

Infusomat® compact^{plus}

Instructions for use

Version 1.0 English

Valid for software 003A



CE 0123

Table of Contents

1	About this document	5	7	Set-up and start-up	21
1.1	Purpose	5	7.1	Setting up and connecting the device	21
1.2	Signs, symbols and tags	5	7.1.1	Attach/remove the compact ^{plus} pole clamp	21
1.3	Warnings	6	7.1.2	Operating the device on a stand	21
1.4	Abbreviations	6	7.1.3	Operating the device in the compact ^{plus} station	21
2	Symbols	7	7.1.4	Operating the device on a wall rail	21
2.1	Symbols on the product and packaging	7	7.1.5	Connecting the device to the mains electricity	21
2.2	Symbols on the device's display	8	7.1.6	Operating the device on battery power	21
3	Intended use	9	7.2	Powering on the device for the first time	21
4	Safety instructions	10	7.3	Configure device options	21
4.1	Safe handling	10	7.3.1	Turning night mode on/off	22
4.1.1	General	10	7.3.2	Setting display brightness	22
4.1.2	Software	10	7.3.3	Setting the audio volume	22
4.1.3	Transport and storage	10	7.3.4	Configuring the pressure alarm limit	22
4.1.4	Set-up and start-up	10	7.3.5	Configuring service settings	23
4.1.5	Stacking	10	7.4	Locking/unlocking the keypad	24
4.1.6	Operation	11	8	Operation	25
4.1.7	Alarms and staff call	11	8.1	Switching on the device	25
4.1.8	Accessories and consumables	11	8.2	Inserting the infusion line	25
4.1.9	Enteral nutrition	12	8.3	Priming the infusion line	26
4.1.10	Transfusion	12	8.4	Setting the infusion values	27
4.2	Electrical connection	12	8.4.1	Entering the delivery rate	27
4.3	Safety standards	12	8.5	Starting and stopping the infusion	27
5	Description of the device	13	8.6	Activating standby	28
5.1	Device overview	13	8.7	Administering a bolus	28
5.2	Interfaces	14	8.7.1	Administering a manual bolus	28
5.3	Display and control elements	15	8.7.2	Administering a bolus with preselected bolus volume/bolus duration	29
5.4	Display overview	17	8.8	Using the drug database	29
5.5	Alarm status display	17	8.8.1	Hard and soft limits	30
6	Menu structure/device functions	18	8.9	Calculating the dose	31
6.1	Main menu	18	8.10	Entering a combination of delivery rate, volume and time	32
6.1.1	Main menu > Rate, volume & time	18	8.11	Resetting the therapy	33
6.1.2	Main menu > Drug	18	8.12	Changing the infusion line	33
6.1.3	Main menu > Dose calculation	19	8.13	Ending the infusion	33
6.1.4	Main menu > Settings	19	8.14	Switching off the device	33
6.1.5	Settings > Service	20			

9	Alarms.....	34
9.1	Device alarms.....	34
9.2	Pre-alarms and operating alarms.....	34
9.2.1	Pre-alarms.....	34
9.2.2	Operating alarms.....	35
9.3	Reminder alarm.....	36
9.4	Note	36
10	Cleaning and care.....	37
10.1	Cleaning.....	37
10.2	Battery operation and maintenance	37
10.2.1	Notes for optimal battery operation	37
10.2.2	Changing the battery	38
11	Decommissioning.....	39
12	Maintenance and repair	39
13	Disposal.....	39
14	Safety inspection / Service.....	39
15	Start-up and trumpet curves	40
15.1	Significance in clinical practice	40
15.2	Typical start-up and trumpet curves	41
15.3	Alarm times.....	42
15.3.1	Infusomat® Plus Line.....	42
16	Technical data.....	43
17	Electromagnetic compatibility.....	46
17.1	Electromagnetic interference emissions...47	
17.2	Electromagnetic immunity.....	48
17.3	Recommended safe distances	51
18	Instructions for use for accessories.....	53
18.1	Interface lead 12 V CP (8718020).....	53
18.2	Interface lead staff call CP (8718030)....	53
19	Ordering data & ordering codes.....	55
19.1	Accessories.....	55
19.1.1	Original Infusomat® compact ^{plus} lines.....	55
19.1.2	Interface lead	57
19.1.3	Short infusion stand.....	57
	Index	58

About this document


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
●	Prerequisite
●	Handling step: Follow the specified instructions.
Key > Key	Press the specified keys one after the other.
	Warning symbol, introduces a warning.
Note:	Information to clarify or optimise work processes
Bold	Name of a navigational or an input element

About this document

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

Symbols

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 2002/96/EC (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
	Batch number

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

Intended use

3 Intended use

The Infusomat® compact^{plus} infusion pump system is a transportable volumetric infusion pump used in combination with specific infusion lines 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 Infusomat® compact^{plus} infusion pump system is intended for use by qualified medical professionals in rooms used for medical purposes, in outpatients and in emergency and transport situations (ambulances). The user must have received training on the device. The use of the Infusomat® compact^{plus} is dependent on the climatic conditions specified in the technical data. The storage conditions are detailed in the technical data.

Safety instructions

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.
- Protect the device against moisture.
- Keep the device clean.
- Close patient access in standby mode.

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

- Devices stored at temperatures above and below the defined operating conditions range must be kept at room temperature for at least one hour before being powered on.

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 switching on the device check it, and the air sensor in particular, for contamination, damage, missing parts and functionality.
- Pay attention to audible and visible alarms, the lighting up of the two status LEDs and the display 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.
- 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.

Safety instructions

4.1.6 Operation

- 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.
- Establish a connection to the patient only after the infusion line has been properly inserted and primed. Disconnect it from the patient when changing infusion line in order to prevent unintended dose administration.
- Only use approved infusion lines/catheters for the 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.
- 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.

