

Space^{plus} Perfusor®

Instructions for use

en Version 1.0 English

Valid for software 019B

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



CE 0123



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About these instructions for use

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!

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
PCA	Patient controlled analgesia
TSC	Technical safety check
VTBI	Volume to be infused

Symbols

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
	When used with Space ^{plus} MRI Station, suitable for use in MRI.
	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

Intended purpose

3 Intended purpose

The Space^{plus} Perfusor® is a transportable syringe infusion pump which is used in combination with approved syringes 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 prescription and the route of administration by a qualified medical professional based on the technical data of the pump.

The Space^{plus} Perfusor® 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} Perfusor® 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} Perfusor®.

There are no product specific side effects.

Infusion therapy and the use of infusion pumps in general bear several risks: Infusion delivery error and medication error (incl. programming error, medication over- and 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).

Safety instructions

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.

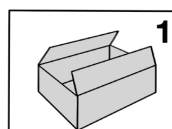
4.2 Inspection on delivery

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.

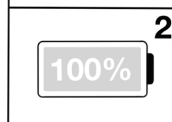
Do not use damaged devices or cables. Inform a trained technician.

4.3 Before and during use



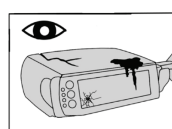
1

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

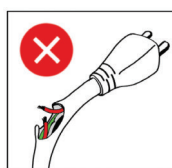


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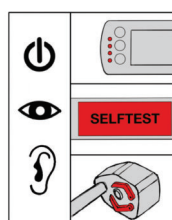
This extends lifetime of the battery and prevents damage.



Check the pump and accessories for damage and heavy soiling!



Do not use damaged cables!



When switching the pump on

- Check that the display is working correctly
- Check that the status LEDs are working correctly
- Check drive head claws
- Check alarm signals (visual & acoustic)

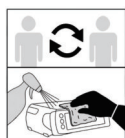
Observe the expiry date on the packaging for all accessories and disposables!

Safety instructions

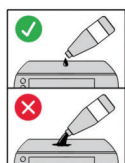
When multiple pumps/infusion lines are connected (parallel infusion), mutual interference cannot be ruled out.

If the display fails (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



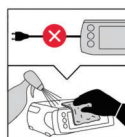
Clean and disinfect the pump before using it with a new patient!



Only use small quantities of cleaning fluid!

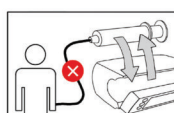


Protect electrical plugs from excessive moisture!



Disconnect from mains power before cleaning!

4.5 Protecting patients



Disconnect from the patient before inserting or removing the syringe!

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 press on the drive head during delivery!

Risk of the infusion being interrupted by an alarm!

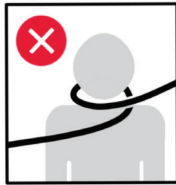


Do not move the pump during delivery!
A change in height while the infusion is in progress can affect the flow rate.
Risk of inaccurate delivery!

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

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

Safety instructions



When using the device at home, make sure that the accessories cannot strangle the patient.

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

4.6 Alarm volume and patient call

Make sure that the alarm volume is high enough!

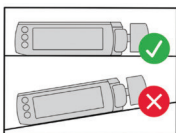
The alarms must be adapted to the physical environment and the ambient noise level.

This also applies when using a secondary alarm systems or when connected to a staff call system.

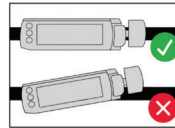
Check the staff call after connection and before the first use of the pump!

Supervise pump alarms locally at the device.

4.7 Setting up the device

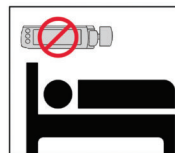


Set the pump up level!



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.

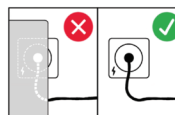


Do not position above a patient!

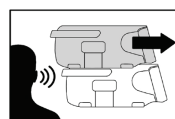
Risk of injury if the pump or its components fall.



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

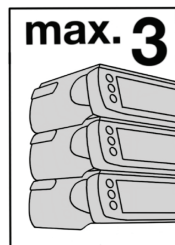


Set up the pump so that the mechanism for disconnecting the mains power is easily accessible (i.e. by unplugging the pump or the mains power plug).



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.

Safety instructions

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

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

The 45° pump clamp is only be used for enteral nutrition. When using the 45° pump clamp, only attach one pump to it and mount it on a wall rail / pole.

4.8 Device environment

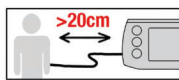


Comply with the recommended distances (at least 30 cm) to devices with higher interference signals (see section 24).

(e.g. electrosurgical equipment, MRI units, mobile phones etc.)



Do not use the pump near corrosive or flammable gases.



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

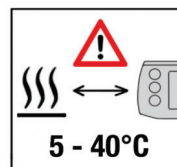
Only store and operate the pump within the specified temperature range! (See section 23)

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



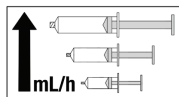
When using the pump at home, make sure that the pump is not placed next to any heat sources (fireplace, oven, central heater). The pump can be operated at temperatures from 5 ... 40°C (41 ... 104°F).

Safety instructions

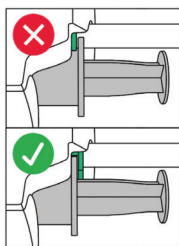
4.9 Using the syringe correctly

Only use syringes and catheters approved for the device (see section 22.2)!

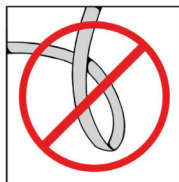
If untested or incompatible disposables are used, delivery accuracy cannot be guaranteed.



Use as small a syringe as possible for low delivery rates.

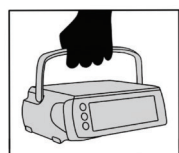


Make sure that the syringe wings are fixed between the syringe guide and the pump housing.



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 drive head!



Do not carry by the front door!

4.11 Avoiding damage to the device



Protect against water and dirt!

Safety instructions

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.

Device overview

5 Device overview





5.1 Front



No.	Name
1	Pump locking button
2	Syringe guide
3	Syringe holder
4	Claws
5	Drive head

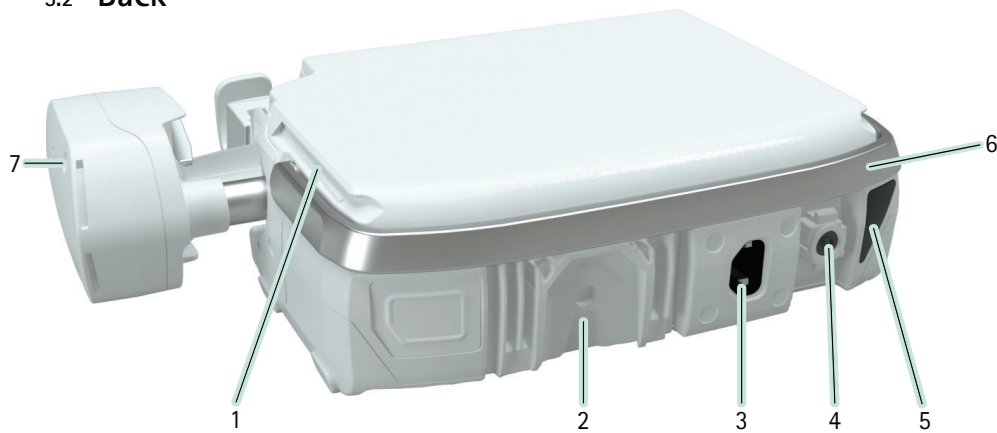
Device overview



No.	Element	Meaning
1		<p>Brightness sensor</p> <p>Lights up green when the pump is delivering</p> <p>Lights up yellow if there are low priority alarms Lights up red if there are high priority alarms</p> <p>Lights up white if pump is connected to the mains power</p>
2		Home menu
3		On/off button: also stops the infusion if a delivery is in progress
4		Stop button

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 mode)
4	Accessory port (e.g. staff call, connection for 12 V cable)
5	Infrared interface (communication in Space ^{plus} Station)
6	Carry handle
7	Claw release

16; 23.2-3

23.4

Ports and connections

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.

