13
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 Actual infusion rate = calculated rate
Note: For micro-infusions, the calculated rate is rounded to ± 0.05 ml/h		

Units and conversion rules

Dilution units	ng, µg, mg, g	mU, U, kU	mEq
	mmol	Cal, kCal	/ml, /Xml

Dose rate units	ng/h	ng/kg/min	ng/kg/h	ng/m^2/24h	µg/min	µg/h
	µg/kg/min	µg/kg/h	µg/m^2/min	µg/m^2/h	mg/min	mg/h
	mg/24h	mg/kg/min	mg/kg/h	mg/kg/24h	mg/m^2/min	mg/m^2/h
	g/h	g/kg/min	g/kg/h	g/m^2/min	g/m^2/h	g/m^2/24h
	mU/min	mU/h	mU/kg/min	mU/kg/h	mU/m^2/min	mU/m^2/h
	U/min	U/h	U/kg/h	U/kg/24h	U/m^2/min	U/m^2/h
	mEq/min	mEq/h	mEq/kg/min	mEq/kg/h	mEq/m^2/min	mEq/m^2/h
	mEq/m^2/24h	mmol/h	kcal/h	kcal/24h	kcal/kg/h	kcal/kg/24h

Note: These 2 unit lists are preselected in the Ward option [Par 20] (see page 48).

Conversion rules	1 µ unit = 1000 n unit	
	1 m unit = 1000 µ unit	
	1 k unit = 1000 unit	
	1 unit/h = 24 unit/24h	
	1 unit/min = 60 unit/h	
	ml/h = $\frac{\text{unit/kg/h (dose rate) x kg (weight)}}{\text{unit/ml (dilution)}}$	Conversion of a dose rate including the unit /kg into volumic flow rate ml/h
	ml/h = $\frac{\text{unit/m}^2\text{/h (dose rate) x m}^2\text{ (body surface)}}{\text{unit/ml (dilution)}}$	Conversion of a dose rate including the unit /m^2 into volumic flow rate ml/h
	ml/h = $\frac{\text{unit/h (dose rate)}}{\text{unit/ml (dilution)}}$	Expression of a volumic flow rate
	ml = $\frac{\text{unit/kg (dose) x kg (weight)}}{\text{unit/ml (dilution)}}$	Conversion of a dose including the unit/kg as volume ml
	ml = $\frac{\text{unit/m}^2\text{(dose) x m}^2\text{ (body surface)}}{\text{unit/ml (dilution)}}$	Conversion of a dose including the unit/m^2 as volume ml
	ml = $\frac{\text{unit (dose)}}{\text{unit/ml (dilution)}}$	Expression of a volume ml

11. Technical characteristics

⚠ Power supply

Use the mains lead supplied with Volumat MC Agilia.

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

⚠Battery

Disconnect battery before opening device. Avoid short circuit and excessive temperature.
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	7.4 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 rate lower than 125 ml/h and more in night mode
Battery recharge	Pump OFF: < 6 h Pump ON: < 20 h

⚠Communication port

The connector located 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 MC 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	Compliant with EN/IEC 60601-1 and EN/IEC 60601-2-24 standards	
EMC (ElectroMagnetic Compatibility)	Compliant with EN/IEC 60601-1-2 and EN/IEC 60601-2-24 standards	
	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

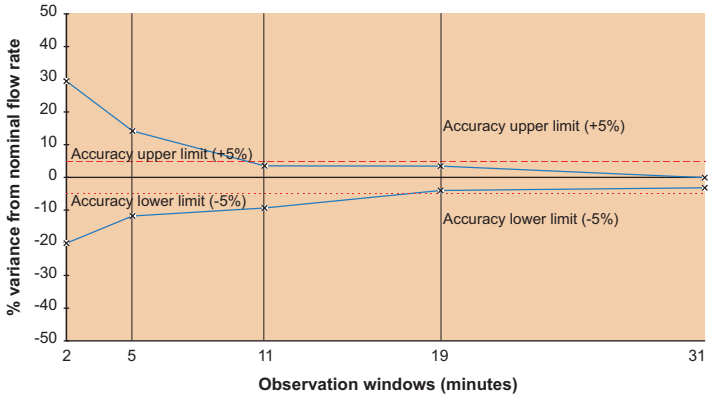
Trumpet curves demonstrate the evolution of the minimum and maximum variance of the pump/set combination versus flow rate.