- Irrespective of the soft limit, 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 the 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

- It is recommended that disposable items are changed after 96 hours (see hygiene rules).
- Only use pressure-tested disposable items (min. 2 bar/1500 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.
- Hydrophobic filters can further reduce the infusion of microbubbles.

Safety instructions

- See the corresponding manufacturer information for possible incompatibilities between the device and medicinal products.
- Use only Luer lock, ENFit or NRFit feed systems, and use only compatible combinations of devices, accessories, wear parts and disposable items.
- Connected electrical components must comply with IEC/EN specifications (e.g., IEC/DIN 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.

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

4.1.9 Enteral nutrition

The Infusomat 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 ENFit feed systems that have been designed and designated for enteral nutrition.

4.1.10 Transfusion

The Infusomat® compact^{plus} can also be used for the transfusion of blood and blood products.

- Only use disposable items and accessories that are intended for this purpose and are labelled as such for the transfusion.

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.

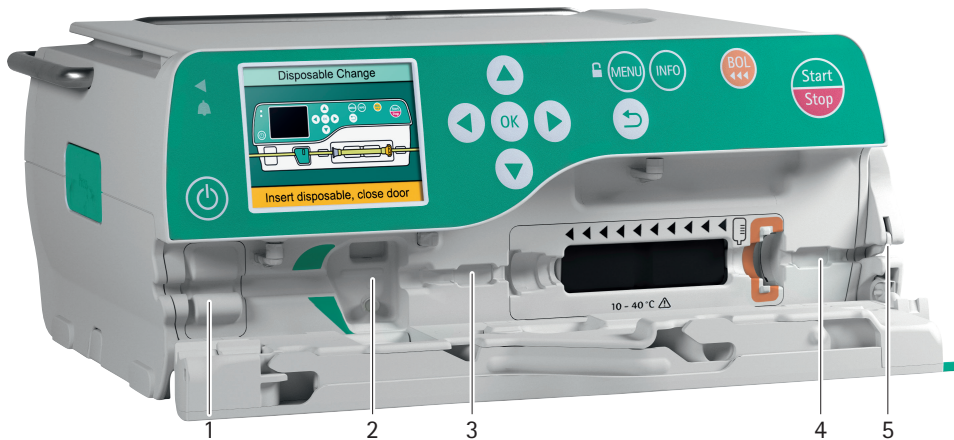
4.3 Safety standards

- 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.

Description of the device

5 Description of the device

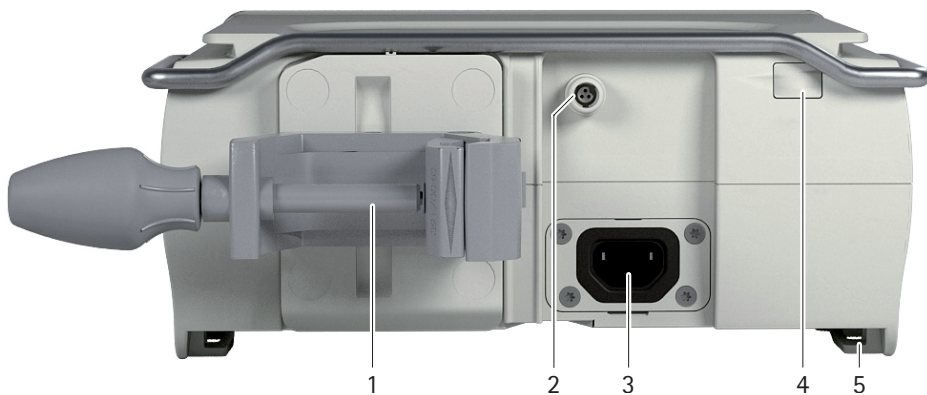
5.1 Device overview



No.	Name
1	Air Sensor
2	Attachment for safety clamp with push button
3	Downstream pressure sensor
4	Upstream pressure sensor
5	Anti-freeflow mechanism

Description of the device

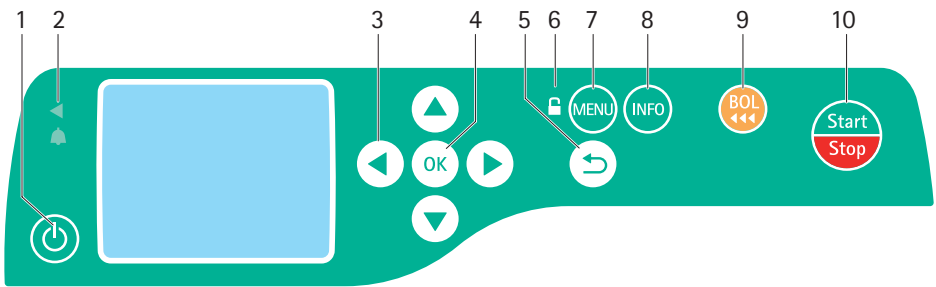
5.2 Interfaces



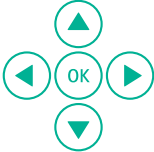



No.	Name
1	Pole clamp
2	Accessory port (e.g. staff call, ambulance)
3	Mains connection (socket for power cable. In the event of a power cut, the device switches to battery mode automatically)
4	Infrared interface (communication in station)
5	Guide rails for connecting pumps







Description of the device

5.3 Display and control elements



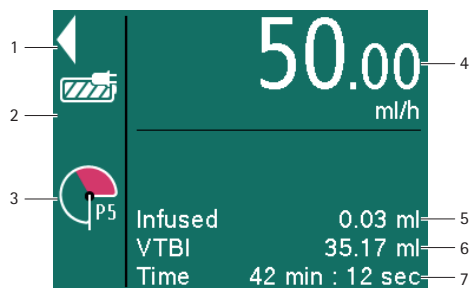
No.	Element	Meaning
1		On/Off key: Switches the device on and off
2		Status display Green LED: Delivery Red LED: Technical alarm, operating alarm
3		Arrow keys: <ul style="list-style-type: none">• Scroll through menus• Change settings• Answer yes/no questions• Select scale values and change between digits when inputting values• Open a function while the infusion is ongoing or suspended
4		OK key: <ul style="list-style-type: none">• Select/confirm function• Confirm value/settings/input/alarms