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.



23.5

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.



Ports and connections

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 bolus button or the staff call into the accessory port on the back of the pump. The accessory cable is safely connected when you hear a clear click.

The bolus button 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.



16.1

Operating the device

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 bar 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.



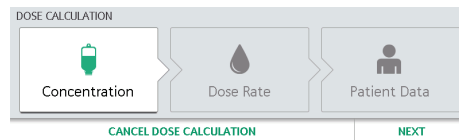
7.3 Deleting values

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.


Display screens

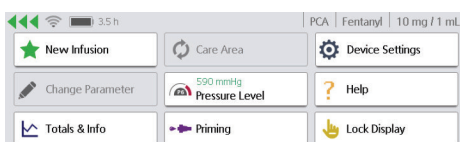
8 Display screens

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.

Button	Function
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.

Display screens

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

DRUG DATA		Propofol 20 mg / 1 mL	
Drug	Propofol	Concentration	20 mg / 1 mL
Care Area	Global Surgery	Infusion Profile	CONT
		Patient Profile	Standard
DRUG	PATIENT	INFUSION	START INFUSION

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):

$$\text{Body surface area [m}^2\text{]} = 0.007184 \times \text{height [cm]}^{0.725} \times \text{weight [kg]}^{0.425}$$

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.

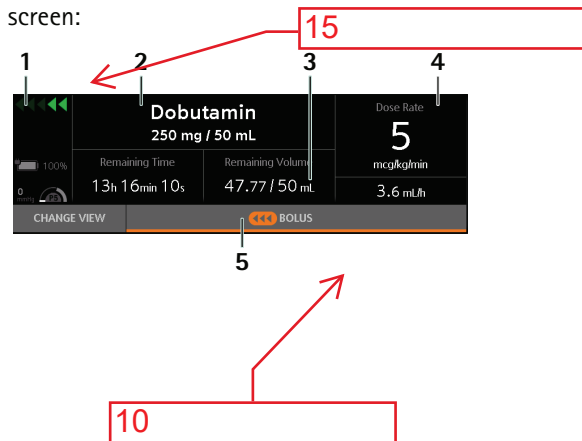
The data you see in the infusion data menu depends on the infusion profile selected.

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 cut-off pressure set (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

Which two infusion parameters 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.

Whether you can change the parameters and which ones are available to you depends on the infusion profile used for the infusion in progress.

8.4.1 Syringe run screen


The syringe run screen displays a visual representation of the syringe with its fill level, the syringe type and syringe size. Press the 'Change view' button to see the different run screens.

Galima individualiai
suprogramuoti
visus specifikacijoje
isvardintus
parametrus ir ne tik

Main functions

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, and the claws close and open.

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  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.

Main functions

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

Press 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

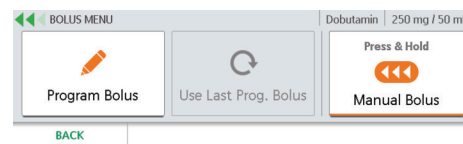
There are 3 options for administering a bolus:

- 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, press the 'Last 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.

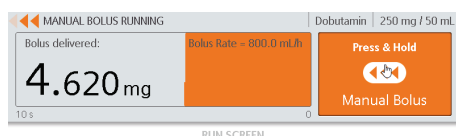
Main functions

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 Setting the standard bolus rate

You can adjust the standard bolus rate in the device settings. This is used, for example, for the manual bolus.

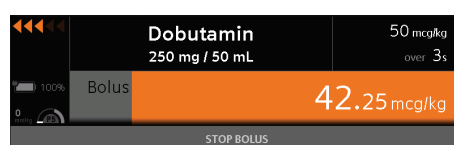
The pump always returns to the original standard bolus rate after a restart, even it had previously been changed manually.

Note: The standard bolus rate depends on the syringe size, the settings in the drug database, and the pump configuration.


9.6.6 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.

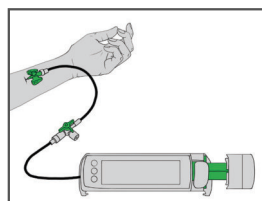


Note: If you pause a programmed bolus using the 'Stop bolus' button on the touchscreen, the infusion continues in the background.

If you stop the programmed bolus with the  button, you also stop the infusion.

9.7 Changing the syringe

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



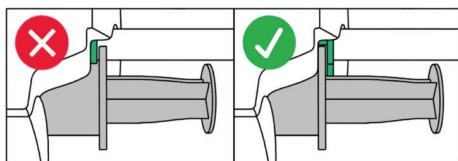
Note: Always stop a running infusion before pulling on the syringe holder.

Pull the syringe holder towards you and turn it to the right to start a syringe change. The pump asks for confirmation of the syringe change or automatically extends the drive head.

Main functions

Insert the syringe and close the syringe holder. The drive head approaches the syringe now until it reaches the syringe plunger.

When inserting the syringe, make sure that the syringe wing is between the syringe guide (shown in green) and the pump housing. The syringe wing shall not be placed to the right of the syringe guide.

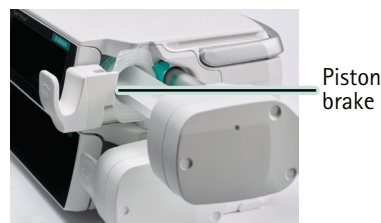


Once the syringe has been inserted, the pump suggests to you the last selected syringe with the same diameter. Confirm the suggestion or select the appropriate syringe (manufacturer and size) from the complete list.

⚠ WARNING: Disconnect from the patient before inserting and removing disposables! Otherwise an overdose may occur due to free flow.

⚠ WARNING: Always make sure that the correct syringe is selected (manufacturer and size) on the pump. Even syringes of the same size differ in some aspects that influence delivery. Incorrect selection can lead to drug overdose or underdose.

Do not touch the piston brake when removing the syringe from the syringe holder.



9.7.1 Opening the claws manually

If the syringe cannot be removed because the claws are blocked, you can open the claws manually.

To do this, use a pointed object (e.g. a pen) to press into the opening on the side of the drive head and, at the same time, push the claws apart.

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 syringe change, 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.

Priming the line improves the syringe's start-up behaviour.

