B|BRAUN
SHARING EXPERTISE

Perfusor® compact^{plus}

Instructions for use

Version 1.0 English

Valid for software 002A

Table of Contents

1 About this document

1.1 Purpose

These instructions for use are part of the device and describe how to use the device safely and correctly.

- Read these instructions for use before using this device.
- Keep these instructions for use available near the device.
- Read and follow other applicable documents.

1.2 Signs, symbols and tags

Symbol	Meaning
Key > Key	Press the specified keys one after the other.
	Warning symbol, introduces a warning.
Note:	Information for a better understanding or to optimise work processes.
Bold	Name of a navigational or an input element

1.3 Warnings

Symbol	Meaning
 DANGER	Danger for people. Non-compliance will lead to death or serious injuries.
 WARNING	Danger for people. Non-compliance could lead to death or serious injuries.
 CAUTION	Danger for people. Non-compliance could lead to minor injuries.
CAUTION	Risk of damage or incorrect operation. Non-compliance could lead to material damage to the device or to incorrect operation.

1.4 Abbreviations

Abbreviation	Meaning
EMC	Electromagnetic compatibility
KVO	Keep vein open
SC	Safety check
LED	Light emitting diode
HF	High frequency
ESD	Electrostatic discharge

2 Symbols

2.1 Symbols on the product and packaging

Symbol	Meaning
	Caution!
	Consult instruction for use
	Refer to instruction manual (Follow instruction for use)
	Labeling of electric and electronic devices according to directive 2012/19/EU (WEEE)
	CE marking according to Directive 93/42/EEC
	ECE test mark
	Alternating current
	Protective insulation; protection class II device
	Defibrillation-proof type CF applied part, see section 19.1 Accessories
	Catalog number

Symbol	Meaning
	Batch number
	Serial number
	Date of manufacture (year-month-day)
	Manufacturer
	Humidity limitation
	Temperature limit
	Atmospheric pressure limitation
	Not MRI safe

Symbols

2.2 Symbols on the device's display

Symbol	Bedeutung
	Delivery in progress
	Delivery stopped
	Mains electricity connection/battery status
	Pressure symbol ("manometer"): Indication of P1 to P9 pressure level set with current system pressure (pointer)
	Attention: pre-alarm
	Attention: operating alarm
	Infusion is above the upper soft limit
	Infusion is below the lower soft limit
	Pre-alarm temporarily muted

3 Intended use

The Perfusor® compact^{plus} infusion syringe pump system is a transportable infusion syringe pump used together with authorised syringes and accessories. The pump is intended for use in adults, children and newborns for the intermittent or continuous administration of parenteral and enteral solutions through standard medical access routes. These access routes include, but are not limited to, intravenous, intra-arterial, subcutaneous, epidural and enteral routes.

The system can also be used to administer drugs indicated for the infusion therapy. These include, but are not limited to, anaesthetics, sedatives, analgesics, catecholamines etc.; blood or blood components; solutions for total parenteral or enteral nutrition and lipids.

A medical professional should decide on specific applicability based on the guaranteed characteristics and technical data.

The Perfusor® compact^{plus} infusion syringe pump system is intended for use by qualified medical professionals in rooms used for medical purposes, in outpatients and in transport situations. The user must have received training on the device. The use of the Perfusor® compact^{plus} is dependent on the climatic conditions specified in the technical data. The storage conditions are detailed in the technical data.

4 Safety instructions

- Read the safety instructions before using the device and observe them.

4.1 Safe handling

4.1.1 General

- Make sure that the introductory training on the device is given by a B. Braun sales representative or another authorised person.
- If the device is dropped or subjected to external forces: stop using the device and have it tested by an authorised service workshop.
- Avoid external loads on the syringe plate sensor.
- Protect the device against moisture.

4.1.2 Software

- Consult the instructions for use following each software update to find out about the most recent changes to the device and its accessories.
- Ensure that the software version on the device corresponds to the version these instructions for use refer to.
- Ensure that all devices used in a station have the same software version installed to avoid mistakes when using differently configured devices.

4.1.3 Transport and storage

- Do not hold the device by the drive head during transport.
- Devices stored at temperatures below the defined operating conditions range must be kept at room temperature for at least one hour before being powered on.
- Do not store the pump with the drive head extended.

4.1.4 Set-up and start-up

- For mobile use (patient transport within the clinic and outside the clinic) ensure secure mounting or positioning of the device. Changes of position and strong vibrations can cause minor changes in the delivery characteristics.
- Ensure that the device is properly positioned and secured, and that it is level.
- Do not position the device above the patient.
- Before powering on, check the device. In particular, inspect the syringe holder and claws for dirt, damage, missing parts and to ensure that they function correctly.
- Pay attention to audible and visible alarms and the lighting up of the two status LEDS during the self-test.
- When fixing the device to a box rail, do not fix the device near the rail bracket.
- Fully charge the battery before the first use without an external power supply.

4.1.5 Stacking

- Stack a maximum of three devices on top of one another.
- Do not stack in ambulances or helicopters.
- When stacking, ensure that the device is correctly and safely locked in. You will hear an audible click sound when the device is locked in.

4.1.6 Control

- Stand in front of the device to operate it. This ensures that you are able to reach all control elements and that the display is clearly visible.
- Only connect the patient once the syringe has been positioned correctly and the syringe plunger plate is being correctly held by the drive head claws. Ensure adequate protection against free-flow when changing syringes in order to avoid an unwanted dose administration.
- Ensure that the syringe plunger plate sits flush with the drive head syringe plate sensor.
- Only use approved syringes/catheters for their intended medical use.
- Position the infusion line to the patient so that it does not have any kinks.
- Ensure that installation in rooms used for medical purposes is done in accordance with the regulations (e.g., VDE 0100, VDE 0107 and/or IEC specifications). Observe all country-specific regulations and national deviations.
- Do not operate the device near inflammable anaesthetics.
- Always check the plausibility of the values shown on the display.
- Ensure that there is additional patient supervision (e.g. monitoring) if life sustaining drugs are administered.
- Do not apply any force to the drive head during delivery as this could trigger an alarm.
- When administering highly-effective drugs, have a second device ready for the drug.
- Avoid mechanical effects on the device. If the device is moved while in operation, the set delivery rate may be exceeded/not be reached.
- Monitor the administration of highly-effective drugs accordingly.
- Irrespective of the soft limits, ensure that the values set for the patients are the medically correct values.
- When using the device near equipment that can cause higher interference emissions (e.g. electrosurgical devices, magnetic resonance imaging units, mobile telephones) keep the device the recommended safe distance away from such equipment.

4.1.7 Alarms and staff call

- The volume of the device's acoustic alarms can be adjusted for the environmental conditions. This ensures that the alarms are clearly audible.
- Always monitor the pump alarms. The use of data communication via an accessory cable or staff call does not adequately replace monitoring the alarms.
- Check the staff call before each use of the device.

4.1.8 Accessories and consumables

- Change the disposables according to your local infection control policy.
- Only use pressure-tested disposable items (min. 2 bar/1,500 mmHg).
- Only use the device with accessories and consumables that have been approved for use with the device.
- Ensure adequate protection against free-flow before changing disposable items.
- Always use the device with the smallest possible syringe, provided the therapy permits this.
- See the corresponding manufacturer information for possible incompatibilities between the device and medicinal products.

Note: The use of untested or incompatible disposable items can affect the technical data.

- Use only Luer lock feed systems and syringes as well as compatible device, accessory, wear part and disposable item combinations.
- Connected electrical components must comply with IEC/EN specifications (e.g., IEC/EN 60950 for data processing equipment). Anyone who connects additional devices is considered a system configurer, and is therefore responsible for compliance with system standard IEC/DIN EN 60601-1-1.
- If more than one appliance/infusion line is connected, mutual interference cannot be ruled out.

4.1.9 Enteral nutrition

The Perfusor® compact^{plus} can be used for enteral nutrition.

- Do not use enteral fluids for the intravenous infusion. This would lead to a risk of severe injury or death for the patient.
- Only use disposable syringes that have been designed and designated for enteral nutrition.

4.2 Electrical connection

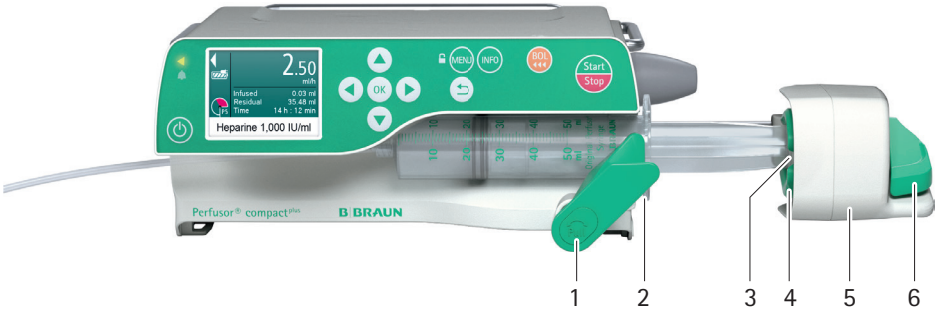
- Do not use the device if the plug has visible damage.
- Do not use an extension cable that has not been approved for use with device.
- Position the power cable so that it does not present a trip hazard.

