B|BRAUN
SHARING EXPERTISE

# Infusomat® compact$^{plus}$ P

Instructions for use

EN – Version 1.0

Valid for software 003A


CE 0123

# 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 |
|---|---|
| • | 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.<br>Non-compliance will lead to death or serious injuries. |
|  WARNING | Danger for people.<br>Non-compliance could lead to death or serious injuries. |
|  CAUTION | Danger for people.<br>Non-compliance could lead to minor injuries. |
| CAUTION | Risk of damage or incorrect operation.<br>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 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 |
| REF | Catalog number |
| LOT | Batch number |

| Symbol | Meaning |
|---|---|
| SN | Serial number |
|  | Date of manufacture (year-month-day) |
|  | Manufacturer |
|  | Humidity limitation |
|  | Temperature limit |
|  | Atmospheric pressure limitation |
|  | Not MRI safe |
| MD | Medical Device |

# Symbols

## 2.2 Symbols on the device's display

| Symbol | Meaning |
|---|---|
|  | Delivery in progress |
|  | Delivery stopped |
|  | Mains connection/battery status |
|   | Pressure symbol ("manometer"):<br>Indication of P1 to P9<br>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 |
|  | Active communication via Infrared |
|  | New Software or Drug Library update available |

## 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 neonates for the intermittent or continuous administration of parenteral and enteral solutions.

The intended medical therapies include predefined or calculated infusion profiles. These are used for the delivery of medications and fluids indicated for infusion via intravenous, intra-arterial, irrigation, subcutaneous, epidural, enteral route of administration considered suitable by qualified healthcare professionals with respect to the technical data of the pump and the prescribing information of the applied medicinal product.

Contraindications are determined by the administered medicinal products' contraindications. There is no implied contraindication for the use of Infusomat® compact$^{plus}$.

The Infusomat® compact$^{plus}$ P infusion pump system is intended for use by qualified healthcare professionals in rooms used for medical purposes, in outpatients and in emergency and transport situations. The user must have received training on the device.

The use of the Infusomat® compact$^{plus}$ P 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.
- Any serious incident that has occurred in relation to this product should be reported to B. Braun and the competent authority of the country in which the product is operated.
- 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.
- The risk of transport damage cannot be completely eliminated despite careful packaging. Please check on delivery that all items are present. Do not use a damaged device. Contact the Service department. Check that the device is working correctly before its first use. This is even a legal requirement in several countries. A corresponding form is available from B. Braun.

### 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 and/or unintentional bolus administration.
- Changing the height during a running infusion may lead to flow rate variations.
- 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.

⚠ **WARNING! The use of this device adjacent to or stacked with other equipment has to be avoided. Nevertheless, if adjacent or stacked use is necessary, the Infusomat compact$^{plus}$ P and the other devices have to be observed to verify normal operation in the configuration in which it will be used.**

Note: A list of equipment with which the Infusomat compact$^{plus}$ P has been tested in a stacked or adjacent configuration and with which stacked or adjacent use is permitted can be found in section 20.1.

### 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.

### 4.1.8 Accessories and consumables

- It is recommended that disposable items are changed after 24 hours (see hygiene rules).
- Only use pressure-tested disposable items (min. 2 bar/1500 mmHg).
- Only use the device with accessories and articles that have been approved for use with the device.

⚠ **WARNING! The use of accessories, transducers, power cords and cables other than those specified, with the exception of those sold by B. Braun Melsungen AG as replacement parts for internal components, may result in increased emissions or decreased immunity of the Infusomat compact$^{plus}$ P.**

Recommended equipment, accessories, transducers and cables for which B. Braun Melsungen AG claims compliance with the requirements of the standards in section 4.3:

- Perfusor® compact$^{plus}$ (8717030)
- Infusomat compact $^{plus}$ (8717050)
- Station compact$^{plus}$ (8717141)
- Cover compact$^{plus}$ (8717145)
- Data module compact$^{plus}$ (8717160)
- Staff call cable compact$^{plus}$ (8718030)
- Connection lead 12 V (8718020)
- Short infusion stand (8713135)
- Accessories according to section 20.1

Note: Special informations with regard to EMC are included in the separate instruction manuals for use for each relevant accessory. Ensure adequate protection against free-flow before changing disposable items.

- Hydrophobic filters can further reduce the infusion of microbubbles.
- 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.
- Where several infusion lines are connected on one single vascular access, the possibility of the lines exerting a mutual influence over each other cannot be excluded.

Note: The use of untested or incompatible disposable items can affect the technical data. PUR lines can't be used with the device.

### 4.1.9 Enteral nutrition

The Infusomat compact$^{plus}$ P 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.

## 4.2 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.

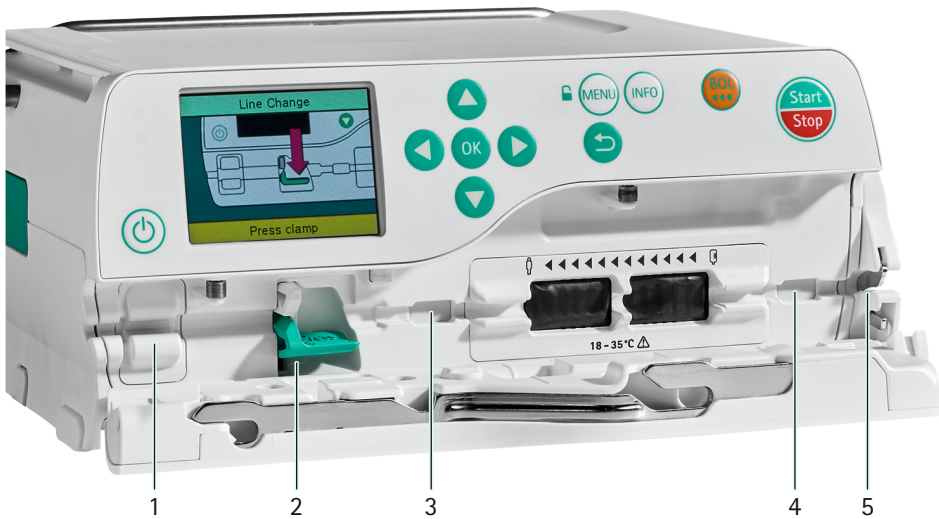
## 4.3 Safety standards

- The Infusomat compact$^{plus}$ P complies with all safety standards for medical electrical devices in accordance with
  - IEC 60601-1:2005
  - IEC 60601-1:2005/AMD1:2012
  - IEC 60601-1-6:2010
  - IEC 60601-1-6:2010/AMD1:2013
  - IEC 60601-1-8:2006
  - IEC 60601-1-8:2006/AMD1:2012
  - IEC 60601-1-12:2014
  - IEC 60601-2-24:2012
- The EMC limits (electromagnetic compatibility) according to
  - IEC 60601-1-2:2007
  - IEC 60601-2-24:2012