The priming process brings the mechanical components of the pump into firm contact

Main functions

with the syringe. Furthermore, it reduces the effect of syringe friction and compliance (i.e. stiffness) which minimises delays and inaccurate delivery during start-up, particularly at low infusion rates.

9.9 Totals & Info

You can access the balance & info menu, which is divided into the following sub-menus, via the [Home menu](#):

- Totals
- Infusion status
- Infusion history

9.9.1 Totals

The pump displays the totals that have been infused since they were last deleted.

Content of the Totals

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 <ul style="list-style-type: none">– A new infusion is selected or– The pump is switched off

Name	Description
Intermediate volume	Volume administered during one infusion. Counts upwards until <ul style="list-style-type: none">– 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 <ul style="list-style-type: none">– A new patient is selected or– The pump is switched off
Total Amount	Total amount administered during one infusion. Counts upwards until <ul style="list-style-type: none">– A new infusion is selected or– The pump is switched off

Main functions

Name	Description
Intermediate Dose	Intermediate amount administered during one infusion. Counts upwards until <ul style="list-style-type: none"> It is manually zeroed A new infusion is selected or The pump is switched off
Total Time	Total time administered during one infusion. Counts upwards until <ul style="list-style-type: none"> A new infusion is selected or The pump is switched off
Intermediate Time	Total time administered during one infusion. Counts upwards until <ul style="list-style-type: none"> It is manually zeroed A new infusion 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 syringe volume	Volume still available in the syringe
Remaining infusion time	Remaining time until the end of the infusion
Remaining syringe time	Remaining time until the end of the syringe
KVO rate	Set KVO rate

Main functions

Name	Description
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 device settings, the pump asks you whether you would like to start KVO after the programmed infusion time or the programmed volume.

The KVO rate depends on the rate of infusion and can vary depending on the configuration.

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.

Main functions

Menu	Meaning
Data lock	Activate or deactivate code lock
KVO	Activate or deactivate KVO
Standard bolus rate	Set 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

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.

Main functions

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. fluctuations in syringe friction, 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: 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.

The drug library

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

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.

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 bolus administration.

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:

The drug library

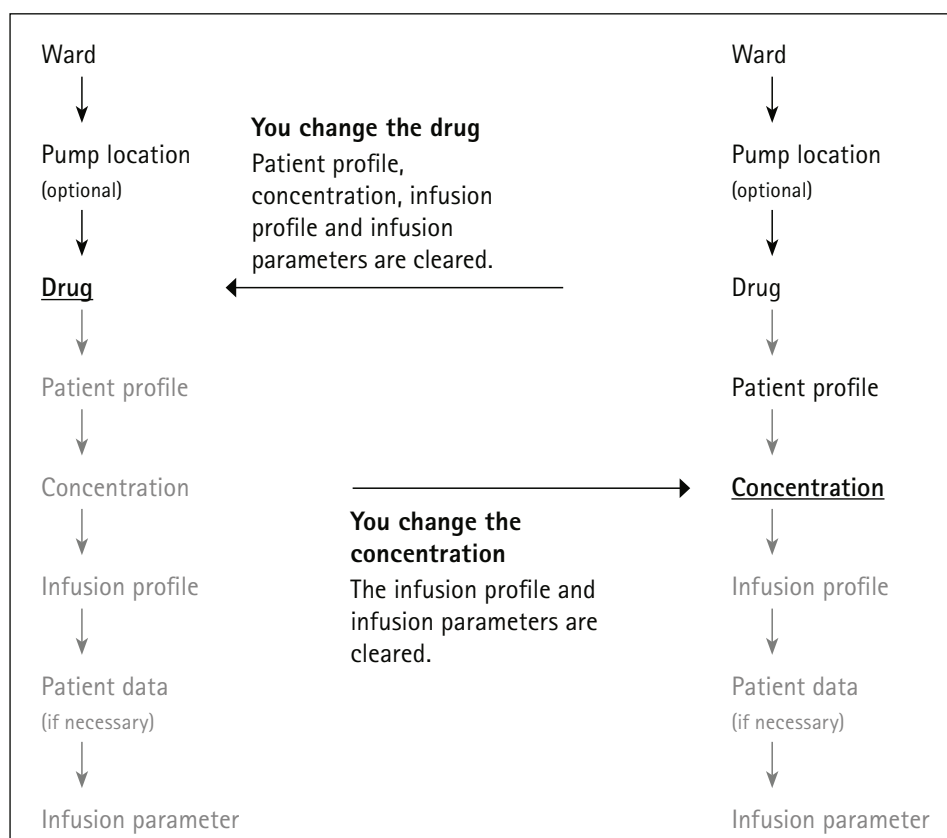


Figure 1: How changing a value affects subsequent options.

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.

The drug library

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.

REVIEW	Adrenalin	5 mg / 50 mL
Dose Rate:	5 mg/24h	
VTBI:	50 mL	
Infusion Time:	24h 0min 14s	
<div><div>DRUG</div><div>PATIENT</div><div>INFUSION</div><div>REVIEW</div></div>		

START
INFUSION

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).

In some cases, the drug concentration can be changed after a syringe change. This is only possible before you continue the infusion after the syringe change.

End the infusion and set up a new infusion if you want to change other drug data.

Description of the infusion profiles

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 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.

6

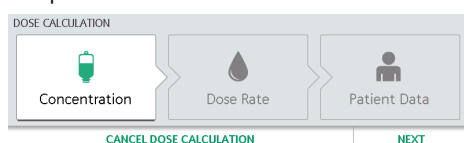
11.2 Dose calculation

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.

Description of the infusion profiles

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.

Paracetamol 10 mg / 1 mL		Flow Rate 200 mL/h
Remaining Time 10 min 55 s	Remaining Volume 36.3 / 50 mL	20 mg / kg over 15 min
CHANGE VIEW		

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

11.4 Autoprogramming

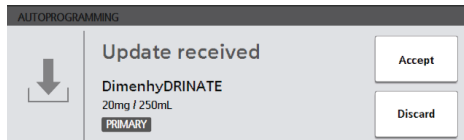
The pump can receive orders from the Electronic Medical Record (EHR) wirelessly and send pump data to the EHR for documentation. The Autoprogramming process with EHR's requires the syringe and patient ID to be scanned followed by scanning the pump barcode to link the order to the pump. Prior to initiating 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.

Description of the infusion profiles



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.

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 in the selected care area but is available in another care area.

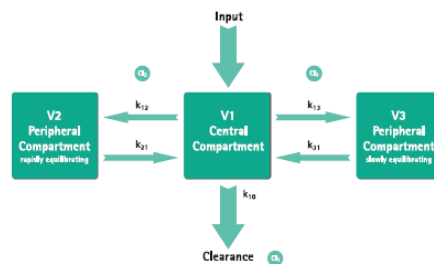
11.5 Target controlled infusion (TCI)

In TCI the user is defining a desired concentration of drug in the human body (target) rather than an infusion rate. The rates necessary to reach and maintain that defined concentration are calculated by the pump using an algorithm based on a three-compartment pharmacokinetic model.

The distribution is characterized by the three compartments and the rate constants k_{12} , k_{21} , k_{13} and k_{31} . Metabolism and direct excretion are characterized by the clearance k_{10} .