4.3 Safety standards

- The device meets all safety standards for medical electrical equipment in compliance with IEC/DIN EN 60601-1 and IEC/DIN EN 60601-2-24.
- It complies with the EMC threshold limits as specified in IEC/DIN EN 60601-1-2 and IEC/DIN EN 60601-2-24.

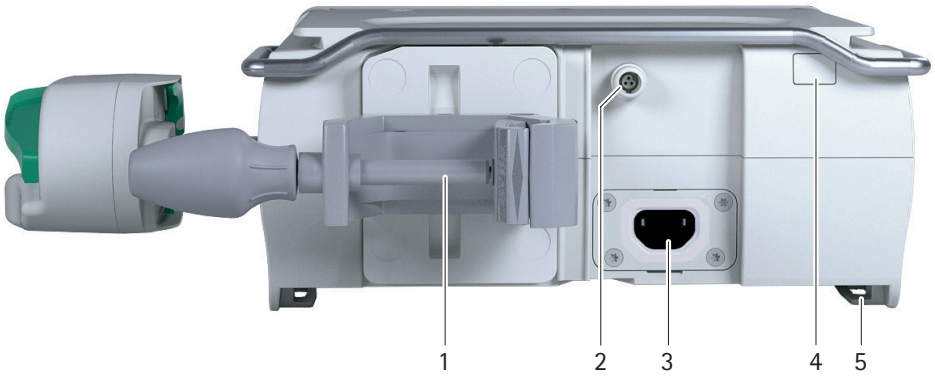
5 Description of the device

5.1 Device overview



No.	Name
1	Syringe holder
2	Syringe wings bracket
3	Syringe plate sensor
4	Claws
5	Drive head with emergency lock key
6	Release lever

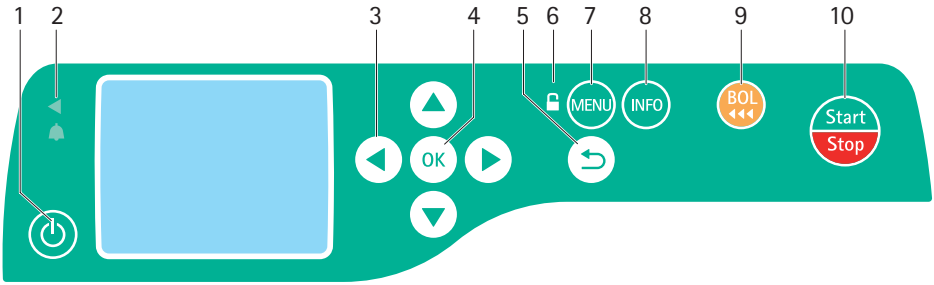
5.2 Interfaces



No.	Name
1	Stand clamp
2	Accessory port (e.g. staff call, ambulance)
3	Mains connection (socket for power cable. In the event of a power cut, the device switches to battery mode automatically)
4	Infrared interface (communication in station, service)
5	Guide rails for connecting pumps

Description of the device

5.3 Display and control elements



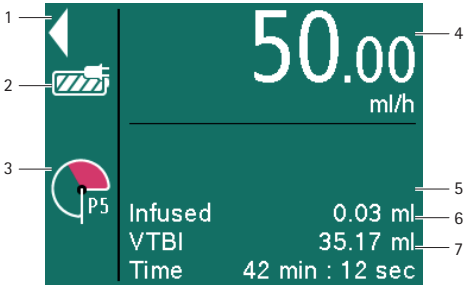
No.	Element	Function
1		On/off key: Switches the device on and off
2		Status display Green LED: Delivery Red LED: Technical alarm, operating alarm
3		Arrow keys: • Scroll through menus • Change settings • Answer yes/no questions • Select scale values and change between digits when inputting values • Open a function while the infusion is ongoing or suspended
4		OK key: • Select/confirm function • Confirm value/settings/input/alarms

Description of the device

No.	Element	Function
5		Back key: Return to the last display or last menu level
6		Lock/unlock symbol: The keypad is locked and unlocked by pressing and holding down the menu key.
7		Menu key: Call up main menu and lock/unlock the device
8		Info key: Call up therapy data from the current infusion
9		Bolus key: Initiate bolus administration
10		Start/Stop key: Start/stop the infusion

Description of the device

5.4 Display overview

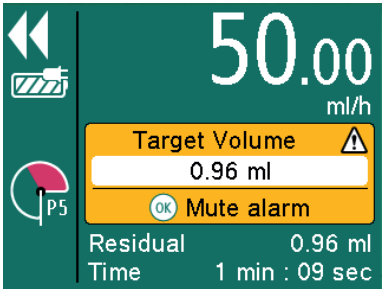


No.	Display / Function
1	Moving arrows: Delivery in progress (stopped delivery is shown by two bars)
2	Mains electricity connection/ battery status
3	Pressure symbol ("manometer"): Indication of P1 to P9 pressure level set with current system pressure (pointer) Note: Pressure detector is also active when the device is stopped or in standby mode.
4	Set delivery rate with drug administration unit
5	Volume already administered during the current infusion
6	Remaining volume for the current infusion
7	Remaining time for the current infusion

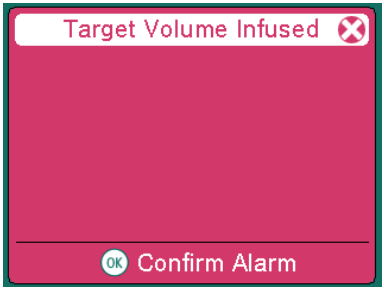
5.5 Alarm status display

Alarms are displayed via a notification on the display, a signal tone and flashing of the red LED (operating alarm):

Yellow: pre-alarm



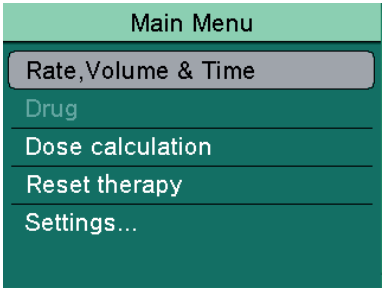
Red: operating alarm



- Press **OK** to acknowledge the alarm.
- Continue the therapy or start new therapy.

6 Menu structure/ device functions

6.1 Main menu



Menu	Function
Rate, volume & time	Enter/change infusion rate or calculate rate by entering the volume limit and infusion duration
Drug	Select the drug for the intended use
Dose calculation	Calculate the rate of administration
Reset therapy	Delete all therapy settings Note: the infused volume (inf. vol.) is not deleted.
Settings...	Configure the device settings

6.1.1 Main menu > Rate, volume & time

The device offers the option of entering the delivery rate, a volume or a time limit. If the volume limit and infusion time are entered, the rate will be calculated automatically.

6.1.2 Main menu > Drug

Menu	Function
Stations	Select station
Patient profile	Select patient profile: Default patient profile or a previously created profile
Categories	Select drug categories
Drugs	Select drug
Concen-trations	Select concentration

Note: All menu items except "Drug" are optional and are only requested if there are corresponding entries in the database.

Menu structure/ device functions

6.1.3 Main menu > Dose calculation

Menu	Function
Dose unit	Select unit: • mg • µg • ng • IU • mEq • mmol
Active substance quantity	Set the concentration by entering the quantity of active substance and volume
Volume	
Calculate using:	Weight: • Enter the patient's weight Body surface area: • Enter the patient's weight and height No patient data
Select dose unit	e.g. mg/min or mmol/24 h
Enter dose	Enter desired dose

6.1.4 Main menu > Settings

Menu	Function
Night mode	Turning night mode on/off
Brightness	Select the brightness: • Level 1 (=lowest level) - to - • Level 9 (=highest level)
Audio Volume	Select the volume: • Level 1 (=lowest level) - to - • Level 9 (=highest level)
Pressure Alarm	Select pressure level: • Level 1 (=lowest level) - to - • Level 9 (=highest level)
Service ...	Configure additional settings: • Language • Date • Time • Bolus rate • KVO • Night schedule • System info • Infusion history

6.1.5 Settings > Service

After the service code has been entered, the following service settings can be changed:

Menu	Function
Language	Select language: • German • English
Date	Set date in DD.MM.YYYY format
Time	Set time
Bolus rate	Enter default bolus rate
KVO	Switch KVO on/off
Night schedule	Set night schedule: • On/off • Activate at... • Deactivate at...
System info	Display system information • Hardware version • Software version • Name of the drug file • Time of next safety check • Station name
Infusion history	Displays a list of changes to the infusion settings

7 Set-up and powering on

7.1 Setting up and connecting the device

7.1.1 Attach/remove the compact^{plus} stand clamp

Note: The compact^{plus} stand clamp is fixed to the device.