  are complied with.

# 5 Description of the device

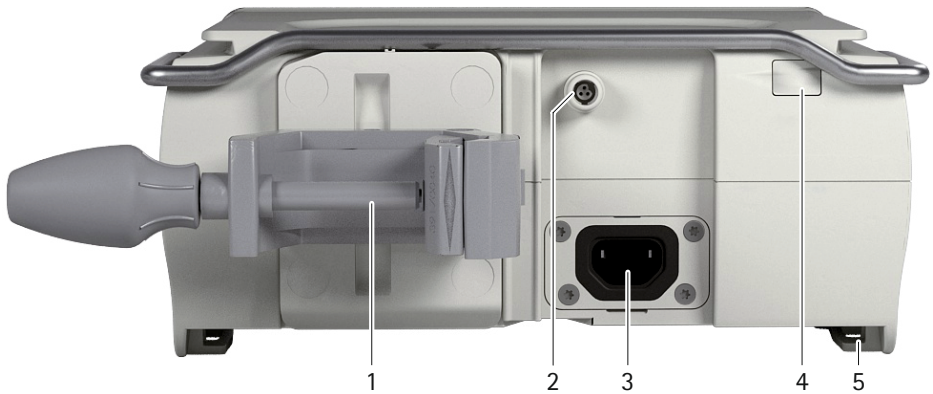
## 5.1 Device overview




| No. | Name |
|---|---|
| 1 | Air sensor |
| 2 | Active safety clamp |
| 3 | Pressure sensor |
| 4 | Upstream sensor |
| 5 | Passive safety clamp |

# Description of the device

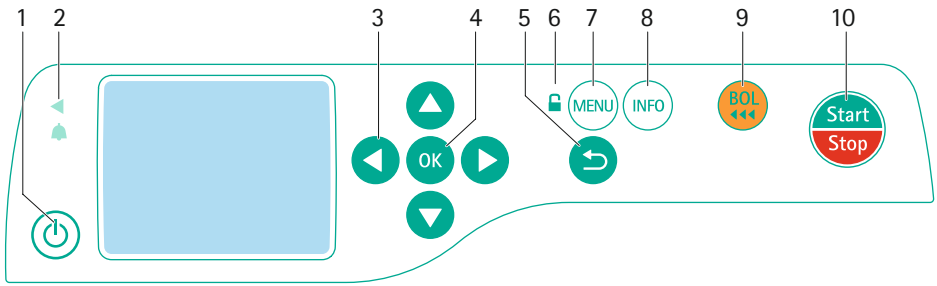
## 5.2 Interfaces




| 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



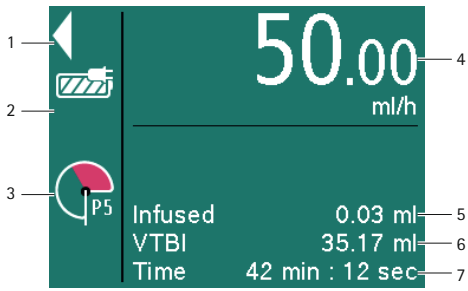

| No. | Element | Meaning |
|---|---|---|
| 1 | | On/Off key:<br>Switches the device on and off |
| 2 | | Status display<br>Green LED: Delivery<br>Two-coloured LED (alarm indicator):<br>- Yellow LED: Pre-alarm (only if enabled in Service Tool)<br>- Red LED: Technical alarm, operating alarm |
| 3 | OK | Arrow keys:<br>• Scroll through menus<br>• Change settings<br>• Answer yes/no questions<br>• Select scale values and change between digits when inputting values<br>• Open a function while the infusion is ongoing or suspended |
| 4 | OK | OK key:<br>• Select/confirm function<br>• Confirm value/settings/input/alarms |

# Description of the device

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

# Description of the device

## 5.4 Display overview



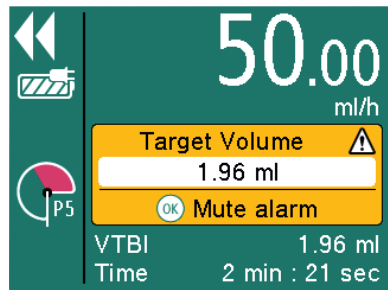

| No. | Display / Function |
|---|---|
| 1 | Moving arrows: Delivery in progress (stopped delivery is shown by two bars) |
| 2 | Mains connection/battery status |
| 3 | Pressure symbol ("manometer"): Indication of P1 to P9 pressure level set with current system pressure (pointer)<br>Note: Pressure detector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

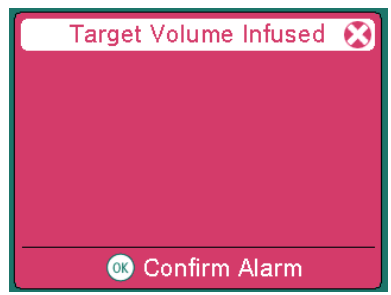
Alarms are displayed via a notification on the display, a signal tone and a LED:

**Yellow: Pre-alarm.**
The alarm indicator LED lights up permanently in yellow.

Note: Yellow LED lights up only if enabled in Service Tool



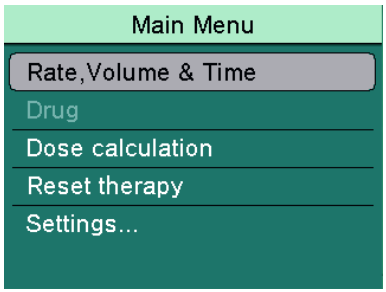

**Red: Operating alarm.**
The alarm indicator LED flashes in red.




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

# 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<br>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 |
| **Concentra-tions** | **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:<br>• mg<br>• µg<br>• ng<br>• IU<br>• mEq<br>• mmol |
| **Active substance quantity** | Set the concentration by entering the quantity of active substance and volume |
| **Volume** | |
| **Calculate using:** | Weight:<br>• Enter the patient's weight<br>Body surface area:<br>• Enter the patient's weight and height<br>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:<br>• Level 1 (=lowest level)<br>- to -<br>• Level 9 (=highest level) |
| **Audio Volume** | Select the volume:<br>• Level 1 (=lowest level)<br>- to -<br>• Level 9 (=highest level) |
| **Pressure alarm** | Select pressure level:<br>• Level 1 (=lowest level)<br>- to -<br>• Level 9 (=highest level) |
| **Service ...** | Configure additional settings e.g.:<br>• Language<br>• Date<br>• Time<br>• Bolus rate<br>• KVO<br>• Night schedule<br>• System info<br>• History |

### 6.1.5 Settings > Service

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

| Menu | Meaning |
|---|---|
| **Language** | • 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:<br>• On/off<br>• Activate at...<br>• Deactivate at... |
| **System info** | Display system information<br>• Hardware version<br>• Software version<br>• Name of the drug file<br>• Time of next safety check<br>• Station name |
| **History** | Displays a list of changes to the infusion settings |

# 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

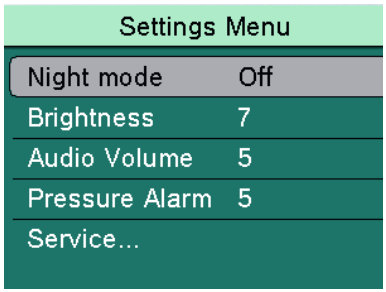
- Device switched on

- **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.




### 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.

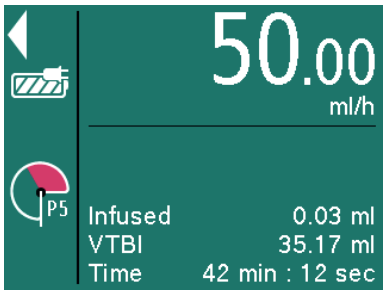
Note: In the event of a pressure alarm, the post occlusion bolus will be automatically reduced.

- 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) |

| 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) |

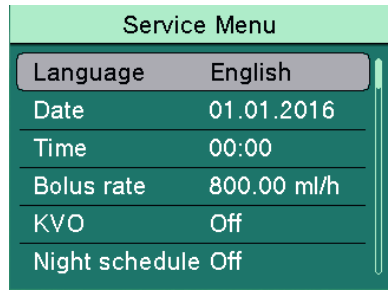
Note: Occlusion must be resolved before the infusion is re-started. Otherwise it will affect the measurement accuracy.




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.




#### 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 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.

# 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. First the green and the yellow LEDs light up, and then the yellow LED changes colour to red.

Note: The yellow LED only lights up if the function has been enabled in the Service Tool.

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

## 8.2 Inserting the infusion line

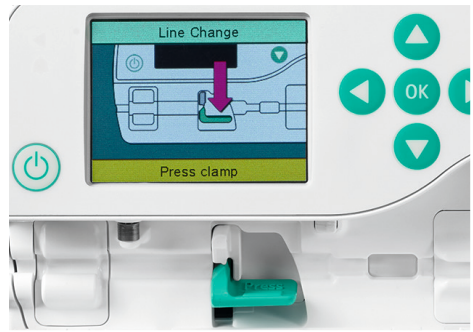
- Device switched on.
- Infusion line primed

- Open the pump door by pulling on the 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.

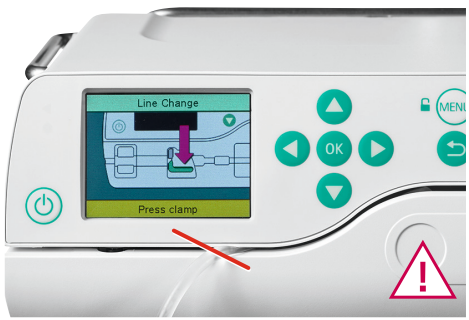
- Inserting the infusion line:
  - Push the active safety clamp down.




  - When inserting the infusion line, pay attention to orientation with regard to the direction of flow (see diagram), as otherwise there is a risk of backflow.
  - Insert the line fully into the guide and press it in.
  - Insert the infusion line into the air sensor on the left and make sure that the line fits tightly.
  - Push the infusion line on the right into the passive safety clamp.


⚠ **CAUTION! Ensure that the line guide is straight and avoid sagging/bending, otherwise the line may be damaged and could cause incorrect dosing.**

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




Do not damage the infusion line.

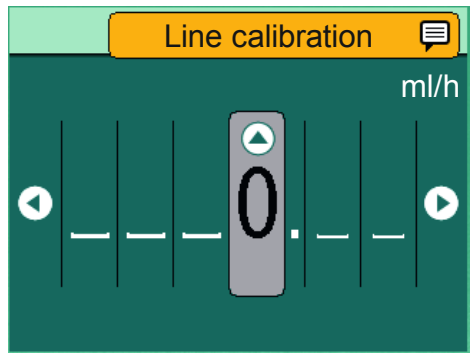
- Follow the instructions on the screen and open the roller clamp.

  The "Select infusion line" message will be displayed.

- Select "Line type" and press OK to confirm. Make sure that the line type displayed is the same as the inserted line.

- The pump will calibrate the infusion line.