11.5.1 TCI by targeting the plasma concentration

In this mode the user selects the desired concentration of a drug in the blood plasma.



Description of the infusion profiles

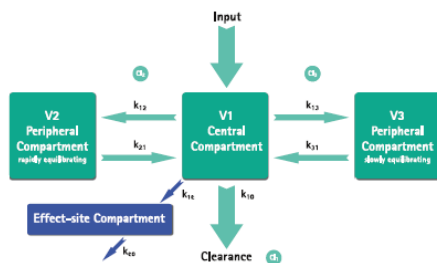
11.5.2 TCI by targeting the effect-site concentration

In this mode the user selects the desired concentration of a drug at the effect-site. A certain overshoot of the concentration in the plasma is resulting from this mode.

With the concentration at the effect-site as a target, there is a link between pharmacokinetics and pharmacodynamics required.

Assumed is that the compartment at the effect-site has no volume, and the rate constant k_{1e} can be ignored, the rate constant k_{e0} is the required parameter to perform TCI with a concentration at the effect-site as a target.

Such a modified pharmacokinetic model is shown schematically in the following figure:



Via the New infusion button in the [Home menu](#) you can access the drug library, see also [chapter 10: "The drug library"](#).

Select the respective TCI drug and the algorithm as well as the mode. The selection and mode of the TCI infusion may already be restricted via the drug library.

Depending on the TCI drug, at least the following patient data must be entered

- Weight
- Size
- Sex
- Age

Some parameter sets are using the Lean Body Mass (LBM) to individualize the parameterization. The LBM calculation may furthermore restrict the scope of patients as it will not allow TCI for obese patients.

After starting the TCI, the patient data can no longer be changed!

The remaining syringe time depends on the calculated rate. Because of the changing TCI algorithm, rate varies and therefore, technically the time for the remaining syringe volume cannot be precisely predicted.

Note: Bolus is disabled for TCI.

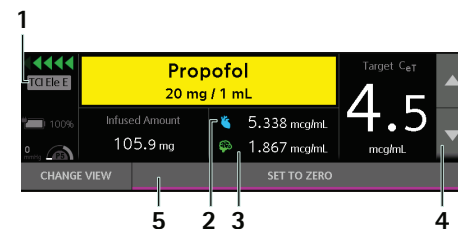


Figure: Run screen of a TCI therapy

- 1 | Therapy display incl. TCI algorithm & mode
 - a) TCI Ma P:
TCI Marsh plasma targeting
 - b) TCI Sc P:
TCI Schnider plasma targeting
 - c) TCI Sc E:
TCI Schnider effect-site targeting

Description of the infusion profiles

- d) TCI Mi P:
TCI Minto plasma targeting
- e) TCI Mi E:
TCI Minto plasma targeting
- f) TCI Ge P:
TCI Gepts plasma targeting
- g) TCI Ge E:
TCI Gepts effect targeting
- h) TCI Ele P:
TCI Eleveld plasma targeting
- i) TCI Ele E:
TCI Eleveld effect-site targeting

2 | Current plasma-concentration

3 | Current effect-concentration

4 | The target value can be easily changed in 0.1 steps using the arrow buttons.

5 | The target value can be set to 0 immediately. At the same time, the running arrows will not continue to move any longer, as the algorithm continues to show how the concentration values are reduced. The pump displays the calculated decrement time till the decrement concentration is reached.

11.5.3 Safety instructions for using TCI



- TCI should only be performed by experienced anesthetists being familiar with the principles of TCI and properly trained in using the present device.
- The use of TCI with this device does not limit the responsibility of the anesthetist for administration of drugs. They need to be fully aware of the available literature for any parameter set used in association with a drug and

need to refer to the prescribed information for rate and dosing limits.

- Pharmacokinetic and pharmacodynamic interactions among anaesthetic drugs are known but are not taken into account into the calculation of the plasma and effect site concentrations. They must be considered by the user.
- In particular, the user must be aware that starting the TCI will result in the automatic infusion of a pre-calculated bolus dose followed by an infusion to achieve the selected target concentration.
- It is essential that the user verifies that the patient characteristics and the selected target concentration as well as the resulting dosages conform to the prescribing information of the relevant country.
- While using TCI an appropriate patient monitoring is mandatory.
- Never administer TCI drugs by a second infusion if you use TCI.

Hints & alarms

12 Hints & alarms

Note: When using the pump at home: stop the pump in critical situations by pressing the  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.

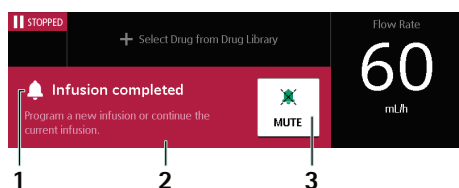


Figure 2: Operating alarm display
1. Alarm title, 2. Instructions on how to rectify the cause of the alarm, 3. Pause alarm sound/minimise alarm window.

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). Click on the small alarm window to display the full size alarm again.

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 on 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. <ul style="list-style-type: none"> – 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. <ul style="list-style-type: none"> – Enter the correct code.
Stand-by time elapsed	The entered stand-by time has elapsed. <ul style="list-style-type: none"> – Put the pump in stand-by mode again or continue the infusion.

Display notification	Meaning
Display touched for too long	The display has been touched for more than 15 seconds without interruption. <ul style="list-style-type: none"> – Make sure that no button is being continuously pressed. – Give the pump to a trained technician if the problem persists.
Voltage outside the rated range	Voltages measured at the pump are not within the rated range. <ul style="list-style-type: none"> – 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. <ul style="list-style-type: none"> – Ensure better cooling. – Give the pump to a trained technician.
Pump too cold	The pump has detected that the temperature is too low. <ul style="list-style-type: none"> – Increase the ambient temperature. – Follow the instructions on the display.

Hints & alarms

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 a syringe in the pump.

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

Display notification	Meaning
Reminder	<ol style="list-style-type: none"> 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.

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 library settings. Additionally the acoustic sound of the pre-alarm can be permanently muted which is indicated by the following symbol: .

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

Display notification	Meaning
Infusion almost ended	The preselected volume has almost been completely infused or the preselected time has almost elapsed. The time remaining is displayed.
Syringe almost empty	There is only a small fluid volume left in the syringe. The time remaining is displayed.
Battery nearly empty	Battery almost discharged. Connect the pump to the mains power. The remaining battery time is displayed

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.

Display notification	Meaning
Infusion ended	<p>The preselected volume has been completely infused or the preselected time has elapsed.</p> <ul style="list-style-type: none"> – Start a new infusion or continue the infusion.