- The compact^{plus} stand clamp should only be removed and re-attached by a service technician.

7.1.2 Operating the device on a stand

- Press the lever on the compact^{plus} stand clamp.
  Turn the compact^{plus} stand clamp to the desired position.
- Turn the compact^{plus} static clamp until the lever clicks into place.

7.1.3 Operating the device in the compact^{plus} station

- Follow the compact^{plus} station instructions for use.

7.1.4 Operating the device on a wall rail

- Press the lever on the compact^{plus} stand clamp.
  Turn the compact^{plus} stand clamp to the desired position.
- Turn the compact^{plus} static clamp until the lever clicks into place.
- Make sure that the compact^{plus} stand clamp is not fixed at the point where the wall rail is attached to the wall.

7.1.5 Connecting the device to the mains electricity

⚠ **DANGER! Risk of death from electric shock.**

- Only connect the device to a mains power supply with a protective earthing conductor.
- Connect the power cable with mains connection to the device.
- Position the power cable so that it does not present a trip hazard.
- Plug the mains plug into the socket.

7.1.6 Operating the device with a battery

- Ensure that the battery in the device is sufficiently charged.

7.2 Powering on the device on for the first time

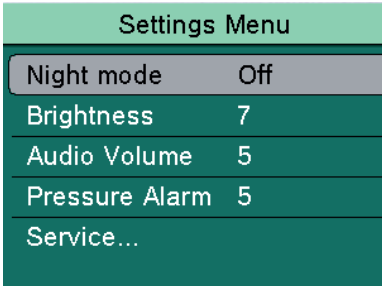
- Device switched on

- Select and insert the syringe, see section 8.2.
- Configure additional device settings, see section 7.3.

7.3 Configure device options

- Device switched on
- No patient connected
- No ongoing infusion

- **Press the Menu** key.
  The **main menu** is displayed.
- Select **Settings...** and press **OK** to confirm.
  The "Settings" screen is displayed.



7.3.1 Turning night mode on/off

In night mode the display brightness is reduced.

- Select **Night mode** and press **OK** to confirm.
- **Select** On/**Off** and press **OK** to confirm.

7.3.2 Setting display brightness

- Select **Brightness** and press **OK** to confirm.
- Select brightness level and press **OK** to confirm.
  - Level 1 (=lowest level)
    - to -
  - Level 9 (=highest level)

7.3.3 Setting the Audio Volume

- Select **Audio Volume** and press **OK** to confirm.
- Select Audio Volume level and press **OK** to confirm.
  - Level 1 (=lowest level)
    - to -
  - Level 9 (=highest level)

7.3.4 Configuring the pressure alarm limit

⚠ **WARNING! Danger to the patient from an incorrectly set pressure alarm limit.**

- Ensure that an appropriate pressure level is selected in order to minimize time to alarm.

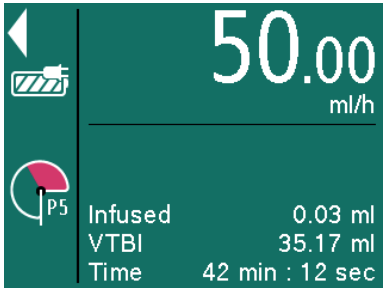
It may be necessary to change the pressure alarm limit due to various influencing factors, e.g. syringe friction, extension line length and inner diameter, fluid viscosity and the filter used in the system set-up.

Note: The set pressure level affects the time to alarm. In order to minimize the time to alarm, it is recommended that you start with a low pressure level and to increase if required.

Note: In the event of a pressure alarm, the post occlusion bolus will be automatically reduced.

- Select **Pressure alarm** and press **OK** to confirm.
- Select alarm level and press **OK** to confirm.
  - Level 1 (=lowest level)
    - to -
  - Level 9 (=highest level)

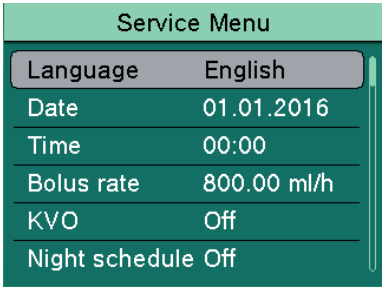
Alarm level	Pressure value
1	0.100 bar (75 mmHg)
2	0.237 bar (178 mmHg)
3	0.375 bar (281 mmHg)
4	0.512 bar (384 mmHg)
5	0.649 bar (487 mmHg)
6	0.787 bar (590 mmHg)
7	0.925 bar (694 mmHg)
8	1.063 bar (797 mmHg)
9	1.200 bar (900 mmHg)



The set pressure level is shown with a P (for pressure) and a number. In addition, a red area shows how quickly the set pressure alarm limit will be reached. The "manometer" display shows the current pressure in the system. The lower the set pressure alarm limit level is, the larger the red area is, the quicker this limit is reached and a pressure alarm triggered.

7.3.5 Configuring service settings

- Select **Service...** and press **OK** to confirm.
- **Enter the service code** and press **OK** to confirm.
  The "Service Menu" screen is displayed.



Configuring the display language

- Select **Language** and press **OK** to confirm.
- Select the language and press **OK** to confirm.

Setting the date and time

- Select **Date** and press **OK** to confirm.
- Enter the day, month and year and press OK to confirm.
- **Select Time** and press **OK** to confirm.
- Enter the time and press **OK** to confirm.

Setting the **bolus rate**

- Select **Bolus rate** and press **OK** to confirm.
- Set the bolus rate and press **OK** to confirm.

Switching KVO on/off

The pump can continue to deliver after a preselected volume or a preselected time with a pre-defined KVO rate (see section 16) has been reached. The duration of the KVO delivery is established in the service program.

- Select **KVO** and press **OK** to confirm.
- **Select** On/**Off** and press **OK** to confirm.

Setting the night schedule

- Select **Night schedule** and press **OK** to confirm.
- Select **On/Off** and press **OK** to confirm.
- **Select** On/**Off** and press **OK** to confirm.
- Select **Activate** and press **OK** to confirm.
- Enter the time and press **OK** to confirm.
- Select **Deactivate** and press **OK** to confirm.
- Enter the time and press **OK** to confirm.

7.4 Locking/unlocking the keypad

Locking the keypad protects the device against accidental use.

- Ongoing infusion
- **Press the menu key** and hold for a few seconds to lock the keypad.
- The process for unlocking the keypad is the same.

Note: The keypad lock is not activated for all keys. It is always possible to stop the infusion using the Start/Stop and On/Off keys.

8 Operation

- Device settings configured

8.1 Switching on the device

- Device connected to the mains electricity or battery fully charged.
- Press the On/Off key on the device. The device will perform a self-test:

Note: Pay attention to audible and visible alarms, the lighting up of the two status LEDs and the display during the self-test.

8.2 Inserting the syringe

- Device switched on.

- Press the release lever and slide the drive head to the right.
- Pull the syringe holder and turn it to the left.
- Insert the syringe. Ensure that the syringe wings have been correctly inserted into the bracket.
- Pull the syringe holder and turn it to its original position.
- Press the release lever and slowly slide the drive head towards the syringe. When the drive head reaches the syringe plunger plate, the syringe is automatically grasped.
  The "Select syringe" message is displayed.
- Select syringe type and press **OK** to confirm. Make sure that the syringe type displayed is the same as the inserted syringe.

Note: "Support for bolus-free insertion" does not release the user from their duty of care when changing the syringe.

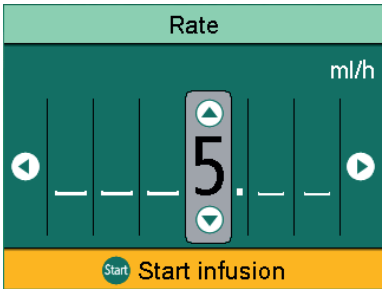
Note: Always use the device with the smallest possible syringe, provided the therapy permits this.
Please see the notes in section 15.2 Typical start-up and trumpet curves.

8.3 Setting the infusion values

- Syringe inserted and selected

Note: Depending on the last therapy, the pump can be set by using the delivery rate or by using drug library.

8.3.1 Entering the delivery rate



- Enter the delivery rate using the arrow keys.
- Start the infusion with the **Start/Stop key**.
  - or -
- Press **OK** to confirm the rate.
  The **Overview** screen is displayed.
- **Select Vol./Time** and press **OK** to confirm.
- Enter the volume or time limit and press **OK** to confirm.

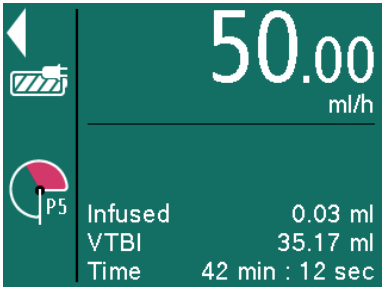
Any values still missing are automatically calculated and displayed.

Note: In addition to the volume and time limit, the infusion rate can also be adjusted in the **Overview** screen.

- Start the infusion with the **Start/Stop key**.