  Entries can be made during the calibration. However, the infusion can only be started after the infusion line has been successful calibrated.




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.

Note: Do not stretch or twist the infusion line during insertion.

Note: Use of a clamp above the drip chamber is dependent on the application (e.g. CytoSet) and is the responsibility of the user.
The status of the clamp (open/closed) is not monitored by the pump.

## 8.3 Priming the infusion line

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 the line. The line must be disconnected from the patient for this purpose.

## 8.4 Use with Intrafix® SafeSet

Note: If Intrafix® SafeSet is used, a VTBI is not required.

A special airtight filter membrane acts as a barrier and helps prevent air entering the line. If the fluid level reaches the membrane, the upstream alarm is triggered and the pump stops so that no air passes through the AirStop filter. For this reason, no additional priming is required when quickly changing to the next container.

In the case of an upstream alarm, the upstream sensor detects a low pressure in the infusion line between the pump and the drip chamber. Therefore, always check whether the roller clamp is open, the line is bent or the bag and/or drip chamber is empty.

The pump should not be restarted until the upstream alarm has been resolved.

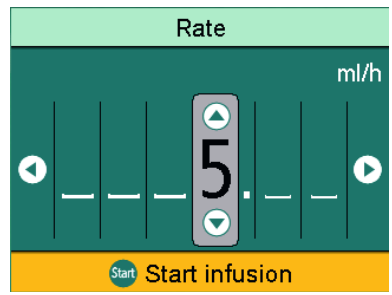
If the pump is started too many times without the problem having been rectified, the upstream sensor calibrates to the low pressure in the line at the time and air can pass through the air stop membrane. In this case, ensure that the drip chamber is refilled, then open the flap to recalibrate the upstream sensor.

## 8.5 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.

### 8.5.1 Entering the delivery rate



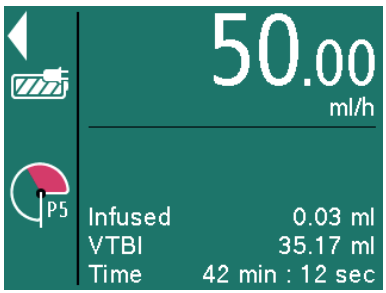

- Enter the **delivery rate** using the arrow keys.
- Start the infusion with **the Start/Stop key**.
  - or -
- Press **OK** to confirm the rate.
  The **Overview** screen is displayed.
- **Select Vol./Time** and press **OK** to confirm.
- **Enter the volume** or **time limit** and press **OK** to confirm.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

## 8.6 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**.

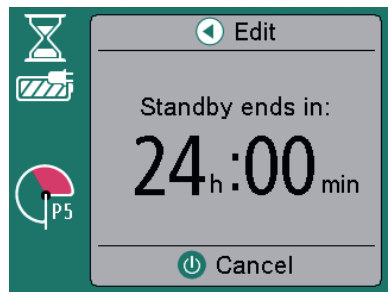
Note: After stopping the therapy, "Reset therapy" must be selected in the menu before a new therapy can be started.

## 8.7 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.

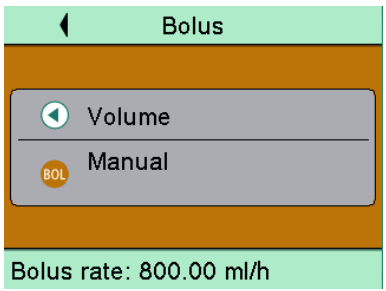
**Ending standby mode**

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

## 8.8 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.

### 8.8.1 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.

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

### 8.8.2 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.

## 8.9 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.

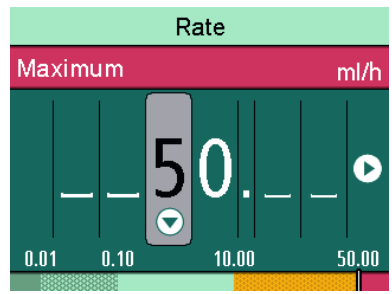
Note: In addition to the volume and time limit, the infusion rate can also be adjusted in the **Overview** screen.

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

### 8.9.1 Hard and soft limits

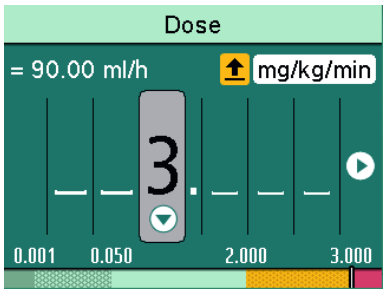
**Hard limits**

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 |

## 8.10 Calculating the dose

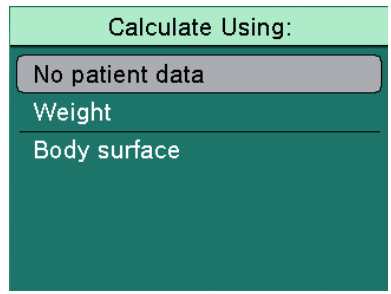
The **Dose calculation** function is used to calculate the delivery rate in ml/h based on the dose parameters entered.

- 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.




### 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.**

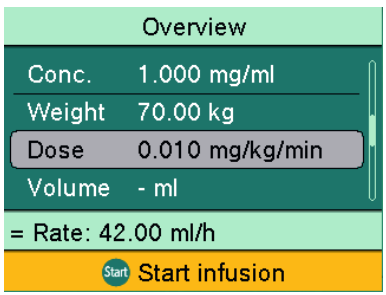
Note: Pressing the OK key brings up the Overview screen.

- 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.




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

**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**.

## 8.11 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
  - 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.

## 8.12 Resetting the therapy

The "Reset therapy" function is used to delete all currently set therapy data. A new therapy can be started.
Additionally, the volume already infused can be reset.

