B BRAUN
SHARING EXPERTISE

Space^{plus} Infusomat®

Instructions for use

en Version 1.0 English

Valid for software 020D

It is recommended that all pumps at your care unit are equipped with the same software version.

CE 0123

Table of contents

Table of contents

1 About these instructions for use

1.1 Purpose of these instructions for use

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 the pump!
- Keep the instructions for use near the pump!
- Please read and follow the accompanying documents!

An electronic instructions for use (eIFU) of all medical devices can be found on the manufacturer's eIFU website: www.eifu.bbraun.com.

By typing the document article number and language code into the search field, the required revision will be available. You can view, save or print the IFU. All previous versions of the IFU are available.

A printed version can be provided by the manufacturer on request free of charge within 7 days in the respective language.

About these instructions for use

1.2 Warnings

Various warnings are used in these instructions for use with the following meaning:

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.

1.3 Abbreviations

Abbreviation	Meaning
BSA	Body surface area
EMC	Electromagnetic compatibility
ESD	Electrostatic discharge
HF	High frequency
KVO	Keep vein open
LED	Light emitting diode
ME device	Medical electrical device
MRI	Magnetic Resonance Imaging
PCA	Patient controlled analgesia
TSC	Technical safety check
VTBI	Volume to be infused

2 Symbols

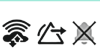
2.1 Symbols on the product and packaging

Symbol	Meaning
	Caution
	Consult instructions for use
	Mandatory action: see instruction for use
	Marking of electrical and electronic equipment in accordance with Directive 2012/19/EC (WEEE)
	CE marking
	Alternating current
	Protective insulation; class II equipment
	Defibrillation-proof type CF applied part
	Catalogue number
	Batch code
	Serial number

Symbol	Meaning
	Date of manufacture
	Manufacturer
	Moisture limit
	Temperature limit
	Atmospheric pressure limitation
	Federal Communications Commission Registration
	For a safe use of the Space^{plus} infusion pump in MRI environment follow the instructions for use "Space^{plus} MRI Station"
	Battery recycling
	Non-ionising electro-magnetic radiation
	Medical device

Symbols

2.2 Status indicators on the display and housing

Symbol	Description
	Takes you to the main menu (home menu); All central functions can be accessed here
	Switches the pump on and off, or puts it in standby
	Infusion running
	Bolus or loading dose running
	Infusion has been paused
	WiFi connected, incl. strength
	WiFi not connected or not available
	Connected to OnlineSuiteplus, incl. strength
	Software or drug library update available
	Pump is in service mode; Do not use with patients!
	Pump is in battery mode; battery level. Battery is red if 20% or less remains
	Pump is connected to mains power; Battery level
	Battery is missing or defective
	Alarm
	Alarm sound is temporarily muted
	Alarm sound is permanently muted
	Parameter is above the upper soft limit
	Parameter is below the lower soft limit
	The pump is too cold
	Connected to OnlineSuite^{plus}; Alarm is distributed to other system
	Connected to OnlineSuite^{plus}; Alarm is distributed to other system; Alarm at Space^{plus} pump / Station is silent

2.1.1

3 Intended purpose

The Space^{plus} Infusomat® is a transportable volumetric infusion pump which is used in combination with approved infusion lines and accessories.

The pump is intended for use on adults, pediatrics, and neonates for the intermittent or continuous delivery of parenteral fluids, enteral fluids, medications, blood and blood products through clinically accepted routes of administration. These routes of administration include intravenous, intra arterial, subcutaneous, epidural, and enteral.

The pump must be considered suitable for the infusion perscription and the route of administration by a qualified medical professional based on the technical data of the pump.

The Space^{plus} Infusomat® is intended to be used by trained healthcare professionals in healthcare facilities, in outpatient and home patient settings, as well as in medical ground and air transport situations (road ambulances, fixed-wing and rotary-wing air ambulances).

The user must have received training on the device.

The use of the Space^{plus} Infusomat® is dependent on the environmental conditions specified in the technical data.

The storage conditions are detailed in the technical data.

Contraindications are determined by the contraindications of the drug being administered.
There are no implied contraindications for the use of the Space^{plus} Infusomat®.

There are no product specific side effects.

Infusion therapy and the use of infusion pumps in general bare several risks: Infusion delivery error and medication error (incl. programming error, medication over- und undersupply, free flow); air infusion leading to air embolism; mechanical hazards (incl. device drop, jamming of fingers); microbial contamination of the infusion pump; electric hazard including thermal hazards; infusion of contaminants into patient; acoustic hazards (by alarms); leaking or disconnection of infusion tube (leading to blood loss, air infusion, microbiological contamination and contamination by leaking infusion solution).

4 Safety instructions

WARNING! Read all the safety instructions before using the device and observe them.

4.1 General use

The device should only be used by trained staff.

Training on the device must be given by a person authorised by B. Braun.

All serious incidents related to this product must be reported to B. Braun and the competent authority in the country where the product is being used.

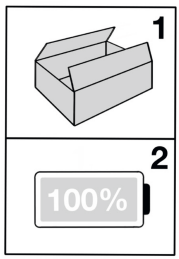
4.2 Inspection on delivery

Check the contents of the delivery for completeness and damage immediately after unpacking.

Transport damage may occur even if the device has been carefully packaged.

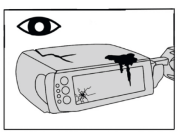
Do not use damaged devices or cables. Inform a trained technician.

4.3 Before and during use

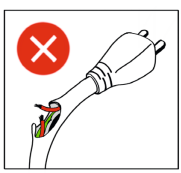


Fully charge the battery before the first use without an external power supply!

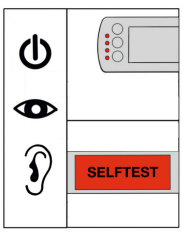
This extends lifetime of the battery and prevents damage.



Check pump and accessories for damage and heavy soiling (especially the air sensor)!



Do not use damaged cables!



When switching the pump on

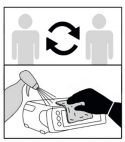
- Check that the display is working correctly (e.g. no pixel errors)
- Check that the status LEDs are working correctly
- Check the alarm signals

Observe the expiry date on the packaging for all accessories and disposables!

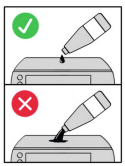
When multiple pumps/infusion lines are connected (parallel infusion), mutual interference cannot be ruled out.

If the display fails (e.g. touch screen stays dark) while an infusion is in progress (green LED illuminated), do not use the touch screen to operate the pump. Give the pump to a trained technician.

4.4 Cleaning

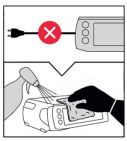


Clean and disinfect the pump before using it with a new patient!



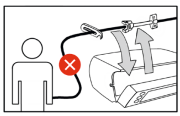
Only use small quantities of cleaning fluid!

Protect electrical plugs from excessive moisture!



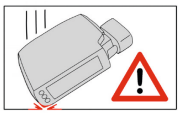
Disconnect from mains power before cleaning!

4.5 Protecting patients



Disconnect from the patient before inserting or removing infusion lines!

Risk of overdose from free flow.



If the pump has fallen/ been dropped or has been subjected to another violent impact, do not use it with patients!
Have the pump checked by trained technician.

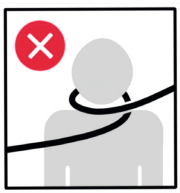
Do not move the pump during delivery!
A change in height while the infusion is in progress can affect the flow rate.

Risk of inaccurate delivery!

When administering high risk medications, have a second device ready for the drug.

The plausibility of the displayed and transferred data must always be crosschecked by the user before any further medical decisions are taken.

It has to be expected that reported data is incomplete. In case of connectivity issues, pump can always programmed at the device.



Make sure that the infusion lines and cables cannot strangle the patient.

Adequate monitoring of vital signs is required when administering high risk medications.

When multiple infusions are administered through the same infusion lines (e.g. concurrent infusions, secondary infusions), consider issues related to chemical interactions and incompatibilities of the medication which can potentially result in precipitants and other issues.

4.6 Alarm volume and patient call

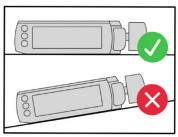
Make sure that the alarm volume is high enough!
The alarms must be adapted to the physical environment and the ambient noise level. This also applies when using a secondary alarm systems or when connected to a staff call system.

Check the staff call after connection and before the first use of the pump!

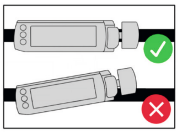
Supervise pump alarms locally at the device unless all devices at the bedside are indicating a successfull connection to a distributed alarm system.

Refer to Instruction for Use ConAct

4.7 Setting up the device

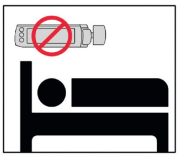


Set the pump up level!



Attach horizontally to the bracket!

Do not secure the pump clamp to the wall rail at the points where the wall rail is attached to the wall.

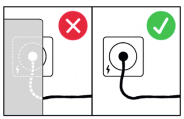


Do not position above a patient!

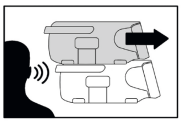
Risk of injury if the pump or its components fall.

Position all cables and infusion lines so that they do not present a trip hazard!

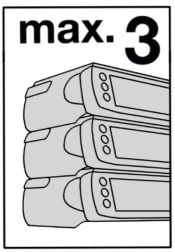
Avoid unconnected power plug sockets connected to AC voltage.



Set up the pump so that the mechanism for disconnecting the mains power is easily accessible (i.e. by unplugging the pump or the mains power plug).

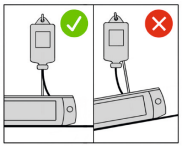


Ensure the pumps fully lock in when connecting them.
Listen for the click!



When using in an inpatient setting, secure a maximum of 3 pumps to each pump clamp.

When using in road and air ambulances only attach one pump to each pump clamp.



Ensure single pump is properly placed on a flat surface before attaching fluid bag to short stand and connecting to patient to assure pump cannot fall and harm patient.

Use only one infusion bag with max. 1000 ml on the short stand.

Do not use the short tripod in road and air ambulances.

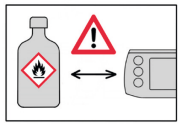
Secure all pumps and do not rely on stacking mechanism in road and air ambulances!

Observe the stability of the IV pole when loaded with devices.

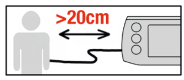
4.8 Device environment

Comply with the recommended distances (at least 30 cm) to devices with higher interference signals (see section 24).
(e.g. electrosurgical equipment, MRI units, mobile phones etc.)

Portable and mobile RF communications equipment should not be permanently used closer than 30 cm to any part of the Space^{plus} System or it's components, including cables, e.g. placing a mobile phone directly onto the pump should be avoided as it could lead to a decrease in the device's performance.



Do not use the pump near corrosive or flammable gases.



Operate the pump at least 20 cm away from the patient.

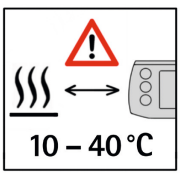
Only store and operate the pump within the specified temperature range!
(See section 23)

If the pump has been stored outside the specified operating temperature range, store the pump within the specified temperature range for at least one hour before being powered on.

The use of this pump immediately next to other devices or when stacked with other devices should be avoided as this could lead to a malfunction.

Nevertheless, if the pump has to be used as described above, it (and the other devices) should be monitored to ensure that they are working correctly.

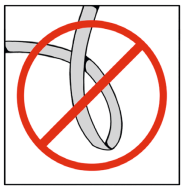
Note: A list of devices that the Space^{plus} Infusomat® has been tested next to or when stacked with, and which have no effect on the proper operation of the Space^{plus} Infusomat® when used in the immediate vicinity or when stacked with it, can be found in section 26.3.



When using the pump at home, make sure that the pump is not placed next to any heat sources (fireplace, oven, central heater). The pump can be operated at temperatures from 10 ... 40°C (50 ... 104°F).

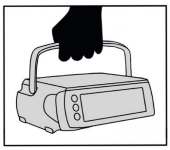
4.9 Using the infusion line correctly

It is recommended that disposable items are changed at least after 96 hours (see hygiene rules).



Make sure that the line is not kinked.

4.10 Transporting the device



Always carry by the handle!

Carry a maximum of 3 stacked devices by the handle!

Do not carry by the front flap!

2.1.27

Safety instructions

4.11 Avoiding damage to the device

Protect against water and dirt!

4.12 Accessories

Only use together with accessories approved by the manufacturer B. Braun Melsungen AG!
Otherwise, function may be impaired.

Only accessories, disposables and spare parts that comply with the EU Medical Device Regulation (MDD/MDR), and have the appropriate certification may be used. To ensure B. Braun Space^{plus} pumps function correctly, we recommend using B. Braun Melsungen AG accessories.

Electrical devices connected to interfaces must meet the requirements of the corresponding IEC specification!
(e.g. IEC 60950 for using the staff call)

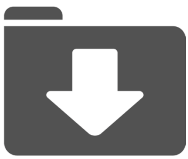
4.13 Maintenance, servicing and spare parts

Only use original spare parts!

Carry out technical safety check on the pumps. These may only be carried out by trained technicians.

If changes are made to the ME device, the appropriate inspections and tests must be carried out to ensure that it is still safe to use.

4.14 Software and updates



Always keep software up to date!