8.4 Starting and stopping the infusion

- Values for the treatment set
- **Press the Start/Stop key** to start the infusion.
  The moving arrows in the display and the green LEDs show that the delivery is taking place.



Note: The infusion rate set can be changed during an ongoing infusion by pressing the **OK key**.

- Interrupt or stop the infusion by pressing the Start/Stop key to start a new therapy.

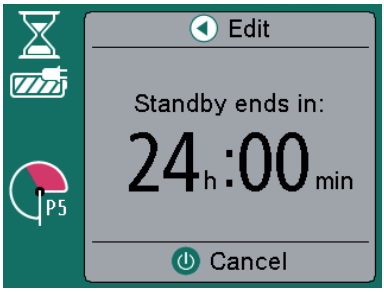
Note: After stopping the therapy, "Reset therapy" must be selected in the menu before a new therapy can be started.

8.5 Activating standby

In the event of longer interruptions, the user has the option of retaining the set values and continuing the infusion at a later time.

Activating standby mode

- Syringe inserted and selected
- Press and hold the On/Off key until the pump display says it is in standby mode.



Adjusting device standby time

- Press the left arrow key.
- Enter the desired time and press **OK** to confirm.

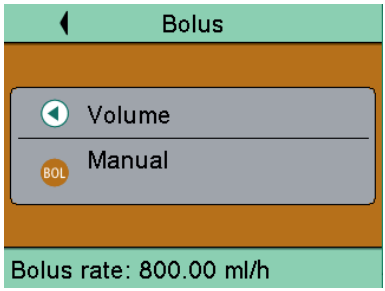
Ending standby mode

- Press the On/Off key or Back key.
- Press the **Start/Stop key.**
  The delivery is re-started with the previously set values.

8.6 Administering bolus

There are three different options for bolus administration:

- Manual bolus
- Bolus with preselection of the bolus volume
- Bolus with preselection of the bolus volume and the bolus duration



Note: If the bolus administration is not started after the Bolus key is pressed, the device automatically returns to the delivery screen for the ongoing infusion.

Note: The pressure threshold is automatically increased during bolus administration.

8.6.1 Administering a manual bolus

- Press the Bolus key.
  The "Bolus" screen is displayed.
- Press the Bolus key again and hold it.
  Fluid is delivered as long as the key is pressed or until the maximum duration/dose have been reached. The delivered bolus volume is displayed.
- Release the Bolus key.
  The bolus administration is ended and the infusion continued.

Note: Manual bolus administration is limited to a max. 10 s or 10% of the syringe content. The bolus administration is automatically stopped, but it can be continued by pressing the Bolus key again.

8.6.2 Administering a bolus with preselected bolus volume/bolus duration

⚠ **WARNING! Danger to the patient from an overdose. At a bolus rate of 1,200 ml/h, 1 ml is reached after 3 s.**

- Press the OK key to stop the bolus administration.

- Press the Bolus key to access the bolus menu.

Entering the bolus volume

- Press the left arrow key and enter the desired bolus volume.
- **Press the Bolus key** to start the bolus administration.

Entering the bolus duration (optional)

- Press **OK** to confirm the entry of the bolus volume.
- Select **Bolus duration** and press **OK** to confirm.
- Entering the desired bolus duration.
  The bolus rate is calculated.
- Press the Bolus key.
  The bolus administration is started.
  After the time has elapsed, the bolus administration is ended and the infusion continued.

8.7 Using the drug database

DANGER! Danger to the patient from incorrectly selected drug.

- Ensure that the correct drug has been selected.

Up to 3,000 freely selectable drug names, including corresponding therapy data and information and up to 10 concentrations per drug in 30 categories, can be stored. The data are loaded using a separate PC programme.
The drug database can be used to select a drug name with saved therapy data.
The procedure for selecting a drug is described below:

- Pump has just been switched on or "Reset therapy" has been selected.
- **Press the Menu** key.
  The main menu is displayed.
- Select **Drug** and press **OK** to confirm.
- If there is more than one profile available:
  - Select station and press **OK** to confirm.
  - Select patient profile and press **OK** to confirm.
- Select drug category and press **OK** to confirm.
- Select drug and press **OK** to confirm.
- If available, read the information in the "Drug info" screen and press **OK** to confirm.
- If necessary, select concentration and press **OK** to confirm.
- Read the information in the "Drug" screen and press **OK** to confirm.
- Enter the delivery rate.
- Start the infusion with the **Start/Stop key.**
  - or -
- Confirm the delivery rate by pressing **OK.**
  The "Overview" screen is displayed.
- Select **Vol./Time** and press **OK** to confirm.
- Enter the volume or time limit and press **OK** to confirm.
  Any values still missing are automatically calculated and displayed.

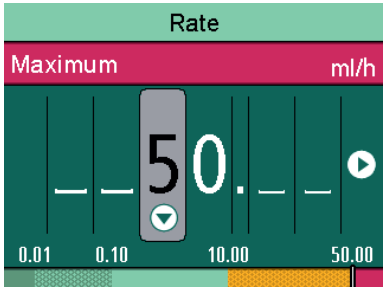
Note: In addition to the volume and time limit, the infusion rate can also be adjusted in the **Overview** screen.

- Start the infusion with the **Start/Stop key.**

8.7.1 Hard and soft limits

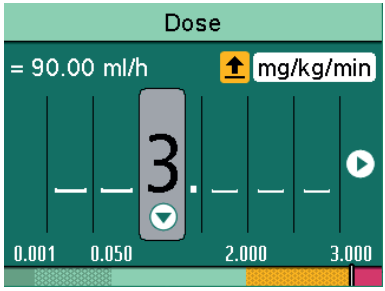
Hard limits

Hard limits are fixed thresholds for the rate/dose/bolus volume and bolus rate stored in the database. Only values within the hard limits can be entered.
If an attempt is made to exceed or go below a hard limit, the following message appears on the display:



Soft limits

Soft limits for rate/dose/bolus volume and bolus rate can also be stored in the database. These can be exceeded but the following message appears on the display.



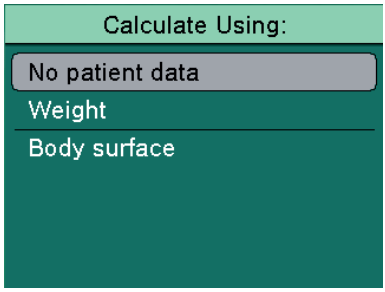
The following symbols that describe the status of the pump with regard to the soft limits are described:

Symbol	Meaning
No symbol	Infusion is within the soft limits
	Infusion is above the upper soft limits
	Infusion is below the lower soft limits

8.8 Calculating the dose

The **Dose calculation** function is used to calculate the delivery rate in ml/h based on the dose parameters entered.

- Syringe inserted and selected
- **Press the Menu** key.
  The main menu is displayed.
- Select **Dose calculation** and press **OK** to confirm.
- Select active substance unit and press **OK** to confirm.
- Enter active substance quantity and press **OK** to confirm.
- Enter volume and press **OK** to confirm.
  The "Calculate Using" screen is displayed.



Calculating without patient data

The delivery rate is calculated without any patient data being entered.

- Select **No patient data** and press **OK** to confirm.
- Select dose unit and press **OK** to confirm.
- Enter dose.

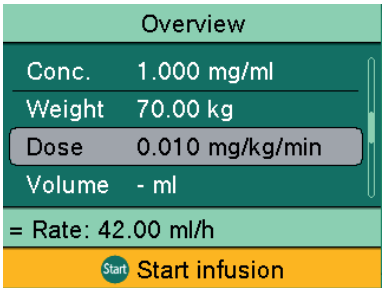
Note: Pressing the OK key brings up the Overview screen.

- Check the plausibility of the displayed values.
- Start the infusion with the **Start/Stop key**.

Calculate using: Weight

- Select **Weight** and press **OK** to confirm.
- Enter weight and press **OK** to confirm.
- Select dose unit and press **OK** to confirm.
- Enter dose.
  The rate is automatically calculated.

Note: Pressing the OK key brings up the Overview screen.



- Check the plausibility of the displayed values.
- If necessary, enter the volume or time.
- Start the infusion with the **Start/Stop key**.

Calculate using: Body surface area

- Select **Body surface** and press **OK** to confirm.
- Enter weight and press **OK** to confirm.
- Enter the patient's height and then press **OK** to confirm.
- Select dose unit and press **OK** to confirm.
- Enter dose.
  The rate is automatically calculated.

Note: Pressing the OK key brings up the Overview screen.

- Check the plausibility of the displayed values.
- Start the infusion with the **Start/Stop key**.

8.9 Entering a combination of delivery rate, volume and time

- Syringe inserted and selected

- **Press the Menu** key.
  The main menu is displayed.
- Select **Rate, volume & time** and press **OK** to confirm.
- Enter two of the following parameters and press **OK** to confirm:
  - Rate
  - Volume
  - Time

  The third parameter is automatically calculated.