Hints & alarms

Display notification	Meaning	Display notification	Meaning
KVO finished	KVO time has elapsed. – End the infusion or continue the infusion.	Code entry required	Someone has stopped the pump without entering the code or has tried to switch it off while the code lock was active. – Enter the correct code.
Syringe empty	No volume is left in the syringe. Due to the different tolerances of syringes from different manufacturers, some fluid may remain in the syringe. Restarting causes the syringe to be completely emptied until a pressure alarm is triggered. – Change the syringe or end the infusion.	Syringe holder open	The syringe holder was opened while an infusion was in progress. – Close the syringe holder.
Pressure too high	There is an occlusion in the infusion line. The set pressure level has been exceeded. Due to the different tolerances of syringes from third-party manufacturers, a pressure alarm can be triggered by high frictional forces on the syringe. The pump automatically reduces the post occlusion bolus. – Check that the line is not bent or damaged, that all connections are open and that all the filters are unblocked.	Syringe not fixed correctly	The syringe is not fixed correctly. – Replace the syringe.
		Pump too hot	The pump has detected that the battery temperature is too high. – Lower the ambient temperature
		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.

Hints & alarms

Display notification	Meaning
Drive blocked	<p>The drive head was obstructed while retracting.</p> <ul style="list-style-type: none"> – Check whether the drive head is blocked by something and, if necessary, remove the object. <p>Note: As a general rule, avoid external interventions.</p>
Code entry required	<p>An action performed on the pump requires a code to be entered (function availability depends on the pump configuration).</p> <ul style="list-style-type: none"> – Enter the correct code. or give the pump to a trained technician.
Pressing of button not processed	<p>The signal from a pressed button could not be processed.</p> <ul style="list-style-type: none"> – Press the button again. – Give the pump to a trained technician if the problem re-occurs.

12.5.5 Device alarms

A device alarm signals that the pump is potentially defective. Disconnect the pump from the patient, remove the syringe 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.


Software & updates

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

 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 and do not put excessive strain on the claws.

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.

Cleaning & disinfection

- 2 | 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.
- 3 | 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

Group	Active substances
QACs (quaternary ammonium compounds)	DDAC (didecyltrimethylammonium 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.

Battery mode

15 Battery mode

The pump is equipped with a modern lithium-ion battery. For optimal battery management, the pump is equipped with protection against overcharge and deep discharge.

The battery is charged by the pump during mains operation. In the event of a power cut or disconnection from the mains power, the pump automatically switches to battery mode.

The battery status is shown in the display.

Under normal environmental conditions, a battery can be fully discharged and recharged around 300 times. Battery is checked within the technical safety check (TSC).

15.1 Notes for optimal battery operation

Battery life may vary due to:

- Ambient temperature
- Charging cycles

Please also pay attention to the following:

- When the device is not connected to the mains power supply, the battery discharges slowly and may be fully discharged after a while even if the device is not in operation. In this case it is enough to connect the device to the mains power for a while to recharge the battery.
- The battery display on the pump is an approximate value based on the current flow rate.

- If the battery is old, the battery indicator may differ from the actual achievable operating time.
- Battery can only be replaced by biomedical engineering.

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 will be 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.

Maintenance and repair

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. Only original replacement 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 of 24 months (with battery charge to be restored every 12 months).

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.

Start-up and trumpet curves

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.

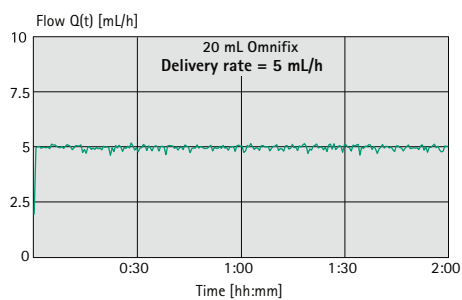
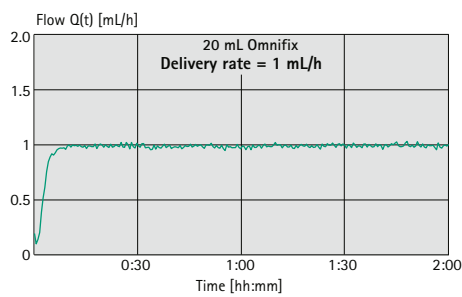
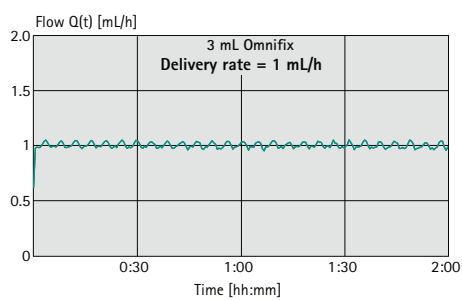
The physiological effect of the drug can be affected by the flow and the syringe.

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

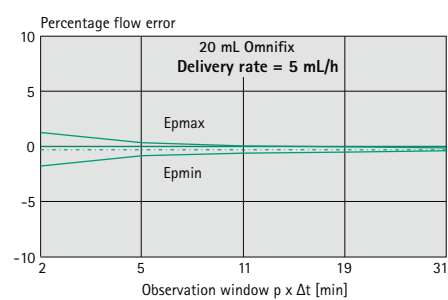
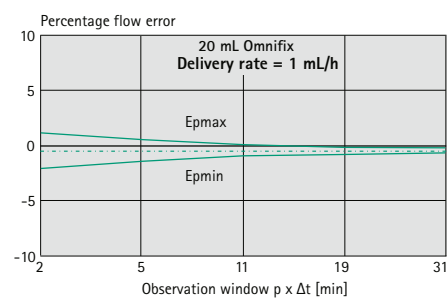
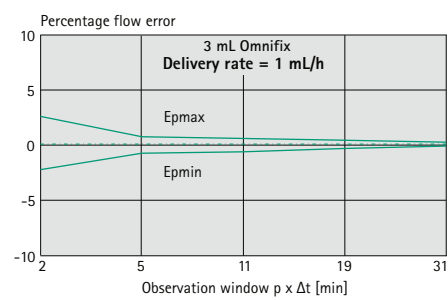
Start-up and trumpet curves

21.2 Typical start-up and trumpet curves

Start-up curves

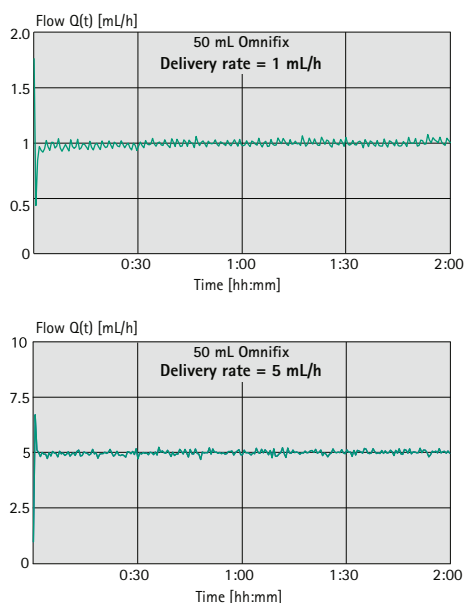


Trumpet curves



Start-up and trumpet curves

Start-up curves



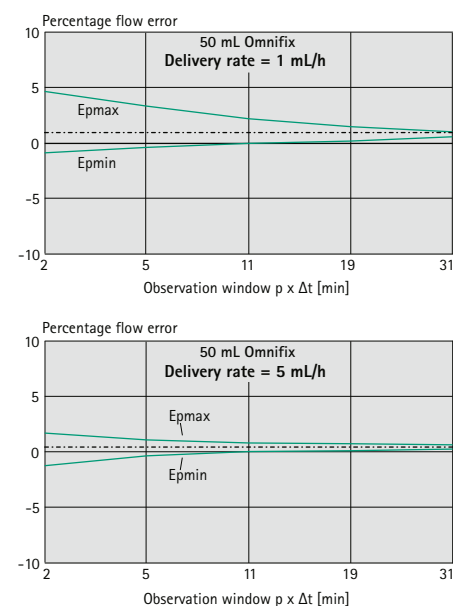
Start-up curves

Measurement interval	$\Delta t = 0.5 \text{ min}$
Measurement duration	$T = 120 \text{ min}$
Flow Q_i	(mL/h)

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

Measurement interval	$\Delta t = 0.5 \text{ min}$
Observation interval	$p \times \Delta t \text{ [min]}$

Trumpet curves



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 type of syringe used (disposable).
- Deviations from the pump's technical data cannot be ruled out when using syringes from competitors.