Only use the instructions for use that correspond to the software version!

Inform yourself of new device functions after software updates!

To maintain IT security, software updates might be necessary.

Always keep passwords, PINs and other credentials secret; use them according to the policies of your organization!

In case you observe or suspect a security problem including B.Braun devices, please contact your B.Braun representative, the B.Braun Product Security Team (productsecurity@bbraun.com) or visit https://www.bbraun.com/productsecurity.

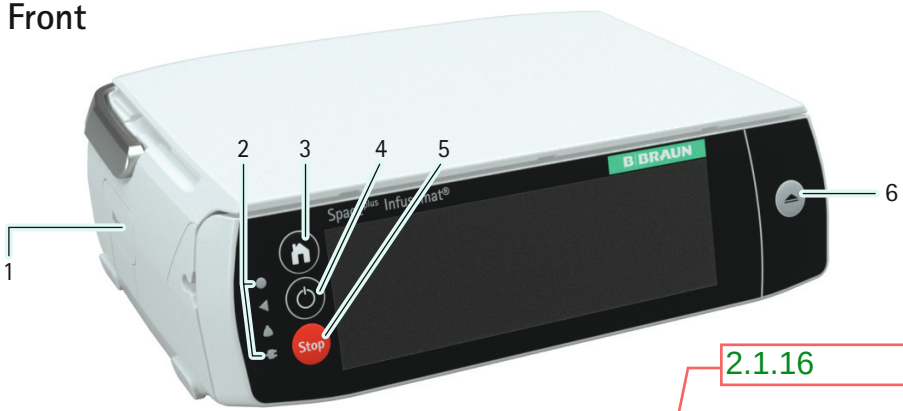
4.15 Safety standards

The device meets all of the following safety standards for medical electrical equipment in compliance with:
IEC 60601-1:2005 + A1:2012 and
IEC 60601-2-24:2012.

The EMC (electromagnetic compatibility) limits according to
IEC 60601-1-2:2014 and
IEC 60601-2-24:2012
are complied with.

5 Device overview

5.1 Front

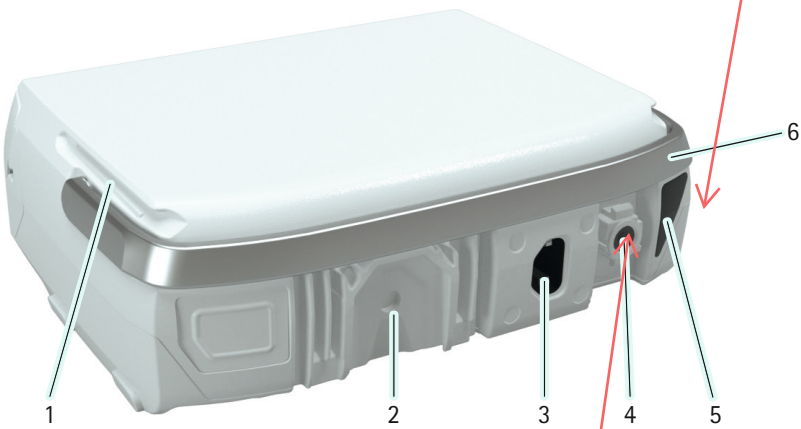


2.1.16

No.	Element	Meaning
1		Pump locking button
2	●	Brightness sensor
	◀	Lights up green when the pump is delivering
	🔔	Lights up yellow if there are low priority alarms Lights up red if there are high priority alarms
	🔌	Lights up white if pump is connected to the mains power
3		Home menu
4		On/off button: also stops the infusion if a delivery is in progress
5		Stop button
6		Open front door

Device overview

5.2 Back



No.	Name
1	Guide rails for connecting pumps
2	Cooling element with the option of attaching the Space^{plus} Pump Clamp
3	Mains connection (connection for mains power; in the event of mains power failure, the pump automatically switches to battery operation)
4	Accessory port (e.g. staff call, connection for 12 V cable)
5	Infrared interface (communication in Space^{plus} Station)
6	Carry handle

2.1.23

2.1.22

6 Ports and connections

6.1 Attaching/detaching the pump clamp

Pull the ring of the pump clamp back in order to use the quick-release mechanism and position the clamp on the wall rail/ the infusion stand. The pump clamp will cover a diameter of 20 mm to 40 mm and is compatible to rectangular rails that have shapes of 10x25 mm to 10x35 mm. Release the ring and turn the pump clamp clockwise to secure.

Please observe the load capacity of the infusion stand / ceiling unit / wall rail.

Attach the pump clamp to the pump as shown in the picture. The pump clamp is safely locked when you hear a clear click.

Remove the clamp from the pump and turn the pump clamp 90° to attach the pump to a vertical or horizontal bracket.

To release the pump, push the lever on the pump clamp backwards and remove the pump upwards.

6.2 Connecting/ disconnecting pumps

Slide the pumps together using the guide rails on the top and bottom of each pump. The pumps have been safely locked in place when you hear a clear click and the locking button on the side of the top pump no longer sticks out.

To release the pump lock, press the locking button on the left side of the top pump and slide this pump backwards.

6.3 Connecting cables

6.3.1 Power cable

Plug the power cable into the socket for the mains connection on the back of the pump.

When the pump is being powered by mains power, the plug symbol on the front of the pump lights up white and a mains plug is shown on the display.

6.3.2 Accessory cable for bolus button and patient call

Plug the accessory cable for the PCA Handset or the staff call into the accessory port on the back of the pump or at the Cover of the Space^{plus} Station when the pump is inserted. The accessory cable is safely connected when you hear a clear click.

The PCA Handset can be in physical contact with the patient and may also be operated by the patient as it can only be used to deliver a PCA bolus. Limits for the PCA bolus need to be set to therapeutically sensible and safe values in the drug library.

6.4 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.

6.5 Attaching / Removing pump to Lockbox

The usage of the Lockbox is limited to pain medication and not for high risk medications.

Attaching the Lockbox

1 | Position the Lockbox so that the Lockbox slides into the guide rails at the upper side of the pump.

2 | Open the door to hang up a bag up to a size of 500 mL.

Door has to be opened prior to inserting a pump.

3 | Attach the pump clamp at the back of the pump and attached it to wall rail / pole for stationary usage.

4 | To prevent tampering the door can be locked by a key. Changes of infusion parameter can be done without opening the door.

Removing the Lockbox

1 | Door has to be unlocked and opened first.

2 | Detach the pump from the pole and remove the pump clamp.

3 | Push the Lockbox backwards to detach the Lockbox from the pump.

7 Operating the device

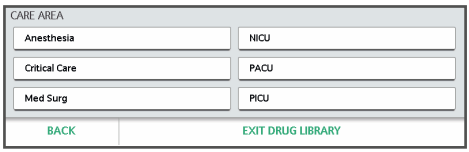
The pump has a touchscreen that can be used to operate all the pump's functions.

The only exceptions are the 3 buttons directly to the left of the touchscreen (see section 5.1) that can be used to switch the pump on/off, stop it, and access the Home menu.

7.1 Categories

The category options displayed (i.e. care area selection) provide the user with information from which to select the best option for the next work step.

If there are more than six options available for selection, use the left and right arrows to switch between the screens.

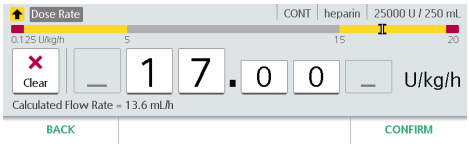


7.2 Entering values

Editors offer you the possibility of entering values. If you click on an item in the editor, the selectable values for the item selected are displayed.

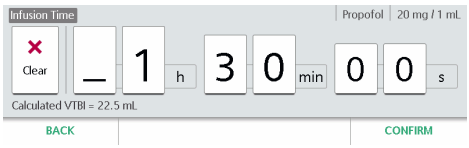
If there are limits for the parameter you are editing, a limit indicator will be displayed in the editor.

The limit bar is always coloured to show the different limit ranges and a limit symbol appears in the header if the entered value is within the soft limit range.



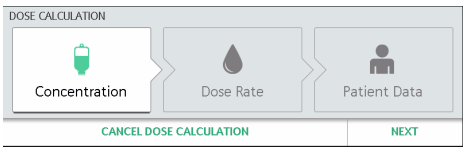
7.3 Deleting values

If you want to delete a value, press the X button in the editor (on the touchscreen). This resets all the numbers you can see in the editor.



7.4 Disabled controls

Disabled controls are shown in grey. In the screen below, for example, the dose rate cannot be changed.



There may be several reasons why a control is inactive. Some controls only become active when certain requirements are met, for example, if parameters have to be entered in a certain sequence.

8 Display screens

8.1 General status displays

The general status displays (e.g. run screen, WiFi connection etc.) are shown in the table in section 2.2.

8.2 Home menu

All important functions have to be accessed from the home menu. Press the button to access the home menu.

Button	Function
New infusion	Allows you to programme a new infusion. Only available when no infusion is running on the pump.
Care Area	To change Care Area when pump moves with patient.
Device settings	Takes you to the list of all possible settings.
Change Parameters	Takes you to the infusion parameters of the current infusion.
Pressure level	Allows you to change the occlusion pressure threshold.
Help	Opens the help menu.
Totals & Info	Shows you status data on the current infusion.
Priming	Allows to prime line whenever required.
Lock display	Locks the display. The display also locks automatically after a certain amount of time or if the front door is open.

8.3 Menus

There are three menus, which give an overview of the programmed data:

- Drug data
- Patient data
- Infusion data

You can see the following information at the top right of each menu, provided this information is available:

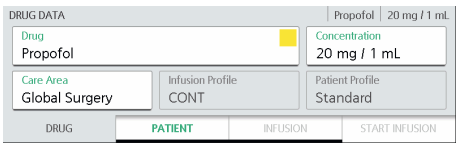
- Selected infusion profile
- Selected drug
- Concentration of the drug

All the data you entered when programming the infusion can be found in the menus.

You can switch between these menus and change the data from them.

You can only switch to the next menu if the data in the current menu is complete.

In this case, the corresponding tab is highlighted in colour.



8.3.1 Drug data menu

The drug data menu gives an overview of all the data you have entered if you have used the drug library (see section 10) for your infusion.

8.3.2 Patient data menu

The patient data menu contains height, weight and body surface area (BSA, if necessary).

The patient data you see here depends on the infusion profile or the settings for the drug.

Note: The patient data menu is only available if patient data is required for the current infusion.

The pump calculates the body surface area using the DuBois formula (DuBois D, DuBois EF. A formula. Arch Intern Med 1916; 17:863):
Body surface area [m^2] = 0.007184 x height [cm]$^{0.725}$ x weight [kg]$^{0.425}$

Check the plausibility of the calculated body surface area and the resulting infusion parameters before starting the infusion.

8.3.3 Infusion data menu

The infusion data menu gives an overview of all parameters relevant to delivery (e.g. flow rate, dose rate, volume).

Additional functions, for example, the initial bolus, can also be accessed from this menu.

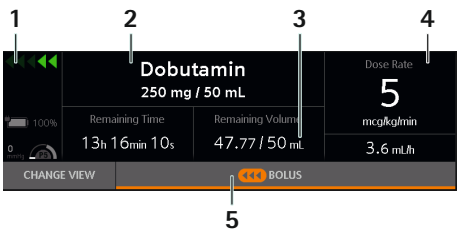
You can only start infusions in this menu.

The data you see in the infusion data menu depends on the infusion profile selected. The data and functions available for an infusion profile are detailed in section 11.

8.4 Run screen

The run screen is displayed when an infusion is in progress. It provides information about the current status of the infusion. The information displayed depends on the infusion profile selected.

The following image shows a typical run screen:



Display screens

No.	Function
1	General status displays (battery status, delivery in-progress indicator, pressure symbol (manometer): display of the pressure level setting (P1 to P9) with current pressure in the infusion system (pointer) in mmHG)
2	Name and concentration of the drug If no drug or concentration has been selected, this section may be empty.
3	Variable run screen parameters
4	Main infusion parameter Click on this infusion parameter to edit the value.
5	Button (bolus, end bolus, etc.)

Variable run screen parameters

The two infusion parameters that are displayed on the run screen in area 3 depends on your selection. To change a parameter, press on one of the two values and select the parameter you want to see.

The option to change a parameter and the parameters that are available to be changed, depends on the infusion profile used for the infusion in progress.

9 Main functions

9.1 Switching on, switching off and standby

Press the ⏻ button (see section 5.1), to switch the pump on.

Self-test

The self-test starts when the pump is switched on.

During the self-test, make sure that

- The LEDs light up (green, red, yellow).
- You hear two acoustic signals.

In addition, the display switches on.

Give the pump to a trained technician if the self-test fails.

Press and hold the ⏻ button to switch the pump off or put it in standby mode.

Note: You can only switch the pump off if there is no disposable inserted. If a disposable is inserted in the pump, you can only put the pump in standby mode.

9.2 Programming an infusion

Press the 'New infusion' button in the Home menu to programme a new infusion. You then have the option to programme the infusion as follows:

- Without drug database
- With drug database

Note: Whether both options are available or not depends on the pump configuration.

How to set the parameters for the drug database is described in section 10.2.

If you need patient data for the infusion, the pump then prompts you to enter the patient data.