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

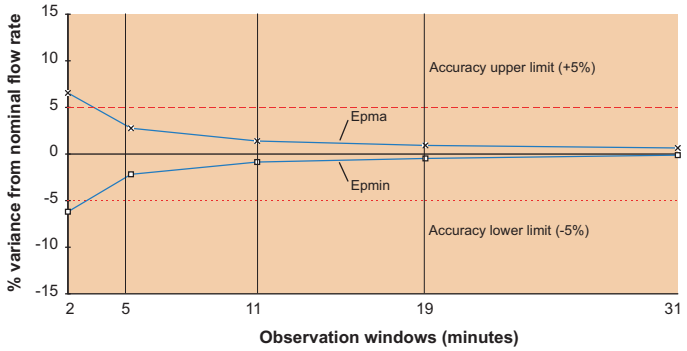
Use these curves to determine the accuracy depending upon your infusion protocol/drug/dilution. These graphs are representative for a VL Volumat infusion set.

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

1 ml/h

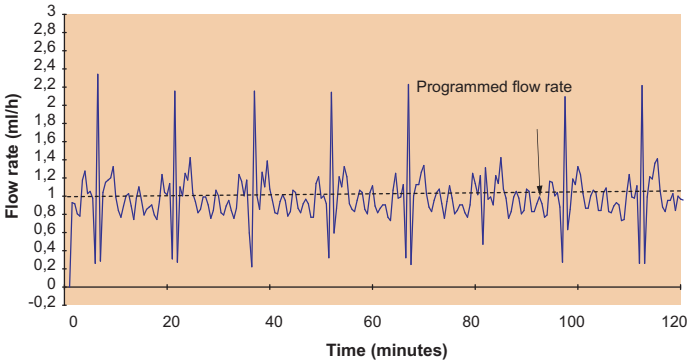


25 ml/h

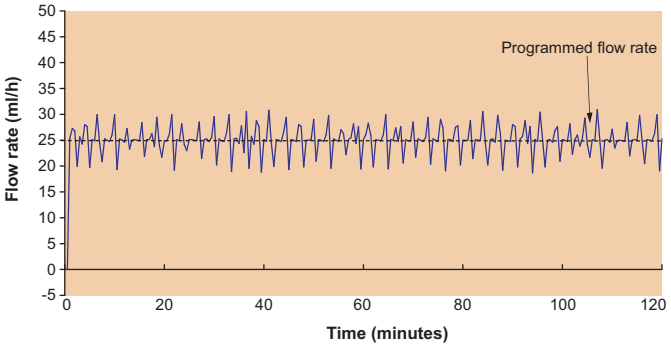


Flow rate/Time curves: start-up and instantaneous flow rate (volume is measured every 30 seconds)