If one or more parameters are entered, changing a parameter has the following effects on the other parameters.

- Rate (or dose rate) changed:
  - If only the volume has been entered, the remaining time is adjusted.
  - If only the time has been entered, the remaining volume is adjusted.
  - If the volume and time have been entered, the remaining time is adjusted.

- Volume changed:
  - If only the rate has been entered, the remaining time is adjusted.
  - If only the time has been entered, the rate (or dose rate) is adjusted.
  - If the rate and time have been entered, the remaining time is adjusted.
- Time changed:
  - If only the rate has been entered, the remaining volume is adjusted.
  - If only the volume has been entered, the rate (or dose rate) is adjusted.
  - If the rate and volume have been entered, the remaining volume is adjusted.

8.10 Resetting the therapy

The "Reset therapy" function is used to delete all currently set therapy data. A new therapy can be started.

Note: **Reset therapy** can only be selected if the therapy has been stopped.

- **Press the menu key** and select **Reset therapy** and press **OK** to confirm.
- Press the up arrow key to reset the therapy.

8.11 Changing the syringe

Do not remove the syringe if the drive head claws are closed.
CAUTION! Damage to the syringe/ drive head claws.

- **Press the Start/Stop key** to stop the infusion.
  The green LED turns off.
- Ensure adequate protection against free-flow.
- Press the release lever and slide the drive head to the right.
- Pull the syringe holder and turn it to the left. Hold the syringe while doing so.
- Remove the syringe.
- Insert the new syringe, see section 8.2.
- Start the infusion, see section 8.4.

8.12 Ending the infusion

Do not remove the syringe if the drive head claws are closed.
CAUTION! Damage to the syringe/ drive head claws.

- **Press the Start/Stop key** to end the infusion.
  The green LED turns off.
- Ensure adequate protection against free-flow.
- Press the release lever and slide the drive head to the right.
- Pull the syringe holder and turn it to the left. Hold the syringe while doing so.
- Remove the syringe.

Note: When removing a syringe if the syringe plunger plate is not released by the claws, the emergency release button should be pressed. The emergency release button is on the outside of the drive head. It can be pressed using a pointed object (e.g. ballpoint pen). Once it has been pressed the claws can be opened by hand and the syringe removed. Send the device to technical service.

- Return the syringe holder to original position
- Slide the drive head towards the pump into parking position.

8.13 Switching off the device

- Infusion ended

Note: The device cannot be switched off if a disposable item is inserted. Instead it will go into standby mode.

Ensure the drive head is in the parking position.

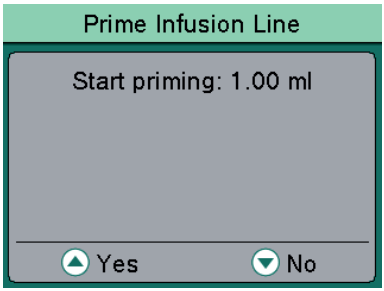
- Press the On/Off key for approx. 1.5 seconds.
  The device switches off.

8.14 Priming the infusion line

Note: This function is not available in the pump factory default. The function can be activated by a service technician on request.

- Connection to the patient removed
- Infusion stopped

- Press the Bolus key.
  The "Prime infusion line" screen is displayed.



- Press the up arrow key to prime the line.
  A message asking if the line is disconnected from the patient is displayed.
- Press the up arrow key to start the priming.
  The disposable item is primed with the maximum delivery rate.

Note: After successful priming, the line can be primed again using the up arrow key.

- Press the down arrow key to end the priming.

9 Alarms

9.1 Device alarms

If a device alarm is triggered the infusion is stopped immediately.

- **Press the On/Off** key to switch off the device.
- Switch the device on again.

If there is another technical alarm:

- Disconnect the patient.
- Remove the disposable article.
- Switch off the device and send it to the technical service.

9.2 Pre-alarms and operating alarms

⚠ **WARNING! Danger to the patient from an incorrectly set alarm limits.**

- Ensure that the alarm limits are set so that the alarm can be triggered in good time. This applies for maximum pressure in particular.

The operating alarm has a high priority. Pre-alarms and reminder alarms have a lower priority. If there are two pre-alarms at the same time, the pre-alarm with the shorter remaining time is displayed.

The time lag between the triggering of the alarm and the activation of a staff call is less than a second and is therefore negligible.

If the power supply to the device is cut for less than 30 seconds, the alarm information is still retrievable because it is stored by capacitors in the device.

9.2.1 Pre-alarms

In the event of a pre-alarm, an acoustic signal sounds and a staff call is activated. The display remains in pre-alarm until the operating alarm goes off. Pre-alarms do not cause delivery to be interrupted.

Display message	Meaning
"Volumes nearly infused"	• Preselected volume has almost been infused • Remaining volume is displayed
"Disposable syringe nearly empty"	Small infusion volume remaining in the syringe
"Infusion time nearly reached"	Preselected time is almost over
"Battery nearly empty"	The battery is almost discharged

A pre-alarm can be muted for 2 minutes by pressing the OK key. The following symbol is shown in the display: 

9.2.2 Operating alarms

In the event of an operating alarm, the infusion is stopped. An acoustic signal sounds, the red LED flashes and a staff call is activated.

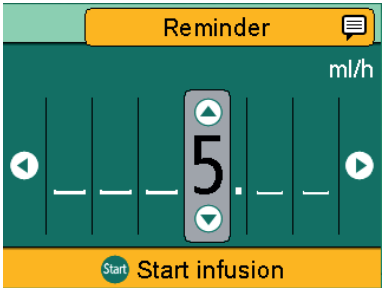
Display message	Meaning
"Target volume reached"	Preselected volume has been infused
"Disposable syringe is empty"	No infusion solution is left in the syringe.
"Time reached"	Preselected time has elapsed
"Battery empty"	The battery is discharged • Connect device to mains and/or have battery replaced by a service technician The battery alarm will sound for 3 min. Then the pump will automatically turn off
"Pressure too high"	There is an occlusion in the system. The set level was exceeded • The pump automatically implements a bolus reduction
"KVO finished"	KVO time has elapsed
"Syringe holder open"	Syringe bracket was opened during the ongoing infusion • Close syringe bracket
"Syringe not correctly inserted"	The wings of the syringe are not correctly inserted • Insert syringe correctly, see section 8.2
"Calibrate device"	Pump calibration data has changed (e.g. after an update) • Recalibrate device using the service programme
"No battery in the device"	It is not possible to use the pump without a battery • Ask a service technician to insert a battery

9.3 Reminder alarm

Reminder alarms are triggered in the following cases:

- A syringe is inserted, the pump is not delivering and the device is not operating for two minutes.
- A value input was started but not completed and confirmed.
- After the standby time has elapsed

A staff call is activated and the following screen is displayed:



10 Cleaning and care

- Device is switched off
- Device is unplugged from the mains
- Device accessories are disconnected

10.1 Cleaning

- No pointed objects should be used for cleaning.
- Do not put excess stress on the claws when cleaning.
- Clean the surface of the device with mild soap solution.
- Do not spray disinfectant into the openings in the housing.
- Do not use disinfectant spray on electrical connections. Recommendation: Use disinfectants manufactured by B. Braun (e.g., Meliseptol, Melsitt 10% and Melsept SF 10%) for wipe disinfection.
- Allow the device to air dry for at least 1 min before operation. Do not spray into device openings (e.g., cooling vents, mains power plugs, interfaces).
- Observe all hygiene regulations.
- Clean accessories according to the instructions.

Note: Substances from the groups of disinfectants listed below are approved, for normal cleaning according to the manufacturer's instructions:

Alcohols	Peroxides
QAC	Active chlorine
Aldehydes	Acids
Alkylamines	Phenoles

10.2 Battery operation and maintenance

The device is equipped with a modern lithium-ion battery that, at the time of delivery, guarantees an operating time of 8 hours at 5 ml/h. For optimal treatment of the battery, the device is equipped with protection against overcharge and deep depletion.
The battery is charged by the device during mains operation. In the event of a power cut or disconnection from the mains, the pump automatically switches to battery mode.
The battery status indicator in the display is a trend display (low, medium, high).

10.2.1 Note for optimal battery operation

Battery life may vary due to

- Ambient temperature
- Varying loads

Therefore, please observe the following:

- Under normal temperature conditions, a battery can be fully discharged and recharged around 300 times before its capacity decreases to around half of the original nominal value.
- When the device is in mains operation, the battery discharges slowly and may be fully exhausted after a month even if the device is not in operation. In this case the battery does not reach its original capacity after one charge; it takes several charging and discharging cycles for the battery to achieve its original capacity.

- Optimal battery life will then only be achieved if the pump is in continuous operation at room temperature in charged state. The battery display on the pump is an approximate value based on the current delivery rate. If the battery is old, the "battery display" may differ from the actual achievable operating time.

CAUTION! Risk of injury from the battery exploding or leaking.

- Do not open or burn the battery.

10.2.2 Changing the battery

- The battery should only be changed by a service technician.