The infusion data (e.g. flow rate) is entered in the Infusion data menu. You can find out which infusion data you have to enter for the infusion profile in section 11.

9.3 Starting an infusion

You can start the infusion in the Infusion data menu once you have entered all the required parameters.

Compare the displayed values with the entered values. Only start the infusion if the values match one another.

Note: The 'Start' button in the infusion data menu lights up green when the required infusion parameters have been completed.

If a running infusion has been interrupted, you can restart the infusion in the infusion data menu or via the run screen.

9.4 Pausing/ending an infusion

Press the Stop button to pause the infusion. You can then continue or end the infusion on the stopped run screen.

If you end the infusion, the programmed infusion parameters are deleted.

9.5 Locking/unlocking the display

The display lock is designed to protect the pump against accidental use when you are not actively working with the pump (like on a smartphone).

Automatically lock the display

The display locks automatically if

- it is not touched for a few seconds.
- you open the front door.

Manually locking the display

Click on the 'Lock display' button in the Home menu to manually lock the display.

Unlocking the display

- Click anywhere on the display.
- Confirm that you want to unlock the display in the message shown.

9.6 Administering a bolus

The pump's bolus function can only be accessed from the run screen. Press the 'Bolus' button to access the bolus menu.

Note: The pump activates the highest pressure level for the duration of bolus administration.

9.6.1 The bolus menu

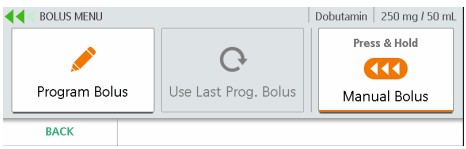
There are 3 options for administering a bolus:

- Programming a bolus
- Reusing a programmed bolus
- Manually administering a bolus

Whether all three options are available to you or not depends on the configuration of your pump and the situation.

Example 1: A manual bolus may not be available due to the pump configuration.

Example 2: If you have not programmed a bolus for your current infusion before, the pump will not offer you the option of reusing a programmed bolus (see the image below).



9.6.2 Programming a bolus

In the bolus menu, press the 'Programme bolus' button. Enter the bolus amount followed by the bolus duration. Start the programmed bolus from the overview menu.

Note: Depending on the configuration, the bolus duration may be calculated for you based on the entered bolus amount and standard bolus rate, and displayed to you in the editor. You can accept or change it.

Note: If you change the bolus duration or the bolus amount, the pump always adjusts the bolus rate.

9.6.3 Reusing a programmed bolus

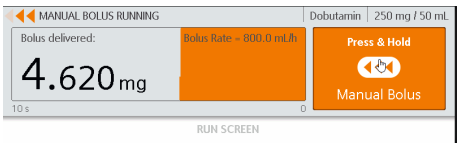
In the bolus menu, touch the 'Use Last Prog. Bolus' button. The pump displays an overview menu that allows you to view and change the values of the last programmed bolus. Start the programmed bolus from the overview menu.

9.6.4 Administering a manual bolus

Press and hold the 'Manual bolus' button in the bolus menu. The pump infuses the bolus for as long as the button is pressed.

The manual bolus is interrupted after 10 seconds and an audible signal sounds.

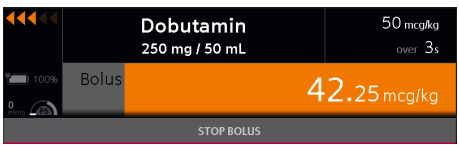
Depending on the pump configuration, an audible signal sounds during manual bolus delivery to inform you that a certain quantity of bolus has been infused. (The audible signal can be (de)activated and the desired bolus quantity set in the configuration data.)



9.6.5 The bolus run screen

When a bolus is infused, the pump displays the bolus run screen. The orange bar on the bolus run screen fills up from right to left (direction of travel of the delivered fluid) and shows the progress of the bolus.

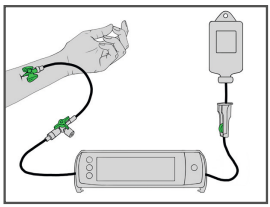
You can stop the bolus on the bolus run screen. In the case of a programmed bolus, press the 'Stop bolus' button. In the case of a manual bolus, release the 'Manual bolus' button.



Note: If you pause a programmed bolus using the 'Stop bolus' button on the touchscreen, the infusion continues in the background.
If you stop the programmed bolus with the Stop button, you also stop the infusion.

9.7 Changing the infusion line

The following diagram is an illustrative example of how to connect the pump to the patient.

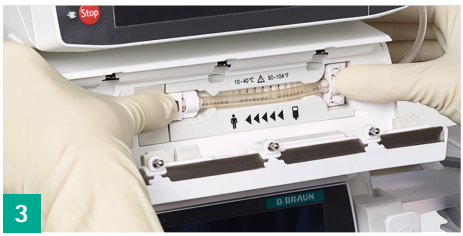


9.7.1 Inserting the infusion line

1 | Press the ⏏ button on the front of the pump to start the opening of the front door. The pumps asks for confirmation of the process and then opens the front door automatically.

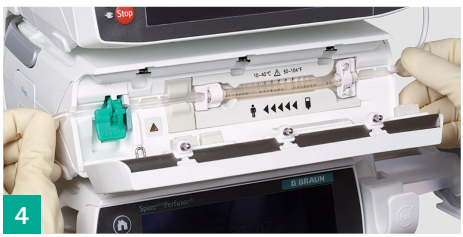
2 | Insert the infusion line into the pump from right to left.

3 | The two white clips on the line's silicone element must be fixed to the corresponding counterpart on the pump.



3

4 | The infusion line must be in the line guide channel at all points. Including the housing side contour.



4

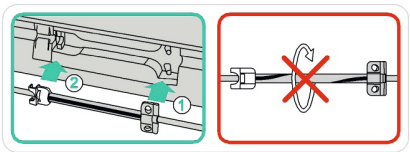
5 | Close the front door by pressing the front door firmly with both hands. Press until you can hear and feel the motorised locking mechanism closing the front door.

5

6 | Select the appropriate infusion line from the list on the pump. If only one line type is available, this step is skipped and you do not have to manually select the line.

Pay attention to the following points when inserting the line:

- The silicone element must not be stretched or twisted.
  If the stars on the infusion line are in a straight line, the silicone element has been inserted correctly.



- The free-flow clamp can only be pushed into the slot provided for it when the release lever is open. Otherwise, the infusion line may be damaged. The release lever is open when it is pressed down and the warning light is flashing orange.

  When closed, the release lever is up and the warning light is off.

Ensure proper placement of the syringe extension line / infusion line, so that it is not kinked or squeezed. Fluid path shall not be blcked unintentionally.

9.7.2 Removing the infusion line

⚠ **WARNING: Stop the infusion in progress, close the roller clamp and disconnect the pump from the patient before opening the front door. Otherwise, free flow may occur.**

Open the release lever by pushing it down and then pull the infusion line out of the pump.

9.8 Priming the line

WARNING: Always disconnect the pump from the patient before priming the line! The air contained in the line must not get into the patient!

After a line change or after an air alarm, you can prime the line using the pump if this option is enabled in the pump configuration or via the Home menu.

If you prime the line, the pump delivers a fixed volume. Depending on the length of the line, you may have to repeat the priming process until the line is completely filled with fluid.

Note: All air alarms are deactivated during priming.

9.9 Totals & Info

You can access the balance & info menu, which is divided into the following submenus, via the Home menu:

- Totals
- Infusion status
- Infusion history

9.9.1 Totals

You can find the infused volumes in the Infused volumes. The pump displays the volumes that have been infused since they were last deleted.

Content of the infused volumes

Depending on the device settings and the infusion profiles used, the pump will display all or some of the following balance data.

Name	Description
Total volume	Total volume administered during one infusion. Counts upwards until – A new infusion is selected or – The pump is switched off
Intermediate volume	Volume administered during one infusion. Counts upwards until – It is manually zeroed – A new infusion is selected or – The pump is switched off Can be deleted separately without deleting the total volume.
Fluid balance volume	This information displays the volumes over all infusions for this patient in mL. Counts upwards until – A new patient is selected or – The pump is switched off

Deleting the infused volumes

If you delete the intermediate volumes, this has no effect on the total volumes. The infused volumes are automatically deleted when you set up a new infusion for a new patient.

The pump shows you when the intermediate infused volume was last deleted.

9.9.2 Infusion status

The infusion status shows you all the infusion-relevant information about the current infusion. The pump displays general and infusion-specific information.

General information

The pump displays the following information for all infusions, provided it is available:

Name	Description
Care unit	Name of the selected care unit
Patient profile	Name of the patient profile selected
Drug name	Name of the selected drug
Drug information	Additional information on the drug selected
Patient data	Patient's weight, height or body surface area
Disposable	Name and description of the disposable selected
Remaining VTBI volume	Remaining total volume to be infused
Remaining infusion time	Remaining time until the end of the infusion
KVO rate	Set KVO rate
Remaining KVO time	Remaining time until the end of KVO
Remaining battery life	Remaining battery life

Additional infusion-specific information can also be displayed.

9.9.3 Infusion history

You can find all the information about events that occurred during the current infusion in therapy history.

The therapy history is split into three sub-groups:

- Infusion history
- Bolus history
- Operating alarm history

Infusion history

The pump displays all the changes made to the current infusion (e.g. rate changes, change of VTBI etc.).

The infusion history is automatically deleted when you set up a new infusion.

Bolus history

The pump displays the last 50 boluses given during the current infusion.

Note: Boluses that were administered automatically as part of the therapy or using the PCA bolus button are not displayed here.

The bolus history is automatically deleted when you set up a new infusion.

Operating Alarm history

The pump displays the last 50 operating alarms.
The operating alarms are automatically deleted when you set up a new infusion.

9.10 Keep vein open (KVO mode)

KVO stands for *keep vein open*. This mode is intended to keep the patient access open after the infusion and to protect it against clotting.

Therefore, in KVO mode, a very low, non-therapeutic rate is delivered.

If the KVO mode is activated in the settings, the pump starts KVO after the programmed infusion time or the programmed volume.

Depending on the settings, every x minutes a high priority alarm informs that KVO is active (alarm does not stop pump).

The KVO rate depends on the rate of infusion and can vary depending on the configuration or based on drug library.

9.11 Changing the device settings

You can change the device settings via the Home menu.

Which settings you can change depends on the configuration of the pump and may vary.

Menu	Meaning
Data lock	Activate or deactivate code lock
KVO	Activate or deactivate KVO
Standard bolus rate	Setting the standard bolus rate
Pressure level	Set the cut-off pressure from 1 (low) to 9 (high)
Audio volume	Set audio volume from 1 (low) to 9 (high)
Display brightness	Set the brightness from 1 (low) to 9 (high) or to activate automatic display brightness by using the brightness sensor
Language	Select language
Date & time	Set the date and time

2.1.26

9.11.1 Activating or deactivating the code lock

The pump can be protected against unauthorised use using the code lock.

Various codes can be stored in the pump: the standard code and special codes for the pain therapy team.

If you have to enter a code, the pump will tell you which code you need.

Protected & non-protected functions

Almost all the functions that can affect the infusion are protected by the codes. You can change some device settings (e.g. pressure) even if the code lock is active.

An infusion can always be stopped. If you stop a code-protected infusion, you must enter the required code within 20 seconds. Otherwise the pump will trigger an alarm.

The pump will also trigger an alarm if you enter the code incorrectly three times.

Activating the code lock

Manually

You can activate the code lock manually in the device settings.

The standard factory code is 9119. It should be changed by a trained technician before the pump is used for the first time.
The code should be kept secret and should only be shared with authorised personnel.

Note: The code lock can only be activated on the pump if the function is enabled for the pump.

Via drug selection

Critical drugs can be protected by the code lock. If you select one of these drugs, you will need to enter the code for further programming.

Deactivating the code lock

You can deactivate the code lock manually in the device settings or by stopping the infusion.

Note: If the code lock was activated via the drug selection, it can only be deactivated by stopping the infusion.

9.11.2 Selecting pressure level

By changing the pressure threshold, the time to alarm following an occlusion in the infusion line can be kept low. The higher the set pressure level, the higher the pressure in the infusion line has to be to trigger a pressure alarm.

Make sure that the pressure level is selected so that an alarm sounds within an acceptable time.

The set pressure level (e.g. P5) is displayed on the run screen. The manometer pointer shows the current pressure in the infusion system. The lower the selected pressure level, the bigger the grey area on the manometer. As soon as the pointer enters this grey area, a pressure alarm is triggered.

It may be necessary to change the pressure level due to various influencing factors, e.g. line length and inner diameter, fluid viscosity and the filter used in the system.

As a general rule, the pressure threshold should always be set higher than the pressure in the infusion system. Start with a low pressure level and adjust it if necessary to ensure short alarm times.

If pressure alarms are triggered at a pressure level despite there being no occlusion in the infusion system, e.g. due to frictional forces, the pressure level must be increased.

Note: The cut-off pressure remains at the set pressure level until it is changed manually or a drug selected from the drug database specifies a pressure level. The pressure level is returned to its original setting if the pump is switched off.

Note: The pressure monitoring is also active when the device is stopped or in standby mode.

Note: If a drug is selected, the pressure level from the drug is activated. If no pressure level on drug is defined, the pressure level is taken from the pump settings.
As long as the drug is running, any pressure level change only relates to the drug.