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

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

## 8.13 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.

## 8.14 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.

## 8.15 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.

# 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"** | • Preselected volume has almost been infused<br>• 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: 

Note: In the Service Tool, there is also the option to display an additional prompt, which enables a permanent mute until the end of treatment alarm. 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<br>• Continue with delivery or start new therapy |
| **"Time reached"** | Preselected time has elapsed<br>• Continue with therapy or select new therapy |
| **"Battery empty"** | The battery is discharged<br>• Connect device to mains and/or have battery replaced by a service technician<br>The battery alarm will sound for 3 min. Then the pump will automatically turn off.<br>Note: If the battery has deep discharged, the notification may also say "Battery warning". |
| **"Pressure too high"** | There is an occlusion in the system. The set level was exceeded<br>• The pump automatically implements a bolus reduction<br>• 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<br>• Continue with therapy or select new therapy |
| **"No battery in the device"** | It is not possible to use the pump without a battery<br>• Ask a service technician to insert a battery |
| **"Air bubble/ accumulated air"** | Air in the system.<br>• Check the line for small air bubbles and, if necessary, disconnect the patient and prime again. |
| **"Line Calibration Error"** | The pump and infusion line are not occluded.<br>• 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. |

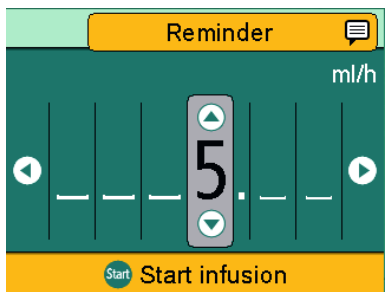
| Display notification | Meaning |
|---|---|
| "Pump door open" | Pump door was opened during delivery. |

## 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 Display Notifications

| Display notification | Meaning |
|---|---|
| "No battery in the device" | It is not possible to use the pump without a battery<br>• Ask a service technician to insert a battery |
| "Temperature too high/low" | Temperature is outside the specified operating temperature. |

# 10 Cleaning and care

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

## 10.1 Cleaning & Disinfection

Cleaning and disinfection can be carried out by qualified medical professionals or by qualified and trained cleaning personnel.

**CAUTION! Before disinfecting the pump, always disconnect the pump from the patient, switch off the device and disconnect from power and other devices (e.g. staff call).**

⚠ **WARNING! Do not allow liquids or detergents to come into contact with accessory ports, electrical connections of the device or any device openings. Fluid exposure in these areas may result in the risk of short circuit, corrosion or breakdown of sensitive electrical components, and/or electrical shock.**

Before use, the device must be completely dry.

**Handling**

1. Make sure to remove any visible residue from all surfaces prior to disinfecting. Clean all exposed surfaces using a clean, soft, lint-free cloth dampened with a mild cleaning solution of warm, soapy water.
2. Do not spray disinfectants directly on the pump, use a soft, wet and lint-free cloth. Always use a new cloth to avoid cross contamination. Wet all surfaces sufficiently and observe the required exposure times according to the manufacturer's instructions.
3. Inspect all connectors for residual moisture and evidence of damage. In case of damage the device should remain unplugged until it can be inspected by a trained technician.

**Recommendation:**
Use disinfectants manufactured by B. Braun: Meliseptol® Foam pure, Meliseptol® Wipes sensitive, Melsitt®, Melsept®, Hexaquart® or Hexaquart® forte.

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

| Group | Active Substance |
|---|---|
| **Alcohols** | 1-Propanol, 2-Propanol (Isopropanol), Ethanol |
| **QAC (Quaternary ammonium compounds)** | DDAC (Didecyldimethyl-ammoniumchloride), BAC (Benzalkonium-chloride) |
| **Acids** | Citric Acid, Milchsäure, Essigsäure |
| **Phenols** | o-phenylphenol, p-Chlor-m-cresol |

| Group | Active Substance |
|---|---|
| **Peroxide** | Hydrogen Peroxide, Peracetic Acid, Monoperoxyphthalat-hexahydrat |
| **Aldehydes** | Glutaral, Glyoxal, Formaldehyde |
| **Alkylamines** | N-(3-aminopropyl)-N-Dodecylpropan-1,3-Diamin, Cocospropylendiamin |

If you have any questions about the use of a particular disinfectant, please contact the manufacturer of the respective disinfectant.

Note: The use of unapproved cleaners and failure to follow the disinfection procedures and the manufacturer's recommended dilutions can result in an instrument malfunction or product damage and could void the warranty.

- No pointed objects should be used for cleaning.

## 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 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 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 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 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 (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.

## 15 Warranty

B. Braun provides 24 months warranty, as from the date of delivery, for every Infusomat® compact$^{plus}$ P. This covers repair or replacement of parts damaged as a result of design/manufacturing errors or material defects.
Modifications or repairs to the unit undertaken by the user/operator or by third parties invalidate the warranty.

The warranty does not cover the following: Elimination of faults attributable to incorrect/unauthorized handling, or to normal wear and tear.

Defective rechargeable battery packs can be returned to B. Braun for further disposal.

⚠ **WARNING! Do not modify this equipment without authorization of the manufacturer.**

## 16 Start-up and trumpet curves

### 16.1 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.

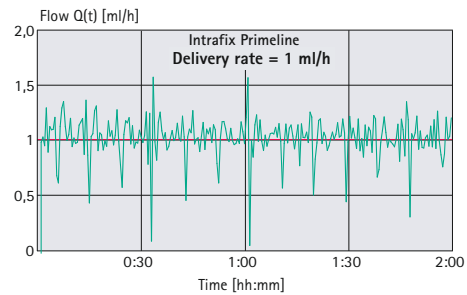
The physiological effect of the drug can be affected by the flow and the disposable article.

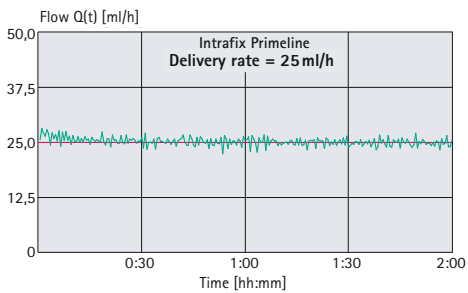
- Ensure that the prescription is in line with the start-up/trumpet curve and the set flow rate.