Description of the device

No.	Element	Meaning
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

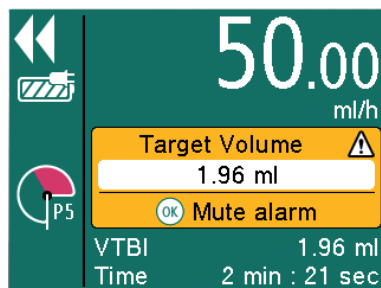


No.	Display / Function
1	Moving arrows: Delivery in progress (stopped delivery is shown by two bars)
2	Mains connection/battery status
3	Pressure symbol ("manometer"): Indication of P1 to P9 pressure level set with current system pressure (pointer) Note: Pressure detector is also active when the device 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

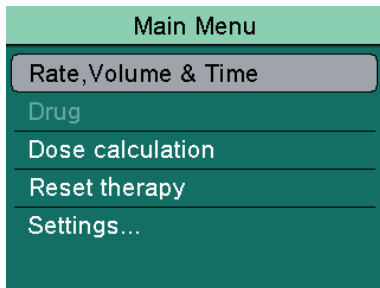


- Press OK to acknowledge the alarm.
- Continue the therapy or start new therapy.

Menu structure/device functions

6 Menu structure/device functions

6.1 Main menu



Menu	Meaning
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
Resetting the therapy	Delete all therapy settings Note: the infused volume (inf. vol.) is not deleted.
Device options...	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	Meaning
Stations	Select station
Patient profile	Select patient profile: Default patient profile or a previously created profile
Categories	Select drug categories
Drugs	Select drug
Concentrations	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	Meaning
Dose unit	Select unit: <ul style="list-style-type: none">• 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: <ul style="list-style-type: none">• Enter the patient's weight Body surface area: <ul style="list-style-type: none">• 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	Meaning
Night mode	Turn night mode on/off
Brightness	Enter brightness: <ul style="list-style-type: none">• Level 1 (=lowest level)- to -• Level 9 (=highest level)
Audio Volume	Select the volume: <ul style="list-style-type: none">• Level 1 (=lowest level)- to -• Level 9 (=highest level)
Pressure alarm	Select pressure level: <ul style="list-style-type: none">• Level 1 (=lowest level)- to -• Level 9 (=highest level)
Service ...	Configure additional settings: <ul style="list-style-type: none">• Language• Date• Time• Bolus rate• KVO• Night schedule• System info• Infusion history

Menu structure/device functions

6.1.5 Settings > Service

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

Menu	Meaning
Language	<ul style="list-style-type: none">• Select language
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: <ul style="list-style-type: none">• On/off• Activate at...• Deactivate at...
System info	Display system information <ul style="list-style-type: none">• 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

Set-up and start-up

7 Set-up and start-up

7.1 Setting up and connecting the device

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

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

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

7.1.2 Operating the device on a stand

- Press the lever on the compact^{plus} pole clamp.
Turn the compact^{plus} pole clamp to the desired position.
- Turn the compact^{plus} pole 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} pole clamp.
Turn the compact^{plus} pole clamp to the desired position.
- Turn the compact^{plus} pole clamp until the lever clicks into place.
- Make sure that the compact^{plus} pole 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.

- 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 on battery power

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

7.2 Powering on the device for the first time

- Device switched on
- Select and insert the line, 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.

Set-up and start-up

Settings Menu	
Night mode	Off
Brightness	7
Audio Volume	5
Pressure Alarm	5
Service...	

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 the pressure alarm level limit is set so that the alarm can be triggered in good time.

It may be necessary to change the pressure alarm limit due to various influencing factors, e.g. temperature, line length and inner diameter 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 increase it if required. The set pressure level affects the alarm time.

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

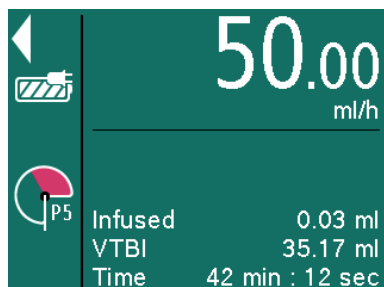
- Select **Pressure alarm** and press **OK** to confirm.
- Select **alarm level** and press **OK** to confirm.
 - Level 1 (=lowest level)
 - to -
 - Level 9 (=highest level)

Alarm level	Pressure value
1	0.067 bar (50 mmHg)
2	0.133 bar (100 mmHg)
3	0.200 bar (150 mmHg)

Set-up and start-up

Alarm level	Pressure value
4	0.300 bar (225 mmHg)
5	0.400 bar (300 mmHg)
6	0.500 bar (375 mmHg)
7	0.700 bar (525 mmHg)
8	0.900 bar (675 mmHg)
9	1.000 bar (750 mmHg)

Note: Occlusion must be resolved before the infusion is re-started. Otherwise it will affect the measurement accuracy.



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.

Service Menu	
Language	English
Date	01.01.2016
Time	00:00
Bolus rate	800.00 ml/h
KVO	Off
Night schedule	Off

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.

Set-up and start-up

Switching KVO on/off

The pump can continue to deliver with a pre-defined KVO rate (see section 16) after a preselected volume or a preselected time 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 it down for several 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.

Operation

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.

Note: Alternatively, the device can be switched on by opening the door.

8.2 Inserting the infusion line

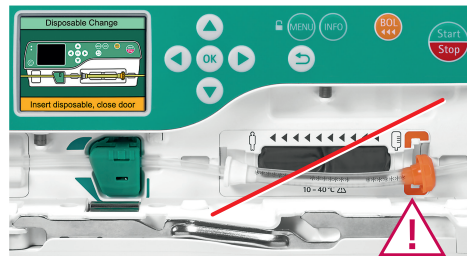
- Device switched on.
- Open the pump door by pressing the door lever. To do this, grip the door lever from behind and pull it forward.