10 The drug library

The drug library is a safety feature that helps to ensure that the infusion parameters are entered correctly.

Note: The extent to which the drug library helps when setting up an infusion depends on the information stored in the library and may vary.

In the following section, you will find information about:

- The logic of the library
- The initial bolus
- Limits
- The review screen

10.1 Accessing the drug library

You can access the drug library by pressing the 'New infusion' button in the Home menu.

If you only realise later in the programming process that you want to use the library, you can access it via the Drug data menu.

It is possible to subsequently assign a drug from the drug library to an already running infusion with the unit mL/h. To do this, select either area no. 2 of the run screen (see section 8.4) or the Drug data menu.

10.2 Programming an infusion with the library

Once you have accessed the drug library, the pump will guide you step-by-step through the following settings:

- Care unit
- Pump location
- Drug
- Patient profile
- Concentration of the drug
- Infusion profile

You can then continue programming the patient data and infusion parameters from the drug data menu.

Note: When you select a parameter, this limits the choices in the next step. If you subsequently change a selected parameter, all the following parameters are cleared (see Figure 1 in this section). You must then select them again.

Note: If the drug library contains only one option for a step, the selection is made automatically and the step is skipped. Exceptions: The drug and the concentration always have to be selected manually.

Selecting the care unit & pump location

Different care units in a hospital require different drugs at different concentrations and quantities.

For this reason, a pump can contain several different drug libraries adapted to the needs of individual wards.

Select a care unit to select the corresponding library.

The pump then only offers you options that are permissible for your care unit for the programming of the infusion.

If the drug library contains several pump locations for the selected care unit, select the pump location.

The drug library

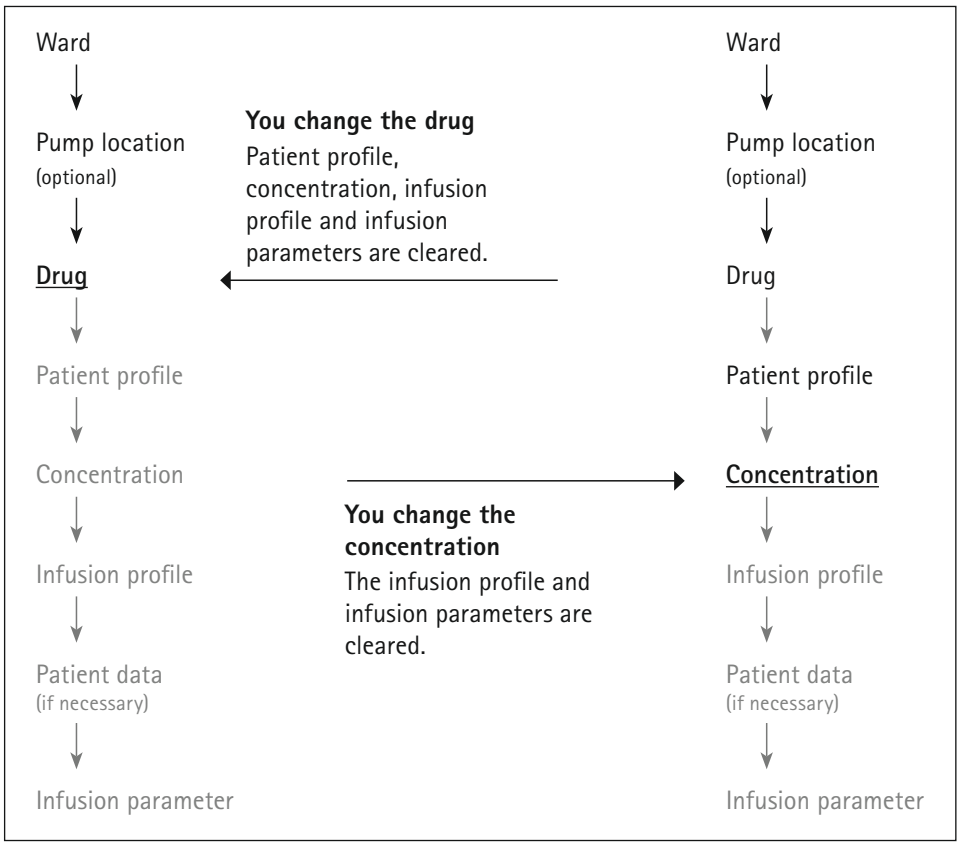


Figure 1: How changing a value affects subsequent options.

The pump location indicates the specific location of a pump. It has no influence on the options that are subsequently available.

Example:
There are two internal medicine intensive care units in a hospital. One with the number 25, the other with the number 26. You select the internal medicine ICU (ward) with the number 26 (pump location).

Selecting a drug

You can select a drug by

- searching for it in the entire database or in a drug category.
- having a list of all available medicines displayed.

For some drugs, the pump shows additional drug information that you should be aware of after the selection has been made.

The drug library

In clinical practice certain colour codes have been established to make it easier to distinguish between different drug groups. These colour codes can be displayed on the pump using the drug database in order to minimise the risk of medication errors (e.g. wrong route of administration).

Selecting the patient profile

Due to restrictions (e.g. liver failure), some concentrations or infusion profiles may be unsuitable for certain patients or may only be approved for certain patients.

Select a patient profile to specify the characteristics of your patient. The pump then only offers you the concentrations and infusion profiles that are permissible for the selected patient profiles for selection.

Selecting the concentration

Select the concentration of your drug. The selection influences the permissible value range for several infusion parameters (e.g. flow rate) and affects the infusion profiles subsequently available.

Enter an individual concentration if no suitable concentration is displayed and individual input is permitted for the drug.

Selecting the infusion profile

Infusion profiles differ with regard to the course of the infusion or the way in which they are programmed.

The descriptions of the infusion profiles can be found in section 11.

Programming a loading dose

The loading dose is a bolus administered immediately after the start of an infusion.

Add the loading dose in the Infusion data menu and programme it like a bolus.

Note: The initial bolus is only available if it has been enabled for the drug selected in the drug library.

Note: The pump activates the highest pressure level for the duration of the loading dose.

10.3 The limits

Limits are limit values for infusion parameters that are designed to prevent incorrect infusion data input. There are two different types of limits:

Soft limits

Soft limits indicate that the programmed infusion parameters are outside the commonly used range.

Setting values that are outside the soft limits is permitted.

If you enter a value within the soft limits, the cursor will enter the yellow part of the limit bar.

If you confirm the value entered, the pump displays a message. You are given the option of confirming or changing the entered value.

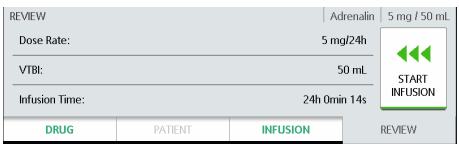
Hard limits

Hard limits are absolute limit values for infusion parameters that cannot be exceeded.

It is not possible to set and confirm values that are outside of the hard limits.

10.4 The review screen

For some drugs, it may be necessary to recheck the entered infusion parameters on the review screen before the infusion is started.



Note: Infusion parameters cannot be changed on the review screen. Go to the corresponding menu to edit the parameters.

10.5 Changing the drug data during an infusion

With the exception of the care unit, drug data cannot be changed during an active infusion (infusion is in progress or paused). End the infusion and set up a new infusion if you want to change drug data.

11 Description of the infusion profiles

The pump offers you different infusion profiles for different purposes.

In this section, you can find descriptions of the infusion profiles, the uses they are intended for and the infusion parameters that are available to you.

Note: Which infusion profiles are available to you depends on the configuration of the pump.

11.1 Rate/volume/time

Rate/volume/time is the standard infusion profile available on every pump.

With this infusion, the pump delivers a fixed volume of drug with a constant flow rate over the programmed period.

You can use this infusion with or without a drug library.

Note: If you use rate/volume/time with the drug library, it may be the case that a dose rate rather than a flow rate has to be programmed for the drug. You can see from the button label whether you have to enter a flow rate (mL/h) or a dose rate (e.g. mg/kg/h).

11.1.1 Overview of infusion parameters

You have to enter two of the three available infusion parameters, the third is automatically calculated by the pump.

Parameter	Description
Rate	Constant flow or dose rate at which the drug is infused
Volume	Quantity of the drug to be infused (in mL)
Time	Time period over which the drug is infused

11.1.2 Use with an Infusomat® Space Line SafeSet

Note: If an Infusomat® Space Line SafeSet is used, no volume has to be input.

A special airtight filter membrane (AirStop) acts as a barrier and prevents air entering the line. If the fluid level reaches the membrane, the 'Check upstream' alarm is triggered and the pump stops the delivery 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 event of a 'Check 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 or drip chamber is empty.

The pump should not be restarted until the 'Check 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 AirStop filter. In this case, ensure that the drip chamber is refilled, then open the pump's front flap to recalibrate the upstream sensor.

11.1.3 Changing the infusion parameters

If you later change the infusion parameters, the pump recalculates the other infusion parameters based on the following logic:

You change	The pump calculates
Rate	Time
Volume	Time
Time	Rate

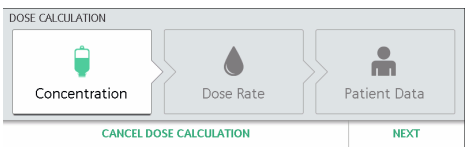
Note: For safety reasons, the pump will indicate when a change leads the rate being recalculated.

11.2 Dose calculation

The dose calculation works like a pocket calculator that the pump uses to calculate the flow rate based on dose information. Flow rate [mL/h] = Dose rate / concentration x patient weight (optional)

Note: The dose calculation is only available for infusions that do not use the drug library.

Select the 'Dose calculation' option in the Infusion data menu to start the dose calculation. You will now see the dose calculation menu, which gives you an overview of the parameters to be entered.



The pump guides you step-by-step through the dose calculation:

- Concentration of the drug
- Dose rate
- Patient data

Once all the data has been entered, the pump calculates a flow rate and takes you back to the Infusion data menu. The infusion can be started from there.

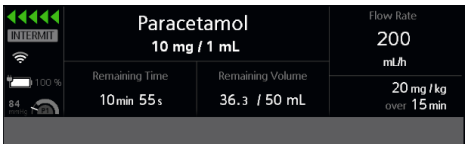
If values that are relevant for the dose calculation are changed (e.g. patient weight), the flow rate changes and the dose rate is maintained.

11.3 Dose over Time

Dose over Time is used for intermittently administered medications that require a specific dose of a medication delivered over a specific time.

Dose over Time can only be used with drugs from the drug library. Limits can be set around both total dose and total time in the drug library. Rate and VTBI are calculated based on drug concentration, dose and time. To achieve administration of the entire dose over the specified time the total volume of the bag and the tubing volume must be accounted for in determining the flow rate. The drug library and pump workflow support programming of bag overfill and flush volumes, both volumes may be pre-set in the drug library or manually programmed prior to starting the infusion or at the end of the infusion.

Description of the infusion profiles



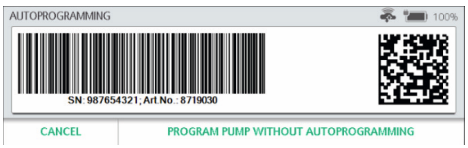
Note: The Bolus functions are disabled during Dose over Time.

11.4 Autoprogramming

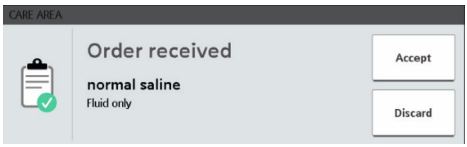
The pump can receive orders from the Elecronic Medical Record (EHR) wirelessly and send pump data to the EHR for documentation. The Autoprogramming process with EHR's requires the bag and patient ID to be scanned followed by scanning the pump barcode to link the order to the pump. Prior to initiating Autoprogramming observe wireless antenna symbol on the pump to verify the pump is connected to the intranet. The pump must be configured for Autoprogramming.

Use barcode scanner to scan the syringe, patient ID and Nurse ID (optional), then select "new/same patient", the pump barcode will then be displayed.

For autoprogramming updates, the barcode can be reached via "Change parameters".



After scanning the pump barcode follow EHR prompt to send the order to the pump.



Note: When selecting a new medication to replace the current infusion medication it is necessary to end the current infusion prior to initiating the workflow for a new medication.

The pump displays all data received from the EHR on the screen for review.

Any missing values or edits may be made using the drug, patient, or infusion tabs.

To autoprogram a secondary infusion select "SECondary" from the primary run screen, the barcode will be displayed.

The Autoprogramming feature may be configured to only accept medications that are in the drug library. In this case the pump will reject the order and display the reason, this could include the drug or concentration are not available for the selected care area or patient profile, hard limits are exceeded etc.

The Autoprogramming feature may also be configured to allow drugs not present in the drug library to be accepted, it will require acknowledgement that medication does not have drug library safety limits. This only applies to drugs not present anywhere in the drug library, the pump will not accept a drug that is not not in the selected care area but is available in another care area.

Description of the infusion profiles

11.5 Secondary / Piggyback

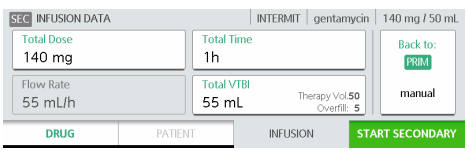
The Space^{plus} Infusomat® allows SECondary (piggyback) infusions to be programmed.