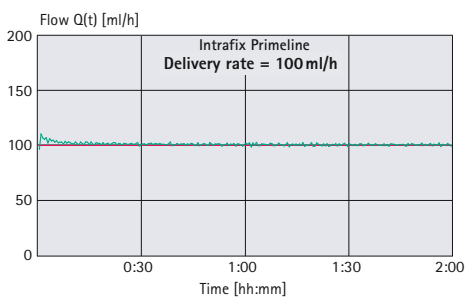
# Start-up and trumpet curves

## 16.2 Typical start-up and trumpet curves

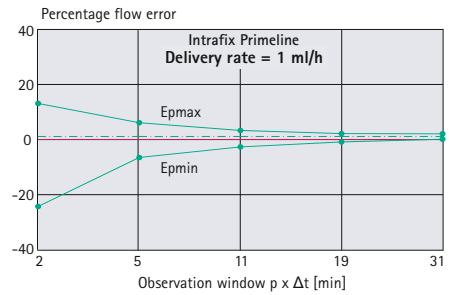
### Start-up curves

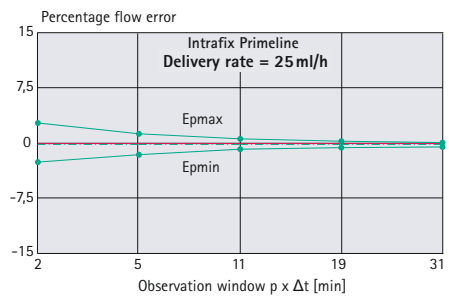


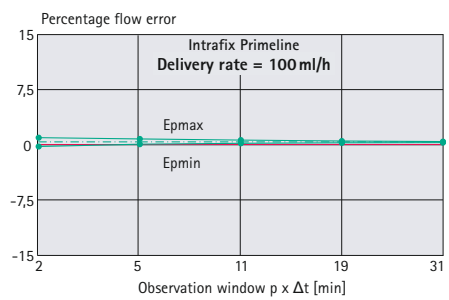




### Trumpet curves



# 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.
- Variations in consumable and consumable handling (e.g. stretching) may affect accuracy.
- A container placed below the pump may result in delivery deviations.

Note: The system accuracy is normally ±5% of the volume, measured using the trumpet curve test method according to IEC 60601-2-24 at a rate of 25 ml/h (at 20 °C ±2 °C) and using the recommended disposable item.

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

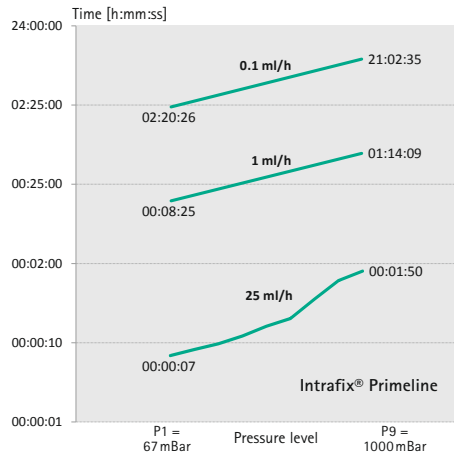
| **Start-up curves** | |
|---|---|
| Measurement interval | Δt = 0.5 min |
| Measurement duration | T = 120 min |
| Flow $Q_i$ | (ml/h) |

## 16.3 Alarm times

The following graphics show alarm times depending on pressure level.

Note: length of disposable and temperature might affect the time to alarm.

### 16.3.1 Intrafix® Primeline



## 17 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:<br>• IIb<br>According to EN 60601-1:<br>• Protection class II<br>• For defibrillation-proof type CF applied part |
| Moisture protection | IP34<br>• Protection against penetration by solid foreign bodies with a diameter of more than 2.5 mm<br>• Protection against splashes from all directions |
| Power supply | • 100-240 V AC, 50-60 Hz, connection via power cable or compact$^{plus}$ station<br>• 12 V DC 12 V CP interface cable |
| Internal battery<br>• Battery life<br><br>• Recharging time | Lithium-ion battery<br>• Approx. 8 h at 25 ml/h<br>2.5 h at 1000 ml/h<br>• Approx. 3 h |
| Power consumption | 10 VA typ. / 40 VA max.<br>Under normal conditions (charged battery, room temperature, 25 ml/h): <3.5 W |
| Current consumption/ charging current | • Max. 0.4 $A_{eff}$ (typ. <0.1 $A_{eff}$) at 100-240 V AC, 50-60 Hz<br>• 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 | DIN EN 60601-1:2006 (IEC 60601-1:2005)<br>DIN EN 60601-1-2:2007 (IEC 60601-1-2:2007)<br>DIN EN 60601-2-24:2015 (IEC 60601-2-24:2012) |
| Time of operation | 100% (continuous operation) |

# Technical data

| Parameter | Value |
|---|---|
| Acoustic alarm signal sound pressure range | Nine available levels:<br>45 dB(A) to 75 dB(A) |
| Interfaces | • Cold connector for mains voltage<br>• Accessory port for interface cable 12 V CP and staff call<br>• IrDA infrared for communication in the station and for service |
| Operating conditions<br>• Temperature<br>• Relative air humidity<br>• Atm. pressure | <br>• +18 °C ... +35 °C / +64 °F ... +95 °F<br>• 30% ... 90% (without condensation)<br>0.54 ... 1.06 bar |
| Storage conditions<br>• Temperature<br>• Relative air humidity<br>• Atmospheric pressure | <br>• –20 °C ... +55 °C / -4 °F ... +131 °F<br>• 20% ... 90% (without condensation)<br>• 0.5 ... 1.06 bar |
| Weight | Approx. 2.0 kg |
| Dimensions in mm (W x H x D) | Approx. 229 mm x 98 mm x 225 mm<br>(including pole clamp 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 | typ. ± 5% according to IEC 60601-2-24<br>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 ... 1000 ml/h in increments of 0.01 ml/h |
| Delivery accuracy for bolus administration | typ. ±5% for bolus volumes > 5 ml |
| Max. bolus volume after bolus reduction | ≤ 0.2 ml at rates ≥ 1ml/h |