CAUTION! Free-flow

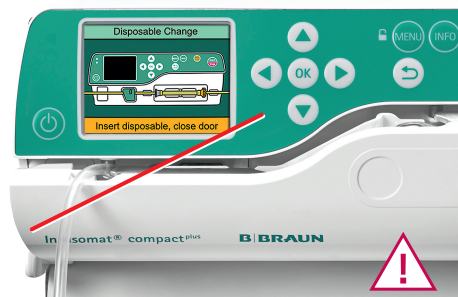
- Make sure that the roller clamp is closed before inserting the line.
- Never leave the pump unattended while the line is being inserted.
- Always insert the line completely and then close the door.
- Inserting the infusion line:
 - Insert the green safety clamp into the green socket on the pump, ensuring that the push button grips it firmly.
 - Clip the orange clip into the orange socket of the pump. The pump is now holding the infusion line.

- Push the infusion line into the air sensor on the left and into the pump based safety clamp on the right.



Ensure that both clips (orange and white) are firmly latched.

- Close the pump door while simultaneously pulling the door lever.



Do not damage the infusion line.

Operation

- Follow the instructions on the screen and open the roller clamp.
- The pump will perform a calibration of the tube.

Note: Only when the pump is switched on, the door is completely closed, and the disposable item is correctly inserted, will the pump have control over the disposable item and thus protect against free flow.

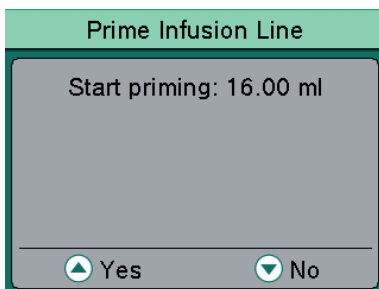
8.3 Priming the infusion line

Manually prime and insert the line. Alternatively, the line can also be primed by the pump. The line must be disconnected from the patient for this purpose.

Note: This additional 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

Note: During priming at the maximum delivery rate (1,200 ml/h), the air sensor is deactivated and the pressure alarm threshold is automatically increased to 9.



- 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.

Note: Priming using the bolus button when the device is stopped is an optional additional function.

Note: The "Prime infusion line" function is started after an air alarm. It enables the line to be primed by the pump without having to remove it. The line must be disconnected from the patient for this purpose.

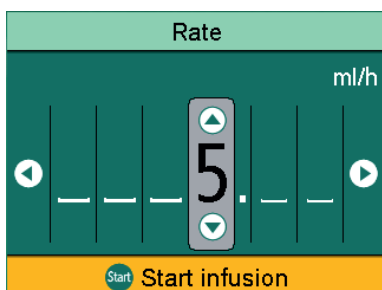
Operation

8.4 Setting the infusion values

- Infusion line inserted and selected

Note: Depending on the last therapy, the pump starts either when the delivery rate is entered or when a drug is selected.

8.4.1 Entering the delivery rate



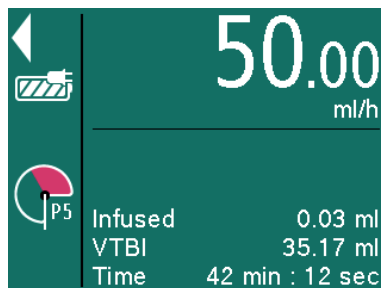
- Enter the delivery rate using the arrow keys.
- Start the infusion with the **Start/Stop** key.
– or –
- Press **OK** to confirm the rate.
The **Overview** screen is displayed.
- Select **Vol./Time** and press **OK** to confirm.
- Enter the volume or time limit and press **OK** to confirm.
Any values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

8.5 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.

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

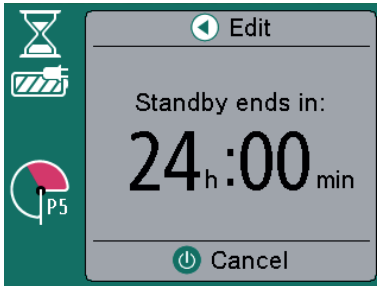
Operation

8.6 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

- Infusion line inserted and selected
- Press the **On/Off** key and hold it down until the pump indicates that it is in standby mode.



Adjusting device standby time

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

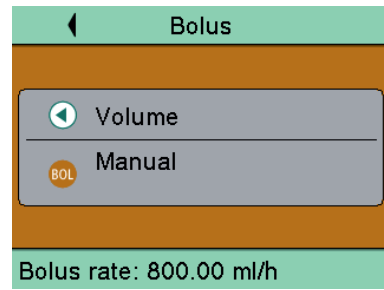
Ending standby mode

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

8.7 Administering a 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 alarm threshold is automatically increased to 9 during bolus administration.

8.7.1 Administering a manual bolus

- Press the **Bolus** key.
The "Bolus" screen is displayed.
- Press the **Bolus** key again and hold it down.
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.

Operation

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

Note: An acoustic signal sounds for every 1 ml of bolus volume delivered

8.7.2 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 interrupt bolus administration.
- Press the **Bolus** key to call up the bolus menu.

Entering the bolus volume

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

8.8 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**.

Operation

- 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.

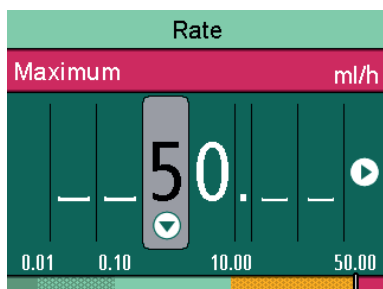
Note: In addition to the volume and time limit, the infusion rate can also be adjusted in the **Overview** screen.