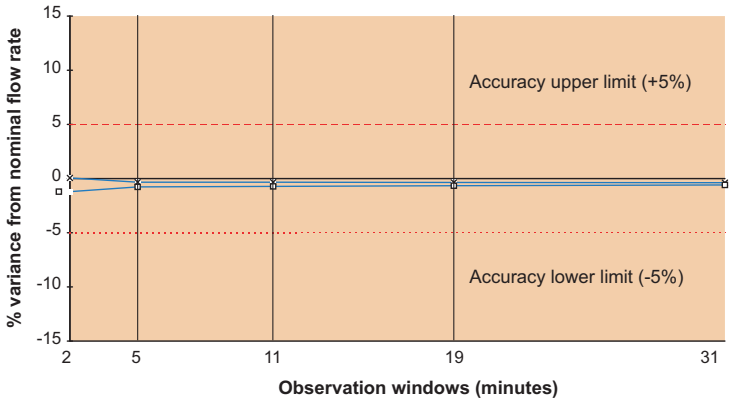
1 ml/h



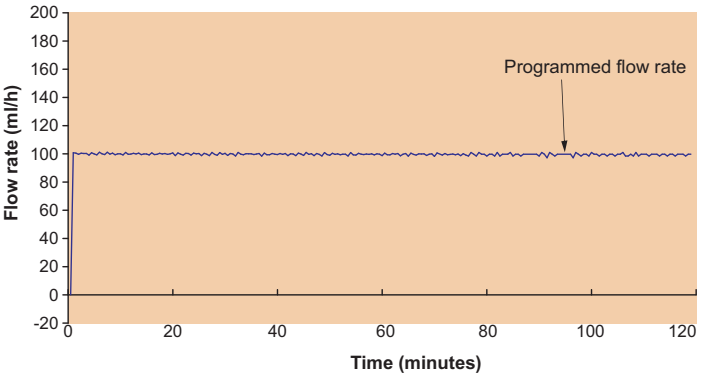
25 ml/h



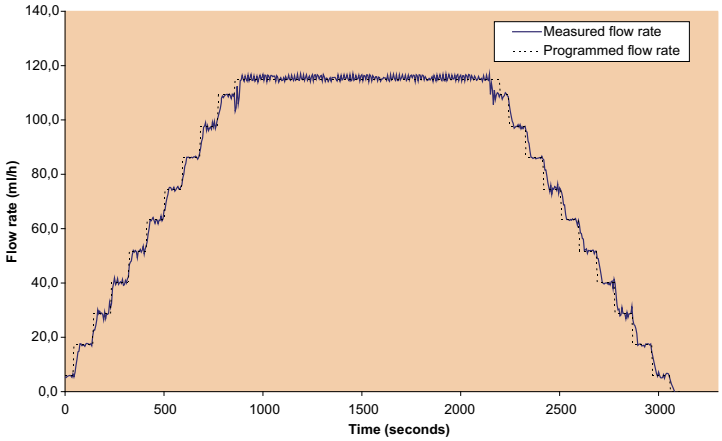
100 ml/h



100 ml/h

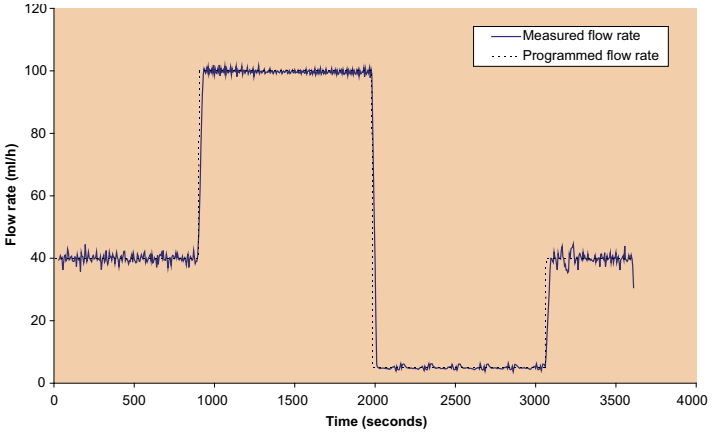


RAMP mode



Ramp up: 15', ramp down: 15', stabilized flow rate: 115 ml/h, total volume: 70 ml.