A selection on the touch screen of the primary infusion provides access to the secondary workflow. The Care Area is retained from the primary infusion, from there the workflow is the same as programming a primary infusion. Spike bag and manually prime SECondary tubing. The secondary tubing should be connected to the needleless port above the pump.

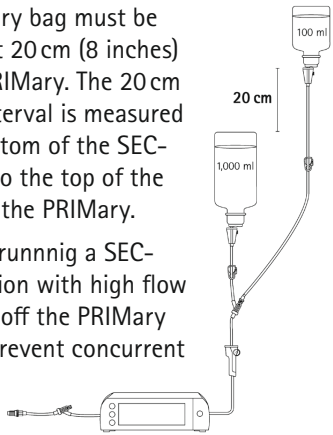
Note: SECondary infusion should not be used for critical infusions.

Select infusion mode, concentration and Clinical Modifier as done above when programming a PRIMary infusion. Medications may be set up in the drug library for SECondary only and will only appear in the drug list when in the SECondary menu. PRIMary medications may be set in drug library to prohibit SECondary infusions.

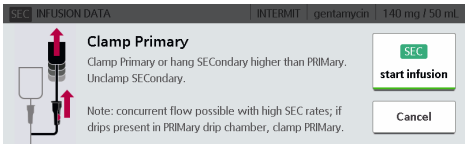
"Back to PRIM" is a modifiable option that allows the pump to be set to require a manual switch back to PRIMary in which case the pump stops and alarms when the programmed SECondary is complete, or autochange whereby the pump converts to the PRIMary setting when the SECondary dose/VTBI is completed.



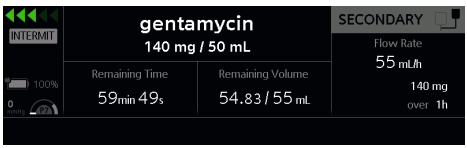
The SECondary bag must be hung at least 20 cm (8 inches) above the PRIMary. The 20 cm (8 inches) interval is measured from the bottom of the SECondary bag to the top of the fluid level in the PRIMary.



Note: When runnnig a SECondary infusion with high flow rates, clamp off the PRIMary infusion to prevent concurrent flow.



After starting SECondary, confirm fluid dropping in SECondary drip chamber. The runscreen indicates which infusion mode is active in upper right corner.



Note: The upstream occlusion alarming will not be able to detect an occlusion in the secondary line unless the primary line is clamped and the medication will be sucked out the primary bag in this case.

11.6 Pain controlled Analgesia (PCA)

The PCA therapy runs with or without a continous rate and the patient can demand for a PCA Dose via the PCA Handset. Additionally, a loading dose can be defined.

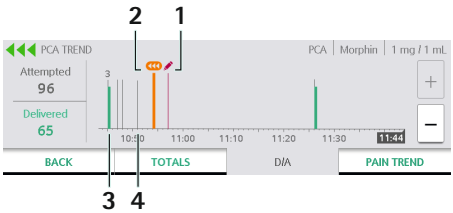
The PCA Limit is the total amount of drug or volume a patient can receive within a certain time including continous rate, PCA Doses and clinician boli. Loading Dose is not calculated in the total dose of the PCA Limit.

The Lockout time is the time after a bolus, in which the pump prevents further PCA Doses via the PCA Handset.

The D/A-ratio indicates the percentage of delivered and attempted boli thus giving an idea about the effectivity of the therapy.

Connecting the PCA Bolus Handset is described in chapter 6. The button on the PCA Handset illuminates in white as a finding light. Additionally, the color of the light can be configured to green to highlight when the lockout time is expired and the patient can demand the next bolus.

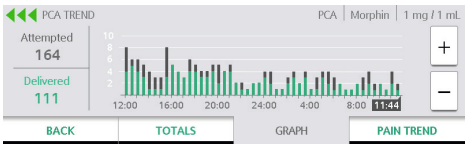
In case the PCA pump is used in a Space^{plus} Station, the PCA Handset connected to the Space^{plus} Cover is only supported when using the PCA therapy at the pump in the lowest slot of the Space^{plus} Station.



PCA Trend figure:

1 | Pencil icon: PCA infusion edited
2 | Bolus icon: clinician bolus
3 | Green bar: delivered bolus
4 | Grey bar: attempted bolus incl. quantity

Time scale can be changed by zooming in and out.



11.7 Programmed intermittent Bolus (PIB)

Programmed intermittent bolus (PIB) is a technique of epidural anesthesia in which boluses of local anesthetic are automatically injected into the epidural space.

The PIB therapy runs only with a intermittent bolus and the PCA Dose via the PCA Bolus Handset. Additionally, a loading dose can be defined.

The PIB Limit is the total amount of drug or volume a patient can receive within a certain time including PCA Doses boli, intermittent boli and clinician boli.

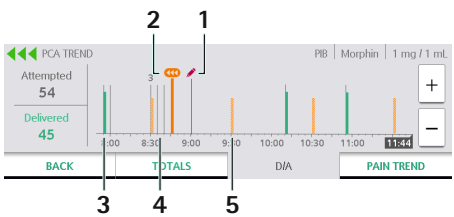
Description of the infusion profiles

Loading Dose is not calculated in the total dose of the PIB Limit.

The Lockout time is the time after a patient bolus, in which the pump prevents further PCA Dose.

The D/A-ratio indicates the percentage of delivered and attempted boli thus giving an idea about the effectivity of the therapy.

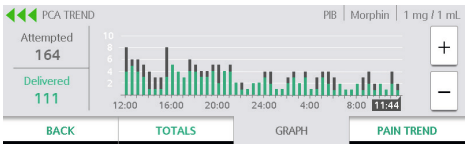
Connecting the PCA Bolus Handset is described in section 6. The button on the PCA Handset illuminates in white as a finding light. Additionally, the color of the light can be configured to green to highlight when the lockout time is expired and the patient can demand the next bolus. In case the PIB pump is used in a Space^{plus} Station, the PCA Handset connected to the Space^{plus} Cover is only supported when using the PCA therapy at the pump in the lowest slot of the Space^{plus} Station.



PIB Trend figure:

1 | Pencil icon: PIB infusion edited
2 | Bolus icon: clinician bolus
3 | Green bar: delivered bolus
4 | Grey bar: attempted bolus incl. quantity
5 | Orange bar: intermittent bolus

Time scale can be changed by zooming in and out.



11.8 Patient Data Synchronization

Patient data will be automatically synchronized for all pumps inserted into a Space^{plus} Station. Running infusions will not be influenced by any patient data change. As soon as a patient parameter is changed, this new value will be shared with the other pumps in the Space^{plus} Station and used for start up of a new therapy for the same patient. It can be still changed at the individual pump.

11.9 Distributed Alarm System

The Space^{plus} infusion pump can be integrated into a Distributed Alarm System. The distribution of medical alarms to 3rd-party systems is based on IEEE 11073 SDC, i. e. the 3rd-party systems need to comply to IEEE 11073 SDC in order to stay silent for an optimized healing environment.

Please refer to Instructions of Use ConAct for further details.

⚠ **WARNING: Due to the nature of Distibuted Alarm Systems, alarms are forwarded to other systems. This may lead to delays in displaying alarms on**

other systems included in the Distributed Alarm System. Information on possible delays and other technical data are inculded in the Instructions for Use ConAct.

Consider all warnings and safety instructions included in the Instruction for Use ConAct.

12 Hints & alarms

Note: When using the pump at home: stop the pump in critical situations by pressing the Stop button and put the pump in standby mode by pressing the button.

12.1 Hints

Hints are used to provide you with contextually relevant information, e.g. when you try to use deactivated functions.

12.2 Service hints

A service hint informs you that a technical check of the pump is necessary. Give the pump to a trained technician.

Service hints do not appear while an infusion is in progress.

12.3 Alarm display

In the event of an alarm, the pump emits an acoustic and optical signal. Figure 2 shows the layout of an alarm window.

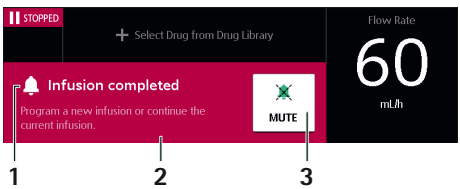


Figure 2: Operating alarm display
1. Alarm title, 2. Instructions on how to rectify the cause of the alarm, 3. Pause alarm sound/ minimise alarm window.

If you mute alarms for two minutes or minimise the alarm window, a small version of the alarm window will remain visible on the display (as long as the cause of the alarm persists).

If there are several alarms at the same time, the pump always displays the most urgent alarm.

If there is more than one alarm of equal urgency, the pump displays the alarm that was triggered first.

12.4 Alarm priorities

The pump distinguishes between two types of alarm priorities.

High priority alarms are visually indicated by a red alarm window and the flashing of the red LED.

Lower-priority alarms will be marked with a yellow alarm window and the steady illumination of the yellow LED.

In addition, the acoustic signals of the two priorities are different from one other.

Depending on the configuration, the alarm can be forwarded via the staff call.

The different alarm types and priorities are described below:

Alarm type	Alarm colour (LED & alarm window)
Notification	Yellow
Reminders	Yellow/grey
Pre-alarm	Yellow
Operating alarm	Red
Device alarm	Red

Hints & alarms

12.5 Alarm types

12.5.1 Notifications

Some notifications act like alarms because they have to be given special attention.

A notification provides information about an event at the pump. This may be directly related to delivery or to a basic function.

If a notification is generated during delivery, the infusion will continue.

Display notification	Meaning
Battery is missing or defective	The pump detects that the battery is missing or defective during an infusion. Delivery is still possible until the pump is replaced. – Always leave the pump connected to mains power supply! – Replace the pump as soon as possible!
Wrong code	The code to deactivate the code lock was entered incorrectly several times. – Enter the correct code.
Stand-by time elapsed	The entered stand-by time has elapsed. – Put the pump in stand-by mode again or continue the infusion.
Display touched for too long	The display has been touched for more than 15 seconds without interruption. – Make sure that no button is being continuously pressed. – Give the pump to a trained technician if the problem persists.
Temperature sensor defective	The temperature sensor triggers an alarm. – Give the pump to a trained technician.
Voltage outside the rated range	Voltages measured at the pump are not within the rated range. – Restart the pump. – Give the pump to a trained technician if the problem re-occurs.
Pump too hot	The pump has detected that the temperature is too high. – Ensure better cooling. – Give the pump to a trained technician.
Pump too cold	The pump has determined that the temperature is too low. There is a risk of free flow. – Increase the ambient temperature. – Follow the instructions on the display.

Display notification	Meaning
No connection to Space^{plus} Station	The pump has detected that it is inserted into a Space^{plus} Station but no communication between pump and station is possible. – Check setup of Space^{plus} Station – Inform a trained technician if problem persists
Alarms will not be distributed	Location was rejected or deleted hence alarms cannot be distributed reliably. – Ensure pump is within earshot – Check locations set up for distributed alarm system in ConAct application
Connection to alarm system lost	The pump has detected that the connection to the distributed alarm system was lost. – Ensure pump is within earshot – Check set up for distributed alarm system

12.5.2 Reminders

A reminder indicates that an action started on the pump has not been completed.

Reminders are only generated when there is an infusion line in the pump.

If a reminder is generated during delivery, the infusion continues.

Display notification	Meaning
Reminder	1. The disposable is inserted; the pump is not pumping and has not been operated for two minutes. 2. The pump is expecting a reaction, e.g., a response to a prompt or continuation of value input, and does not receive it within 20 seconds. 3. A bolus was stopped and neither canceled nor resumed whithin 20 seconds.

12.5.3 Pre-alarms

A pre-alarm signals the presence of an operating alarm.

Length of time between the pre-alarm and the operating alarm can be changed via a trained technician or via the drug libary settings. Additionally the acoustic sound of the pre-alarm can be permantely muted which is indicated by the following symbol on the user interface:  .

The infusion continues in the event of a pre-alarm.

Hints & alarms

Display notification	Meaning
Infusion ends in...	The preselected volume has almost been completely infused or the preselected time has almost elapsed. The time remaining is displayed.
Battery empty in...	Battery almost discharged. Connect the pump to the mains power. The remaining battery time is displayed.
SECondary ends in ...	The SECondary programmed volume or time will end based on prealarm setting. The display shows the time remaining until the operating alarm occurs

12.5.4 Operating alarms

An operating alarm gives information about a situation that requires immediate action.

The infusion is stopped by an operating alarm.

If alarm keep recurring without a clear reason, consider replacing the disposable or the pump.

Display notification	Meaning
Infusion ended	The preselected volume has been completely infused or the preselected time has elapsed. – Start a new infusion or continue the infusion.
Pressure too high	There is an occlusion in the infusion line. The set pressure level has been exceeded. The pump automatically reduces the post occlusion bolus (non-Piggyback IV sets). – Check that the line is not bent or damaged, that all connections are open and that all the filters are unblocked.
KVO started	– The preselected volume has been completely infused or the preselected time has elapsed and pump has switched to KVO mode. – End the infusion or continue the infusion.
KVO running	KVO is running. – Stop KVO to resume or end the infusion.
KVO finished	KVO time has elapsed. – End the infusion or continue the infusion.