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

8.8.1 Hard and soft limits

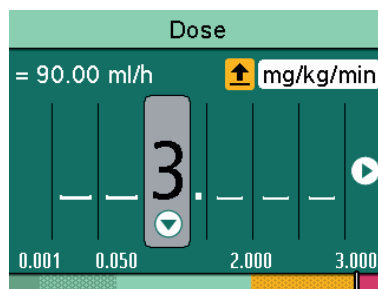
Hard limits

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 with no restriction 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 limit
	Infusion is below the lower soft limit

Operation

8.9 Calculating the dose

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

- Infusion line 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.

Calculate Using:	
No patient data	
Weight	
Body surface	

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.

Calculation 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.

Overview	
Conc.	1.000 mg/ml
Weight	70.00 kg
Dose	0.010 mg/kg/min
Volume	- ml
= Rate: 42.00 ml/h	
Start Start infusion	

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

Operation

Calculation using: Body surface area

- Select **Body surface area** 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.

8.10 Entering a combination of delivery rate, volume and time

- Infusion line 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
 - TimeThe 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.

Operation

8.11 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.

Note: the infused volume (inf. vol.) is not reset.

8.12 Changing the infusion line

- Press the **Start/Stop key** to stop the infusion.
The green LED turns off.
- Disconnect the line from the patient and close the roller clamp.
- Open the pump door by pulling the door lever. Grip the door lever from behind and pull it forward.
- Remove the infusion line.
- Insert the new infusion line, see section 8.2.
- Start the infusion, see section 8.4.

8.13 Ending the infusion

- Press the **Start/Stop key** to end the infusion.
The green LED turns off.
- Disconnect the line from the patient and close the roller clamp.
- Open the pump door by pulling the door lever. Grip the door lever from behind and pull it forward.

- Remove the infusion line.
- Close the pump door while simultaneously pulling the door lever.

8.14 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.

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

Alarms

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! Setting alarm thresholds incorrectly may endanger the patient.

- 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 alarms have 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.

The alarm pre-settings are retained in the event of a power failure.

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 notification	Meaning
"Volumes nearly infused"	<ul style="list-style-type: none">• Preselected volume has almost been infused• Remaining volume is displayed
"Infusion time nearly reached"	Preselected time is almost over
"Battery nearly empty"	The battery is almost discharged
"KVO runs for another xx min:sec"	Volume/time have been reached and the pump continues with KVO rate.

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

Alarms

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.

Note: If an operating alarm is not acknowledged within two minutes, another acoustic signal sounds.

Display notification	Meaning
"Target volume reached"	Preselected volume has been infused <ul style="list-style-type: none"> Continue with delivery or start new therapy
"Time reached"	Preselected time has elapsed <ul style="list-style-type: none"> Continue with therapy or select new therapy
"Battery empty"	The battery is discharged <ul style="list-style-type: none"> 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. <p>Note: If the battery has deep discharged, the notification may also say "Battery warning".</p>

Display notification	Meaning
"Pressure too high"	There is an occlusion in the system. The set level was exceeded <ul style="list-style-type: none"> The pump automatically implements a bolus reduction Check that there are no kinks in the tubing and that it is undamaged and that there is IV and filter patency
"KVO finished"	KVO time has elapsed <ul style="list-style-type: none"> Continue with therapy or select new therapy
"No battery in the device"	It is not possible to use the pump without a battery <ul style="list-style-type: none"> Ask a service technician to insert a battery
"Air bubble/accumulated air"	Air in the system. <ul style="list-style-type: none"> Check the line for small air bubbles and, if necessary, disconnect the patient and prime again.
"Occlusion test failed"	The pump and infusion line are not occluded. <ul style="list-style-type: none"> Close the roller clamp and perform a line replacement.
"Upstream pressure alarm"	The pressure on the container-side is too low, e.g. because the container is empty.

Alarms

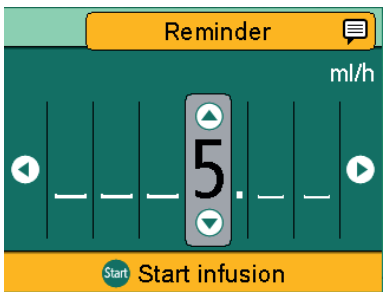
Display notification	Meaning
"Pump door open"	Pump door was opened during delivery.

9.3 Reminder alarm

Reminder alarms are triggered in the following cases:

- An infusion line is inserted, the pump is not delivering and no input has been made on the device for two minutes.
- A value input was started but not completed and confirmed within 20 seconds.
- After the standby time has elapsed

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



9.4 Note

Display notification	Meaning
"No battery in the device"	It is not possible to use the pump without a battery <ul style="list-style-type: none">• Ask a service technician to insert a battery
"Temperature too high/low"	Temperature is outside the specified operating temperature.

Cleaning and care

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.
- 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) 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 permitted, provided the manufacturer's instructions for normal cleaning are followed:

Alcohols	Peroxides
QACs	Active chlorine
Aldehydes	Acids
Alkylamines	Phenols

10.2 Battery operation and maintenance

The device is equipped with a modern lithium-ion battery that, at the time of delivery and after being fully charged, guarantees an operating time of 6 hours at 25 ml/h. For optimal treatment of the battery, the device is equipped with protection against over-charge 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 Notes 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 mode, 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.

Cleaning and care

- 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.

Decommissioning

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 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 inspection / Service

A safety check (SC) 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.

Start-up and trumpet curves

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.