SEQUENTIAL mode



40 ml/h for 10 ml, 100 ml/h for 30 ml, 5 ml/h for 1.5 ml, 40 ml/h for 6 ml

12. Guidance and manufacturer's declaration on EMC

Electromagnetic emissions - Table 201

Volumat MC Agilia is intended for use in the electromagnetic environment specified below. The user of Volumat MC 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 MC 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 MC 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 MC Agilia is intended for use in the electromagnetic environment specified below. The user of Volumat MC 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 MC Agilia is used exceeds the applicable magnetic field compliance level above, the Volumat MC 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 MC Agilia, or install magnetic shielding.

Electromagnetic immunity - Table 204

Volumat MC Agilia is intended for use in the electromagnetic environment specified below. The user of Volumat MC 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
Conducted RF IEC 61000-4-6	10 Vrms 150 kHz to 80 MHz	10 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the Volumat MC Agilia including cables, than the recommended separation distance calculated from the equation applicable to the frequency of transmitter. Recommended separation distance: D = 0.35 √ P , for a frequency of 150 kHz to 80 MHz D = 0.35 √ P , for a frequency of 80 MHz to 800 MHz D = 0.7 √ 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).
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2,5 GHz	10 V/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 MC Agilia is used exceeds the applicable RF compliance level above, Volumat MC 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 MC Agilia, or install magnetic shielding.

(b)Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

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

Volumat MC Agilia is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The user of Volumat MC Agilia can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and Volumat MC 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. However, if adjacent use is necessary, the device should be monitored 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 MC Agilia is part of the patient's immediate environment. It is advisable to clean and disinfect the device 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. 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.

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 the battery.
- Do not use a 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 67 only.

■ Excessive lowering of pressure in the line 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.

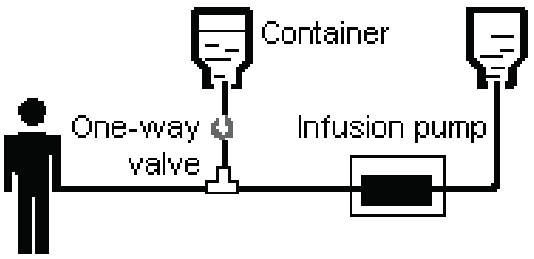
■ During the use without drop sensor, the adjusted volume to be infused must be less or equal to the volume actually contained into the bag, bottle or burette. The right adjustment of the volume to be infused contributes to the air injection risk reduction.

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 for 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 when 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.

CAUTION: 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 void damages to the pump or user.

Servicing

For further information concerning the device servicing, technical information 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.

⚠ At the end of the device life, return it to an organization competent in the treatment of the electrical and electronic equipment waste. Remove the battery from the device and return it to a competent recycling organization.

Data racks, accessories and maintenance tools

Volumat MC Agilia is compatible with the range of Agilia accessories.

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

Duo Agilia	2 channels accessory for power supply centralization	073495
Y Duo Agilia cable	2 channels cable for DC/DC power centralization	073497
DC-DC converter Agilia	Cable for transportation (ambulances)	073494
Nurse call Agilia	Nurse call cable (4000 V isolated)	073496
Link 4 Agilia	Rack 4 slots for power centralization	073480
Link 6 Agilia	Rack 6 slots for power centralization	073481
Link 8 Agilia	Rack 8 slots for power centralization	073498
Link 4 + Agilia	Rack 4 slots for power centralization and communication capabilities	073482
Link 6 + Agilia	Rack 6 slots for power centralization and communication capabilities	073483
Link 8 + Agilia	Rack 8 slots for power centralization and communication capabilities	073499
Drop sensor	Fixed to the drip chamber for use in "Simple rate" mode and end of bottle sensing.	073200

Disposables

For further information, please refer to the catalogue of Volumat Lines.