11 Decommissioning

- No ongoing therapy
- No patient connected

- Remove accessory parts and dispose of according to the instructions.
- Switch off the device and disconnect from the mains.
- Prepare the device for storage or disposal.
  - Comply with the storage conditions.
  - Follow the notes on disposal.

12 Maintenance and repair

WARNING! Risk of injury and/or malfunction from incorrect repair.
The device does not contain any parts that the user can repair themselves.

- Do not repair defective devices independently.
- Send defective devices to the B. Braun service.

WARNING! Risk of injury and/or malfunction from device modifications.

- Do not modify the device.

Note: Modifications and/or incorrect repair of medical devices can lead to a loss of guarantee/warranty claims and any authorisations.

- Replace damaged accessories with original accessories.

13 Disposal

The device should be returned to B. Braun for further disposal.

- Observe all country-specific regulations when disposing of equipment locally.
- Do not dispose of electrical devices and batteries in domestic waste.

14 Safety check/service

A safety check must be performed on the device every two years in accordance with the checklist, with results entered into the medical device log. The service may only be performed by personnel who have received training from B. Braun.

15 Start-up and trumpet curves

15.1 Significance in clinical practice

Trumpet curves show the recorded maximum and minimum deviations in flow rate compared to the delivery rate per time interval.
In clinical practice, the trumpet curve makes it easier for the treating doctor to decide if the pump is sufficiently precise for the administration of the desired drug.

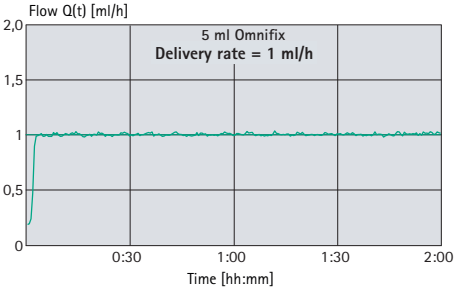
- Reconcile drugs with short half lives, in particular, with the delivery accuracy in this period on the trumpet curve.

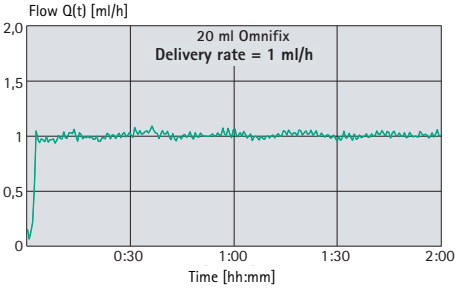
The physiological effect of the drug can be affected by the flow and the disposable article.

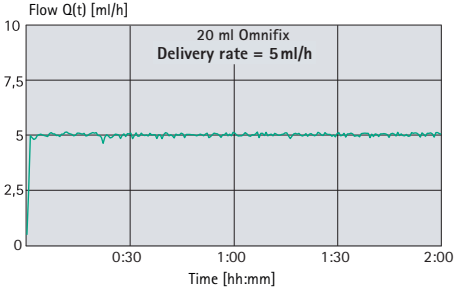
- Ensure that the prescription is in line with the start-up/trumpet curve and the set flow rate.

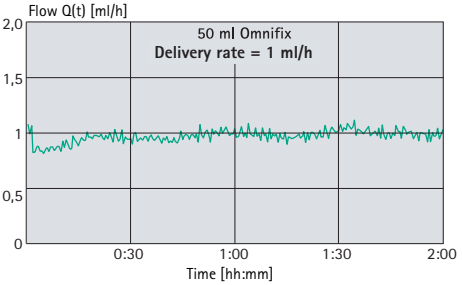
15.2 Typical start-up and trumpet curves

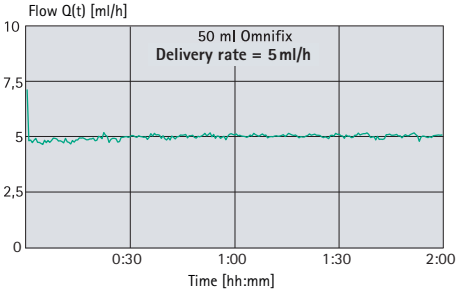
Start-up curves





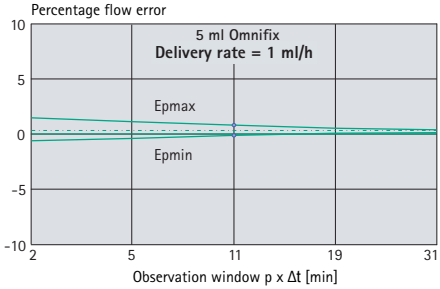


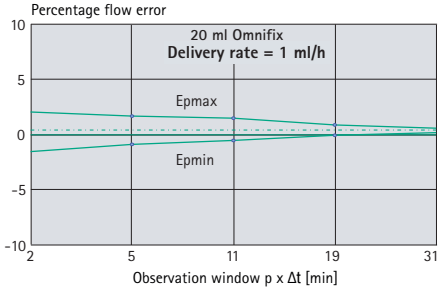


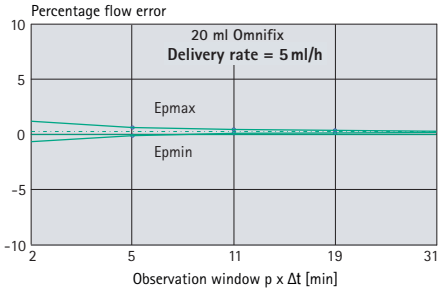


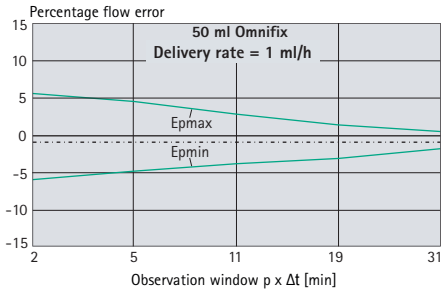
Start-up and trumpet curves

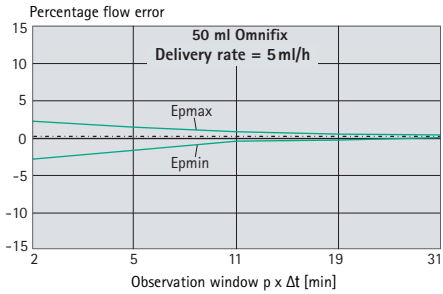
Trumpet curves











Note: Every syringe has certain tolerances in start-up behaviour (depending on the syringe manufacturer, syringe plunger material, siliconisation of the cylinder etc.).

In order to keep the delay as short as possible, the syringe should be as small as possible and the plunger moved before the syringe is inserted in order to work through the rubber stopper's breakloose force behaviour.

The device is equipped with start acceleration, which enables a quick infusion start after each syringe change.

Note: Always use the device with the smallest possible syringe, provided the therapy permits this.

Start-up and trumpet curves

This is particularly important if highly concentrated or life-sustaining drugs with short half-lives are to be infused at low infusion rates.

When infusing at low rates and with large syringes, there can be deviations from the pump's technical data, which can lead to delivery deviations, delayed start-up behaviour and longer alarm times in the event of system occlusions (pressure alarms).

Recommendation			
Syringe size [ml]	50/60	30	20
Recommended minimum rate [ml/h]	1	1	0.5

Recommendation			
Syringe size [ml]	10	5	3
Recommended minimum rate [ml/h]	0.1	0.05	0.01

These graphs show the accuracy and uniformity of flow over time. Take into account:

- The delivery behaviour and the delivery accuracy are fundamentally affected by the type of syringe used (disposable item).
- Deviations from the pump technical data cannot be ruled out for competitors' syringes.

Note: The system accuracy is normally ±2% of the volume, measured using the trumpet curve test method according to IEC 60601-2-24 at a rate of 1 ml/h (at 20 °C ± 2 °C) and using the recommended syringes.

Start-up curves	
Measurement interval	Δt = 0.5 min
Measurement duration	T = 120 min
Flow Q_i	(ml/h)

Trumpet curves (Measured values for second hour in each case)	
Measurement interval	Δt = 0.5 min
Observation interval	p x Δt [min]

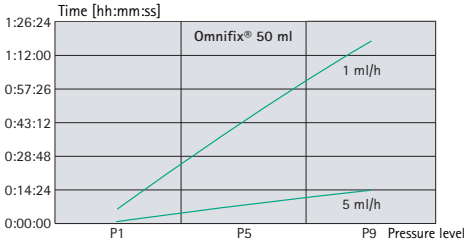
Start-up and trumpet curves

15.3 Alarm times

The following graphs show the alarm times of the B. Braun syringe shown according to pressure and syringe type.

Note: The alarm times for syringes from other manufacturers may vary slightly.

15.3.1 Omnifix® 50 ml



Note: At a rate of 0.01 ml/h the alarm time is > 4 h.