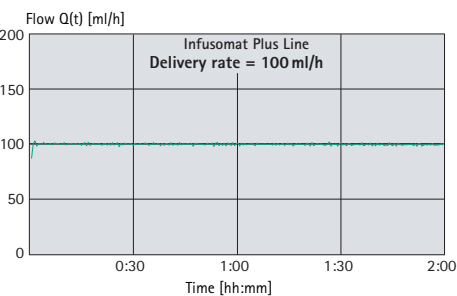
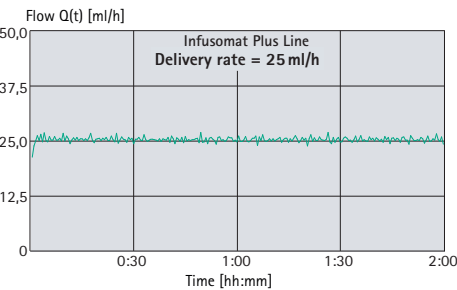
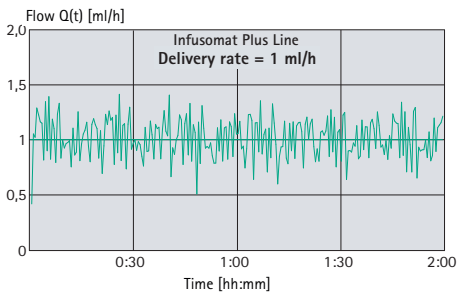
The physiological effect of the drug can be affected by the flow and the disposable article.

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

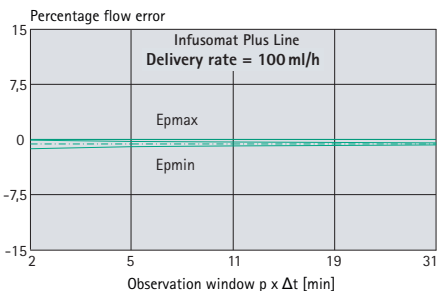
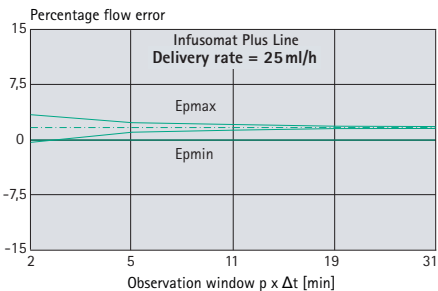
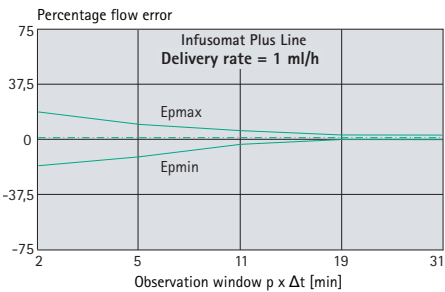
Start-up and trumpet curves

15.2 Typical start-up and trumpet curves

Start-up curves



Trumpet curves



Start-up and trumpet curves

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 disposable item used.

Note: The system accuracy is normally $\pm 5\%$ of the volume, measured using the trumpet curve test method according to IEC 60601-2-24 at a rate of 1 ml/h (at $20^\circ\text{C} \pm 2^\circ\text{C}$) and using the recommended disposable item.

Trumpet curves (Measured values for second hour in each case)

Measurement interval $\Delta t = 0.5 \text{ min}$

Observation interval $p \times \Delta t [\text{min}]$

Start-up curves

Measurement interval $\Delta t = 0.5 \text{ min}$

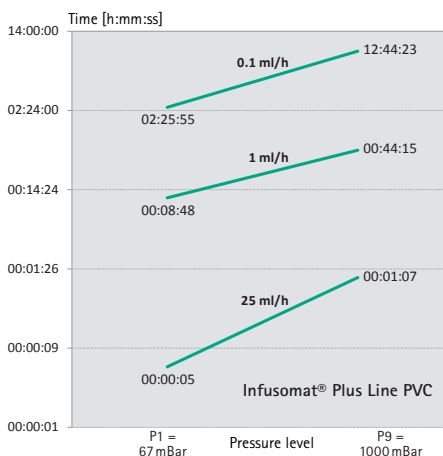
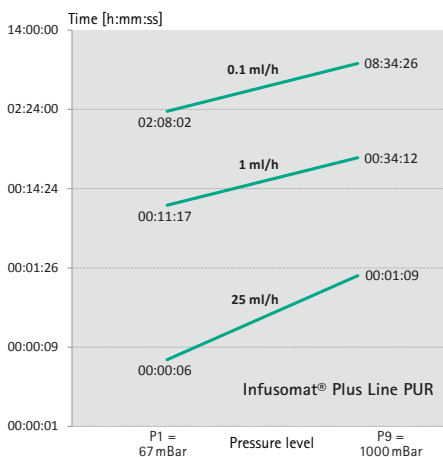
Measurement duration $T = 120 \text{ min}$

Flow Q_i (ml/h)

15.3 Alarm times

The following graphics show alarm times depending on pressure level.