# Technical data

| Parameter | Value |
|---|---|
| KVO rate | • Rate: ≥ 10 ml/h: KVO rate 3 ml/h<br>• Rate: < 10 ml/h: KVO rate 1 ml/h<br>• 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 | Technical sensitivity:<br>Detection of air bubbles ≥ 0.01 ml.<br><br>Alarm trigger:<br>Individual air bubble alarm: 0.02 – 0.3 ml<br>(standard 0.3 ml)<br>Cumulative air alarm: 0.5 – 3.8 ml/h<br>(standard 1.5 ml/h)<br>Trigger: 0.01 ml |
| History protocol | • 1,000 history entries<br>The oldest entries are overwritten if necessary.<br>• 100 events for system diagnosis<br>The history is retained when the device is switched off or the battery removed. |

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 ±5%. The accuracy can deviate when administering small bolus volumes.

**Essential performance characteristics 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)

## 18 Electromagnetic compatibility

⚠ WARNING! The Infusomat compact$^{plus}$ P needs special precautions regarding EMC. The device must be set up, powered on and services in accordance with the EMC information in this section. The safe distances and ambient/operation conditions specified must be ensured and complied with.

Portable and mobile RF communications equipment can affect medical electrical equipment. Portable RF communications equipment (radio communications equipment) (including its accessories, e.g. antenna cables) should not be used closer to the Infusomat compact$^{plus}$ P than the safe distance specified in this section.

Non-compliance could lead to a decrease in the device's performance.

Portable and mobile RF comunications equipment can affect medical electrical equipment.

⚠ WARNING! The use of accessories, transducers, power cords and cables other than those specified, with the exception of transducers and cables sold by B. Braun Melsungen AG as replacement parts for internal components, may result in increased emissions or decreased immunity of the compact$^{plus}$ System.

⚠ WARNING! Functional reliability is only guaranteed if accessories that have been approved, and therefore recommended by B. Braun Melsungen AG, are used. Accessories are listed in section 20.1.

⚠ WARNING! If the equipment is operated in the vicinity of other equipment which may cause high levels of interference (e.g. HF surgical equipment, nuclear spin tomography units, mobile telephones etc.), this equipment may be disturbed. Maintain the protective distances recommended by the manufacturers of these devices.

⚠ WARNING! In Order to meet with the following compliance levels, only original accessories and replacement parts may be used. Otherwise, there may be increased emissions or reduced device immunity.

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

CAUTION!: The device is unsafe to use in proximity to Magnetic Resonance Imaging (MRI) equipment. The device must not be used near a Magnetic Resonance Imaging unit without protection.

Note: The following guidelines may not be applicable in all situations. Electro magnetic wave propagation is affected by the absorptive and reflective qualities of the surrounding structures, objects and people.

# Electromagnetic compatibility

## 18.1 Electromagnetic interference emissions

The device is designed to be used in the electromagnetic environmental conditions described below. Customers or users of the compact$^{plus}$ system or its components should ensure that the system is being operated in such an environment.

| Interference emission measurements | Compliance | Electromagnetic environment guidelines |
|---|---|---|
| RF emission as per CISPR 11 | Group 1 / Class B (see Note 1/ Note 2 below) | The Infusomat compact$^{plus}$ P uses RF energy for its internal functions only. As such, its RF emissions rate is very low and it is unlikely to interfere with nearby electronic equipment. |
| Voltage fluctuation/flicker emissions according to IEC 61000-3-3 | Conforms | 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 | |

Note 1: The limits for interference emissions are measured with individual components as well as with the maximum set-up (fully equipped compact$^{plus}$ system).

Note 2: If Class A equipment is attached to the compact$^{plus}$ system, the compact$^{plus}$ system will become Class A too. This equipment/system may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as re-orienting or relocating the compact$^{plus}$ system or shielding the location.

# Electromagnetic compatibility

## 18.2 Electromagnetic immunity

The device is designed to be used in the electromagnetic environmental conditions described below. Customers or users of the compact$^{plus}$ system or its components should ensure that the system 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 61000-4-2 | **Contact discharge** IEC 60601-1-2: ±6 kV<br>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 floors are covered with synthetic material, the relative humidity should be at least 30 %. |
| | **Air discharge** IEC 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 61000-4-4 | for power supply lines ±2 kV | ±2 kV | Mains power quality should be that of a typical commercial or hospital environment. |
| | For input and output lines ±1 kV | ±1 kV | |
| Surges according to IEC 61000-4-5 | Differential mode voltage ±1 kV | ±1 kV | Mains power quality should be that of a typical commercial or hospital environment. |
| | Common mode voltage ±2 kV | ±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 RF interference according to IEC 61000-4-6 | IEC 60601-1-2: 150 kHz to 80 MHz 3 $V_{RMS}$ outside and 10 $V_{RMS}$ in ISM frequency bands<br><br>IEC 60601-2-24: 150 kHz to 80 MHz 10 $V_{RMS}$ | 10 $V_{RMS}$ 150 kHz to 80 Mhz in all frequency bands | Do not use portable radio communications equipment closer to the Infusomat compact$^{plus}$ P (including connection cables) than the recommended safe distance calculated using the appropriate equation for that frequency. **Recommended safe distance:** $d = 1.2 \sqrt{P}$ [1)] |

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

# Electromagnetic compatibility

| Immunity tests | Test level<br>EN 60601-1-2<br>EN 60601-2-24 | Compliance level | Electromagnetic environment guidelines |
|---|---|---|---|
| Radiated RF interference according to IEC 61000-4-3 | 10 V/m<br>80 MHz to 2.5 GHz | 10 V/m<br>80 MHz to 6 GHz | The field strength should be lower than 10 V/m<br>$d = 1.2 \times \sqrt{P}$ [2)]<br>80 MHz to 800 MHz<br>$d = 2.3 \times \sqrt{P}$ [2)]<br>800 MHz to 6 GHz<br>Field strengths from stationary RF transmitters should be below the compliance level for all frequencies, based on an on-site test.<br>Interference is possible in the vicinity of equipment that has the following symbol.<br>  |

[2)] With P as the maximum rated power of the transmitter in watts (W) according to the transmitter manufacturer specifications and d 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 2.5 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$^{plus}$ P is being used in exceeds compliance levels, monitor the Infusomat® compact$^{plus}$ P 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.