Manufactured by	Syringe type	Article number	Pressure level = 1 0.1 bar max. alarm times [mm:ss]	Pressure level = 9 1.2 bar max. alarm times [mm:ss]
B. Braun	OPS 50ml KK	8728810F-06	01:07	15:20
B. Braun	OMNIFIX 50 KK	4617509F	01:31	14:24
B. Braun	OMNIFIX 30	4617304F	00:52	09:28
B. Braun	OPS 20ml	8728615	01:16	06:12
B. Braun	OMNIFIX 20	4617207V	00:40	06:28
B. Braun	OMNIFIX 10	4617100V	01:02	05:04
B. Braun	OMNIFIX 5ml	4617053V	00:26	02:35
B. Braun	OMNIFIX 3ml	4617022V	00:11	01:57
B. Braun	OMNIFIX 2ml	4617029V	00:31	02:13
Terumo	Terumo 50ml	SS+50L1	03:07	22:43
Terumo	Terumo 30ml	SS*30LE1	02:24	13:58
Terumo	Terumo 10ml	SS*10LE1	01:20	05:30
Terumo	Terumo 5ml	SS*05LE1	01:08	03:45
Becton Dickinson	Plastipak 50ml	300865/300869	04:48	19:20
Becton Dickinson	Plastipak 30ml	301229	03:06	10:17
Becton Dickinson	Plastipak 20ml	300629	02:44	10:34
Becton Dickinson	Plastipak 10ml	305959	01:49	05:10
Becton Dickinson	Plastipak 5ml	309649	00:16	02:22
Becton Dickinson	Plastipak 3ml	309658	00:44	02:35
Fresenius Kabi AG	Injectomat 50ml	9000701	06:21	23:42
Stanislaw Margol	Margomed 50ml	007111, 007121	01:44	22:56
Becton Dickinson	Precise 50ml A/P	300144	04:13	18:58
Becton Dickinson	Precise 20ml A/P	300141	01:36	06:12
Becton Dickinson	LuerLok 10ml A/P	302149	01:28	04:54
Becton Dickinson	LuerLok 5ml A/P	302135	01:02	04:05
Becton Dickinson	LuerLok 3ml A/P	302113	00:23	02:27

16 Technical data

Note: The delivery accuracy, pressure alarm and alarm reaction times apply at room temperature and with water as the test material. Different media viscosities and temperatures may lead to deviations.

Parameter	Value
Type of device	Infusion syringe pump
Product classification	According to Directive 93/42 EEC: • IIb According to EN 60601-1: • Protection class II • For Type CF applied parts with defibrillation protection
Moisture protection	IP34
Power supply	• 100-240 V, 50-60 Hz, connection via power cable or compact^{plus} station • 12 V DC 12 V CP interface cable • 10 VA typ.
Internal battery • Battery life • Recharging time	Lithium-ion battery • Approx. 8 h at 5 ml/h with 50 ml syringe • Approx. 4 h
Power consumption	<20 W
Current consumption/ charging current	• Max. 0.6 A_{eff} (typ. <0.1 A_{eff}) at 100-240 V, 50-60 Hz • Max. 1.5 A (typ. <0.5 A) at 12 V DC
Staff call	Max. 24 V / 0.5 A / 24 VA (VDE 0834)
EMC	IEC/EN 60601-1-2 / 60601-2-24
Time of operation	100% (continuous operation)
Acoustic alarm signal sound pressure range	Nine available levels: 45 dB(A) to 75 dB(A)

Technical data

Parameter	Value
Interfaces	• Cold connector for mains voltage • Accessory port for interface cable 12 V CP and staff call • IrDA infrared for communication in the station and for service
Operating conditions • Temperature • Relative humidity • Atmospheric pressure	 • +5 °C ... +40 °C (+41 °F ... +104 °F) • 30% ... 90% (without condensation) • 0.54 ... 1.06 bar
Storage conditions • Temperature • Relative humidity • Atmospheric pressure	 • -20 °C ... +55 °C (-4 °F ... +131 °F) • 20 % ... 90% (without condensation) • 0.5 ... 1.06 bar
Weight	Approx. 2.3 kg
Dimensions in mm (W x H x D)	Approx. 290 mm x 98 mm x 220 mm (including compact^{plus} stand clamp)
Safety check	Every 2 years
Volume preselection	0.1 ml - 9,999 ml in increments of 0.01 ml
Time preselection	00:01 h - 99:59 h
Delivery accuracy	±2% according to IEC/EN 60601-2-24
Occlusion alarm pressure	9 levels from 1.2 bar ± 0.2 bar. Post occlusion bolus will be automatically reduced.
Alarm in the case of incorrect dose	In the event of an incorrect dose of max. 0.2 ml due to pump malfunction, the pump will automatically switch off.
Max. bolus volume after bolus reduction	≤0.2 ml

Technical data

Parameter	Value
KVO rate	• Rate: ≥ 10 ml/h: KVO rate 3 ml/h • Rate: < 10 ml/h: KVO rate 1 ml/h • Rate: < 1 ml/h: KVO rate = rate set using the service program (factory default rate 0.1 ml/h) or current rate if this is lower.
History protocol	• 1,000 history entries The oldest entries are overwritten if necessary. • 100 events for system diagnosis The history is retained when the device is switched off or the battery removed.

Delivery rates

Continuous delivery rates/bolus rates according to the syringe size used:

Syringe size [ml]	Continuous delivery rate [ml/h]	Bolus rate [ml/h]	Preset bolus rate [ml/h]
50/60	0.01 to 200 Or alternatively: 0.01 to 999.9	1 to 1 800	800
30/35	0.01 to 100	1 to 1 200	600
20	0.01 to 100	1 to 800	400
10/12	0.01 to 50	1 to 500	200
5/6	0.01 to 50	1 to 300	150
2/3	0.01 to 25	1 to 150	80

Note: The delivery rate can be set in steps of 0.01 ml.

Note: The preset bolus rate can be changed via the service menu or once via the combination of bolus volume and bolus time.

Delivery rate accuracy in bolus administration is generally ± 2%. The accuracy can vary when administering low bolus volumes.

17 Electromagnetic compatibility

Note: In order to meet with the following compliance levels, only original accessories and replacement parts may be used. Otherwise, there may be elevated emissions or reduced device immunity.

Note: If the device is used in a system involving other devices (e.g. electrosurgery), this system should be checked to ensure correct operation of the system.

Note: The device must not be used near a magnetic resonance imaging unit without protection.

Note: The device must not be stacked, placed or used immediately next to or with other devices, except for B. Braun devices.

The device is designed to be used in the following electromagnetic environment. The device users and customers should ensure that it is being operated in such an environment.

Electromagnetic compatibility

17.1 Electromagnetic interference emissions

Interference emission measurements	Compliance	Electromagnetic environment guidelines
HF emissions According to CISPR 11	Group 1	The device uses HF energy for its internal functions only. As such, its HF emissions rate is very low and it is unlikely to interfere with nearby electronic equipment.
HF emissions According to CISPR 11	Class B	The device is intended for use in all establishments (including residential areas and similar) directly connected to a public power grid that also supplies buildings used for residential purposes.
Harmonic emissions according to IEC 61000-3-2	Not applicable	
Voltage fluctuation/flicker emissions according to IEC 61000-3-3	Conforms	

Electromagnetic compatibility

17.2 Electromagnetic immunity

The device is designed to be used in the electromagnetic environment described below. The device users and customers should ensure that it is being operated in such an environment.

Immunity tests	Test level EN 60601-1-2 EN 60601-2-24	Compliance level	Electromagnetic environment guidelines
Electrostatic discharge (ESD) according to IEC 60601-4-2	**Contact discharge** EN 60601-1-2: ±6 kV IEC 60601-2-24: ±8 kV	±6 KV without interference ±8 KV outage with alarm permitted	Floors should be wood, concrete, or ceramic tile. If the floor covering is made of a synthetic material, relative air humidity needs to be at least 30%.
	Air discharge EN 60601-1-2: ±8 kV IEC 60601-2-24: ±15 kV	±8KV without interference ±15KV outage with alarm permitted	
Electrical fast transient/ bursts according to IEC 60601-4-4	for power supply lines ±2 kV	±2 kV	The supply voltage quality should be the same as that of a typical commercial or hospital environment.
	For input and output lines ±1 kV	±1 kV	
Surges according to IEC 61000-4-5	±1 kV outer conductor - outer conductor voltage	±1 kV	The supply voltage quality should be the same as that of a typical commercial or hospital environment.
	±2 kV voltage Outer conductor - ground	±2 kV	

Electromagnetic compatibility

Immunity tests	Test level EN 60601-1-2 EN 60601-2-24	Compliance level	Electromagnetic environment guidelines
Voltage dips, brief supply voltage interruptions and fluctuations according to IEC 61000-4-11	< 5% UT [1] for ½ periods (>95% dip)	Complies through the use of an internal energy source	The supply voltage quality should be the same as that of a typical commercial or hospital environment.
	40% UT [1] for 5 periods (60% decline)		
	70 % UT [1] for 25 periods (30 % decline)		
	<5% UT [1] for 5 s (>95% dip)		
Magnetic field at supply frequency (50/60 Hz) according to IEC 61000-4-8	3 A/m	400 A/m	Magnetic fields at the supply frequency should correspond to those typically found in commercial and hospital environments.
Conducted HF interference according to IEC 61000-4-6	3 V_{eff} 150 kHz to 80 MHz Outside ISM bands	10 V_{eff} In all bands	Do not use portable and mobile radio communications equipment closer to the Perfusor® compact^{plus} (including connection cables) than the recommended safe distance calculated using the appropriate equation for that frequency. **Recommended safety distance:** $d = 1.2 \sqrt{P^3}$
	10 V_{eff} Within ISM bands		

Electromagnetic compatibility

Immunity tests	Test level EN 60601-1-2 EN 60601-2-24	Compliance level	Electromagnetic environment guidelines
Radiated HF interference according to IEC 61000-4-3	10 V/m 80 MHz to 2.5 GHz	[E1] 10 V/m 80 MHz to 6 GHz und 500 MHz to 3 GHz	The field strength should be lower than 10 V/m d = 12/E1 √P [2] 80 MHz to 800 MHz d = 23/E1 √P [2] 800 MHz to 6 GHz Field strengths from stationary RF transmitters should be below the compliance level for all frequencies, based on an on-site test. Interference is possible in the vicinity of equipment that has the following symbol. 