Note: System accuracy is typically $\pm 2 \%$ 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 $20^\circ\text{C} \pm 2^\circ\text{C}$ and $1013 \text{ mbar} \pm 20 \text{ mbar}$ ambient pressure), using the approved syringes.

Time to alarm

Recommendations			
Syringe size [mL]	10	5	2/3
Recommended min. flow rate [mL/h]	0.1	0.1	0.1

Recommendations			
Syringe size [mL]	50/60	30	20
Recommended min. flow rate [mL/h]	0.5	0.2	0.2

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

In order to reduce start up delay; select the smallest syringe size possible and mobilise the syringe plunger before inserting the syringe. Mobilising the syringe plunger with reduce the rubber stopper's 'break loose' force.

The device is equipped with quick start, which enables an infusion to be started quickly after a syringe change.

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

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

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

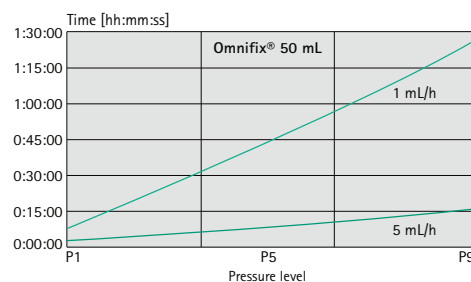
Note: Under the worst-case conditions (high ambient temperature, low flow rate of under 0.1 mL/h, while simultaneously charging a heavily discharged battery, or with poor device ventilation), the device generates heat that can result in warming of the drug in the syringe.

22 Time to alarm

The following graph shows the time to alarm after an occlusion of the B. Braun syringe shown according to pressure and syringe type.

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

22.1 Omnifix® 50 mL



Note: At a rate of 0.01 mL/h, the alarm activation time is > 4 h for an Omnifix 50 mL.

Time to alarm

22.2 Compatible syringes

1; 2

When using representative syringes, the following typical alarm times apply at 5 mL/h. The alarm times vary depending on the pressure level and delivery rate.

Manufacturer	Syringe type	Catalogue number	Pressure level = 1 0.1 bar at 5 mL/h	Pressure level = 9 1.2 bar at 5 mL/h
			Typical alarm activation time [mm:ss]	Typical alarm activation time [mm:ss]
B.Braun	OPS 50 ml	8728810F-06	02:15	14:49
B.Braun	OPS 20 ml	8728615	00:48	04:44
B.Braun	Omnifix 50 ml	4617509F	01:52	14:04
B.Braun	Omnifix 30 ml	4617304F	01:40	08:55
B.Braun	Omnifix 20ml	4617207V	00:46	05:03
B.Braun	Omnifix 10 ml	4617100V	00:13	02:13
B.Braun	Omnifix 5 ml	4617053V	00:16	01:37
B.Braun	Omnifix 3 ml	4617022V	00:24	01:12
B.Braun	Omnifix 2 ml	4617029V	00:21	01:14
B.Braun	Enteral 60 ml	4616029-01	00:40	09:31
B.Braun	Enteral 20 ml	4616028-01	00:25	04:27
B.Braun	Enteral 10 ml	4616027-01	00:18	02:11
B.Braun	Enteral 5 ml	4616026-01	00:10	01:35
Becton Dickinson	Plastipak 50 ml	300865	01:42	15:03
Becton Dickinson	Plastipak 30 ml	301229	03:02	08:29
Becton Dickinson	Plastipak 20 ml	300629	00:38	05:35
Becton Dickinson	Plastipak 10 ml	305959	00:42	03:14
Becton Dickinson	Plastipak 5 ml	309649	00:36	02:48
Becton Dickinson	Plastipak 3 ml	309658	00:25	02:12
Vygon	NutriSafe2 60 ml	1.015.603	04:13	14:30
Vygon	NutriSafe2 20 ml	1.015.213	01:29	06:33
Vygon	NutriSafe2 10 ml	1.015.103	01:14	04:47
Vygon	NutriSafe2 5 ml	1.015.053	00:41	02:28
Vygon	Nutrifit 60 ml	1.015.607	02:30	16:01

Time to alarm

Manufacturer	Syringe type	Catalogue number	Pressure level = 1 0.1 bar at 5 mL/h	Pressure level = 9 1.2 bar at 5 mL/h
			Typical alarm activation time [mm:ss]	Typical alarm activation time [mm:ss]
Vygon	Nutrifit 20 ml	1.015.207	00:56	07:41
Vygon	Nutrifit 10 ml	1.015.107	01:02	03:53
Vygon	Nutrifit 5 ml	1.015.058	00:38	02:47
Vygon	Nutrifit 2,5 ml	1.015.028	00:17	01:35
Terumo	Syringe 50/60 ml	SS+50L1, SS+60L	02:58	19:34
Terumo	Syringe 30 ml	SS+30L1MP	01:03	09:07
Terumo	Syringe 20 ml	SS+20L1	02:19	07:55
Terumo	Syringe 10 ml	SS+10L1	01:02	03:16
Terumo	Syringe 5 ml	SS*05LE1	00:27	02:05
Codan	Syringe 50/60 ml	628.426	01:19	09:44
Codan	Syringe 10 ml	626.706	00:09	01:17
Codan	Syringe 2 ml	622.637	00:05	00:21
Avanos	NeoConnect 60 ml	PNM-S60NC, NM-S60NC	00:40	09:31
Avanos	NeoConnect 20 ml	PNM-S20NC, NM-S20NC	00:25	04:27
Avanos	NeoConnect 12 ml	PNM-S12NC, NM-S12NC	00:18	02:11
Avanos	NeoConnect 6 ml	PNM-S6NC, NM-S6NC	00:10	01:35
Fresenius	Injectomat 50 ml	M93000010	1:56	20:55
Becton Dickinson	Syringe US 50 ml	309653	1:36	13:38
Becton Dickinson	Syringe US 30 ml	302323	0:50	6:48
Becton Dickinson	Syringe US 20 ml	302830	0:34	4:32
Becton Dickinson	Syringe US 10 ml	302995	0:28	2:54
Becton Dickinson	Syringe US 5 ml	309646	0:38	2:03
Becton Dickinson	Syringe US 3 ml	309657	0:37	1:25
Covidien	Monoject 35 ml	1183500777	1:13	10:16
Covidien	Monoject 20 ml	1182000777	0:49	6:02
Covidien	Monoject 6 ml	1180600777	0:53	2:13
Covidien	Monoject 3 ml	1180300777	0:34	1:27
Margomed	Margomed 50/60 ml	007111	1:25	22:16