# Electromagnetic compatibility

## 18.3 Recommended safe distances between portable and mobile RF telecommunications equipment and the Infusomat compact$^{plus}$

The Infusomat compact$^{plus}$ is designed for use in an electromagnetic environment in which emitted RF disturbances are controlled. Customers or users of the Infusomat compact$^{plus}$ or its components can help prevent electromagnetic interference by complying with the minimum distances between portable and mobile RF telecommunications devices (transmitters) and the Infusomat compact$^{plus}$ and its components, as recommended below in accordance with the maximum output power of the communication device.

Note: The higher value applies at 80 MHz and 800 MHz.

Note: For transmitters whose rated power is not specified in the table above, the distance can be determined using the equation for the relevant column. P is the transmitter's rated power in W according the manufacturer's specifications.

Note: A factor of 10/3 is used to calculate the recommended safe distance of transmitters in the frequency range between 80 MHz and 2.5 GHz, in order to reduce the probability of a mobile communication device used unintentionally in the patient area causing a fault.

| Transmitter rated power in W | Safe distance according to transmitter frequency m | | |
|---|---|---|---|
| | 150 kHz to 80 MHz 1.2√P | 80 MHz to 800 MHz 1.2√P | 800 MHz to 6 GHz 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 |

# 19 Instructions for use for accessories

## 19.1 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.

## 19.2 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 Station compact$^{plus}$.
- 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.

## 19.3 Station compact$^{plus}$ (8717141)

Station for up to three pumps. For further information see "Instructions for Use" of Station compact$^{plus}$.

## 19.4 Data module compact$^{plus}$ (8717160)

Central interface for a connection to an external IT system. For further information see "Instructions for Use" of Data module compact$^{plus}$.

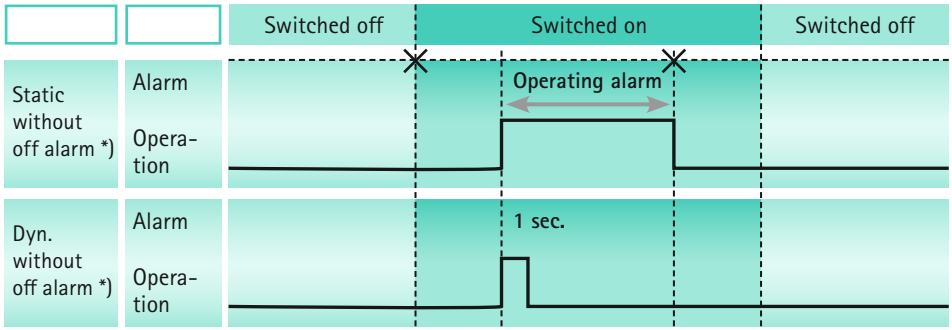
## 19.5 Short stand SP (8713135)

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.

# 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.

**Technical data**

| Mode: | Status red LED | Status Changeover Contact (wire color white - green) | Status Changeover Contact (wire color white - brown] |
|---|---|---|---|
| **Operating:** | off | closed | opened |
| **Alarm:** | on | opened | closed |

| Accessory | Parameter | Value |
|---|---|---|
| Interface lead 12 V CP (8718020) | Dimensions in mm (W x H x D) | Approx. 75 mm x 43 mm x 15 mm |
| | Cable length in mm | Approx. 2568 mm |
| Interface lead staff call CP (8718030) | Dimensions in mm (W x H x D) | Approx. 75 mm x 43 mm x 15 mm |
| | Cable length in mm | Approx. 2553 mm |

## 20 Ordering data

| Art. no. | Name |
|---|---|
| 8717070 | Infusomat® compact$^{plus}$ P |

## 20.1 Recommended accessories for Infusomat® compact$^{plus}$ P

| Art. no. | Name |
|---|---|
| 8717141 | Station compact$^{plus}$ |
| 8718020 | Connection lead 12 V compact$^{plus}$ |
| 8718030 | STAFF CALL connection lead compact$^{plus}$ |
| 8713135 | Short stand SP |

## 20.2 Power cords

| Art. no. | Name | Description |
|---|---|---|
| 8717110 | Power cord EU | Power cord Typ E+F |
| 8717111 | Power cord GB | Power cord Typ G |
| 8717112 | Power cord US | Power cord NEMA 5-15p (hospital grade) |
| 8717113 | Power cord AU | Power cord Typ I |
| 8717114 | Power cord CH | Power cord Typ J |
| 8717115 | Power cord ZA, IN | Power cord Typ M |
| 8717117 | Power cord CN | Power cord Typ I, Var.3 |
| 8717118 | Power cord DK | Power cord Typ K |
| 8717121 | Power cord AR | Power cord Typ I, Var.2 |
| 8717119 | Power cord BR | Power cord Typ N |

# Ordering data

## 20.3 Infusomat® compact$^{plus}$ P lines

| Art. no. | Name | Length |
|---|---|---|
| SafeSet | | |
| 4063000 | Intrafix SafeSet | 180 cm |
| 4063001 | Intrafix SafeSet with back check valve | 180 cm |
| 4063005 | Intrafix SafeSet with injection port | 180 cm |
| Primeline | | |
| 4062182 | Intrafix Primeline with injection port | 180 cm |
| 4062957E | Intrafix Primeline | 150 cm |
| 4063287 | Intrafix Primeline with back check valve | 180 cm |
| 4062981L | Intrafix Primeline | 180 cm |

# Index

**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

**38932401 • Drawing no. I0002700004**
**2020-10-14 • Information as of: October 2020**

**Printed on 100% chlorine-free bleached cellulose**