15.3.1 Infusomat® Plus Line



Technical data

16 Technical data

Note: The data given, e.g. 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	Volumetric infusion pump
Product classification	According to Directive 93/42 EEC: <ul style="list-style-type: none"> • IIb According to EN 60601-1: <ul style="list-style-type: none"> • Protection class II • For defibrillation-proof type CF applied part
Moisture protection	IP34 <ul style="list-style-type: none"> • Protection against penetration by solid foreign bodies with a diameter of more than 2.5 mm • Protection against splashes from all directions
Power supply	<ul style="list-style-type: none"> • 100-240 V AC, 50-60 Hz, connection via power cable or compact^{plus} station • 12 V DC 12 V CP interface cable
Internal battery <ul style="list-style-type: none"> • Battery life • Recharging time 	Lithium-ion battery <ul style="list-style-type: none"> • Approx. 6 h at 25 ml/h • Approx. 3 h
Power consumption	<20 W
Current consumption/ charging current	<ul style="list-style-type: none"> • Max. 0.4 A_{eff} (typ. <0.1 A_{eff}) at 100-240 V AC, 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	<ul style="list-style-type: none"> • 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	
<ul style="list-style-type: none"> • Temperature • Relative air humidity • Atmospheric pressure 	<ul style="list-style-type: none"> • +10 °C ... +40 °C / +50 °F ... +104 °F • 30% ... 90% (without condensation) • 0.54 ... 1.06 bar
Storage conditions	
<ul style="list-style-type: none"> • Temperature • Relative air humidity • Atmospheric pressure 	<ul style="list-style-type: none"> • -20 °C ... +55 °C / -4 °F ... +131 °F • 20% ... 90% (without condensation) • 0.5 ... 1.06 bar
Weight	Approx. 1.9 kg
Dimensions in mm (W x H x D)	Approx. 229 mm x 98 mm x 220 mm (including compact ^{plus})
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	±5% according to IEC/EN 60601-2-24 Note: valid for 50 cm water column
Occlusion alarm pressure	9 levels up to 1 bar
Alarm in the case of incorrect dose	In the event of an incorrect dose of 1 ml due to pump malfunction (electronics, software), the pump will automatically switch off.
Delivery rate increments	0.1 ml/h ... 1200 ml/h in increments of 0.01 ml/h
Delivery accuracy for bolus administration	typ. ±5% for bolus volumes > 1 ml
Max. bolus volume after bolus reduction	≤0.2 ml

Technical data

Parameter	Value
KVO rate	<ul style="list-style-type: none"> • 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.
Air detector	<p>Technical sensitivity: Detection of air bubbles ≥ 0.01 ml.</p> <p>Alarm trigger: Individual air bubble alarm: 0.02–0.3 ml (standard 0.3 ml) Cumulative air alarm: 0.5–3.8 ml/h (standard 1.5 ml/h) Trigger: 0.01 ml</p>
History protocol	<ul style="list-style-type: none"> • 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. <p>Note: For more information, see the separate History Viewer documentation.</p>

Note: The preset bolus rate (800 ml/h) can be changed via the service menu or once via the combination of bolus volume and bolus time. Delivery accuracy during bolus administration is typically $\pm 5\%$. The accuracy can deviate when administering small bolus volumes.

Essential Performance for Infusion pumps:

- Infusion of liquids without variation of infusion rate
- Pressure limitation as protection from the bursting of the infusion line
- Protection from air-infusion
- Protection against unintended bolus volumes and occlusion (added by IEC 60601-2-24)
- Alarm signal of high priority (added by IEC 60601-2-24)

Electromagnetic compatibility

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 as per 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 as per 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 as per 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 following electromagnetic environment. 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	±6 kV without interference	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%.
	IEC 60601-2-24: ±8 kV	±8 kV outage with alarm permitted	
	Air discharge EN 60601-1-2: ±8 kV	±8 kV without interference	
	IEC 60601-2-24: ±15 kV	±15 kV 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 as per 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	<div><5% UT ¹ for ½ periods (>95% dip)</div> <div>40% UT ¹ for 5 periods (60% decline)</div> <div>70% UT ¹ for 25 periods (30% decline)</div> <div><5% UT ¹ for 5 s (>95% dip)</div>	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.
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	<div>3 V_{rms} 150 kHz to 80 MHz Outside ISM bands</div> <div>10 V_{rms} Within ISM bands</div>	<div>10 V_{rms} In all bands</div>	Do not use portable and mobile radio communications equipment closer to the Infusomat compact ^{plus} (including connection cables) than the recommended safe distance calculated using the appropriate equation for that frequency. Recommended safe distance: $d = 1,2 \sqrt{P^3}$

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	<p>The field strength should be lower than 10 V/m</p> <p>$d = 12/E1 \sqrt{P}^2$ 80 MHz to 800 MHz</p> <p>$d = 23/E1 \sqrt{P}^2$ 800 MHz to 6 GHz</p> <p>Field strengths from stationary RF transmitters should be below the compliance level for all frequencies, based on an on-site test.</p> <p>Interference is possible in the vicinity of equipment that has the following symbol.</p> 

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).

Electromagnetic compatibility

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 Infusomat compact^{plus} is being used in exceeds compliance levels, monitor the Infusomat 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.

Instructions for use for accessories

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 Interface lead staff call CP (8718030)

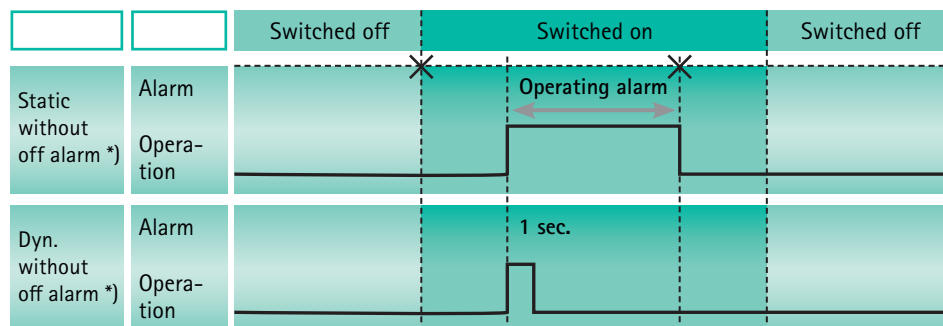
Connect device to the staff call system

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.

18.3 Short infusion stand (8713135)

Use the short infusion stand to attach an infusion container to the pump.

- Caution: Note that the pump connected to the short infusion stand can only be used on a flat surface and must not be carried by the handle.
- Only use infusion containers with max. 1000 ml with the short infusion stand.