Hints & alarms

Display notification	Meaning
Code entry required	An action performed on the pump requires a code to be entered. – Enter the correct code. or give the pump to a trained technician.
Pump too hot	The pump has detected that the battery temperature is too high. – Lower the ambient temperature or inform a trained technician.
Pump too cold	The pump has detected that the battery temperature is too low. – Increase the ambient temperature.
Battery empty	The battery is discharged. The battery alarm is signalled for 3 min. Then the pump will automatically turn off. – Connect the pump to the mains power.
Check upstream	The upstream sensor triggers an alarm. – Check whether the roller clamp is closed or the infusion line is bent.
Air bubble/ accumulated air	Air in the system. – Check the line for small air bubbles. Disconnect from the patient if necessary. Disconnect and prime the line.
No free-flow clamp	The pump has not detected a free-flow clamp. – Check that the infusion line has been inserted correctly.
Front door open	The pump has detected an open front-door during delivery. – Close the front door, give the pump to a trained technician if it is closed.
IV line inserted incorrectly	The pump does no longer detect a free-flow clamp or has detected an open front- door during delivery. – Check that the infusion line has been inserted correctly – Give pump to a trained technician if problem persists
Drive blocked	There is a problem with the internal drive. – Give the pump to a trained technician.

Display notification	Meaning
Pressing of button not processed	The signal from a pressed button could not be processed. – Press the button again. – Give the pump to a trained technician if the problem re-occurs.
Secondary completed	If the back to primary is set to manual, the screen will display secondary completed when secondary infusion is complete. – End secondary infusion, or add overfill if available, to then switch to Primary infusion.
PCA/PIB not possible	The pump has detected that more than one pump in the Space^{plus} Station is used for PCA/PIB. – Remove one PCA/PIB pump from the Space^{plus} Station to resume the infusion(s)
Invalid slot	The pump has detected that it is not inserted to the lowest slot of the Space^{plus} Station and therefore will not start boluses triggered by the PCA Handset. – Move the pump to the lowest slot of the Space^{plus} Station in order to use the PCA Handset

12.5.5 Device alarms

A device alarm signals that the pump is potentially defective. Disconnect the pump from the patient, remove the infusion line and switch the device off and on again.

Give the device to a trained technician if the device alarm is triggered again after the pump has been restarted.

The infusion is immediately stopped by a device alarm.

When using the pump at home: Inform the qualified medical professional if a device alarm has been triggered.

13 Software & updates

You can check which software (firmware) version is currently installed on the pump in the following ways:

- When switching on the pump, on the start display.
- If the pump is switched off but connected to mains power and you touch the display briefly.
- In the pump settings (depending on the pump configuration).

Updates are downloaded to the pump via the hospital network.

The availability of an update is indicated by a symbol (see section 2.2) regardless of the type of update. This is either displayed in the header (e.g. in the Home menu) or on the left of the run screen.

13.1 Updating the drug library

If an update is available, the drug library is automatically activated by the pump as soon as there is no active infusion. The pump informs you of the availability of the new drug library.

13.2 Activating additional updates

When the pump is switched off, you are given the option of activating the update (e.g. disposables list, configuration data).

You can decide whether to activate the update immediately or postpone it until a later date.

The pump cannot be used during the update.

Note: If you do not respond to this prompt, the pump automatically activates the update after 60 seconds.

14 Cleaning & disinfection

⚠ **WARNING: Always disconnect the pump/accessories from the patient before cleaning and disinfecting. Switch the pump off and disconnect it from the mains power supply and other devices (e.g. connecting cables).**

⚠ **Caution! Do not spray disinfectant directly onto the mains power connections, interfaces or pump openings. Do not immerse the pump in liquid, and do not allow moisture or disinfectants to penetrate electrical connections/openings. This can lead to short circuits, corrosion or malfunction of sensitive electronic components and/or to electric shocks.**

The pump must be completely dry before use.

Do not use sharp objects for cleaning.

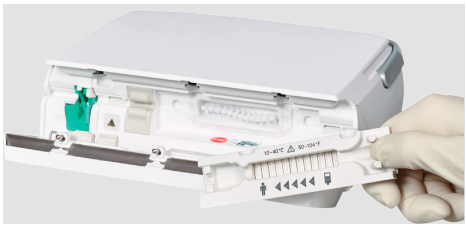
Procedure

1 | Remove all visible dirt from all surfaces. If necessary, use a non-fixing surface disinfectant with a clean, soft, lint-free cloth or low-lint cloth.

2 | The line guide element can be lifted with a pointed object (ballpoint pen) inserted in the lower right corner and then removed.

Cleaning & disinfection

⚠ **CAUTION! Do not touch the line guide element or the peristaltic pump part of the pump with the pointed object. When the line guide element is inserted, ensure that it is not damaged and audibly locks in place.**



3 | Disinfect the pump/accessories with damp cloths. Use a new cloth to prevent the spread of germs. Wet all the surfaces sufficiently and observe the exposure times required according to the manufacturer's instructions.

4 | Check all connections for residual moisture and visible damage. In case of damage, give the pump to a trained technician.

Every time the device is used on a new patient, it must be cleaned and disinfected. Should the device show signs of contamination or dirt, cleaning and disinfection is recommended immediately. Additionally, the hygiene regulations of the issuing institution must be adhered to.

Recommendations

Use the following B. Braun surface disinfectants: Meliseptol® Foam pure, Meliseptol® Wipes sensitive, Melsept® SF, Hexaquart® XL or Hexaquart® forte.

The substances listed in the following table can generally be used for cleaning and disinfection according to the recommendations of manufacturer of the respective disinfectant:

Group	Active substances
Alcohol	1-propanol, 2-propanol (isopropanol), ethanol
QACs (quaternary ammonium compounds)	DDAC (didecyldimethyl-ammonium chloride), BAC (benzalkonium chloride)
Acids	Citric acid, lactic acid, acetic acid
Phenols	o-phenylphenol, p-chloro-m-cresol
Peroxides	Hydrogen peroxide, peracetic acid
Aldehydes	Glutaraldehyde, glyoxal, formaldehyde
Alkylamines	N-(3-aminopropyl)-N-dodecylpropane-1,3-diamin, coco propylene diamine

If you are unsure about using a particular disinfectant, please contact the manufacturer of the disinfectant in question.

Note: Use of unauthorised cleaning agents or failure to follow disinfection procedures using the concentrations recommended by the manufacturer may cause pump malfunctions or product damage, and may void the warranty.

15 Battery operation and care

The device is equipped with a lithium-ion battery, which contains protection against overcharging and deep discharge. The charging state of the battery is shown in the display. During mains operation, the battery is charged by the device. In the event of a power failure or disconnection from mains power, the device automatically switches to battery operation.

15.1 Notes on battery life

The battery life depends on

- ambient temperature
- state of charge during long-term storage (> 6 months)
- Number of discharge/charge cycles

Please also pay attention to the following:

- The displayed remaining battery time is an approximate value, based on the current delivery rate.
- Under normal temperature conditions, a battery can be fully discharged and recharged at least 300 times until its capacity has dropped to about half of the nominal value.
- When the device is not operated on mains power, the battery will discharge even if the device is switched off. In this case, the battery may be completely discharged after a few weeks if the charge level is low. The entire battery capacity is then only available again after a complete charging process.
- In the case of long-term storage (> 6 months), the device should be supplied with mains voltage for at least one hour approximately every six months to avoid deeply discharged batteries.
- The optimum battery life is achieved when the device is operated on mains power at room temperature mainly.

15.2 Battery change

⚠ **WARNING: Risk of injury due to Explosion or leakage of the battery.**

- Do not open or burn the battery.
- The battery shall be replaced by trained technical personnel only.

16 Decommissioning

- Switch the pump off and disconnect it from the mains power supply.
- Remove any accessories.
- Dispose of any accessories and the pump according to the instructions.

17 Warranty

The warranty encompasses the repair or replacement of faulty parts, whether these are due to faulty design, fabrication, or materials.

The warranty is rendered void if the owner or third parties modify or repair the device.

The warranty will also be rendered void if the pump is damaged, exhibits signs of premature wear or malfunctioning, or otherwise operates improperly due to the use of a non-original accessory (e.g., a battery).

Exceptions to the warranty:

Rectifying faults that are the result of manipulation, improper handling, or normal wear and tear.

Defective batteries should be returned to B. Braun for further disposal.

Do not modify the device without manufacturer permission.

18 Maintenance and repair

⚠ **Caution! Risk of injury and/or malfunction from incorrect repair or device modifications.**

Repairs should only be carried out by trained technicians according to the B. Braun service manual. Only original replacements parts may be used.

19 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.

20 Technical Safety Check (TSC)/service

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

The expected service life according to the definition in IEC 60601-1 and 60601-1-11 is 10 years for the pumps, their components, and the accessories. This period may be longer or shorter depending on the conditions of use.

The technical safety check allows to evaluate the condition of the device. It is recommended to check the devices every two years. The expected service life specified pursuant to IEC 60601-1 has no influence on the warranty described in Chapter 17.

Pursuant to IEC 60601-1-11, the pump, its components, and the accessories have a shelf life (time of the product, component be stored in its original container) of 24 months (consider notes for battery operation and care in chapter 15).

20.1 Electrical Safety Inspection

The organization, which is operating the devices, is responsible for conducting the necessary electrical safety inspections in compliance with the applicable local regulations.

21 Start-up and trumpet curves

21.1 Significance for clinical practice

Trumpet curves show the recorded maximum and minimum deviations in flow rate compared to the delivery rate per observation interval, measured in the second hour after the start of delivery.

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.

This is particularly important for drugs with a short half-life. Find the observation period that corresponds to the half-life of your drug on the trumpet curve. Check the delivery accuracy for this period and decide whether the pump is sufficiently precise for the drug.

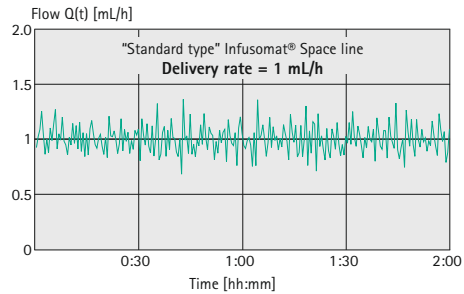
The physiological effect of the drug can be affected by the flow and the infusion line.

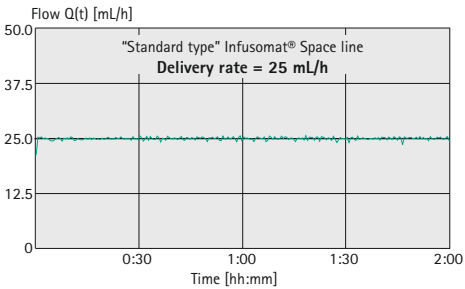
During use, the prescription must be adapted in consideration of the start up and trumpet curves and the flow rate set.

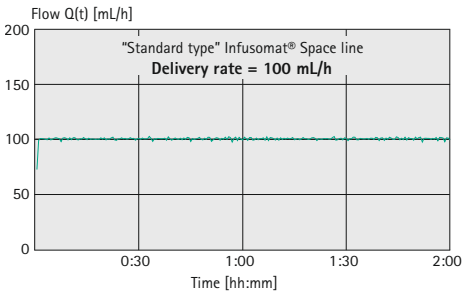
Start-up and trumpet curves

21.2 Typical start-up and trumpet curves

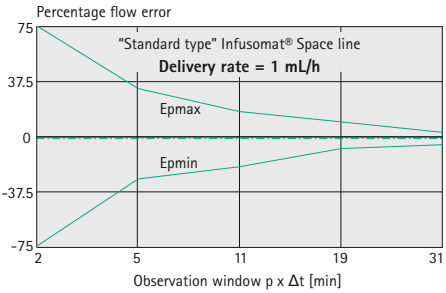
Start-up curves

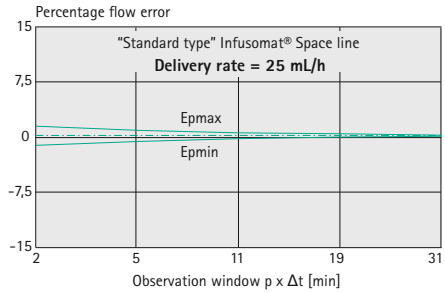


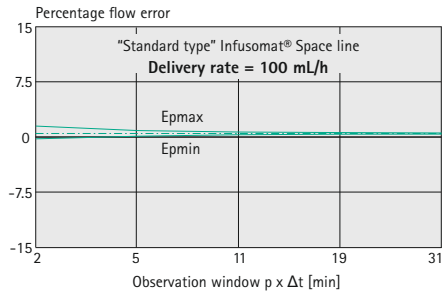




Trumpet curves







Time to alarm

These graphs show the accuracy and uniformity of flow over time. It must be remembered that:

- The delivery characteristics and the delivery accuracy are significantly affected by the disposable used.

Note: System accuracy is typically ±3 % of the volume, measured with the help of the trumpet curve test method pursuant to IEC 60601-2-24 at a rate of 1 mL/h (at 20 °C ±2 °C and 1013 mbar ±20 mbar ambient pressure), using the approved infusion lines

Note: Under the worst-case conditions (high ambient temperature, low flow rate of 0.1 mL/h and simultaneous charging of a significantly discharged battery or if the device is poorly ventilated), the device will generate heat that could lead to the warming of the drug in the tube guide. Ensure proper ventilation and consider alternative administration of temperature sensitive drugs.