Technical data

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	Infusion syringe pump
Product classification	according to Directive 93/42 EEC and Regulation (EU) 2017/745: <ul style="list-style-type: none"> – IIb according to IEC 60601-1: <ul style="list-style-type: none"> – Protection class II – For Type CF applied parts with defibrillation protection – Continuous operation: 100% time of operation according to FCC Rules part 15: <ul style="list-style-type: none"> – Mobile device: Intended for use > 20 cm from the body
Protection against liquids and particles	IP44 <ul style="list-style-type: none"> – 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. 4 W (9 VA), max. < 14 W (34 VA)
– 12 V supply	– Typ. 3 W, max. < 11 W
Internal battery	Lithium-ion battery: 7.2 V DC, 3000 mAh, 21.6 Wh
– Battery life	– At 25 mL/h, 50 mL syringe, 22 °C and new battery: <ul style="list-style-type: none"> – Approx. 13 h with WiFi interface switched off – Approx. 11 h with WiFi interface connected – At 1800 mL/h, 22 °C, with 50 mL syringe, new battery: <ul style="list-style-type: none"> – Approx. 6.5 h with WiFi interface connected
– Recharging time	– Approx. 4 h

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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	<ul style="list-style-type: none"> – 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	<ul style="list-style-type: none"> – Temperature: +5°C ... +40°C (+41°F ... +104°F) – Relative humidity: 15 % ... 95 % (without condensation) – Atm. pressure: 500 ... 1060 mbar
Storage conditions	<ul style="list-style-type: none"> – Temperature: -20°C ... +55°C (-4°F ... +131°F) – Relative humidity: 30 % ... 90 % (without condensation) – Atm. pressure: 500 ... 1060 mbar <p>Note: For long-term storage, ambient conditions of 22°C and 50% humidity are recommended.</p>
Weight	Approx. 1.9 kg (without pump clamp)
Dimensions in mm (W x H x D)	Approx. 255 mm x 70 mm x 170 mm (without pump clamp and impact protection) 399 mm x 70 mm x 170 mm (with drive extended)
Safety check (SC)	Every 2 years
Volume preselection	0.01 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

Technical data

Parameter	Value
Delivery rate setting	0.01 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 ... 1800 mL/h in increments of 1 mL/h
Delivery accuracy	±2% according to IEC 60601-2-24
Delivery accuracy for bolus administration	Typ. ±2% for bolus volumes > 1 mL
Occlusion alarm pressure	9 levels up to 1.2 bar ± 0.2 bar. Note: Bolus volume is automatically reduced after occlusion alarm.
Alarm in the case of incorrect delivery	In the event of an incorrect delivery of max. 0.1 mL due to a technical fault, the pump will automatically stop off and trigger an alarm.
Max. bolus volume after occlusion alarm	≤ 0.2 mL
KVO rate	<ul style="list-style-type: none"> Rate: ≥ 10 mL/h: KVO rate 3 mL/h Rate: < 10 mL/h: KVO rate 1 mL/h Rate: < 1 mL/h: KVO rate 0.1 mL/h or current rate if this is lower Note: KVO rates can only be changed by trained technicians.
History protocol	<ul style="list-style-type: none"> 1,000 history entries The oldest entries are overwritten if necessary. 100 events for system diagnosis The history is retained when the pump is switched off or the battery removed.

Delivery rates

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

Syringe size [mL]	Continuous delivery/ Bolus rate [mL/h]	Preset bolus rate [mL/h]
50/60	1 to 1,800	800
30/35	1 to 1,200	600
20	1 to 800	400

Technical data


Syringe size [mL]	Continuous delivery/ Bolus rate [mL/h]	Preset bolus rate [mL/h]
10/12	1 to 500	200
5/6	1 to 300	150
2/3	1 to 150	80

Note: The maximum delivery rate can be increased to up to 1800 mL/h using the disposable item data.


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

Note: The bolus rate is determined based on the pre-defined standard value (table above), 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.

 **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.

 **WARNING!** For reasons of patient safety, disposables without Luer lock connections should only be used for enteral infusions (e.g. via gastric feeding tube).

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 generator does not work for technical reasons, an alternative alarm generator (piezo) sounds.

Technical data

23.2 WiFi interface

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.
16.3	Security standards: Wireless Equivalent Privacy (WEP) Wi-Fi Protected Access (WPA) IEEE 802.11i (WPA2) 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

Technical data

23.3 Technical data of TCI

Drug / Parameter	Propofol Marsh ¹⁾	Propofol Schnider ²⁾	Propofol Eleveid ³⁾	Remifentanyl Minto ⁴⁾	Sufentanil Gepts ⁵⁾
Vc = V1 [ml]	0,228 * weight	4270	6,28 * $\frac{f_{\text{central}}(\text{PatientWeight})}{f_{\text{central}}(\text{PatientWeight}_{\text{ref}})}$	5,1 - 0,0201 * (Age - 40) + 0,072 * (LBM - 55)	14300
V1 [Liter]	--	---	--	--	--
k10 [min-1]	0,119	0.443 + 0.0107 * (Weight - 77) -0.0159 * (LBM - 59) + 0.0062 * (Height - 177)	--	[2,6 - 0,0162 * (Age - 40) + 0,0191 * (LBM - 55)] / [5.1 - 0.0201 * (Age - 40) + 0.072 * (LBM - 55)]	0,0645
k12 [min-1]	0,112	0.302 - 0.0056 * (Age - 53)	--	[2,05 - 0,0301 * (Age - 40)] / [5.1 - 0.0201 * (Age - 40) + 0.072 * (LBM - 55)]	0,1086
k13 [min-1]	0,0419	0,196	--	[0,076 - 0,00113 * (Age - 40)] / [5.1 - 0.0201 * (Age - 40) + 0.072 * (LBM - 55)]	0,0229
k21 [min-1]	0,055	[1.29 - 0.024 * (Age - 53)] / [18.9 - 0.391 * (Age - 53)]	--	[2,05 - 0,0301 * (Age - 40)] / [9,82 - 0,0811 * (Age - 40) + 0,108 * (LBM - 55)]	0,0245
k31 [min-1]	0,0033	0,0035	--	0.01402 - 0,0002085 * (Age - 40)	0,0013
ke0 [min-1]	--	0.456	--	0,595 - 0,007 * (Age - 40)	0,112
Patient age	40 - 50	16 - 100 J	--	< 90 J	14 - 68 J
Patient weight	30 - 200 kg	30 - 120 kg	--	30 - 120 kg	47 - 94 kg
Patient height	--	--	--	1,3 - 2,2 m	--

Technical data

Reference:

- ¹⁾ Gepts E, Camu F, Cockshott ID, Douglas EJ. Disposition of propofol administered as constant rate intravenous infusions in humans. *Anesth Analg* 1987; 66(12):1256–63.
- ²⁾ Schnider TW, Minto CF, Gambus PL, Andresen C, Goodale DB, Shafer SL et al. The influence of method of administration and covariates on the pharmacokinetics of propofol in adult volunteers. *Anesthesiology* 1998; 88(5):1170–82.
Schnider TW, Minto CF, Shafer SL, Gambus PL, Andresen C, Goodale DB et al. The influence of age on propofol pharmacodynamics. *Anesthesiology* 1999; 90(6):1502–16.
- ³⁾ Eleveld D, Colin P, Absalom A, Struys M. Pharmacokinetic-pharmacodynamic model for propofol for broad application in anaesthesia and sedation. *Br J Anaesth* 2018; 120(5):942–59.
- ⁴⁾ Minto CF, Schnider TW, Egan TD, Youngs E, Lemmens HJ, Gambus PL et al. Influence of age and gender on the pharmacokinetics and pharmacodynamics of remifentanyl. I. Model development. *Anesthesiology* 1997; 86(1):10–23.
- ⁵⁾ Gepts E, Shafer SL, Camu F, Stanski DR, Woestenborghs R, van Peer A et al. Linearity of pharmacokinetics and model estimation of sufentanil. *Anesthesiology* 1995; 83(6):1194–204.
Scott JC, Cooke JE, Stanski DR. Electroencephalographic quantitation of opioid effect: comparative pharmacodynamics of fentanyl and sufentanil. *Anesthesiology* 1991; 74(1):34–42.


Electromagnetic compatibility


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. electro-surgical 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. electro-surgery), 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 1/2 periods 0% U_T ¹⁾ for 1 period 70% U_T ¹⁾ for 25/30 periods 0% U_T ¹⁾ for 250/300 periods	Complies through the use of an internal energy source	Mains power quality should be that of a typical commercial or hospital environment.
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	<p>The field strength should be lower than 10 V/m</p> <p>$d = 1.2 \times \sqrt{P}$ ²⁾ 80 MHz to 800 MHz</p> <p>$d = 2.3 \times \sqrt{P}$ ²⁾ 800 MHz to 2.7 GHz</p> <p>Field strengths from stationary RF transmitters should be below the compliance level for all frequencies, based on an on-site test.</p> <p>Interference is possible in the vicinity of equipment that has the following symbol.</p> 

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

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.

Electromagnetic compatibility

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.

Instructions for use for accessories

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.

Check the staff call before each use of the device.

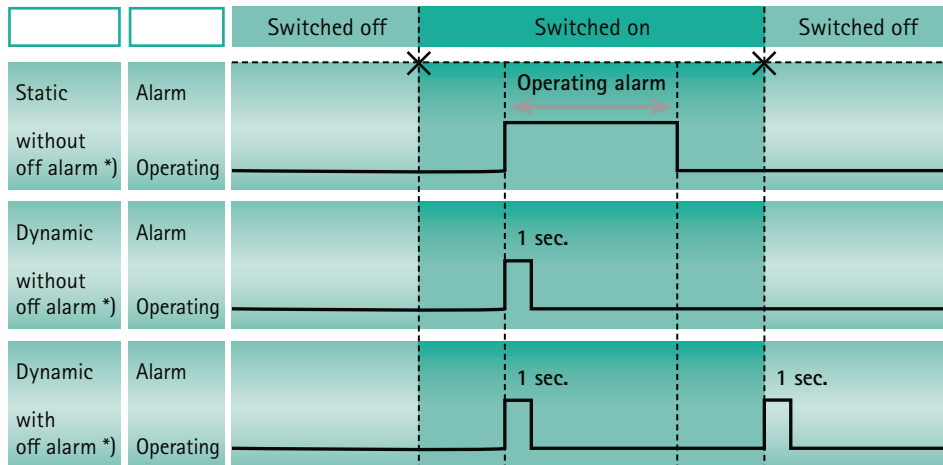
 **CAUTION!** As the staff call can fail and this can go undetected, and it is not tested during the pump self test, the user is also responsible for monitoring the alarms on the pumps.

 **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

Ordering data

26 Ordering data

26.1 Infusion pump

Art. no.	Name
8719030	Space ^{plus} Perfusor®

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
8719166	Space ^{plus} 45° pump Clamp

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26.4 Power cord

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

Ordering data

Art. no.	Name	Description
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
8717119	Power cord BR	Type N power cable

26.5 Disposables

26.5.1 Syringes

Original Perfusor® syringe with Luer lock attachment

Art. no.	Product	Volume	Graduation
8728615	Original Perfusor® syringe 20 ml	20 ml	1.0 ml
8728623	Original Perfusor® syringe 20 ml with aspiration cannula	20 ml	1.0 ml
8728844F-06	Original Perfusor® syringe 50 ml	50 ml	1.0 ml
8728810F-06	Original Perfusor® syringe 50 ml with aspiration cannula	50 ml	1.0 ml
8728852F-06	Original Perfusor® syringe 50 ml with aspiration cannula with 15 µm particle filter	50 ml	1.0 ml

Original Perfusor® syringe with Luer lock attachment, photo-resistant barrel

Art. no.	Product	Volume	Graduation
8728861F-06	Original Perfusor® syringe 50 ml with aspiration cannula with 15 µm particle filter, transparent orange with light protection up to 520 nm	50 ml	1.0 ml

Ordering data

Omnifix® Solo syringe with Luer lock attachment

Art. no.	Product	Volume	Graduation
4617022V	Omnifix® Solo 3 ml	3 ml	0.1 ml
4617053V	Omnifix® Solo 5 ml	5 ml	0.2 ml
4617100V	Omnifix® Solo 10 ml	10/12 ml	0.5 ml
4617207V	Omnifix® Solo 20 ml	20 ml	1.0 ml
4617304F	Omnifix® Solo 30 ml	30 ml	1.0 ml
4617509F	Omnifix® Solo 50 ml	50/60 ml	1,0 ml
4617510F-06	Omnifix® 50 ml UV Protect	50/60 ml	1,0 ml

B. Braun syringes with NRFit® attachement (neuraxial)

Art. no.	Product	Volume	Graduation
4617003	Omnifix® 3 ml NRFit® Lock	3 ml	0.1 ml
4617006	Omnifix® 5 ml NRFit® Lock	5 ml	0.2 ml
4617014	Omnifix® 10 ml NRFit® Lock	10 ml	0.5 ml
4617021	Omnifix® 20 ml NRFit® Lock	20 ml	1.0 ml
4617508F-01	Omnifix® 50 ml NRFit® Lock	50 ml	1.0 ml
8728845F-01	Original Perfusor® syringe 50 ml, type NRFit®	50 ml	1.0 ml

B. Braun enteral syringes with ENFit™ attachment

Art. no.	Product	Volume	Graduation
4616025-01	B. Braun enteral syringe with ENFit™, 2.5 ml	2.5 ml	0.1 ml
4616026-01	B. Braun enteral syringe with ENFit™, 5 ml	5 ml	0.1 ml
4616027-01	B. Braun enteral syringe with ENFit™, 10 ml	10 ml	0.2 ml
4616028-01	B. Braun enteral syringe with ENFit™, 20 ml	20 ml	1.0 ml
4616029-01	B. Braun enteral syringe with ENFit™, 60 ml	60 ml	1.0 ml

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

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