Ordering data & ordering codes

19 Ordering data & ordering codes

Art. no.	Name
8717050	Infusomat® compact ^{plus}

19.1 Accessories

Recommended accessories for the Infusomat® compact^{plus}

19.1.1 Original Infusomat® compact^{plus} lines

Art. no.	Name	PUR (PVC-free)	Length	Fill volume
SafeSet				
8700200	Infusomat ^{plus} Line SafeSet, Standard PVC, 240 cm	PVC (DEHP-free)	240 cm / 150 cm	17.3 ml
8700210	Infusomat ^{plus} Line SafeSet, Standard PVC, 300 cm	PVC (DEHP-free)	300 cm / 200 cm	21.2 ml
8700220	Infusomat ^{plus} Line SafeSet, Standard PUR, 240 cm	PUR (PVC-free / DEHP-free)	240 cm / 150 cm	17.8 ml
8700240	Infusomat ^{plus} Line SafeSet, Standard PVC, 300 cm, needle free Y-Port	PVC (DEHP-free)	300 cm / 200 cm	22.2 ml
8700250	Infusomat ^{plus} Line SafeSet, Standard PUR, 300 cm, needle free Y-Port	PUR (PVC-free / DEHP-free)	300 cm / 200 cm	22.9 ml
Basic				
8700310	Infusomat ^{plus} Line, Standard PVC, 240 cm	PVC (DEHP-free)	240 cm / 150 cm	17.3 ml
8700320	Infusomat ^{plus} Line, Standard PUR, 240 cm	PUR (PVC-free / DEHP-free)	240 cm / 150 cm	17.8 ml
8700330	Infusomat ^{plus} Line, Standard PVC, 300 cm, needle free Y-Port	PVC (DEHP-free)	300 cm / 200 cm	22.2 ml
8700340	Infusomat ^{plus} Line, Standard PVC, 300 cm, needle based Y-Port	PVC (DEHP-free)	300 cm / 200 cm	21.7 ml

Ordering data & ordering codes

Art. no.	Name	PUR (PVC-free)	Length	Fill volume
Transfusion				
8700350	Infusomat ^{plus} Line, Transfusion, PVC, 240 cm	PVC (DEHP-free)	240 cm / 150 cm	17.3 ml
8700360	Infusomat ^{plus} Line, Transfusion, PVC, 240 cm, needle free Y-Port	PVC (DEHP-free)	300 cm / 200 cm	18.0 ml
UV-light protect				
8700260	Infusomat ^{plus} Line SafeSet, UV-protect, PUR, 240 cm	PUR (PVC-free / DEHP-free)	240 cm / 150 cm	17.8 ml
8700270	Infusomat ^{plus} Line SafeSet, UV-protect, PUR, 240 cm, Y-Port	PUR (PVC-free / DEHP-free)	300 cm / 200 cm	18.9 ml
Oncology				
8700300	Infusomat ^{plus} Line SafeSet, type Oncology, 0.2 Filter, PUR, 240 cm	PUR (PVC-free / DEHP-free)	240 cm / 150 cm	20.3 ml
Flushing Set				
8700280	Infusomat ^{plus} Line SafeSet, FlushingSet / PUR, 300 cm	PUR (PVC-free / DEHP-free)	300 cm / 200 cm	19.0 ml
Enteral (ENFit)				
8700370	Infusomat ^{plus} Line, type Enteral Nutrition, Multispike ENFit	PUR (PVC-free / DEHP-free)	330 cm / 220 cm	28.0 ml
8700400	Infusomat ^{plus} Line, type Enteral Nutrition, Cross Spike ENFit	PVC (DEHP-free)	330 cm / 220 cm	23.1 ml
8700380	Infusomat ^{plus} Line, type Enteral Nutrition, 1000ml Nutri Bag ENFit	PVC (DEHP-free)	260 cm / 150 cm	18.5 ml
Epidural (NRFit)				
8700410	Infusomat ^{plus} Line, type epidural anaesthesia NRFit	PUR (PVC-free / DEHP-free)	300 cm / 200 cm	21.8 ml

Ordering data & ordering codes

19.1.2 Interface lead

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

19.1.3 Short infusion stand

Art. no.	Name
8713135	Short infusion stand

Index

A

- Abbreviations 6
- Accessories 53, 55
- Accessories and consumables 11
- Administering bolus 28
- Alarms 34
- Alarms and staff call 11
- Alarm status 17
- Alarm times 42
- Audio Volume 22

B

- Battery operation 37

C

- Calculating the dose 31
- Change battery 38
- Changing the infusion line 33
- Cleaning 37
- Configure device options 21
- Configuring service settings 23
- Control elements 15

D

- Decommissioning 39
- Delivery rate 18, 27
- Description 13
- Device overview 13
- Display 15, 22
- Display screen 17
- Disposal 39
- Drug database 29

E

- Electrical connection 12
- Electromagnetic compatibility 46
- Ending the infusion 33
- Enteral nutrition 12

- Enter time 18
- Enter volume 18

G

- General 10

I

- Inserting the infusion line 25
- Intended use 9
- Interface lead 57
- Interface lead 12 V CP 53
- Interface lead staff call CP 53
- Interfaces 14

K

- Keys 15

L

- Language 20
- Locking/unlocking the device 24
- Luftalarm 26

M

- Main menu 18
- Maintenance 39
- Menu structure 18

N

- Night mode 22

O

- Operation 11, 25
- Ordering data 55

P

- Pole clamp 14, 21
- Pressure alarm limit 22
- Priming 26

R

Rate, volume & time 18

Repair 39

S

Safe handling 10

Safety check 39

Safety instructions 10

Safety standards 12

Service settings 20

Setting the infusion values 27

Set-up 21

Set-up and start-up 10

Short infusion stand 57

Software 10

Stacking 10

Standby 28

Starting and stopping the infusion 27

Start-up 21

Start-up and trumpet curves 40

Switching off 33

Symbols 5, 7

Symbols on the device's display 8

Symbols on the product and packaging 7

T

Tags 5

Technical data 43

Transfusion 12

Transport and storage 10

W

Wall rail 21

Warnings 6

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

Sales:
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

38932201 • Drawing no. I0002700000
2018-03-23 • Information as of: March 2018

Printed on 100% chlorine-free bleached cellulose