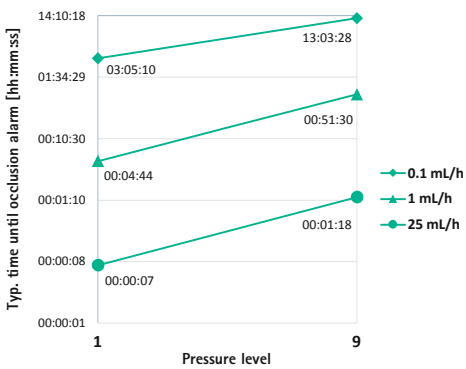
Start-up curves	
Measurement interval	Δt = 0.5 min
Measurement duration	T = 120 min
Flow Q_i	(mL/h)

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

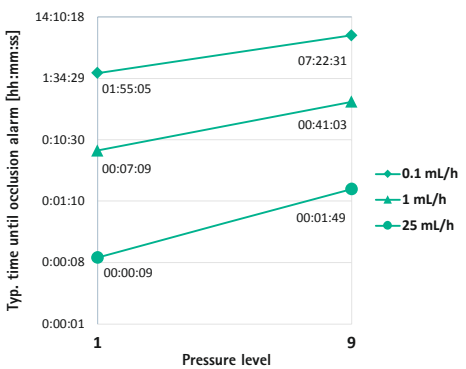
22 Time to alarm

The following graphics show the time to alarm after an occlusion depending on the pressure level. Besides the pressure level, alarm times and remaining bolus volume following an occlusion alarm are influenced by the type of infusion line, the associated elements (e.g. filter), the temperature, and the viscosity of the infusion medium, among other things.

Infusomat® Space Line PVC



Infusomat® Space Line Neutrapur



23 Technical data

23.1 Pump

The technical data applies to all operation locations listed in the intended purpose including home use as well as emergency and transport situations (road ambulances, fixed-wing and rotary-wing air ambulances).

Parameter	Value
Type of device	Volumetric infusion pump
Product classification	according to Directive 93/42 EEC and Regulation (EU) 2017/745: – IIb according to IEC 60601-1: – Protection class II – For Type CF applied parts with defibrillation protection – Continuous operation: 100% time of operation According to FCC Rules part 15: – Mobile device: Intended for use > 20 cm from the body
Protection against liquids and particles	IP44 – Protection against penetration by solid foreign bodies with a diameter of more than 1 mm – Protection against splashes from all directions
Power supply	
– Mains power supply	– 100 ... 240 V AC, 50 ... 60 Hz, max. 0.55 A, connection via power cable or via Space^{plus} Station
– 12 V supply	– 11 ... 16 V DC, max 0.9 A, connection via 12 V interface cable
Power consumption	
– Mains power supply	– Typ. 6 W (12 VA), max. < 14 W (34 VA)
– 12 V supply	– Typ. 6 W, max. < 11 W
Internal battery	Lithium-ion battery: 7.2 V DC, 3000 mAh, 21.6 Wh
– Battery life	– At 100 mL/h, 22 °C and with new battery: - Approx. 11 h with WiFi interface switched off - Approx. 8.5 h with WiFi interface connected – At 1200 mL/h, 22 °C, with new battery: - Approx. 4.5 h with WiFi interface connected
– Recharging time	– Approx. 4 h

2.1.19

Technical data

Parameter	Value
Staff call	Max. 24 V / 0.5 A / 24 VA (VDE 0834)
EMC	IEC 60601-1-2 / IEC 60601-2-24 DO-160G category M (section 21, WiFi off) and DO-160G category T (section 20) Warning: Only use in combination with devices/accessories approved by B. Braun. Otherwise, this can lead to higher emissions or reduced immunity.
Acoustic alarm signal sound pressure range	Adjustable between 45 dB(A) and 70 dB(A)
Interfaces	– Power inlet for mains voltage – Accessory port for 12 V interface cable, staff call and service – Infrared interface for communication in the Space^{plus} Station
Operating conditions – Temperature – Relative humidity – Atm. pressure	 – +10°C ... +40°C (+50°F ... +104°F) – 15 % ... 95 % (without condensation) – 500 mbar ... 1060 mbar
Storage conditions – Temperature – Relative humidity – Atm. pressure	 – -20°C ... +55°C (-4°F ... +131°F) – 30 % ... 90 % (without condensation) – 500 mbar ... 1060 mbar Note: Long-term storage (beyond 6 months): Ambient conditions of 22 °C (+72 °F) and 50 % humidity are recommended. Limits for long-term storage conditions are: – Temperature: +5 °C ... +40 °C (+41 °F ... +104 °F) – Relative humidity: 15 % ... 95 % (without condensation) – Atm. Pressure: 500 ... 1060 mBar During long-term storage, preventive maintenance must also be carried out in the specified intervals.
Weight	Approx. 1.9 kg (without pump clamp)
Dimensions in mm (W x H x D)	Approx. 215 mm x 70 mm x 170 mm (without pump clamp)
Safety check	Every 2 years

Technical data

Parameter	Value
Volume preselection	0,1 mL ... 99.99 mL in increments of 0.01 mL 100.0 mL ... 999.9 mL in increments of 0.1 mL 1,000 mL ... 9,999 mL in increments of 1 mL
Time preselection	00 h : 00 min : 00 s – 99 h : 59 min : 59 s
Flow rate setting	0,1 mL/h ... 99.99 mL/h in increments of 0.01 mL 100.0 mL/h ... 999.9 mL/h in increments of 0.1 mL/h 1000 ... 1200 mL /h in increments of 1 mL/h
Flow rate range – Continuous – Bolus	 0.1 mL/h ... 1,200 mL/h settable up to 1,200 mL/h, standard bolus rate 800 mL/h Note: The selectable flow rate range and the standard bolus rate can only be changed by trained technicians.
Delivery accuracy	±3% according to IEC 60601-2-24 Note: Valid for 50 cm water column in supply line
Delivery accuracy for bolus administration	typ. ±5 % with bolus volume > 1 mL Note: Accuracy may deviate when administering smaller bolus volumes.
Administration set change interval	Delivery accuracy is maintained for at least 96h with a Infusomat® Space line.
Occlusion alarm pressure	9 levels up to 1.1 bar ± 0.3 bar. Note: Bolus volume is automatically reduced after occlusion alarm (non-Piggyback IV sets).
Alarm in the case of incorrect delivery	In the event of an incorrect delivery of max. 1.0 mL due to a technical fault, the pump will automatically stop off and trigger an alarm.

Technical data

Parameter	Value
Max. bolus volume after occlusion alarm	≤ 0.2 mL ≤ 0.9 mL for Piggyback IV sets (see ordering data) The expected bolus volume after occlusion alarm is ≤ 0.2 mL under the following conditions: PVC tubing, occlusion at 1 m downstream from the pump, room temperature, and no check valves. The maximum bolus volume after occlusion alarm can be greater if using longer tubing, added check valves or other components such as filters, higher temperatures and/or higher viscosity fluids. The maximum bolus volume after occlusion alarm can be reduced by setting a lower pressure level.
KVO rate	– Rate: ≥ 10 mL/h: KVO rate 3 mL/h – Rate: < 10 mL/h: KVO rate 1 mL/h – Rate: < 1 mL/h: KVO rate 0.1 mL/h or current rate if this is lower Note: KVO rates can only be changed by trained technicians.
Air detector	– Technical sensitivity: Detection of air bubbles ≥ 0.01 mL. – 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, air bubbles ≥ 0.01 mL are counted) Note: The air alarm limits can only be changed by trained technicians or via the drug library settings. Additionally, there is the option to deactivate the cumulative air alarm.
History protocol	– 1,000 history entries The oldest entries are overwritten if necessary. – 100 events for system diagnosis The history is retained when the pump is switched off or the battery removed.

Note: The maximum delivery rate can be increased to up to 1200 mL/h using the disposable item data.

2.1.2

2.1.8

Technical data

Note: The default flow rate for priming is 1200 mL/h and can be adjusted by trained technical personnel.

Note: The bolus rate is determined based on the pre-defined standard value of 800 mL/h, which can be adjusted by trained technicians. The bolus rate can also be defined by entering a combination of bolus volume and bolus time.

Note: The delivery accuracies, occlusion pressure threshold, and alarm response times apply at room temperature and with water as the test substance. Different media viscosities and temperatures may lead to deviations.

Note: „Standard" type Infusomat® Space lines (8700036SP and 8250731SP) were used to obtain the technical data given in these instructions for use. The technical data may change when using set configurations.

⚠ **Caution! Only use pressure-tested (min. 2 bar/1500 mmHg) and B. Braun approved disposables to avoid negatively affecting performance data and patient safety.**

Only use combinations of devices, accessories, spare parts and consumables approved by B. Braun.

Essential performance characteristics of the infusion pump

- Infusion of fluids without variation in the flow rate.
  → In the event of a fault, the pump stops and triggers an alarm.
- Pressure limitation to protect against rupture of infusion line.
  → If the pressure limitation fails, the pump triggers an alarm and stops the delivery.
- Protection against unintended bolus volumes and occlusion (added by IEC 60601-2-24).
  → In the event of a fault, the pump stops and triggers an alarm.
- High priority alarm signal (added by IEC 60601-2-24).
  → If the regular alarm emitter does not work for technical reasons, an alternative alarm emitter (piezo) sounds.
- Protection against air infusion
  → If the air detection fails, the pump triggers an alarm and stops the delivery.

Technical data

23.2 WiFi interface

2.1.17

WiFi can be deactivated by trained technician.

Parameter	Value
WiFi interface	Wi-Fi certificates: WLAN interfaces supported: 802.11a, 802.11b, 802.11g, 802.11n. WPA Enterprise, WPA2 Enterprise.
	Security standards: Wireless Equivalent Privacy (WEP) Wi-Fi Protected Access (WPA) IEEE 802.11i (WPA2) FIPS 140-2 Level 1
	Encryption: Wireless Equivalent Privacy (WEP, RC4 algorithm), Temporal Key Integrity Protocol (TKIP, RC4 algorithm), Advanced Encryption Standard (AES, Rijndael algorithm). Encryption key provisioning: Static (40 and 128 bit lengths). Pre-Shared (PSK) 802.1X Extensible Authentication Protocol: Types: EAP-TTLS, PEAP-GTC, PEAP-MSCHAPv2, PEAP-TLS.
	802.11 a/b/g/n at 20 MHz (2.4 GHz), 20/40 MHz (5 GHz) bandwidth
	Effective radiant power: ≤ 100 mW Operate > 20 cm from the body at all times.

Radio equipment type approval

Regulatory area	Certifications	Certification ID
ETSI	EN 300 328 (Wi-Fi) EN 300 328 v1.8.1 (BT 2.1) EN 301 489-1 EN 301 489-17 EN 301 893 EN 60950-1 EU 2002/95/EC (RoHS)	Not applicable
FCC	FCC 15.247 DTS – 802.11b/g (Wi-Fi) – 2.4 GHz FCC 15.407 UNII – 802.11a (Wi-Fi) – 5 GHz FCC 15.247 DSS – BT 2.1	FCC ID: SQG-WB50NBT

Technical data

WiFi specifications

Feature	Description
Supports WLAN data transfer rates	802.11a (OFDM): 6/9/12/18/24/36/48/54 Mbit/s 802.11b (DSSS, CCK): 1/2/5.5/11 Mbit/s 802.11g (OFDM): 6/9/12/18/24/36/48/54 Mbit/s 802.11n (OFDM, HT20, MCS 0-15): Full guard interval: 6.5/13/19.5/26/39/52/58.5/65/78/104/117 Mbit/s Short guard interval: 1.2/14.4/21.7/28.9/29.9/43.3/57.8/65/72.2/86.7/115.6/130/144.4 Mbit/s
Modulation	BPSK @ 1/6/9/6.5/7.2/13 and 14.4 Mbit/s QPSK @ 2/12/18/13/14.4/19.5/21.7/26/28.9/39/43.3 Mbit/s CCK @ 5.5 and 11 Mbit/s 16-QAM @ 24/36/26/29.9/39/43.3/52/57.8/78/86.7 Mbit/s 64-QAM @ 48/54/52/57.8/58.5/65/72.2/104/115.6/117/130/144.4 Mbit/s
2.4 GHz frequency bands	ETSI: 2.4 GHz to 2.483 GHz MIC: 2.4 GHz to 2.495 GHz FCC: 2.4 GHz to 2.483 GHz KC: 2.4 GHz to 2.483 GHz
2.4 GHz operating channels	ETSI: 13 (3 non-overlapping) MIC: 14 (4 non-overlapping) FCC: 11 (3 non-overlapping) KC: 13 (3 non-overlapping)
5 GHz frequency bands	ETSI 5.15 GHz to 5.35 GHz (channel 36/40/44/48/52/56/60/64) 5.47 GHz to 5.725 GHz (channel 100/104/108/112/116/120/124/128/132/136/140) FCC 5.15 GHz to 5.35 GHz (channel 36/40/44/48/52/56/60/64) 5.47 GHz to 5.725 GHz (channel 100/104/108/112/116/120/124/128/132/136/140) 5.725 GHz to 5.85 GHz (channel 149/153/157/161/165) MIC (Japan) 5.15 GHz to 5.35 GHz (channel 36/40/44/48/52/56/60/64) 5.47 GHz to 5.725 GHz (channel 100/104/108/112/116/120/124/128/132/136/140) KC 5.15 GHz to 5.35 GHz (channel 36/40/44/48/52/56/60/64) 5.47 GHz to 5.725 GHz (channel 100/104/108/112/116/120/124) 5.725 GHz to 5.825 GHz (channel 149/153/157/161)
5 GHz operating channels	ETSI: 19 non-overlapping MIC: 19 non-overlapping FCC: 24 non-overlapping KC: 19 non-overlapping

24 Electromagnetic compatibility

Using the device near magnetic resonance imaging (MRI) units is not safe. The device must not be used near a magnetic resonance imaging unit without protection.