VL ST00	Standard infusion set, 15 µ filter	M46441000
VL ST10	Standard infusion set, 15 µ filter, rotating Luer Lock, stopflow cap	M46441300
VL ST01	Standard infusion set, 15 µ filter, injection site	M46441600
VL ST02	Standard infusion set, 15 µ filter, needle-free access K-Nect	M46441900
VL ST22	Standard infusion set, 15 µ filter, 2 x K-Nect needle-free accesses	M46442500
VL ST42	Standard set for infusion, 15µ filter, 2 K-Nect needle-free accesses, 1 one-way check valve	M46442600
VL TR00	Set for transfusion, 200 µ filter	M46442800
VL TR12	Vented set for transfusion, 200 µ filter, 1 K-Nect needle-free access	M46442700
VL TR22	Set for transfusion and infusion, 200 µ filter, 2 x K-Nect needle-free accesses	M46443000
VL TR42	Vented set for transfusion, 200 µ filter, 2 K-Nect needle-free accesses, 1 one-way check valve	M46442900
VL SP22	Dual set for transfusion / infusion, 200 µ filter, K-Nect needle free access	M46443100
VL SP62	Set for drugs incompatible with PVC, 15 µ filter, K-Nect needle-free access	M46443400
VL SP90	PVC-free set for infusion of nitroglycerine, opaque, 15 µ filter	M46443500

VL SP92	PVC-free set for infusion of nitroglycerine, opaque, 15 µ filter, 1 K-Nect needle free access	M46443600
VL PN20	Parenteral nutrition set, 15 µ filter, upstream Luer Lock connection	M46443700
VL PN00	Parenteral nutrition set, 1.2 µ air eliminating filter	M46444300
VL PN02	Parenteral nutrition set, 1.2 µ air eliminating filter, 1 K-Nect needle-free access	M46444400
VL ON10	Oncology set for infusion in closed system, 1 side line, 15 µ filter	M46445500
VL ON20	Oncology set for infusion in closed system, 2 side lines, 15 µ filter	M46445700
VL ON30	Oncology set for infusion in closed system, 3 side lines, 15 µ filter	M46445900
VL ON42	Oncology set for multi infusion of drugs in closed system, 4 K-Nect needle-free accesses, 15 µ filter	M46444000
VL ON70	Oncology set for infusion, 0.2 µ filter	M46444600
VL ON72	Oncology set for infusion, 0.2 µ filter, 1 K-Nect needle free access	M46444100
VL ON90	Oncology set for infusion of light sensitive drugs, 15 µ filter	M46444900
VL PA02	Paediatric infusion set, 15 µ filter, K-Nect needle-free access	M46442200
VL PA92	Paediatric set with 150 ml graduated burette, 15 µ filter, K-Nect needle-free access	M46445200

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
Vigilant Ethernet cable for Agilia	Communication cable for Ethernet connection (4000V isolated)	073490

Maintenance CD & tools

Agilia Partner	Maintenance CD	067037

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Notes

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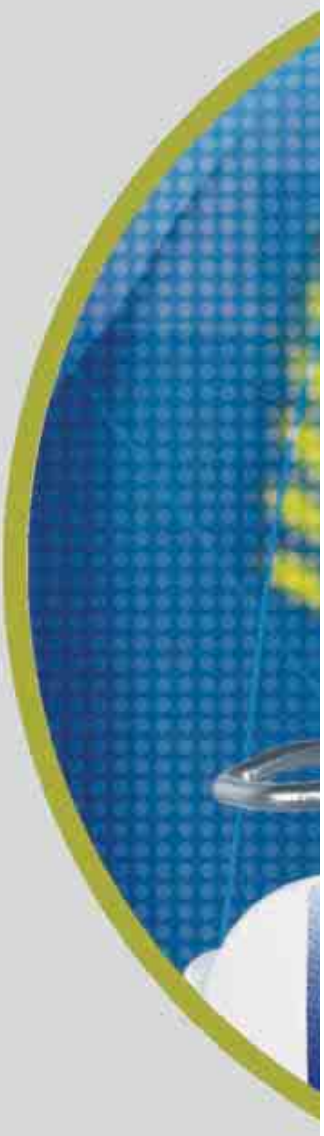

FRESENIUS KABI

caring for life

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