[1] UT is the AC mains voltage prior to test level application

[2] With P as the maximum rated power of the transmitter in watts (W) according to the transmitter manufacturer specifications and as the recommended safe distance in metres (m).

Note: The deviating test values derived from IEC 60601-2-24 are labelled in the table. However, these test values allow one outage with an alarm while the test values according to DIN EN 60601-1-2 do not allow any outages.

The compliance levels for ISM frequency bands between 150 kHz and 80 MHz and in the 80 MHz to 6 GHz frequency range are designed to minimise the likelihood of mobile/portable communications equipment causing interference if accidentally brought into the patient area. For this reason the additional factor 10/3 is used when calculating the recommended safe distances in these frequency ranges.
Field strengths emitted from stationary transmitters (such as base stations for cordless telephones and land mobile radio devices, amateur radio stations, or AM and FM radio and television broadcasts) theoretically cannot be predicted exactly. Consider conducting a study of the site to determine electromagnetic environmental conditions as regards stationary transmitters. If the measured field strength in the area the Perfusor® compact^{plus} is being used in exceeds compliance levels, monitor the Perfusor® compact^{plus} to ensure that it is functioning properly. If abnormal performance is observed, additional measures may be necessary, e.g., changing the device's location or facing it in a different direction.

17.3 Recommended safe distances

The device is designed for use in an electromagnetic environment in which HF disruptions are controlled. Customers or users of the device can help avoid electromagnetic interference by maintaining a minimum distance between portable or mobile HF telecommunications equipment (transmitters) and the device – depending on the communication equipment's output power, as described below.

Electromagnetic compatibility

Transmitter rated power in W	Safe distance according to transmitter frequency m		
	150 kHz to 80 MHz[1] 1.2√P	80 MHz to 800 MHz 1.2√P	800 MHz to 6 GHz[1] 2.3√P
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.27
100	12	12	23

[1] The higher frequency range applies with 80 MHz and 800 MHz.

Note: Distances for transmitters whose maximum rated power is not specified in the table above can be determined using the equation for the relevant column, with P being the transmitter's maximum rated power in watts (W) according to manufacturer specifications.

Note: These guidelines may not be applicable in all cases. Electromagnetic propagation is affected by the absorptive and reflective qualities of the surrounding structures, objects and people.

The compliance levels for ISM frequency bands between 150 kHz and 80 MHz and in the 80 MHz to 6 GHz frequency range are designed to minimise the likelihood of mobile/portable communications equipment causing interference if accidentally brought into the patient area. Therefore, the additional factor 10/3 has been included in the formula and used when calculating the recommended safe distances in these frequency ranges.

18 Instructions for use for accessories

18.1 Interface lead 12 V CP (8718020)

Connect the device for charging the battery with vehicle socket

⚠ **WARNING! Risk to the patient from electric shock!**

- Do not use the device on patients if the emergency ambulance is connected to the vehicle charger.

- Plug interface cable 12 V CP into the accessory port on the side of the device.
- Plug interface cable 12 V CP into the vehicle socket.
- If necessary, remove the red adapter on the vehicle socket by gently turning it and pulling on it at the same time. The green LED on the electronics box shows the operating voltage.

18.2 Staff call interface lead CP (8718030)

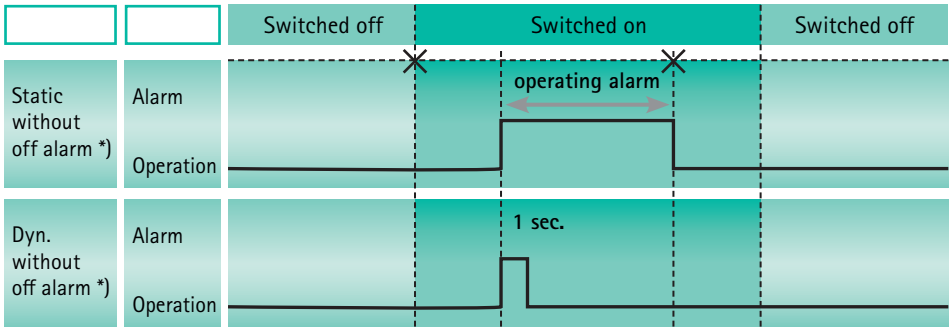
Connect device to the staff call system

The staff call system must comply with the requirements of VDE 0834.

- Observe country-specific regulations on staff calls.
- Plug the STAFF CALL interface lead CP into the accessory port on the side of the device or service port on the compact^{plus} station.
- Connect the STAFF CALL interface lead to the staff call system.
- Set the staff call operating mode using the service programme. Follow the staff call system procedure.
- Check the staff call before each use of the device.

Instructions for use for accessories

The device has two different staff call operating modes:



* In "static without off alarm" mode, the staff call can be disabled by pressing the OK key.

19 Ordering data

Art. no.	Name
8717030	Perfusor® compact^{plus}

19.1 Accessories

Recommended accessories for the Perfusor® compact^{plus}

19.1.1 Original Perfusor® lines

Art. no.	Name
8255172	Original Perfusor® line, made of PVC; 50 cm
8722960	Original Perfusor® line, made of PVC; 150 cm
8722862	Original Perfusor® line, made of PVC; 200 cm
8255490	Original Perfusor® line, made of PVC; 250 cm
8255253	Original Perfusor® line, made of PVC; 300 cm
8255059	Original Perfusor® line, made of PE; 50 cm
8255067	Original Perfusor® line, made of PE; 100 cm
8722935	Original Perfusor® line, made of PE; 150 cm
8723060	Original Perfusor® line, made of PE; 200 cm
8272565	Original Perfusor® line, made of PE; 250 cm
8722820	Original Perfusor® line, type SafeSite, made of PVC, with SafeSite safety connector; 150 cm
8723001	Original Perfusor® line, type Filter, made of PVC, with 0.22 µm injection filter; 200 cm
8726019	Original Perfusor® line, type PCA, made of PVC, with rotary nut lock; 168 cm
8722870	Original Perfusor® line, type MR, made of PVC, with rotary nut; 75 cm
8255504	Original Perfusor® line, type MR, made of PVC, with 150 cm
8723010	Original Perfusor® line, made of PE, black; 150 cm

Ordering data

19.1.2 Interface lead

Art. no.	Name
8718020	Interface lead 12 V CP
8718030	Interface lead staff call CP

19.1.3 Syringes

Art. no.	Name
8728615	Original Perfusor® syringe, 20 ml
8728623	Original Perfusor® syringe, 20 ml with needle
8728801F-06	Original Perfusor® syringe, 50 ml, protected against light, yellow with filter needle
8728810F-06	Original Perfusor® syringe, 50 ml with needle
8728844F-06	Original Perfusor® syringe, 50 ml
8728852F-06	Original Perfusor® syringe, 50 ml with filter needle
8728861F-06	Original Perfusor® syringe, 50 ml, protected from light, orange with filter needle
4617509F	Omnifix® 50 ml
4617510F-06	Omnifix® 50 ml, protected from light, orange

Note: All syringes have a Luer lock attachment for safety reasons.

Note: Depending on the syringe type and size, there will be slight variations in the residual volume in the syringe.

Index

Manufactured by:
B. Braun Melsungen AG
34209 Melsungen
Germany
Tel +49(0) 56 61 71-0
www.bbraun.com
www.space.bbraun.com

Distributed by:
B. Braun Melsungen AG
Hospital Care Division
34209 Melsungen
Germany
Tel +49 (0) 56 61 71-0
Fax: +49 (0) 56 61 71-20 44
www.bbraun.com

38932101 • Drawing no. I0002700001
2017-05-18 • Information as of: March 2017

Printed on 100% chlorine-free bleached pulp