Note: Specific EMC instructions can be found in the separate instructions for use for the respective accessories.

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

⚠ **WARNING! The device has special requirements for electromagnetic compatibility (EMC). The device must be set up, switched on and operated in accordance with the EMC instructions. The safety distances and ambient/ operating conditions specified must be complied with.**

⚠ **WARNING! Portable HF telecommunications equipment (radio communications equipment) (including its accessories, such as antenna cables and external antenna) should not be used closer than 30 cm (12 inches) to the Space^{plus} pump. Non-compliance could lead to a decrease in the device's performance.**
Portable and mobile HF telecommunication devices can impair the functioning of electrical medical equipment.

⚠ **WARNING! The use of accessories, transformers and cables other than those specified, with the exception of those sold by B. Braun Melsungen AG as spare parts for internal components, may cause elevated emissions from the Space^{plus} pump or reduce its immunity.**

⚠ **WARNING! Reliable operation can only be guaranteed by using articles approved and recommended by B. Braun Melsungen AG. These articles are listed in the ordering data section.**

⚠ **WARNING! When using the device near equipment that can cause higher interference emissions (e.g. electrosurgical devices, magnetic resonance imaging units, mobile telephones etc.), the device may be subjected to interference. Observe the safe distances recommended by the equipment manufacturers.**

⚠ **WARNING! To achieve the compliance levels described below, only original accessories and spare parts may be used. Otherwise, there may be elevated emissions from the device or reduced device immunity.**

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.

Electromagnetic compatibility

WARNING! The use of accessories, transformers, cables and lines other than those specified or provided by B. Braun Melsungen AG can cause increased electromagnetic interference emissions or reduced device electromagnetic immunity and could cause a malfunction.

Recommended devices, accessories, transformers and cables for which B. Braun Melsungen AG guarantees compliance with the requirements of the standards named in the "Safety standards" section can be found in section 26.

Necessary precautions to maintain the basic safety and essential performance characteristics over the entire expected operational lifetime:

- Safety check, servicing, repair, updates, battery care, cleaning, disinfection and maintenance as described in these instructions for use.
- No additional precautions are necessary.

Electromagnetic compatibility

24.1 Electromagnetic interference emissions

The device is designed to be used in the following electromagnetic environment.
The customer or the user of the Space^{plus} system or its components should ensure that it is used in such an environment.

Interference emission measurements	Compliance	Electromagnetic environment guidelines
HF emission as per CISPR 11	Group 1 / Class B (See comment 1/ comment 2 below)	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. Note: The integrated WLAN module (2.4 and 5 GHz/≤ 100 mW) can interfere with devices in the vicinity. Please observe the required minimum distances.
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 acc. to IEC 61000-3-2	Not applicable	

Comment 1: The limit values for interference emissions are measured with individual components.

Comment 2: When a Class A device is connected to the Space^{plus} system, the Space^{plus} system becomes a Class A device also. This device/system may cause interference or interfere with the operation of device in the vicinity. It may be necessary to take risk mitigation measures, such as re-orienting or relocating the Space^{plus} system, or shielding the location.

Electromagnetic compatibility

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

Electromagnetic compatibility

Immunity test	Test level IEC 60601-1-2 IEC 60601-2-24	Compliance level	Electromagnetic environment guidelines
Voltage dips and power interruptions according to IEC 61000-4-11	0% U_T [1] for ½ periods	Complies through the use of an internal energy source	Mains power quality should be that of a typical commercial or hospital environment.
	0% U_T [1] for 1 period		
	70% U_T [1] for 25/30 periods		
	0% U_T [1] for 250/300 periods		
Power-frequency magnetic fields (50/60 Hz) according to IEC 61000-4-8	30 A/m	400 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Conducted disturbances, induced by radio-frequency fields according to IEC 61000-4-6	150 kHz to 80 MHz 3 V_{eff} outside and 10 V_{eff} within ISM and amateur radio frequency bands	10 V_{rms} In all bands	Do not use portable and mobile radio communications equipment closer to the Space^{plus} pump (including cables) than the recommended safe distance calculated using the appropriate equation for the corresponding frequency. **Recommended safe distance:** $d = 1.2 \sqrt{P}$ [2]

[1] U_T 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's specifications and d as the recommended safe distance in metres (m).

Electromagnetic compatibility

Immunity test	Test level IEC 60601-1-2 IEC 60601-2-24	Compliance level	Electromagnetic environment guidelines
High-frequency electromagnetic fields according to IEC 61000-4-3	10 V/m 80 MHz to 2.7 GHz	10 V/m 80 MHz to 6 GHz	The field strength should be lower than 10 V/m d = 1.2 x sqrt(P) [2)] 80 MHz to 800 MHz d = 2.3 x sqrt(P) [2)] 800 MHz to 2.7 GHz Field strengths from stationary RF transmitters should be below the compliance level for all frequencies, based on an on-site test. Interference is possible in the vicinity of equipment that has the following symbol. 

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 2.7 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) cannot be predicted theoretically with accuracy. To assess the electromagnetic environment generated by fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength of the location where the Space^{plus} pump is being used exceeds compliance levels, monitor the Space^{plus} pump 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 moving it to face in a different direction.

24.3 Recommended safe distances

The device is designed for use in an electromagnetic environment in which HF interference is 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.

Note: Distances for transmitters whose maximum rated power is not specified in the following table 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.

The compliance levels for ISM frequency bands between 150 kHz and 80 MHz and in the 80 MHz to 2.7 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.

Transmitter nominal power rating [W]	Safe distance according to transmitter frequency [m]		
	150 kHz to 80 MHz[1] $1.2\sqrt{P}$	80 MHz to 800 MHz $1.2\sqrt{P}$	800 MHz to 2.7 GHz[1] $2.3\sqrt{P}$
<0.1	0.3	0.3	0.3
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

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

25 Instructions for use for accessories

25.1 12 V interface cable (871923112)

Connecting the device to the vehicle power outlet to charge the battery

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

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

Plug the 12 V interface cable into the accessory port on the backside of the device.

Plug the 12 V interface cable into the vehicle power outlet.

If necessary, remove the red adapter from the vehicle power outlet by gently turning it and pulling on it at the same time.

The green LED on the electronics box shows the presence of the operating voltage.

25.2 Staff call interface cable (8718031)

Connecting the device to the call system

Observe country-specific regulations for the staff call.

Plug the staff call interface cable into the accessoryport on the back of the device or service port on the Space^{plus} Station.

Connect the patient call interface cable to the patient call system.

The staff call operating mode depends on the service settings and should be adapted to the patient call system.

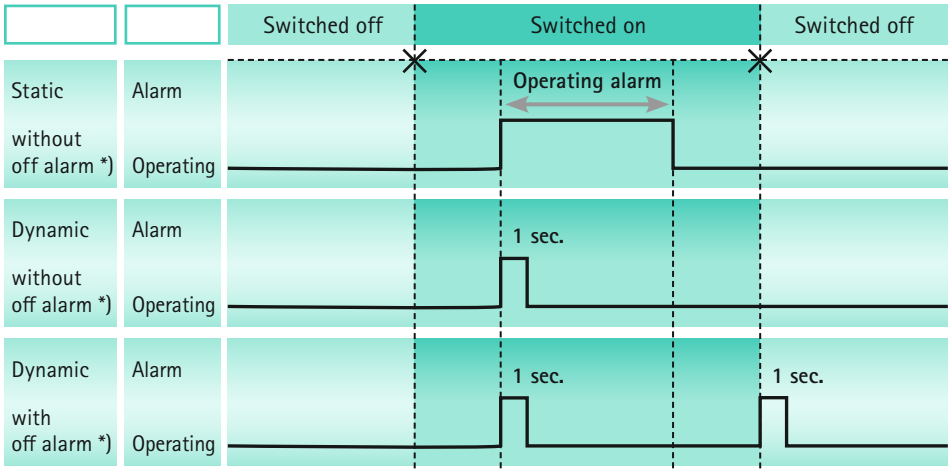
⚠ **Caution! As the staff call can fail and this can go undetected, and it is not tested during the pump self test, the user is also responsible for monitoring the alarms on the pumps.**

⚠ **WARNING! Electrical devices connected to interfaces must meet the requirements of the corresponding IEC specification! (e.g. IEC 60950 when using the staff call)**

⚠ **WARNING! Check the staff call before each use of the device.**

Instructions for use for accessories

The device has three different staff call operating modes:



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

Mode:	Red status LED	Changeover contact status (wire colour: white-green)	Changeover contact status (wire colour: white-brown)
Operating:	Off	Closed	Open
Alarm:	On	Open	Closed

26 Ordering data

26.1 Infusion pump

Art. no.	Name
8719050	Space^{plus} Infusomat®

26.2 Interface cable

Art. no.	Name
871923112	Connection lead 12V
8718031	Staff call cable

26.3 Recommended accessories

Art. no.	Name
8719141	Space^{plus} Station
8719145	Space^{plus} Cover
8719165	Space^{plus} Pump Clamp
8713135	Short stand SP
8719155	Space^{plus} MRI Station
8719152	Space^{plus} MRI Station with Trolley
8719554	Space^{plus} PCA Button
8719558	Space^{plus} Infusomat Lockbox
MCS765011	Space^{plus} Transportbox
MCS762120	Rotation fixation of Transportbox
MCS781000	Fixation clamp of Transportbox

26.4 Power cord

Art. no.	Name	Description
8717110	Power cord EU	Type E+F power cable

Ordering data

Art. no.	Name	Description
8717111	Power cord GB	Type G power cable
8717112	Power cord US	NEMA 5-15p power cable (suitable for hospitals)
8717113	Power cord AU	Type I power cable
8717114	Power cord CH	Type J power cable
8717115	Power cord ZA,IN	Type M power cable
8717117	Power cord CN	Type I power cable, var. 3
8717118	Power cord DK	Type K power cable
8717121	Power cord AR	Type I power cable, var. 2

26.5 Disposables

26.5.1 Infusomat® Space lines

IV - standard

Art. no.	Product
8700036SP	PVC (250 cm)
8700435SP	PVC (250 cm), ward package (10 x10 pcs.)
8270350SP	PVC, extra long (300 cm)
8250731SP	Neutrapur (250 cm)
8700087SP-01	with needle based Eurofix injection port – EU Label version
8700087SP-26	with needle based Eurofix injection port – AP/SA Label version
8700110SP	Neutrapur - with Safeflow needle free Y-port (300 cm)

Ordering data

SafeSet IV – Standard

Art. no.	Product
8701148SP	PVC, 250 cm
8270358SP	PVC, extra long (300 cm)
8700130SP	PVC with needle free CareSite Y-port (300 cm)
8701149SP	Neutrapur (250 cm)
8700118SP	Neutrapur - with Safeflow needle free Y-port (300 cm)

UV light protected

Art. no.	Product
8700127SP	Amber – light protected, orange tubing
8700128SP	SafeSet, amber – light protected, orange tubing
8250437SP	Amber – light protected, needle free Y-Port, orange tubing
8250438SP	SafeSet, amber – light protected, needle free Y-Port, orange tubing
8700142SP	Dosifix PUR UV-Protect Y-Port LL (300 cm)

Transfusion

Art. no.	Product
8270066SP-01	with 200 µ blood filter – EU Label version
8270066SP-26	with 200 µ blood filter – AP/SA Label version

Enteral Nutrition

Art. no.	Product
8250830SP	EN 1L Nutribag, ENFIT (230 cm)
8250832SP	W. Multiconnector ENFIT,PUR (320 cm)
8250834SP	EN Spike ENFIT, PVC (320 cm) BV

Ordering data

Neonate / Dosifix

Art. no.	Product
8700140SP	Dosifix, PVC, LL (330 cm)
8700141SP	Dosifix, PUR, Y-PORT, LL (300 cm)
8700142SP	Dosifix, PUR, UV-Protect Y-PORT, LL (300 cm)

Sets with 0.2 µm Sterifix® filter

Art. no.	Product
8700095SP	Neutrapur® – with inline 0.2 µm Sterifix® filter
8700098SP	SafeSet Neutrapur® – with inline 0.2 µm Sterifix® filter

Short-term infusion sets

Art. no.	Product
8250719SP	Flushing Set, SafeSet, PVC-free
8250720SP	Flushing Set, SafeSet, PVC

Piggyback

Art. no.	Product
8250710SP	With needle free Safeflow injection port and integrated BCV
8250718SP	SafeSet with needle free Safeflow injection port and integrated BCV
4062877	Secondary line with integrated BCV
4062878	SafeSet secondary line with integrated BCV

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